Summary

Introduction

1. At the time this Inquiry was set up in January 2001, it was known that Shipman had murdered 15 patients during the years 1995 to 1998. It was also suspected that he might have killed others over a much longer period. When, at the end of his trial, it came to light that, in 1976, Shipman had been convicted of offences of forgery, of unlawful possession of pethidine and of obtaining pethidine by deception, many people began to ask how it was that he had been able to return to unsupervised general practice in 1977, just over a year later. They also wondered how it was that his repeated killing of patients had escaped the notice of the authorities responsible for general practitioners (GPs) such as him. One of the Inquiry's Terms of Reference required me to look into **'the performance of the functions of those statutory bodies, authorities, other organisations and individuals with responsibility for monitoring primary care provision ... and to recommend what steps, if any, should be taken to protect patients in the future'**. I interpreted the word 'monitoring' in its broadest sense, as I am confident was the intention of Parliament.

2. By the time the Inquiry was ready to embark upon hearings relating to this aspect of its work in 2003, the First Report had already been published. I had found that, between 1975 and 1998, Shipman had killed no fewer than 215 patients. Thus, in order to comply with its Terms of Reference, the Inquiry has had to examine the provisions for the monitoring of GPs working in the NHS over a period of 23 years. That included examination of the powers of the primary care organisations (PCOs) responsible for the administration of general practice during that period, their involvement in the selection of GPs to fill practice vacancies, the monitoring tools (if any) that were available to them, the regulations governing the disciplining of GPs and the methods by which patient complaints about GPs were handled. As well as considering how the systems operated in general, the Inquiry had to examine how they operated in respect of Shipman. One question of particular interest to the Inquiry was whether anybody had harboured any suspicions about him and, if so, how easy it was for them to raise their concerns effectively with an appropriate authority. The Inquiry was also interested to discover whether it was feasible for PCOs to monitor the death rates of the patients of GPs and whether any PCOs in fact did so.

3. In addition to examining the systems operating within the NHS, the Inquiry also scrutinised the operation of the fitness to practise (FTP) procedures of the General Medical Council (GMC) over the same period of 23 years. The FTP procedures are an integral part of the monitoring of all doctors. The GMC is the only body which can erase or suspend a doctor's right to practise medicine in the UK; it can also impose conditions on a doctor's right to practise. The GMC's FTP procedures are, in effect, the 'teeth' behind all the other monitoring and disciplinary systems. As well as considering how the GMC's FTP procedures worked in general, the Inquiry has examined how the GMC dealt with Shipman in 1976, when he was reported to it following his conviction for the drug-related offences to which I have already referred. The outcome was that Shipman was given a warning as to his future conduct and he was thereafter free to continue in practice. I have also examined how the GMC handled cases of drug abusing doctors after the introduction of

its 'health procedures' in 1980. Shipman was also reported to the GMC in respect of less serious matters in 1985 and 1994 and I have described what happened on those occasions.

4. Because the Inquiry's Terms of Reference also require me to make recommendations for the better protection of patients in the future, the Inquiry has had to examine the systems for monitoring GPs in place at the present time and those that are envisaged for the future. In order to do that, it has been necessary to look at the developments in the arrangements for primary care and for the regulation of the profession which have taken place since 1998, when Shipman ceased practice. It has been a period of great and rapid change. Change is still continuing. Also, the GMC's FTP procedures have recently been overhauled and the GMC has been developing its proposals for the revalidation of the registration of all doctors practising in the UK. Revalidation is due to be introduced in April 2005. To some extent, the Inquiry has been focussing on a changing picture. However, that has not prevented me from reaching conclusions and making recommendations which will, I believe, help to achieve the Inquiry's primary aim of seeking to ensure that, in the future, the behaviour of a seriously dysfunctional doctor like Shipman would not remain undetected for so long.

The Framework of General Practice

5. The NHS came into being in 1948 and, from that time, general medical services have been provided and administered locally by PCOs. I shall confine my description to those that have existed in England during the relevant period. The composition and functions of PCOs have changed from time to time over the years. In 1974, when Shipman first entered general practice, general medical services were administered by family practitioner committees (FPCs). Today, the local bodies responsible are the primary care trusts (PCTs). There are about 300 PCTs in England. PCTs are responsible for the provision of all primary care services, including general medical services.

6. There are about 34,500 GPs in active practice in England today. Most of them are self-employed independent contractors, although some are employed directly by PCTs or others. Traditionally, GPs have been fiercely protective of their self-employed status, their independence and their clinical autonomy. General medical services are provided under a contract (the General Medical Services (GMS) Contract), the terms of which are negotiated – and from time to time renegotiated – between the Government and representatives of the profession. The GMS Contract provides for the remuneration of GPs and for various allowances for the running of a practice. Until the mid-1960s, many GPs were single-handed practitioners. A new GMS Contract, which came into effect in 1966, provided incentives for GPs to join together into larger groups and to improve their premises and employ more staff. This Contract marked the beginning of modern team-based general practice. All GMS Contracts until that of 2004 also imposed upon GPs a number of personal duties, known as the terms of service. One important duty was to tender to their patients all necessary and appropriate personal medical services of the type usually provided by GPs.

7. During almost the whole period of Shipman's practice as a GP, from 1974 to 1998, the role of PCOs was primarily that of provider and facilitator of GP services to the population.

FPCs continued in operation until 1990 when they were replaced by family health services authorities (FHSAs). These, in turn, were replaced by health authorities (HAs) in 1996. HAs were abolished in 2002 and were replaced by PCTs. FPCs did not exercise a supervisory role over GPs; their functions were purely administrative. Only in the 1990s did FHSAs and HAs begin to exercise a monitoring or quasi-management role in respect of the GPs practising in their area. The powers of the PCOs to monitor and 'manage' GPs have increased markedly over the last ten years and, today, PCTs are responsible not only for the provision of general medical services but also for putting in place arrangements for monitoring and improving the quality of health care provided. In order to fulfil their responsibilities, PCTs have been given a wide range of powers, some of which I shall describe later.

The Circumstances of Shipman's Appointment to the Donneybrook Practice in 1977

8. From the inception of the NHS, one of the important functions of PCOs has been to keep a list (formerly known as the medical list) of all GPs practising in the area. Before any doctor is entitled to practise as a GP in a particular locality, s/he must be admitted to the list held by the relevant PCO. In 1977, when Shipman was appointed to the Donneybrook practice, the keeping of the medical list was a purely administrative task. Apart from ensuring that the doctor was on the medical register, the FPC was not required or empowered to make any further checks on the suitability of the doctor for work in general practice before admitting him/her to the list. A doctor could be removed from the list only if s/he had ceased to be a registered practitioner, had failed to provide medical services for six months or had been erased or suspended from the medical register by the GMC. PCOs could make representations to the NHS Tribunal seeking a doctor's removal from its list on the grounds that s/he prejudiced the efficiency of the services it provided. This was a cumbersome process and not much used.

9. Until 2000, if a vacancy arose in an existing general practice, the local PCO played a very limited role in filling it. If notified of a vacancy by the remaining partners in the practice, the PCO would apply to the Medical Practices Committee (MPC), a national body whose function was to ensure the equitable distribution of GPs throughout the country. If the MPC agreed that a replacement doctor was needed, it was entirely a matter for the partners in the practice to select a replacement. If the successful candidate was not already on the medical list of the relevant FPC, s/he would apply for admission to the medical list and, provided s/he was on the medical register, s/he would be admitted to the list and would be free to take up the post.

10. In February 1976, following the detection four months earlier of his controlled drugs offences, Shipman took up a post with the Durham Area Health Authority in the field of child health. In April 1976, the GMC considered his case and decided to allow to him to continue in practice. In the summer of 1977, he applied for a vacancy at the Donneybrook practice in Hyde, Greater Manchester. At the interview, he admitted to members of the practice that he had had a drug problem in the past, but he was able to assure them (as was true) that the GMC had not thought it necessary to erase or suspend him from the medical register. Nor had the Home Secretary imposed any restrictions on Shipman's prescribing rights, as

had been open to him under section 12 of the Misuse of Drugs Act 1971. The partners were disarmed by Shipman's apparent frankness about his past difficulties and impressed by his enthusiasm and his recent experience in the field of child health. They made enquiries of the GMC and of the Home Office and ascertained that Shipman was free to practise without restriction. They spoke to one of the psychiatrists who had treated him and were told that Shipman had had a problem which had been satisfactorily resolved. They spoke to a partner in his former practice who, although angry at the fact that Shipman had stolen or misappropriated pethidine from the practice, spoke highly of his abilities as a doctor. They may have spoken to his employers. If they did, they would doubtless have received an encouraging account of his progress and would have learned that there appeared to have been no recurrence of his former drug problem. Following these enquiries, the members of the Donneybrook practice decided to offer Shipman the vacancy. They considered that it was reasonable to rely on the GMC's judgement that Shipman was fit to practise medicine. I do not criticise them for that.

11. Shipman applied for inclusion on the medical list held by the Tameside FPC. An enquiry was made of the GMC to ensure that he was registered. The GMC's response indicated that Shipman was fully registered. The FPC was not told of Shipman's recent involvement with the GMC. Indeed, even if the GMC had been specifically asked whether Shipman had had any previous involvement with the GMC, the FPC would not have been told about that involvement. Shipman had been dealt with by the GMC in private and the fact that that he had received a warning would have been treated by the GMC as confidential.

12. Shipman was then admitted to the medical list of the Tameside FPC, the officers of which were completely unaware that he had been convicted of controlled drugs offences some 20 months earlier. They and their successors remained in ignorance of that fact throughout the period that Shipman was in practice in Tameside. Even if they had known of the convictions, they would not have been able to refuse Shipman admission to the medical list in 1977. He was on the medical register; he was entitled to practise and was entitled to be admitted to the list. The Tameside FPC is not to be criticised for admitting him to its medical list. Nor can members of the Donneybrook practice be criticised for failing to tell the Tameside FPC about Shipman's past history. The limited role played by FPCs at that time meant that it simply did not occur to anyone at the practice that the FPC had an interest in receiving this information.

Monitoring Systems during Shipman's Years in General Practice

13. In the 1970s and 1980s, as I have said, the FPCs were purely administrative organisations. They had no management role. Nor did they have any responsibility for professional competence or quality of care. Those were matters left entirely to the profession. At a local level, elected committees of GPs (local medical committees (LMCs)) assumed responsibility for maintaining professional standards and had responsibility for adjudicating on such matters as excessive prescribing, failure to exercise reasonable care when issuing medical certificates and failing to keep proper medical records. These issues were regarded as matters to be regulated by the medical profession, not by the PCOs. LMCs also had a formal statutory role in disciplinary and complaints procedures involving GPs. Nationally, the GMC was responsible for regulating the conduct of doctors

on its register. During this period, there was a recognition in some quarters (notably the Royal College of General Practitioners) that standards of care among GPs were, in general, extremely variable, and, in the case of some, unacceptably low. Some members of the profession began to take steps aimed at raising standards. Meanwhile, the FPCs lacked the necessary powers to undertake any systematic monitoring of clinical performance or of the quality of services offered by GPs.

14. There was, however, one way in which a PCO might become aware that a doctor was not practising to an acceptable standard. A complaint about substandard practice might be made by or on behalf of a patient. Until 1996, patients' complaints were directed to the PCO. Thus, the PCO became aware of complaints as they were made and could, if it chose, undertake some analysis of those complaints and, by that means, identify 'problem doctors'. The complaints and disciplinary systems were linked so that it was possible, in some cases, for a PCO to initiate disciplinary measures when a complaint was upheld. However, detecting poor practice by means of complaints was a purely reactive process. During the 1970s and 1980s, there was very little proactive monitoring of GPs that might have been capable of detecting malpractice or poor performance. The Regional Medical Service (RMS) employed doctors known as regional medical officers (RMOs) who visited all GPs in their area. Each GP might expect a visit about every two years. The RMOs' role was largely pastoral although they had the power to inspect GPs' controlled drugs registers (CDRs) and their arrangements for storing controlled drugs. Theoretically, they could inspect medical records but it appears that, by the mid-1960s, this power had fallen into disuse. In 1991, the RMS ceased to have any responsibility for GPs.

15. In November 1987, the Government published a White Paper, 'Promoting Better Health', which contained a number of proposals designed to improve the range and quality of primary care services. FPCs were given increased responsibilities and a 'managerial' role. In an attempt to enhance the managerial role, the new FHSAs, which came into existence in 1990, had fewer GP members than the FPCs and those members were appointed by the regional health authorities instead of (as had hitherto been the case) by the LMCs. FHSAs were required to employ medical advisers independent of the local medical profession who could provide expert clinical advice. New GPs' terms of service required doctors to be more active in the field of preventive medicine and contained other provisions aimed at improving the quality of primary care services. FPCs were encouraged to set targets for the provision of special services such as vaccination, immunisation and cervical screening. Incentive payments were made if targets were achieved. Also, the Prescription Pricing Authority began to analyse data collected from the prescriptions issued by GPs. These data analyses were sent to FHSAs, whose medical advisers visited GPs and discussed their prescribing practice. Later, FHSAs began to employ specialist pharmaceutical advisers for this purpose. Initially, this exercise was designed to bring about a reduction in the cost of drugs prescribed; GPs were to be persuaded to prescribe the cheaper generic equivalents of the more expensive proprietary drugs they had formerly used. Before long, the objective shifted and medical and pharmaceutical advisers focussed their attention on trying to ensure that doctors prescribed rationally and well.

16. In the early 1990s, the Government began to encourage medical or clinical audit, a process by which doctors analyse data drawn from various aspects of their clinical

practice and, it is intended, use the results to improve their practices. Incentive payments were offered to doctors who would take part. Clinical audit can reveal a good deal about the quality and standards of the care provided by the doctor. However, the doctors would not allow officers of the PCO to see the results of their audits. The process was wholly formative; that means that it was to be regarded as a learning experience and was not to be used as a means of inspection or testing. Audit results were confidential and were reported annually to the FHSA only in an aggregated, anonymised form.

17. During the period up to 1998, considerable progress was made by the PCOs (first the FHSAs and, from 1996, the HAs) in the collection of information about GP practices and in encouraging GPs, by means of financial incentives, to improve the range and quality of their services. Nevertheless, there were still considerable limitations on the ability of the PCOs to deal with those GPs who were not amenable to change. Medical and pharmaceutical advisers had limited powers and had to proceed by way of persuasion and the use of influence. After 1996, there was a change in the system for dealing with patient complaints. From that time, complaints were made direct to GP practices and HAs might remain completely unaware that a complaint had been made. Consequently, they had less opportunity to gain intelligence about poor practice in their area. The complaints and disciplinary systems operated separately. Disciplinary action involved a cumbersome process and was seldom initiated. HAs still had only limited powers to remove a doctor from their lists. By 1998, local arrangements for dealing with poorly performing doctors, which came into existence after the introduction by the GMC of its performance procedures in 1997, were in general only in the planning stages.

Shipman in the 1980s and Early 1990s

Shipman's Time at the Donneybrook Practice

18. Throughout the 1980s, Shipman had practised at the Donneybrook practice, which was then described as a 'group practice'. In fact, the Donneybrook practice was not what would now be described as a group practice, i.e. one in which the doctors share the care of the patients on their joint list. Most of the doctors in the Donneybrook practice, including Shipman, had their own list of patients. They cared for each other's patients only under mutual arrangements for half days, holidays and out of hours cover. They did not become familiar with the health or problems of each other's patients. The other doctors in the practice had little opportunity to form an opinion about the quality of care provided by Shipman and no reason at all to suppose that he might be harming his patients deliberately.

Shipman's Move to the Market Street Surgery

19. In late 1991, Shipman decided to leave the Donneybrook practice and to set up as a single-handed practitioner. Although, strictly speaking, he did not need the permission of the Tameside FHSA to do so, he did need its approval and support because it could have withheld the financial allowances he needed to set up the new practice premises. However, support was readily forthcoming. Shipman was held in high regard at the FHSA. He was well known to officers of the FHSA; he had been a member of its predecessor PCO,

the Tameside FPC, for several years while secretary of the LMC. He was not universally liked; many people regarded him as arrogant and 'prickly'. But there was no reason to believe that he was providing other than a high standard of care for his patients and certainly no reason to think that he might be killing them. Moreover, as there were no other small or single-handed practices in Hyde, it was thought that the new practice would provide appropriate diversity of service. On 1st January 1992, Shipman set up as a sole practitioner, still working from rooms within Donneybrook House, where the Donneybrook practice had been situated. His new surgery premises at 21 Market Street, Hyde, were not ready for occupation until August 1992.

Shipman's Clinical Practice

20. Shipman gave the appearance of being a competent doctor. He was enthusiastic about preventive medicine and undertook regular clinical audit. He seemed to be modern and progressive and was well liked by his patients. It is possible (as some have suggested) that he created an appearance of greater professional competence that he in fact possessed. Whether or not that was so, it is unlikely that routine examination of the limited amount of data available to the PCOs during the time he was in practice would have raised any concerns about his competence or professional conduct. Although complaints were made to the Tameside PCO about Shipman in 1985, 1990 and 1992, they were not such as to raise serious doubts about his overall competence or conduct and they would certainly have raised no suspicions about his criminality. Most conventional monitoring techniques would, therefore, have failed to identify him as a dysfunctional doctor.

Shipman's Prescribing

21. The only respect in which Shipman was an 'outlier' was in relation to his prescribing practice. He prescribed expensive drugs. For a time, he would not comply with requests to prescribe generic drugs rather than the more expensive proprietary brands. Also, he was enthusiastic about the effect of statins (lipid-lowering drugs), which had only recently appeared on the market. They were expensive and many doctors doubted their efficacy. Shipman insisted on prescribing them. Time has shown that his confidence in them was well placed. When tackled by medical or pharmaceutical advisers about his use of expensive drugs, Shipman was always able to justify his prescribing practice by reference to published research. There was no concern about the quality of his prescribing – only about the cost.

Shipman's Vulnerable Points

22. The two aspects of Shipman's activities which rendered him most vulnerable to detection were his acquisition of large quantities of diamorphine, which he used to kill his patients, and the high number of deaths among his patients.

Shipman's Acquistion of Diamorphine

23. As I have said, during the period for which Shipman was in practice, RMOs and, later, medical advisers had the power to inspect GPs' CDRs and their arrangements for storing

controlled drugs. When asked whether he kept a CDR, Shipman replied that he did not and had no reason to do so, since he did not keep a supply of controlled drugs for emergency use. There was no reason to doubt the truth of that assertion. It was not unusual for a GP to elect not to maintain a stock of controlled drugs. In fact, as is now known, Shipman did keep a stock of diamorphine and used it to kill patients. There was no means by which the RMOs or medical advisers could have known this.

24. Shipman did, however, prescribe controlled drugs for patients. His prescribing of controlled drugs did not give rise to concern. The limited amount of prescribing data available in the 1980s and early 1990s – and the fact that, until 1992, Shipman's data was included within the data for the whole Donneybrook practice – would have made any abnormality in his prescribing practices difficult, if not impossible, to detect. In the years after November 1993, Shipman obtained diamorphine by prescribing it for patients who did not in reality require it, by removing it from the houses of patients who had died of cancer or by collecting it on behalf of terminally ill patients and keeping some or all of the drug for himself. None of these methods of acquisition would have been likely to be detected by monitoring of his prescribing and the Tameside PCOs had no means of knowing about them. Nor, prior to Shipman's conviction, did PCOs routinely undertake monitoring specifically directed at GPs' prescribing of controlled drugs. On one occasion, a pharmacy consultant (not an employee of the FHSA) noticed that he appeared to be prescribing large amounts of diamorphine; when she asked about this (not because of any concern or suspicion, but so that she could plan the future drugs budget), Shipman explained that the drug was needed for a terminally ill patient. He produced the medical records to demonstrate that this was so. The consultant had no reason to suspect that he might be stealing diamorphine from patients and using it to kill. Nor did the Tameside PCOs.

25. In my Fourth Report, I made recommendations which would make it far more difficult for a doctor or other healthcare professional to obtain illicit supplies of controlled drugs and which would also make it more likely that a doctor who succeeded in obtaining drugs illicitly would be detected. Monitoring of GPs' prescribing of controlled drugs, using the techniques now available, should also be of assistance, and I have recommended that doctors who have had a drug problem in the past or who are suspected to have a current problem should be subjected to particularly close scrutiny.

The Number of Patient Deaths

26. Before 1998, it was not the practice of PCOs to monitor the death rates among patients of individual GPs. There was no requirement that they should do so and there would have been considerable practical difficulties. Had monitoring been carried out, Shipman's excess patient deaths would have become evident, probably in the 1980s but certainly in the 1990s. However, there can be no criticism of the PCOs in Tameside for not having undertaken this type of monitoring. There is still no system of routinely monitoring GP patient deaths. The task of devising such a system is not straightforward. It involves the linkage of large amounts of data and complex statistical analysis. To be effective, it must be done on a national basis.

27. I have examined the feasibility of setting up a national monitoring system. The Inquiry commissioned Dr Paul Aylin, Clinical Senior Lecturer in Epidemiology and Public Health, Imperial College of Science, Technology and Medicine, to carry out research into the desirability and feasibility of such a system. Dr Aylin and his team prepared a report and gave a presentation of their work to the Inquiry. The topic was then discussed at a two-day seminar attended by experts in the field and representatives of most of the organisations that would be involved in the development and operation of such a system. On the basis of Dr Aylin's work and of discussions at the seminar, I have concluded that a national system of monitoring GP patient mortality rates (particularly if coupled with the reform of the systems of death certification and investigation I recommended in my Third Report) would be likely to deter a doctor from criminal activities such as those of Shipman. Even if it did not, it would greatly improve the chances of detecting such activities. I also believe that the collection and analysis of GP patient mortality data would have a beneficial effect on the quality of patient care. I have therefore recommended that the DoH should take the lead in developing a national system for monitoring GP patient mortality rates.

The Adequacy of Local Monitoring

28. I have considered the arrangements for the monitoring and supervision of doctors that were in place in Tameside during the time that Shipman practised there. I have also compared the arrangements in Tameside with those in operation elsewhere. Having carried out that exercise, I have concluded that the performance of the PCOs in Tameside was typical of that of most PCOs up and down the country at the time. There were areas where other PCOs had taken innovative steps, not taken in Tameside, in an attempt to raise standards and to identify doctors who were performing poorly. However, it is clear that the Tameside PCOs discharged their duties conscientiously and properly. They cannot be criticised just because they may not have been in the vanguard. They were doing all that was required of them.

29. In a written submission to the Inquiry, the Tameside Families Support Group referred to the bewilderment of its members that, during the period when Shipman practised in Hyde, the State should apparently have abdicated its responsibility for monitoring GPs. I can understand that sentiment. Viewed through today's eyes, it seems extraordinary that, until less than a decade ago, the PCOs should have had so few powers to regulate GPs' behaviour.

30. The explanation lies, I think, in the historical status of GPs as independent contractors. That status has imposed constraints on attempts by successive PCOs to control and supervise GPs effectively. Until recently, GPs could be compelled to comply with their terms of service but no more. In the early part of the period during which Shipman was in practice, there was a strong belief, apparently shared by Government, that the medical profession itself provided the best (indeed the only) means of imposing high standards of clinical care and professional conduct on doctors and of monitoring those standards. It was believed that it would do so rigorously. Hence, matters of professional concern arising locally were left to be determined by LMCs, with the GMC as ultimate arbiter of fitness to practise. This belief, which was fostered by the profession, was difficult to challenge in an area involving questions of professional expertise.

31. It is clear that, by the 1980s, there was a realisation on the part of Government that, if consistency of service and standards among GP practices was to be achieved, some element of management by PCOs must be introduced. The matter could no longer be left to the profession. The process of change began in the mid-1980s and has continued ever since. It has been accompanied by a growing recognition of the importance of tackling poor performance among GPs. As I shall go on to describe, there have been considerable developments in the arrangements for monitoring GPs since 1998. Until that time, progress was slow and, in retrospect, it is natural to wish that the process of change had started sooner. However, the fact that it did not, cannot in my view, be attributed to fault on the part of any person or organisation.

Developments since Shipman's Arrest in 1998

The New National Bodies

32. Since Shipman's arrest, there have been radical changes within the NHS. On a national level, there has been the imposition on NHS bodies of the duty of quality to which I referred earlier, the introduction of National Service Frameworks and the development of core standards of service. The Commission for Health Improvement was set up to inspect the performance of local NHS bodies. In 2004, its functions were taken over by the Commission for Healthcare Audit and Inspection, now known as the Healthcare Commission. The National Clinical Assessment Authority (NCAA) was set up to provide local NHS bodies with advice and support in the detection and assessment of substandard performance by NHS doctors and in the remediation of any problems detected.

The New Local Bodies

33. At a local level, HAs (which were quite large organisations) were replaced by PCTs. These much smaller organisations have a wide range of powers. The Inquiry is concerned only with those powers that relate to the monitoring and supervision of GPs. Each PCT has a limited number of GPs on its list (usually about 100 plus some locums) and should therefore be able to develop a close knowledge of their strengths and weaknesses. PCTs now have much more information available to them when considering whether to admit a doctor to their lists. They have the right to refuse to admit a doctor to the list in certain circumstances. They also have a wide range of 'list management powers', by which they can remove or suspend GPs from their lists or impose conditions upon their continued inclusion. These powers are new and the evidence suggests that, as yet, they are not being fully exercised in all areas. However, these powers enable PCTs to take effective action for the protection of patients. They are no longer entirely dependent upon other bodies such as the NHS Tribunal (now abolished) or the GMC to do so on their behalf.

Attempts to Improve Standards

34. A variety of quality marker schemes has been developed, by which GPs and GP practices can work in order to improve services, and also to demonstrate that they have achieved high standards of practice organisation, individual competence and/or

performance. Participation in these quality marker schemes is voluntary. It is obviously to be encouraged as it can serve only to raise standards. Another innovation has been the new GMS Contract, which came into operation in April 2004 and which introduces a system of financial incentives to encourage practices to achieve certain quality standards. The new GMS Contract requires GP practices (not individual doctors) to sign up to it. The GMS Contract is in its early days and it is impossible to assess with any confidence the impact it is likely to have on the quality of patient care. Another unknown factor is the extent, if any, to which practices where the standards of care are poor will attempt to raise standards in order to qualify for the financial incentives that are available under the GMS Contract.

Clinical Governance

35. Also at a local level, there is a new framework of monitoring, known as clinical governance. I describe this initiative in Chapter 12. Very briefly, in the context of primary care, it is intended that it should consist of an integrated system of different types of activity, all aimed at improving quality of care. One part of the system involves the collection and analysis of data relating to doctors' clinical practice both by the PCT and within general practices. At the moment, the types of data available are limited, the accuracy of the data is imperfect and the structures for making use of the data require further development. There are particular difficulties in attributing data to individual doctors, as opposed to GP practices. Clinical governance will not reach its full potential until it includes the collection of data relating to individual doctors. It is clear from the evidence I have heard that there is some way to go before clinical governance is fully implemented in primary care. In my view, the real obstacle to implementing clinical governance is the position of GPs as independent contractors and the consequent inability of PCTs to 'manage' them for clinical governance purposes. This is not to say that GPs should lose their independence and self-employed status. However, it seems to me that PCTs may need to be given greater powers if they are to discharge their clinical governance responsibilities effectively and if they are to be accountable for discharging the duty of quality placed upon them. They will also need leadership and determination if they are to make quality their first priority and to root out substandard practice.

36. In my view, if properly developed and well resourced, clinical governance could provide the most effective means of achieving two important aims. First, it could enable PCTs to detect poorly performing or dysfunctional GPs on their lists. Second, it could have the beneficial effect of helping doctors who are performing satisfactorily or well to do even better.

Appraisal

37. Annual appraisal is now mandatory for all GPs. The Inquiry heard a considerable amount of evidence about the way in which appraisal is carried out and about its proposed link with revalidation, which I shall refer to later in this Summary. It is clear that appraisal has had some positive effects; it gives GPs an opportunity to talk with a colleague about themselves, their practices and their personal development needs. However, appraisal

does not constitute an evaluation or assessment of the appraisee's performance; it is not intended to do so. It yields little information that can assist the PCT in its clinical governance function. It might help the PCT to decide what types of continuing professional development should be provided for local GPs, but that is all. As currently constituted, appraisal cannot be regarded as a clinical governance tool. I have recommended that there should be clarity about the purpose that appraisal is intended to serve and that, once clarity has been achieved, steps should be taken to ensure that appraisal fulfils its purpose as effectively as possible.

Single-Handed and Small Practices

38. Because Shipman was practising as a single-handed practitioner for the last six years of his professional life, the period in which he killed most of his victims, there have been calls from some quarters for single-handed practice to be phased out. It is true that I have found that the greatest concentration of Shipman's killings occurred when he was in single-handed practice, but I have also found that he killed 71 patients while he was at the Donneybrook practice. As I have already explained, however, that was not a 'group practice' as the term is now ordinarily understood.

39. The Inquiry has examined the particular problems of isolation that may be associated with single-handed practice and has also considered the benefits that such practice may bring to patients. First, many patients prefer small or single-handed practices because the doctors are able to provide continuity of care. Second, for geographical and demographic reasons, the system cannot manage without small and single-handed practices. Therefore, I have concluded that the focus of endeavour should be, not on reducing further the number of small practices in existence, but on improving the services that they provide and, in particular, removing the causes and mitigating the effects of isolation. In Chapter 13, I discuss some of the ways in which this might be achieved.

The Availability of Information about Doctors

Information Available to Employers and Primary Care Organisations

40. I have already mentioned that, throughout the period during which Shipman was in practice, the PCOs in Tameside were unaware of his past convictions for drug-related offences and his subsequent referral to the GMC. Since 1998, steps have been taken to increase the amount of information available to PCTs about doctors who are on, or who apply to join, their lists. GPs are now required, when applying for admission to a list, to make declarations about, *inter alia*, previous or current involvement in criminal proceedings, in disciplinary proceedings by the GMC or a regulatory body elsewhere, in list management action taken by another PCT and in disciplinary action by a previous employer. GPs already on the list have had to make 'catch up' declarations and have an ongoing duty to report any such involvement to their PCT. In addition, PCTs are obliged to make certain checks before admitting doctors to their lists and doctors are now required to provide enhanced criminal record certificates when applying for admission to a list. In 2005, there is to be a 'catch up' exercise for the provision of criminal record certificates by GPs already on PCT lists. The additional information now available to PCTs enables

them to make more informed decisions about whether to admit a doctor to their lists and also makes it possible for them to keep a watchful eye on those doctors who have a past disciplinary or criminal history. Since 2000, the GMC has had a statutory duty to disclose to a doctor's employer or PCO the fact that a complaint or report about a doctor received by the GMC has reached a certain point in its FTP procedures. Cases that are rejected at an early stage need not be notified. Nevertheless the introduction of this duty means that the PCOs receive information about doctors' involvement with the GMC that was not previously available to them.

41. Despite these improvements, there are still gaps in the PCTs' information about doctors. PCTs are largely dependent on applicants on the list being truthful about their disciplinary histories. They have no information about complaints made or concerns raised about a doctor which have not resulted in disciplinary or list management action or which have not been investigated or substantiated. They have no information about clinical negligence claims that may have resulted in a finding against the doctor or in a settlement for a significant amount of damages. Recent reports into the activities of two GPs, Clifford Ayling and Peter Green, have illustrated the difficulty (and also the crucial importance to patient safety) of being able to draw together and track the records relating to separate but similar complaints raised about the same doctor. This exercise can be even more difficult when doctors have a peripatetic working pattern. As well as the fact that the information available to PCOs may be incomplete, the task of collecting what is available can be inconvenient and time-consuming.

42. In order properly to fulfil their clinical governance responsibilities and to provide adequate protection for patients, PCTs need to be able to access as much information as possible about the doctors who are on or who might apply to join their lists. Other bodies – such as the Healthcare Commission, the GMC, the NCAA and the Department of Health (DoH) – also need access to this information. I have therefore recommended the creation of a central database of information about every doctor in the UK. This would contain certain categories of information and would also be linked to sources from which additional relevant information could be obtained. The existence of sensitive information that is not in the public domain could be 'flagged', so that further enquiries could be made when necessary. The database would be accessible to NHS bodies, accredited private sector employers and other organisations with a legitimate interest. Doctors would be able to access their own entries to check the accuracy of the information held.

43. Not only would such a central database make it far simpler for an employer or PCO to conduct pre-employment or pre-admission checks, but the reliability of those checks would be greatly enhanced. The great majority of doctors would have nothing to fear; their entries would contain no more than their qualifications and their *curriculum vitae*. However, those doctors who cause problems, and who move on from place to place causing more problems, would very soon be identified, thus enabling appropriate action to be taken to protect patients.

Information Available to the Public and to Patients

44. During the Inquiry, there was discussion about how much information about doctors should be made available to the public and to patients. This was appropriate in the context

of an Inquiry into the activities of a doctor who, 24 years before being convicted of murder, had been convicted of a series of criminal offences in connection with his dependence upon a controlled drug. It is entirely natural that the relatives and friends of Shipman's victims should say 'If only we had known.'

45. The information available to patients and prospective patients about an individual GP is very limited under the present system. The public may become aware of a doctor's criminal convictions or involvement in disciplinary matters through press coverage or 'on the grapevine'. However, there is no means by which comprehensive information can be obtained. In my view, such information should be readily available to anyone who seeks it.

46. I have recommended two measures to address this need. First, I recommend that the GMC operates a system of tiered disclosure. This would mean that current and recent information about a doctor's disciplinary record with the GMC (including information about any criminal convictions reported to the GMC), together with information about the doctor's registration and revalidation status, should be accessible on the GMC's website or to anyone requesting the information from the GMC by telephone or other means. After a period, some (but not all) of that information would be removed from the website and would be replaced by a note, indicating that further information was available by telephoning the GMC. All that information would remain available to anyone requesting it for as long as the doctor remained in practice. In Shipman's case, this would have meant that a prospective patient viewing his entry on the GMC's website in 1997 or 1998 would have been alerted to the fact that there was something more to be known about him and would, by telephoning the GMC, have been able to find out about his convictions in 1976. Alternatively, if s/he had telephoned the GMC in the first place, the information would have been available by that means. I think that this arrangement provides a reasonable balance between the interests of the doctor in being able to put the past behind him/her (which would be difficult if full information remained on the website indefinitely) and the right of the public and patients to find out everything about the doctor that has at one time or another been in the public domain.

47. The second measure I recommend relates to information to be given to patients when a doctor resumes work at a GP practice after a period of suspension or erasure or where conditions have been imposed on his/her registration. In those circumstances, the practice should send a letter of explanation to all patients. The draft letter should be approved by the PCT. Patients should have the opportunity to refuse to be treated by a doctor who is subject to conditions or who has resumed work after suspension or erasure. They are entitled to make an informed choice about this important matter.

Patient Complaints and the Disciplining of General Practitioners

The System prior to April 1996

48. I have already explained that, until 1996, complaints made by or on behalf of patients would go to the PCO. If the complaint amounted to an allegation that the doctor had breached one of his/her terms of service, it would often be referred to a medical services committee (MSC), a disciplinary committee administered by the PCO. The MSC would

decide (with or without an oral hearing) whether the GP had breached his/her terms of service and would recommend what action should be taken. In the event that a breach was found, the FPC could administer a warning or withhold remuneration from the doctor up to a maximum amount of £500. If the FPC believed that a more severe penalty was indicated, it could make recommendations to the Secretary of State (SoS) for Health and Social Security (later the SoS for Health) or make representations to the NHS Tribunal seeking removal of the doctor from the medical list. At that time, therefore, the system of dealing with patients' complaints was linked directly with the disciplinary powers of the PCO, backed by the SoS, the NHS Tribunal and, ultimately, by the GMC.

49. However, the system for handling complaints was far from ideal. There was no independent investigation of the complaint; it was left to the complainant to gather the evidence and present the case. There were a number of technical rules that disadvantaged complainants. A complaint had to be brought within a very short time after the events complained of; hearsay evidence was often not admitted. Doctors, who were usually represented by their medical defence organisation, often appeared to be at an advantage. However, at least there was a mechanism by which complaints could be aired and decided. Also, there was a standard (i.e. that set in the terms of service) against which complaints could be judged. Disciplinary measures could be taken if the doctor was found in breach of his/her terms of service and, if the matter was serious enough, it could be reported to the NHS Tribunal or the GMC.

Complaints against Shipman

50. Shipman was the subject of three formal complaints which were referred to a MSC, one in 1985, one in 1990 and one in 1992. I have described in Chapter 6 the events giving rise to those complaints and their course and outcome. The first complaint was dismissed by the MSC without a hearing. In response to the second complaint, Shipman admitted that he had breached his terms of service. The MSC issued a warning. On the third occasion, Shipman disputed the circumstances, whereupon the MSC held an oral hearing and found against him. On that occasion, the sum of £800 was withheld from his remuneration and he was again warned to comply more closely with his terms of service. The handling of all three complaints illustrates some of the shortcomings of the system in operation during the years before 1996. In particular, it illustrates the problems which could arise when the complainant was expected to assemble the evidence in support of the complaint and yet had neither the power nor the resources to do so.

51. Bearing in mind that Shipman was an established serial killer of his patients, it seems remarkable that such complaints as were made about him in the years between 1977 and 1996 were not of a more serious nature. No complaint was received about his treatment of, or failure to treat, any patient whom he had in fact killed. Even if they had been investigated in great detail, the three complaints to which I have referred would not have thrown any light on Shipman's true character as a murderer. With the benefit of my knowledge of Shipman's habitual dishonesty, I have detected signs of dishonest behaviour in two of the cases. However, such signs were by no means obvious and it is not surprising that they were not detected at the time.

52. The Family Health Services Appeal Authority, on behalf of the SoS for Health, decided to refer the 1990 and 1992 complaints to the GMC. However, the GMC took the view that the two matters did not give rise to a question of serious professional misconduct (SPM) and declined to take any further action. In my view, even if the GMC had decided to take action, the most that would have happened is that Shipman would have been given a further warning. It is most unlikely that Shipman's name would have been either erased or suspended from the medical register or that any further enquiries would have been made that could have revealed his true nature.

The System after April 1996

53. In 1996, the arrangements for handling complaints made by or on behalf of patients were changed. Thereafter, complaints about GPs had to be made direct to the GP practice concerned. Following this change, if the complaint was 'resolved' at that stage, possibly by an apology and an assurance that there would be no repetition of whatever had given dissatisfaction, the PCO might never know that a complaint had been made. In some cases, the PCO might be involved in arranging conciliation between the doctor and the patient. This may have been a satisfactory system for some, although research suggests that many patients were reluctant to make a complaint direct to the practice of the doctor concerned. Also, it appears that some practices were not as open and helpful in handling complaints as they should have been.

54. If the complaint was not resolved to the complainant's satisfaction at this stage, s/he could proceed to the second stage of the procedures. At that stage, the PCO would become aware of the complaint and what it was about. However, the PCO was still not responsible for investigating the complaint. Instead, if a 'convenor' (usually a non-executive member of the PCO Board) decided that the complaint required resolution, the PCO would set up an independent review panel (IRP), which would conduct a hearing designed to find out whether the complaint was justified. There were no standards by which the complaint was to be judged. Nor could an IRP impose, or even recommend the imposition of, any sanctions upon the doctor. The IRP would write a report of its findings for submission to the PCO, which could, if it wished, take disciplinary action against the doctor. In other words, the handling of complaints was no longer directly connected to the disciplinary procedures for doctors. Although, in theory, PCOs could still bring disciplinary proceedings against doctors for alleged breaches of their terms of service, in practice they rarely did.

55. In my view, the arrangements for handling patients' complaints against GPs after 1996 became even less effective as a means of detecting malpractice or poor performance than the previous arrangements had been. However, so far as is known, no complaints of any significance were made against Shipman between 1996 and 1998, despite the fact that, during this period, he was killing so frequently; he killed 30 patients in 1996, 37 in 1997 and 18 in 1998 before he was eventually detected.

Recent Changes to the System

56. The system for handling patient complaints within the NHS is in a state of transition. The second stage of the procedures has been changed recently. Instead of complaints being

heard by IRPs, they are now referred to the Healthcare Commission. The Healthcare Commission has the resources to investigate complaints and to arrange an oral hearing before a panel. It is independent of the NHS. The first stage of the complaints procedures except as it affects GP practices has also been changed. However, the first stage of the procedures for GP practices remains the same as it has been since 1996. The Government intends to reform it but is awaiting publication of this Report before doing so. I hope that my recommendations in that regard will be taken into account.

The Future

57. In Chapter 27, I have made detailed recommendations about the way in which complaints from patients and their representatives should be handled. I do not propose to rehearse them here. Instead, I shall summarise the main points. The complaints system should be directed at giving satisfaction to the person making the complaint, wherever possible, at securing patient safety and at being fair to doctors about whom complaints are made.

58. For this reason, it is important to differentiate at an early stage between those complaints which are relatively minor in nature and relate to purely 'private grievance' matters and those which have a relevance to clinical governance, i.e. those that might indicate that a doctor has placed a patient at risk or has delivered a poor standard of care. Complaints in the first category can be dealt with by way of conciliation and mediation, with the object of restoring, if possible, the relationship of trust and confidence between doctor and patient. Those in the second category should be taken over by the PCT and dealt with in such a way as to further its clinical governance responsibilities.

59. The Government proposes that, under the first stage of the new GP complaints procedure, patients should be given a choice where to lodge their complaint: at the GP practice concerned or with the PCT. I welcome this change and agree that patients should be given this choice. In order to enable PCTs to monitor the complaints lodged with practices and to identify any that raise clinical governance issues, I have recommended that GP practices should be required to report to the PCT all complaints within a short time of receipt. The PCT can then 'call in' those complaints which have or might have a relevance to clinical governance. Since the average number of complaints received is one complaint per GP per annum (and many of these are likely to be 'private grievance' complaints), the number of 'clinical governance complaints' to be dealt with by a PCT in any one year is not likely to be large.

60. As I have already explained, previous complaints systems have made no proper provision for the investigation of a complaint. In my view, the provision of arrangements for the prompt and thorough investigation of 'clinical governance complaints' is the single most important issue to be tackled in the reform of the complaints procedures. PCTs are not equipped to carry out such investigations themselves. If proper investigations are to be carried out, skilled and experienced investigators will be required. A single PCT would not have a sufficiently frequent need for an investigator to justify employing anyone full-time in that capacity.

61. I have therefore recommended that groups of PCTs should set up joint investigative teams and that 'clinical governance complaints' (save those which do not involve serious issues

of patient safety and where the underlying facts giving rise to the complaint are clear and undisputed) should be referred to the investigation team so that it can carry out an investigation and report back to the PCT. If the investigation becomes more complex than was at first thought (e.g. because it concerns both primary and secondary care), it should be referred to the Healthcare Commission. I have also recommended that, if the result of the investigation is inconclusive because there is a dispute of evidence (e.g. if the doctor and the patient disagree about the events giving rise to the complaint), the complaint should be referred to the Healthcare Commission for an oral hearing before a panel. Once the outcome of the investigation (with or without a hearing) is known, the PCT will be in a position to decide what action to take. It should have a firm basis of fact on which to act.

62. I have also recommended that concerns expressed about a GP by someone other than a patient or a patient's representative (e.g. by a fellow healthcare professional) should be dealt with in the same way as patient complaints. Such concerns should be investigated (where necessary) by the inter-PCT investigation team or, in a case raising difficult or complex issues, by the Healthcare Commission. I have also recommended that complaints handling systems in the private sector should be aligned as closely as possible with those in the NHS.

63. One of the (probably unforeseen) consequences of the dissociation of disciplinary proceedings from patient complaints in 1996 was the loss of any (even partially) objective standard by which a complaint could be judged. Before 1996, a complaint was upheld if the doctor was found to have breached his/her terms of service. The sanction imposed depended upon the gravity of the breach and the doctor's past record. After 1996, however, disciplinary proceedings could be instituted for alleged breaches of the doctor's terms of service but rarely were. Complaints could be lodged in respect of all matters, whether or not they were covered by the GP's terms of service. From April 2004, when the new GMS Contract came into effect, there have not even been terms of service to act as a background framework. In effect, a complaint is upheld if the decision-makers think it should be. There is no standard by which it is to be judged.

64. As a result, there is no means by which patients can know what their reasonable expectations are and whether those expectations have been met. There is an urgent need for standards which can be applied by PCTs, by other NHS bodies and by the Healthcare Commission in dealing with complaints. I have therefore recommended that objective standards, by reference to which complaints can be judged, should be established as a matter of urgency.

Support for Complainants

65. It is clear that there is a good deal of confusion about the right place to direct a complaint about a doctor. Many complainants think, erroneously, that they know where to lodge their complaints and send them to the wrong place. Some do not know where to direct them. A similar problem exists for people who wish to make a confidential report relating to some sort of suspected malpractice about which they are concerned. No doubt a sustained programme of public education could improve the position for complainants and those who wish to report a concern, but the problem is bound to persist to some extent.

66. In the course of the Inquiry, the GMC suggested a possible solution to this problem. It proposed that there should be a 'single portal' which people wishing to make a complaint could approach. Advice could be given as to the appropriate destination for the complaint to be received and handled. In other words, the 'single portal' would act as a signpost, indicating the appropriate direction for the complaint. Since the Inquiry hearings, the Healthcare Commission and the GMC have commissioned some preliminary work on the various options for providing such a service.

67. In my view, what is needed is a service that fulfils two functions. It should advise people who have already decided to complain or to raise a concern where to lodge their complaint or concern. It should also inform people who are uncertain whether or not they wish to complain or raise a concern where they can find the advice that they need. For that purpose, there should be a telephone helpline, as well as access by means of a website. I think it would be helpful also if, in addition to providing advice about the right destination for a complaint, the 'single portal' service were to be prepared to forward the complaint to the appropriate body if the complainant wished that to be done. Whatever form the 'single portal' takes, it must be extensively advertised. It needs to be as well known as NHS Direct and the Samaritans.

68. For many years, until 2003, Community Health Councils (CHCs) provided advice and support for people wishing to pursue a complaint. The abolition of the CHCs in 2003 was met with widespread expressions of dismay, particularly from organisations representing patients' interests. Two new services, the Patient Advice and Liaison Services (PALS) and the Independent Complaints Advocacy Service (ICAS) were formed. PALS does not provide independent support for a complainant. It would be inappropriate for it to do so, as it is staffed by NHS employees. However, ICAS is intended to provide independent advice and assistance.

69. The Inquiry has received no evidence about how ICAS is functioning. From the information on its website, it seems likely that it will provide support for complainants throughout the complaints process. There is a need for complainants and potential complainants to have access to free, independent and well-informed advice. It is not sufficient that a complainant is told how to proceed. He or she needs someone with whom to discuss the issues and the merits of the complaint. He or she needs advice about whether, and exactly how, to proceed. He or she needs someone to support him/her at a hearing, if any. If ICAS is indeed able to provide such advice and support, its work is very much to be encouraged.

70. Accordingly, I have recommended that, about two years after the new arrangements for complaints come into force in their entirety, an independent body should be commissioned to review the operation of the new arrangements for advising and supporting patients who wish to make a complaint. Any deficiencies identified by that review should be corrected.

Disciplinary Procedures

71. As I have already explained, with the introduction of the new GMS Contract in April 2004, GPs' terms of service have ceased to exist. They have been replaced by contractual

arrangements which are made with a GP practice, rather than with an individual GP. However, PCTs now have powers of list management. A PCT can remove or suspend a GP from its list or impose conditions upon his/her inclusion on the list. There is no power to order a withholding of remuneration; nor is there an official power to administer warnings or reprimands. This seems to me to be a *lacuna* in the PCTs' powers.

72. I can see advantages in PCTs having a wide range of sanctions available to them once they have conducted an investigation into a complaint or concern and found that it is justified, although not so serious as to merit the use of their list management powers or referral to the GMC or some other body. It seems wrong, in those circumstances, that the PCT should be powerless to act. I have therefore recommended that the powers of PCTs should be extended so as to enable them to issue warnings to GPs and to impose financial penalties in respect of misconduct, poor professional performance or deficient clinical practice. That is not to say that I think that PCTs should spend their time conducting disciplinary proceedings if they can deal with the matter in a simpler way which is both constructive and effective. After all, the most important aim is to improve clinical performance.

Raising Concerns

The Raising of Concerns by Medical Colleagues

73. It has always been possible for a doctor who was concerned about the treatment given to a patient by another doctor to report his/her concerns about that treatment to an appropriate authority. However, many doctors were not prepared to do that; they had been 'brought up' to regard it as improper to criticise or deprecate the conduct of a fellow professional. The culture was that it was 'not done'. However, by the early 1990s, the GMC had made clear that it was the duty of a doctor to report to an appropriate authority any concern s/he had about another doctor's treatment of a patient if the concern gave rise to issues of patient safety. The evidence heard by the Inquiry suggests that, although the GMC had made this quite clear by 1993 at the latest, many doctors were reluctant to make such reports. The old culture lingered on. The Inquiry was told that the culture had not changed until the events that had occurred at Bristol Royal Infirmary came to light. The GMC took disciplinary action against doctors who had failed to act on information and reports that the death rate among paediatric patients undergoing cardiac surgery at the Hospital was abnormally high. I was told that events in Bristol had had a salutary effect on the profession, which now recognised that its duty to protect patients had to override loyalty to colleagues. However, in his report of the Inquiry into those events, published in 2001, Professor (now Sir) Ian Kennedy suggested that the old culture among doctors was still alive at that time. Evidence received by this Inquiry suggests that, in some quarters, it survives even today.

The Case of Mrs Renate Overton

74. The evidence received by this Inquiry focussed upon the culture in the mid-1990s. In 1994, Shipman gave a gross overdose of diamorphine to a 46 year old patient, Mrs Renate Overton. Mrs Overton suffered from asthma and had called Shipman out because she was

suffering an attack. Diamorphine – and indeed any opiate drug – is contraindicated for asthmatics. Shipman injected her with diamorphine with, I am quite satisfied, the intention of killing her. Mrs Overton became unconscious and went into respiratory and cardiac arrest. Her daughter, Mrs Sharon Carrington, who was in the house, was summoned by Shipman and called an ambulance, which arrived in time for the paramedics to prevent Mrs Overton's death. Mrs Overton was admitted to Tameside General Hospital where she remained, in a persistent vegetative state, until her death 14 months later.

75. Information received from the paramedics, Mrs Overton's daughter and Shipman suggested that Mrs Overton had received a large dose of either morphine or diamorphine, apparently given as a 'bolus' dose, meaning that it was given all at once rather than gradually, as would be the usual way. Members of both the medical and the nursing staff at the hospital believed that Shipman had been wrong to give Mrs Overton an opiate drug in any quantity (because she was asthmatic) but that the error was the more serious because it appeared that the dose was excessive and had been given too quickly. In short, they realised that Mrs Overton's condition was due to Shipman's actions although they never for a moment suspected that he might have harmed her deliberately. No member of staff reported these events to an appropriate authority with a view to an investigation into Shipman's conduct being carried out.

76. I examined the events surrounding Mrs Overton's admission to hospital in some detail in my Third Report. I concluded that, if there was any responsibility to report these events, it lay upon the two consultants in charge of Mrs Overton's care at the time of her admission. The junior doctors and nursing staff were entitled to rely on the consultants to act appropriately. The consultants were Dr Ceri Brown, a consultant anaesthetist, and Dr Murtaza Husaini, a consultant cardiologist, who shared responsibility for the hospital's intensive care unit. Dr Brown admitted that he had not made any report about Shipman's role in Mrs Overton's collapse. Dr Husaini said that he had recognised his duty to do so and had in fact made a report to, among other people, the Chief Executive designate of the NHS Trust responsible for the hospital. I found that he had not. I deferred consideration of whether these two doctors should be criticised for their failure to make a report until the final stage of the Inquiry, when I would receive evidence about the advice given by the GMC, the way in which doctors understood that advice and the culture within the profession at the material time.

77. Having heard the evidence, I have concluded that, in 1994, no doctor should have been unaware of his/her ethical duty to report to an appropriate authority any concerns s/he may have had about the conduct of another doctor, if that conduct gave rise to issues of patient safety. Shipman's conduct plainly did give rise to such concerns and should have been reported. I considered Dr Brown's explanations for why he had not made such a report, as he admitted that he had not. First, he believed that the circumstances of Mrs Overton's collapse were so uncertain that he could not reasonably act. I rejected that contention. It was clear from a witness statement that Dr Brown gave to the police in 1999 that it was his view that Shipman's management of Mrs Overton had been 'highly unusual, even dangerous'. Second, Dr Brown said that he believed the only possible route open to him was to make a complaint to the GMC. However, he did not think it appropriate to do so; he thought that the GMC would not accept a complaint unless and until it had been more

thoroughly investigated than this one was. As I shall explain, I do not think that belief was without foundation and I can understand why he would have hesitated to make a report about a GP to that quarter. Dr Brown said that he did not know to whom he could make a report about a GP within the local NHS arrangements. He knew what the procedures were for raising a concern within the hospital but this potential complaint concerned a GP, not a hospital doctor. The procedures were different and he did not know what they were. I can accept that he did not know what the procedures were but cannot accept that that was an excuse for not reporting his concerns. Dr Brown was a member of the Medical Defence Union (MDU), which operates a helpline for members who face ethical problems. If he had not thought of discussing the problem with the Chief Executive designate or Medical Director designate of the NHS Trust (either of whom would have been an appropriate recipient for his concern), Dr Brown should have consulted the MDU which, I am satisfied, would have given him sound advice.

78. Dr Brown also said that professional etiquette played a part in his decision not to make a report. He felt that there was a tension between the duty to report a colleague's misconduct and the need to avoid an accusation against a colleague that might turn out to be false. He said that he was worried that, if he made a report, the GMC might criticise him for disparaging Shipman. I accept that Dr Brown genuinely held these reservations about professional etiquette. Finally, Dr Brown said that he felt that he ought to honour the wishes of Mrs Overton's family that no complaint should be made against Shipman. Dr Brown had told Mrs Overton's brother (Dr Michael Overton, a GP) that Mrs Overton had been given morphine, despite the fact that she was known to be asthmatic. He had, he said, put the family in a position to make a complaint or bring a claim if they chose to do so. I reject that as an explanation. Dr Brown did not give Dr Overton the full facts as known to him; he did not tell Dr Overton what he believed to be the size of the morphine dose; nor did he say that it had apparently been given as a bolus dose. Dr Brown certainly became aware that Mrs Overton's family did not intend to make a complaint or a claim. He knew therefore that, if anyone were to instigate an investigation into Shipman's conduct, it would have to be himself or Dr Husaini.

79. I have concluded that both Dr Husaini and Dr Brown must be criticised for their failure to report Shipman's actions in respect of Mrs Overton. However, my criticism is tempered because I accept that the culture within the profession at the time, in 1994, was that to report a colleague was 'not done'. Many doctors throughout the country would have failed to act, as these two doctors did.

80. I found that, if Shipman had been reported at this time, it is possible, although unlikely, that the true nature of his actions in respect of Mrs Overton would have been discovered. I found that, if a complaint had been made locally, the investigative procedures would have been unlikely to uncover the truth. It is unlikely that Shipman would have been reported to the police. Similarly, if the complaint had been reported to the GMC, it is unlikely that the facts and background would have been thoroughly investigated. It is likely that the GMC would have taken the view that Shipman had made an error. Having reviewed a number of cases in which the GMC dealt with doctors who had made serious errors in prescribing or administering dangerous drugs, I concluded that it was most unlikely that Shipman would have been erased from the medical register. The most

beneficial effect, so far as his potential victims were concerned, would have been that he might well have ceased killing for a time and some lives might have been saved. I cannot say how many or whose.

The Future

81. A decade has passed since Dr Brown and Dr Husaini failed to report Shipman. As I have said, there are signs that the culture of mutual self-protection has changed since then, although the process is by no means complete. It is inevitable that deeply ingrained attitudes take a long time to change. In my view, it is important that young doctors are imbued with the new culture from the start. But it is also vital that the leaders of the profession consistently put the message across to the present generation of doctors. There can be no room today for the protection of colleagues where the safety and welfare of patients is at issue. I believe that the willingness of one healthcare professional to take responsibility for raising concerns about the conduct, performance or health of another could make a greater potential contribution to patient safety than any other single factor.

Concerns about Shipman

82. Shipman's position as a respected doctor, his ability to lie convincingly and the degree of trust placed in him by his patients and their families meant that surprisingly few people had any concerns at all about the number of his patients who were dying or about the circumstances of their deaths. The vast majority of the bereaved relatives and friends of Shipman's victims had no suspicions whatever about the deaths at the time. They were frequently surprised at the suddenness with which a death had occurred but, in general, they accepted Shipman's explanation without question. Those very few who had misgivings were not concerned about the possibility of *criminal* behaviour; more usually, the concerns were that Shipman might have given substandard care – perhaps by failing to attempt resuscitation or to summon an ambulance, or by leaving a dying patient alone. Sometimes, the concerns amounted only to a general feeling of unease that there was something 'not quite right' about a death. But, until Shipman was under investigation for the death of Mrs Kathleen Grundy, none of the bereaved relatives and friends reported their concerns to the authorities. Some were intimidated at the prospect of questioning the actions of a doctor; others were persuaded by members of their families that their worries were unfounded. Several have told the Inquiry that they did not know to whom they could take their concerns. There were, however, a few individuals who became suspicious of Shipman.

The Concerns of Mrs Christine Simpson

83. Mrs Christine Simpson was one of those individuals. She was the resident manager of Ogden Court, a sheltered housing development in Hyde, which was then under the administration of the Manchester & District Housing Association. Between 1988 and 1998, Shipman killed nine residents of Ogden Court. Mrs Simpson became increasingly concerned about the suddenness of the deaths and about their proximity to visits from Shipman. She became suspicious that he might be killing his patients. In 1995 or 1996,

she decided to mention her concerns to her line manager, Mrs Janet Schofield. Mrs Simpson was diffident about doing this and I accept that she conveyed her concerns in a rather oblique way. I am satisfied, however, that, when speaking to Mrs Schofield, she linked the deaths with visits by Shipman and gave what she believed to be a clear indication of her concern that all was not as it should be. I am satisfied also that Mrs Schofield dismissed Mrs Simpson's concerns. Her view was that Mrs Simpson was a somewhat difficult personality, with a negative attitude to authority. She did not question Mrs Simpson about her concerns, nor did she take them further. While Mrs Simpson did not raise her concerns again in any formal manner, I am satisfied that she referred to them in conversation with Mrs Schofield by means of comments linking Shipman's name with deaths at Ogden Court. On occasion, she probably used the name 'Dr Death' to describe Shipman.

84. As a manager, Mrs Schofield should have been alert to the kind of oblique message of concern that Mrs Simpson was trying to convey to her, and she should have taken any such concerns seriously. If, after discussion, it appeared that there was any possibility that the concerns might be well founded, she should have taken them forward. I think Mrs Schofield's attitude towards Mrs Simpson inhibited her willingness or ability to listen carefully to what Mrs Simpson was telling her and to think about its implications. However, the concerns which Mrs Simpson was trying to raise were quite extraordinary and would probably have seemed to many to be preposterous. A friend to whom Mrs Simpson voiced her concerns advised her not to mention them to anyone else because people would say she was 'mad'. The friend was perceptive; Mrs Schofield attributed Mrs Simpson's concerns to an 'obsession' with death. My criticism of Mrs Schofield is muted. She did not listen carefully to Mrs Simpson's attempts to raise her concerns. That was due in part to her own personality and to her attitude towards Mrs Simpson. But I think also that her attitude was understandably affected by the belief that any suggestion that a doctor might deliberately be harming his patients was unthinkable.

The Concerns of Others

85. Mrs Dorothy Foley, Mrs Elizabeth Shawcross, Mr John Shaw and Mrs Shirley Harrison all had suspicions about Shipman. Mrs Foley and Mrs Shawcross worked as home helps for Tameside Social Services. They became concerned when three of their elderly clients died (two in 1986 and one in 1989) during, or shortly after, a visit from Shipman. They heard similar tales from other home helps. Mr Shaw ran a taxi service in Hyde. A lot of his customers were elderly people who had regular transport arrangements with him. He got to know many of them and they became personal friends. Over the years between 1992 and 1998, Mr Shaw noticed that several of his customers died very unexpectedly; they were all patients of Shipman. He gradually came to suspect that Shipman was killing his patients. Mrs Harrison also came to suspect Shipman of murder. Following the death of her aunt, Mrs Erla Copeland, in January 1996, Mrs Harrison harboured the suspicion that Shipman had 'helped her aunt to die'. I have found that Shipman killed Mrs Copeland. Mrs Harrison thought he had done this in order to save her aunt from suffering. Twenty months later, a neighbour of hers, Mrs Mavis Pickup, was found dead a few hours after Shipman had visited. Although Mrs Pickup had recently been bereaved, she had

appeared to be in good health. Mrs Harrison became very suspicious but also felt that she was 'reading too much into everything'.

86. There must not be a word of criticism of these people for what, on the face of it, appears to be failure to raise serious concerns in the appropriate quarter. These people did not fail to act because they were irresponsible; they failed to act because they felt 'disempowered'. The culture at the time was such that they feared that their concerns would not be taken seriously but would be dismissed as irrational. Some of them feared that they might be wrong to harbour suspicions about Shipman and that, if they spoke out, the consequences for them would be serious. Some of them had no one to whom they could turn for independent and confidential advice. In my view, this need must be addressed.

87. Two other people who came to suspect Shipman of killing his patients were Mr David and Mrs Deborah Bambroffe, funeral directors in Hyde. I have described in my Second Report how their suspicions arose. For some time, they delayed telling anyone outside their family about their concerns. They were afraid that they might be wrong; they were worried that they might not be taken seriously. Mr and Mrs Bambroffe said that they would have been more confident in reporting their concerns if there had been an independent organisation which they could have approached confidentially. In February 1998, Mrs Bambroffe expressed her concerns to Dr Susan Booth, one of the GPs at the Brooke Practice, Hyde. Dr Booth reported those concerns to some of her partners. Meanwhile, the late Dr Linda Reynolds, also a member of the Brooke Practice, became aware that there appeared to be a high death rate among Shipman's patients. In March 1998, it was decided that Dr Reynolds should report her concerns, and those of her partners, to the Coroner. He passed the information to the police. Unfortunately, the first police investigation resulted in the conclusion that the concerns were without foundation.

The Future

88. Since 1998, there has been a considerable change of attitude towards those who wish to raise a concern about some aspect of health care. All NHS bodies now have a 'whistleblowing' policy which advises employees how to raise a concern and gives an assurance that concerns will be given serious consideration and that there will be no victimisation even if the concern turns out to be unfounded. The Public Interest Disclosure Act 1998 (PIDA) provides a measure of protection against victimisation for all employees who raise concerns. Also, independent advice is now provided by a charitable body, Public Concern at Work. Nevertheless, more needs to be done. I have recommended that there should be some provision (probably a telephone helpline) to enable any person, whether working within health care or not, to obtain advice about the best way to raise a concern about a healthcare matter and about the legal implications of doing so. In my view, this should be provided on a national basis. I have not made any recommendation as to the means by which it should be provided. However, it seems to me that it might be possible to link the helpline with the 'single portal' which I have already mentioned. I have also recommended amendments to the PIDA which would afford greater protection to employees who report their concerns.

Shipman's Practice Staff

89. In Chapter 9, I have considered the position of the administrative staff at Shipman's practice at 21 Market Street, Hyde. They worked in close proximity to him during the years in which he was killing patients very frequently. Many people have suggested that these members of staff must have known what he was doing. I am quite satisfied that they did not know. They did not harbour any suspicions about the number of deaths. Nor did they realise that it was unusual for deaths to occur on surgery premises. There is to be no criticism of them. They are themselves victims of Shipman's breach of trust.

90. The position of Sister Gillian Morgan, the practice nurse, is slightly different. I am quite satisfied that she did not suspect that Shipman was harming his patients. She did not question the number of deaths among Shipman's patients. Her professional relationship with Shipman was one of deference. That was not at all uncommon at the time. Moreover, I think she is, by nature, not a curious or questioning person. A number of events occurred which, had she been of a more questioning nature, would have caused her to feel a sense of unease. One such was the death of Miss Joan Harding, whom Shipman killed in the surgery. He required Sister Morgan to 'help' him to resuscitate Miss Harding at a time when she was already dead. This was a charade so far as Shipman was concerned but a genuine attempt for Sister Morgan. Yet Sister Morgan did not question the fact that Shipman did not fetch or ask her to fetch the resuscitation equipment that was available at the surgery. Nor, in early 1998, did Sister Morgan question the strange features connected with the sudden deaths of Miss Maureen Ward and Mrs Margaret Waldron. I repeat that I entirely accept that Sister Morgan did not suspect Shipman. She deferred to him professionally and did not question what he told her. Had she shown greater curiosity and independence of mind, she might have acted as a deterrent to Shipman. He might have been wary of her. I think it important for the future that all healthcare professionals recognise, as a duty, the fact that they should view the actions and performance of fellow professionals with independence of mind and professional objectivity.

The Concerns of Practice Staff Generally

91. I have found that Shipman's practice staff had no concerns about him or his clinical practice. However, practice staff may be uniquely well placed to notice signs of poor clinical practice by a doctor or other healthcare professionals with whom they work. They may become aware of complaints from patients, locums and others with whom they have dealings. They may observe instances of poor practice or aberrant behaviour for themselves. They may become aware of failures of organisation within the practice (e.g. poor record keeping) which might put patients at risk. Yet staff employed in GP practices can experience particular difficulty in raising any concerns of this nature. GP practices are small organisations and there may be conflicts of loyalty and a reluctance to bring criticism about one member of the practice to the attention of his/her colleagues. The smaller the practice, the greater the problems are likely to be. In a single-handed GP practice, for example, there is likely to be no one within the practice to whom a member of staff could voice a concern about his/her employer. These problems are exacerbated by the fact that the staff of GP practices often function in isolation, both from staff in other practices and

from the local PCO. They may have no experience of working in another practice. They may have no idea which procedures are usual and which are entirely outside the norm. They may be uncertain whom to turn to for advice.

92. In order to address these problems, I have recommended that every GP practice should have a written policy setting out the procedure to be followed by any member of the practice staff who wishes to raise a concern, in particular a concern about the clinical practice or conduct of a healthcare professional within the practice. I have also made recommendations about the steps that should be taken by PCTs in order to lessen the isolation of practice staff (in particular, those working in single-handed and small practices) and to facilitate the raising of any concerns they may have.

The General Medical Council's Handling of Shipman's Case in 1976

93. In 1976, the GMC had the power to erase or suspend the registration of any doctor convicted of a criminal offence. The police were required to report to the GMC any convictions that might reflect on a doctor's suitability to practise medicine. Reports of such convictions were submitted for consideration to the Penal Cases Committee (PeCC), which sat in private and whose function was to decide whether the case should be referred 'for inquiry' to the Disciplinary Committee (DC). The DC sat in public and wielded the powers of erasure and suspension. At this time, the health procedures had not come into operation, although the Report of the Committee of Inquiry into the Regulation of the Medical Profession, chaired by Dr (later Sir) Alec Merrison (the Merrison Report), which recommended the introduction of health procedures, had been published in 1975.

94. Shipman had been convicted of three offences of dishonestly obtaining a controlled drug (pethidine) by deception, two cases of forgery of a NHS prescription and three cases of unlawful possession of a controlled drug. He had also asked for 74 similar offences to be taken into consideration. This course of criminal conduct had covered a period of almost 14 months. At the Halifax Magistrates' Court, he had been fined and ordered to pay compensation. By the time his case came to be considered by the PeCC, Shipman had undergone treatment at a psychiatric hospital in York, apparently for an addiction to or dependence upon pethidine. The psychiatrist who had treated him there reported favourably upon his progress. Since Shipman's discharge from hospital, he had found work in the field of child health in County Durham. A report from his employer said that he was doing well in his new position. The psychiatrist responsible for his care following his discharge from hospital also reported favourably. Solicitors for the MDU, the medical defence organisation to which Shipman belonged, submitted these reports to the GMC for consideration by the PeCC. In April 1976, the PeCC decided that there was no need for Shipman's case to be referred to the DC for a public hearing. It decided to close his case with a warning against any repetition of his former misconduct.

95. That decision has given rise to much public concern and some criticism. The Inquiry examined other cases of a similar nature to see how the GMC generally dealt with them at that time. Such cases were and still are by no means rare. It is clear to me, as I have explained in Chapter 16, that, in 1976, the GMC's policy in respect of a doctor who had been abusing drugs was to allow the doctor to continue in practice while attempting to

secure his/her rehabilitation. The PeCC had the power to adjourn cases before deciding whether or not to refer them to the DC. I found that it often exercised its power to adjourn for the purpose of giving the doctor an opportunity to seek psychiatric treatment. The cases that were referred to the DC were, in general, those in which the doctor had not sought treatment or had not produced medical evidence about such treatment. Those cases that were referred to the DC were only very rarely dealt with by suspension of registration. The DC had the power to postpone judgement and it frequently exercised that power (sometimes several times in the same case) to give the doctor the chance to obtain treatment and to produce evidence of having done so. Meanwhile, the doctor would remain in practice. Both the PeCC and the DC took the view that acts of dishonesty committed in association with drug abuse were not indicative of general dishonesty but were 'all part of the illness' of drug dependence. In short, the GMC dealt with Shipman much as it dealt with other doctors reported for similar offences at that time.

96. In Chapter 16, I have concluded that, in approaching such cases as it did, the GMC focussed too much on the interests of the doctors and not sufficiently on the public interest and the need for patients to be protected from drug abusing doctors. I recognise that, in the years between the publication of the Merrison Report and the introduction of the health procedures in 1980, the GMC was in a difficult position. The need for the health procedures was recognised but they did not yet exist. It is not surprising therefore that the PeCC and the DC tried to fill the gap by the use of their powers to adjourn or postpone. It seems to me that the problem was that they did not manage to strike the right balance. The Merrison Committee had proposed health procedures whereby patients could be protected at the same time as the doctor was rehabilitated. That was to be achieved by placing conditions and restrictions upon the doctor's practice and by requiring him/her to accept supervision. However, both the PeCC and the DC appear to have been determined to provide an opportunity for rehabilitation, even though they were not in a position to provide adequate protection for the public by imposing conditions, restrictions and/or supervision. In fact, in my view, they could have done far more than they did to protect the public by giving a doctor the option of accepting undertakings, with suspension as the alternative. That was not done. The result was that the GMC placed too much weight on the interest of the doctor in rehabilitation and too little on the need of the public to be protected from a doctor who had not yet been shown to have recovered from the addiction or dependence that had led him/her into criminal conduct.

97. I make other criticisms of the GMC's handling of Shipman's case, which are set out in Chapter 16. In particular, I criticise the fact that the GMC made so little attempt to investigate the background to Shipman's case. However, I recognise that, even if Shipman's case had been handled as I think it should have been, it is unlikely that the outcome would have been very different from the actual outcome. I accept that Shipman's registration would probably not have been suspended and that his name would certainly not have been erased from the medical register. He would probably have been put 'on probation' for a few years at most. There is no evidence that he ever relapsed into his former habit of drug abuse.

98. The GMC's decision to warn Shipman rather than to suspend him or to erase his name from the register must be set in the context of the practices and philosophy of the time. First, it

was the GMC's practice to deal with drug abusing doctors by helping them towards rehabilitation rather than suspending or erasing their registration. It had not been publicly criticised for that. Indeed, it appears that the Government of the day accepted the philosophy underlying the Merrison Report and its recommendations for the creation of health procedures. These recommendations were implemented in the Medical Act 1978 and came into force in 1980. The philosophy was that sick doctors, including those who abused drugs, must be helped towards rehabilitation in a way that provided adequate protection for patients. My criticism of the GMC is not that they adopted a rehabilitative approach, only that, in pursuing it, they gave insufficient weight to the need to protect patients until the process of rehabilitation could be clearly demonstrated to be complete. After the GMC's health procedures came into operation in 1980, the same rehabilitative approach continued. It seems that it has never, until now, been called into question. If the current policy gives rise to public concern, there must be an open debate about how drug abusing doctors should be dealt with.

99. In my view the GMC cannot be criticised for failing to foresee that Shipman's foray into the abuse of pethidine might be the forerunner of something far more serious. In short, I reject any suggestion that, if the GMC procedures had been satisfactory, Shipman's later criminality could have been prevented and many lives saved. It is possible that a period of 'probation' might have delayed the resumption of his illegal use of drugs on patients and might have saved the lives of one or two of his victims. I am quite satisfied, however, that 'probation' and the medical supervision that would have accompanied it would not have had any profound or lasting effect upon his future conduct.

The General Medical Council's 'Old' Fitness to Practise Procedures

100. As I have said, the GMC is the only body that can erase or suspend a doctor's right to practise in the UK. It can also impose conditions on a doctor's registration. If the GMC takes any of these steps, it is said to be 'taking action on the doctor's registration'. Under the 'old' FTP procedures, which operated until 1st November 2004, the GMC was empowered to take action on a doctor's registration only if s/he had been found guilty of SPM, if his/her professional performance had been found to be seriously deficient or if his/her fitness to practise was found to be seriously impaired by reason of a physical or mental condition. Under the 'new' FTP procedures, the circumstances in which the GMC will be able to take action are different and I shall return to those in due course. Under the old FTP procedures, cases of SPM were dealt with under the conduct procedures. Cases of seriously deficient performance (SDP) were dealt with under the performance procedures, which were introduced in July 1997, and cases of serious impairment of fitness to practise by reason of ill health were dealt with under the health procedures which, as I have said, were introduced in 1980.

101. The GMC has accepted that some aspects of the old procedures were unsatisfactory. On the day on which the Inquiry's oral hearings turned to examine the work of the GMC, Leading Counsel for the GMC, Mr Roger Henderson QC, made frank admissions in relation to many of the shortcomings that had become evident during the Inquiry's investigations. He accepted that the GMC's FTP procedures had failed in many respects to meet the reasonable expectations of patients and the public. His message to the Inquiry

was that the deficiencies had been recognised and were being addressed. He spoke of the paramount duty of the GMC to safeguard patient protection, while having due regard for the interests of doctors. At the time he spoke, the GMC was in the process of developing the new FTP procedures that have now been introduced.

102. Despite the concessions made on behalf of the GMC and despite the fact that the old FTP procedures have recently been replaced, it has been important for the Inquiry to examine their operation in some detail, together with the attitudes and ethos which has underlain their operation. It has been necessary for me to form a view as to whether the GMC will, in the event, be willing and able to ensure that all will indeed be different in the future. It is axiomatic that the best indicator of future attitude and performance is past attitude and performance. As part of its investigation, the Inquiry sought and obtained a large number of files relating to cases dealt with in the FTP procedures between the 1970s and 2003. The Inquiry has not carried out an audit of cases during the relevant period but the examination of the case files has afforded a valuable insight into the way in which the procedures have operated in practice.

The Health Procedures

103. Where a complaint or report was made about a doctor and it appeared that his/her fitness to practise might be seriously impaired by reason of a physical or mental condition, the matter could be referred to a 'health screener' for consideration. There were usually two health screeners at any one time. They were members of the GMC and generally, although not invariably, consultant psychiatrists. If the health screener agreed that there was evidence of serious impairment of fitness to practise, the doctor would usually be invited to undergo medical examinations. If those examinations confirmed that the doctor's fitness to practise was seriously impaired by ill health, the doctor would be invited to give undertakings as to his/her future conduct. He or she would be required to submit to medical supervision. In a case involving dependence on drugs or alcohol, s/he might be required to undertake to abstain from the relevant substance. Often, restrictions would be placed on the doctor's practice. If the doctor agreed to give the undertakings, s/he would be dealt with under the voluntary health procedures, where s/he would remain for a period, usually at least two years, until the health screener was satisfied that it was safe for the doctor to practise without restriction. If the doctor did not agree to appropriate undertakings, s/he would be referred to the Health Committee, which had the power to suspend the doctor's registration or to impose restrictions on it. The doctor would then be supervised for a period and his/her case would be reviewed.

104. In general, it seems to me that these procedures worked well, particularly after the late 1990s, when an independent evaluation of the health procedures was commissioned by the GMC. That evaluation revealed the need for improvements in the arrangements for medical supervision and for dealing with doctors who failed to comply with their voluntary undertakings. In short, it showed that the voluntary health procedures needed 'tightening up'. The GMC acted on the recommendations made and is, in my view, deserving of congratulation for its action both in commissioning the evaluation and in responding so positively to it.

105. Nevertheless, I have some concerns about the way in which doctors who had been abusing drugs were referred more or less automatically into the voluntary health procedures. When the health procedures came into operation, it became the almost invariable practice to refer doctors convicted of drugs offences (and those doctors accused of misconduct in relation to the use or theft of controlled drugs) into the health procedures. This was not the case if the doctor had been found to be prescribing irresponsibly or supplying drugs illegally to patients or others; however, it was the practice if the drugs had been obtained for his/her own use. In my judgement, this practice has not always operated in the best interests of patient protection.

106. In Chapter 23, I have explained my conclusion that there are some cases in which it is appropriate to treat doctors who are dependent on drugs as being ill and in need of treatment and rehabilitation, but that there are also some cases in which such a rehabilitative approach is not appropriate and does not provide adequate protection for patients. I have described the GMC's readiness to conclude, without close examination, that a doctor was a 'victim' of addiction. As a rule, the GMC did not investigate the background to cases of drug abuse and, in particular, the effect that the drug abuse had had on the doctor's patients and on his/her clinical practice generally. Often, the GMC did not carry out any adequate assessment of the risk that the doctor posed to patient safety. I have seen some cases in which the GMC referred a doctor into the health procedures without making any findings of fact as to the nature or extent of the drug-related misconduct alleged and in circumstances where the doctor him/herself was denying that s/he had a 'drug problem' at all. I have made recommendations in respect of these issues in Chapter 23.

The Conduct Procedures

107. The GMC receives many complaints and reports about doctors. The number has increased markedly over the last ten years or so. In 1994, the GMC received about 1600 complaints and reports. In 2003, the figure was about 4000. These communications cover a wide range of topics; not all amount to a complaint against a doctor. Some complaints are very minor. Plainly, a regulatory body such as the GMC must have some process for determining which complaints fall, or might fall, within its jurisdiction and which should be rejected or directed elsewhere.

108. Under the old procedures, the body charged with the power to take action on registration was the Professional Conduct Committee (PCC), which would hold a public hearing and, if the doctor had been convicted of a criminal offence or if SPM was proved or admitted, would decide whether action on registration was necessary. Before a case reached the PCC, however, it had to pass through three filtering processes. The first of these was an initial sift carried out by GMC staff; the second was the 'screening' process which, until recently, was carried out by medically qualified and lay members of the GMC. The third filtering process was consideration of the case by the Preliminary Proceedings Committee (PPC). All three processes were carried out in private. Only a very small proportion (no more than about 5%) of cases survived the three filtering processes and reached the PCC. In 2003, at least 65% of complaints were closed at the stage of the initial sift by GMC staff.

109. The way in which the filtering processes operated under the old FTP procedures had an important bearing on patient protection. If cases were filtered out which should or might have warranted action on a doctor's registration, the fact that that doctor was continuing to practise unrestricted might have put patients at risk. For that and other reasons, the Inquiry examined the operation of each filtering process in considerable detail. The results of that examination are set out in Chapters 18 to 20.

The Meaning of Serious Professional Misconduct

110. I describe, in Chapter 17, the difficulties that have been experienced over the years in defining and recognising SPM. As this was for some decades the basis of the GMC's jurisdiction, it was plainly important, in the interests of consistency and transparency, that all decision-makers should have a clear and agreed view as to what SPM was. Yet the GMC has never formulated agreed standards, criteria and thresholds by reference to which decisions about what was and was not SPM could be taken. The problem became more acute over the years. Until the early 1990s, the GMC was mainly concerned with cases of misconduct involving dishonesty, drug abuse, indecency, improper relationships with patients and breach of confidence. The GMC would also consider allegations that a doctor had disregarded his/her professional obligations, for example, by failing or refusing to visit a patient or to provide necessary treatment. In effect, the GMC was concerned with cases involving wilful, deliberate or reckless misconduct. At that time, the GMC did not generally concern itself with allegations of incompetence or negligence, even serious negligence. It regarded those as a matter for the civil courts. However, following a decision of the Privy Council in 1987, it became clear that acts of negligence, if serious enough, could amount to SPM. The number of allegations of that kind received by the GMC has increased steadily over the years. This increase led to more problems arising from the difficulty in defining and recognising SPM. First, the concept of negligence, even if serious, does not fit comfortably with that of 'serious professional misconduct'. Second, there was an even greater need for standards, criteria and thresholds to be set for deciding such cases. The GMC has been advised of this on several occasions. It is true that, in 1995 the GMC produced a booklet entitled 'Good Medical Practice', which sets out the standards to be expected of a doctor. That booklet is very good so far as it goes. It sets out the standards to which doctors should aspire, but it says nothing about the standards below which a doctor must expect to face disciplinary proceedings. No agreed standards, criteria and thresholds for SPM had been established at the time when the old conduct procedures became defunct in November 2004. As a consequence, the operation of the conduct procedures was beset by inconsistent decisions.

The Initial Sift by the Administrative Staff

111. In Chapter 18, I have described the initial administrative procedures by which complaints received by the GMC were 'sifted' by GMC staff with the intention of eliminating those which clearly did not fall within the GMC's jurisdiction because they did not 'raise a question of SPM'. I found that this sifting process was defective in some important respects. Many cases were 'closed' without the GMC having considered whether the

allegation might raise a question of SPM. If it appeared that the complainant had not pursued any available local complaints procedures to their conclusion, the GMC would not accept the case unless it appeared that the doctor was a danger to patients. That was not the correct statutory test and many cases must have been rejected or closed that ought to have been accepted. The fact that it would have been open to the complainant to return to the GMC when the local procedures were exhausted was no answer to the criticism, not least because many did not in fact return. The GMC was not providing proper protection to patients; instead, it was putting the onus back onto complainants to pursue their allegations elsewhere. Furthermore, the GMC was well aware of the defects of the NHS complaints procedures, to which I have already referred. PCOs had no facilities for the investigation of complaints and it was left to complainants themselves to assemble the necessary evidence.

112. The GMC itself did little to investigate those complaints which survived the initial sift. It had no in-house investigation unit and, in general, it would not send a case to its solicitors for investigation unless and until it had passed through all three filtering processes and had been referred to the PCC. Many complaints (in particular, those made by private individuals and those relating to substandard clinical practice) had been filtered out before that point, some for lack of investigation.

113. Further defects at the early stage were the GMC's unwillingness to make any enquiries in order to discover background information about the doctor. The GMC would receive a complaint, consider it and, provided that the local complaints procedures had been exhausted and the allegation raised a question of SPM, accept it. However, no further information would be sought before the case was submitted to the screening stage. Until recently, the GMC's attitude towards the collection of information from employers and PCOs was that it was not its task to make out a complaint against the doctor; that would be unfair to doctors. The GMC's role was to give the complainant the opportunity to advance his/her complaint and no more. This attitude did not adequately protect patients or the public interest.

The Screening Stage

114. The next stage of the conduct procedures, which I describe in Chapter 19, was the screening process. Historically, screening was the province of the President but, during the period with which I have been concerned, he delegated the task to other, personally chosen, colleagues at the GMC. Until 1990, all screening was carried out by medically qualified members but, after that time, lay members played an important role. In general, a case could not be closed at the screening stage without the agreement of a lay screener.

115. The statutory test for screeners was, for many years, very imprecise. The screener was required to refer a case onwards to the PPC, unless it appeared to him/her that the matter 'need not proceed further'. As, for many years, no guidance was provided as to the circumstances in which the matter 'need not proceed further', the result was that screeners exercised a largely subjective discretion about which cases should proceed and which should be closed. I heard evidence that, until the mid-1990s, the usual approach of screeners was to close cases unless there was a positive reason for them to

proceed. In other words, the statutory test was 'reversed'. I was told that this attitude changed gradually from the mid-1990s onwards. However, in a series of cases of judicial review beginning in 1997, it became apparent that screeners were still not applying the correct statutory test. In 1997, the GMC produced a handbook of guidance for screeners but, even after that, there were cases of judicial review which revealed that the screeners had closed cases because they had formed a concluded view that the case did not amount to SPM, rather than applying the correct statutory test. Screeners did not always prove to be receptive to guidance. As some screeners also sat on the PPC and the PCC, it appears that, on some occasions, they took a broad view as to whether the case would result in a finding of SPM if it went to the PCC and, if they thought that it would not, they would close it. This approach must have resulted in the closure of many cases which should have proceeded at least to the next stage of the FTP procedures. It was suggested by the GMC that the screeners were anxious to bring the full value of their experience and expertise to the task of screening and found it difficult to accept that the test should not involve the exercise of a wide discretion. That may be so, but the way in which the screening process operated for many years was not satisfactory and did not operate for the protection of patients.

116. In recent years, real attempts were made to introduce some consistency into the screening process by the use of standard forms that guided the decision-making process. Training was introduced and more guidance was available. Nevertheless, as I describe in Chapter 19, these efforts were not entirely successful and there was a resistance on the part of certain screeners at least to some of the changes that had been introduced with the aim of promoting consistency in screening decisions.

Consideration by the Preliminary Proceedings Committee

117. In Chapter 20, I describe the procedures of the PPC. This Committee comprised members of the GMC and, for many years, was chaired by the principal medical screener. This dual role seems clearly unsatisfactory to modern eyes. However, it was regarded as appropriate until 1999, when Dr Robin Steel, who had held that dual role for several years, retired from the GMC. The Human Rights Act 1998 was due to come into force the following year. No doubt that forthcoming event provided an impetus for change.

118. The statutory function of the PPC was to decide whether a case 'ought to be referred for inquiry', to the PCC or to the Health Committee. If not, the case would be closed, although a warning might be given if the facts of the case were not in dispute. The test to be applied by the PPC was very imprecise. It was also not very different from the test applied at the screening stage, which was, as I have said, that the case should proceed unless the screener was of the view that it 'need not proceed further'. Neither the statutory Rules nor GMC guidance provided any criteria by which the PPC was to decide whether or not the case 'ought to be referred' onwards. The result was that the PPC exercised a wide discretion just as the screeners did.

119. Professor Isobel Allen, Emeritus Professor of Health and Social Policy, University of Westminster Policy Studies Institute (PSI) was commissioned by the GMC on several occasions to carry out research into its conduct procedures. The object of the research

was to investigate the possible existence of racial bias within the procedures. She and her colleagues were given complete access to the GMC's files and she pointed out to the Inquiry that there were not many organisations which would have agreed to afford such open access and would have allowed publication of the results. I agree that the GMC's decision to commission and publish this research was greatly to its credit. In the course of Professor Allen's work, which began in the mid-1990s, she and her colleagues made a large number of recommendations about steps that the GMC should take to improve both its administration of the conduct procedures and its decision-making processes. The GMC accepted and acted upon many, although not all, of those recommendations, with considerable beneficial effect.

120. Professor Allen and her colleagues examined the decisions of the PPC made in the years 1997, 1998 and 1999. They set out their findings in a report written in 2000. They expressed concern about a number of matters. In particular, they found that there were unexplained inconsistencies between decisions of the PPC. They recommended that the PPC should give reasons for its decisions, which it had not done hitherto. That suggestion was adopted soon afterwards.

121. Professor Allen and her team observed a series of 11 meetings of the PPC between June 1999 and January 2000. Their 2000 Report was critical of many aspects of the PPC's decision-making process. In brief, the processes lacked consistency, transparency and fairness. The Report noted that there was substantial confusion and disagreement between members about what constituted SPM and what the threshold for SPM should be. Views differed widely. Members tended to speculate about why someone had acted as they had or how certain situations had arisen, when there was no evidence on which to base such speculation. Members had difficulty in dealing with expert evidence. If two conflicting expert views were before the PPC, members might accept one or the other for no clear reason. Some members did not have a clear understanding of the GMC's FTP procedures or of the powers open to them. Professor Allen was also concerned about the frequency with which cases were closed because it did not appear to members of the PPC that there was sufficient evidence to support the allegation. At that stage, of course, no steps had been taken to gather the available evidence.

122. The main cause for concern about the decision-making processes of the PPC was its propensity to reach a conclusion about whether the allegation did in fact amount to SPM, rather than to limit itself to deciding whether the case ought to proceed to the PCC. In reaching such conclusions, the PPC was arrogating to itself the function of the PCC. In Chapter 20, I have reported on two cases of judicial review in which decisions of the PPC were subject to criticism. In both cases, the High Court pointed out that it was not the function of the PPC to resolve conflicts of evidence. That was for the PCC. I cannot say whether these cases of judicial review were representative of the general standard of PPC decisions at the time, although they did accord with the observations of the PSI team. Certainly, the mistakes made were of a very fundamental nature. I have been driven to the conclusion that decisions of the PPC not to refer cases to the PCC were wrong in a significant number of cases and that these cases give rise to a real cause for concern that the PPC was far too much influenced by its desire to be 'fair to doctors' and far too little concerned about the protection of patients and the public.

123. Following the 2000 Report of the PSI team and other developments that occurred at about the same time, there were attempts to improve decision-making within the PPC. Guidance was issued and an *aide memoire* developed with a view to directing the minds of members to the correct issues. It is difficult to know how successful these measures were in the absence of a complete audit of PPC decisions. However, a Paper produced by the PSI team in 2003 drew attention to apparent inconsistencies in the way in which the PPC had dealt with conviction cases in the period from 1999 to 2001. In Chapter 23, I have referred to the striking difference in the PPC's treatment at a meeting in November 2002 of two cases that had many similar features. Such differences are not surprising, given the lack of standards, criteria and thresholds to which I have already referred.

The Operation of the Professional Conduct Committee

124. In Chapter 21, I consider the operation of the PCC. Under the old procedures, this was the Committee that could impose erasure, suspension or conditional registration following a finding of SPM. Until 2000, the PCC comprised 30 members of the GMC and sat in panels for which the quorum was five members, including one lay member. From 2000, the GMC acquired the power to co-opt non-members (associates) onto PCC panels. This step was necessary as the PCC's caseload had increased markedly and it made it possible for multiple panels of the PCC to sit simultaneously. Also, the quorum was reduced to three, to include at least one lay and one medical member. The procedure to be followed at the hearing was akin to that of a criminal trial, although there was a general discretion to admit evidence that would not usually be admissible at a criminal trial (such as hearsay evidence) if its admission was desirable in the light of the PCC's duty to 'make due inquiry'. The evidence suggests that the discretion was not often used. The standard of proof to be applied to findings of fact was the criminal standard of proof. The chairman of the panel was not legally qualified and the panel received legal advice from a legal assessor.

125. In conviction cases, the PCC had the power to erase, suspend or impose conditions upon the doctor's registration. In conduct cases, the powers arose only after the panel had found that the doctor had been guilty of SPM. The panel would first decide what facts it found proved or admitted and would then consider whether they amounted to SPM. As I have said, there have never been any agreed standards, criteria and thresholds by which cases of SPM were to be judged. Sir Donald Irvine, immediate past President of the GMC, who had long experience of sitting on PCC panels, said that disputes about what amounted to SPM gave rise to much 'heat' and 'emotion'. The absence of standards was bound to lead to inconsistent decisions.

126. For many years, there was no official guidance about the imposition of sanctions for the use of members of PCC panels. In 1999, an internal Working Group reviewed all decisions on sanction made by the PCC over a ten-year period. The review was undertaken partly on account of concern within the GMC about public and media criticism of PCC decisions as being inappropriate or inconsistent with previous decisions. One of the tasks of the Working Group was to ascertain whether there was or appeared to be any inconsistency of the approach of the PCC to sanction. The Working Group found instances where it appeared that an inappropriate sanction had been imposed or where there had been apparent inconsistency. However, its work was hampered by the absence of anything

other than brief explanations by PCC panels of their decisions. It was impossible in many cases to tell whether a decision had been genuinely aberrant or whether there had been some exceptional mitigation which had not been made explicit in the decision given by the PCC panel. The review clearly gave rise to some concern and the Working Group recommended the development of a statement about sanctions. This led, in 2001, to the production of Indicative Sanctions Guidance for panel members. This guidance (which has since been updated) is helpful, although it has its limitations. A recent internal review of PCC panel decisions revealed some outcomes that 'appeared surprising'. However, as in 1999, the failure of panels to give detailed reasons for their decisions made it impossible to know whether these outcomes resulted from aberrant decisions or had been justified by the circumstances of the case.

Appeals

127. Historically, doctors had the right to appeal to the Privy Council in respect of findings of SPM and sanctions that were alleged to be too severe. In 2003, that right of appeal was transferred to the High Court. At the same time, the Council for the Regulation of Healthcare Professionals (now known as the Council for Healthcare Regulatory Excellence (CRHP/CHRE)) acquired the right to refer to the High Court any sanction which it considered was unduly lenient or any acquittal on a charge of SPM which it considered was wrong. The CRHP/CHRE can act only if it considers that it is necessary to do so in the public interest. This is a most welcome innovation and the CRHP/CHRE has already made its mark by referring a number of cases to the High Court. The existence of this right of referral on behalf of the public interest can only result in improved decisions by the PCC or, under the new procedures, by FTP panels.

The Performance Procedures

128. The performance procedures which I describe in Chapter 24, were introduced in 1997. Like the health procedures, they could operate on a voluntary or a compulsory basis. When information was received suggesting that a doctor's performance might be deficient, the doctor was invited to undergo a performance assessment. The methods and instruments used in GMC's performance assessment enjoy worldwide renown. They provide for a very thorough assessment and are, as an almost inevitable consequence, expensive and time-consuming to undertake. The assessment comprised two phases. The first consisted of a peer review undertaken by a team of assessors. The second comprised a series of objective tests which, in the case of GPs, were calibrated at the level of performance which new entrants to general practice must achieve. Doctors falling below an acceptable level of performance might be invited to agree to a voluntary statement of requirements as to their future practice. This might include requirements for retraining or supervision. It might also include restrictions on the circumstances in which the doctor was allowed to practise. If the doctor declined to agree the statement of requirements, or if his/her deficiencies were regarded as too serious to be dealt with by voluntary measures, the doctor was referred to the Committee on Professional Performance (CPP). If, following a hearing, the CPP found that the doctor's professional performance was seriously deficient, it could suspend the doctor from the register or

impose conditions upon the doctor's registration. In the latter case, a period of supervision would follow after which there might be one or more resumed hearings. The objective would be that the doctor's performance should improve to the extent that s/he could practise safely without restriction.

129. My main concern about the operation of these procedures was that the evidence suggested that the standards of performance imposed by the CPP were very low (lower than the standard at which the second phase of the performance assessment was calibrated) and did not always provide adequate protection for patients and the public. I was also concerned that doctors were not always supervised as well as they should have been and were sometimes allowed to resume unrestricted practice without having produced adequate evidence of improvement. I have made recommendations about these matters in the context of the new FTP procedures.

The General Medical Council's New Fitness to Practice Procedures

130. Chapter 25, in which I describe the development of the new procedures and the way in which I believe they will operate, is almost 100 pages in length. It is difficult to summarise succinctly and readers who wish to understand the detail will have to refer to that Chapter. Here I shall only describe the procedures in very broad outline.

131. In 2001, the GMC set out its vision for the new FTP procedures. They were firmly based on the ideal of instituting procedures that would provide proper protection for patients without sacrificing the need to be fair to doctors. My general conclusion has been that, in implementing the new procedures, the GMC has to some extent lost sight of its earlier vision. In developing the new procedures, there has been a good deal of 'chopping and changing'. It has been difficult to recognise the principles underlying many of the changes.

132. An important innovation is the amalgamation of the old conduct, health and performance procedures into one set of FTP procedures. There will be only one type of hearing, a FTP panel hearing. Allegations of different types (for example, conduct and performance) against the same doctor will be capable of being heard at the same time. Under the provisions of the Medical Act 1983, as amended, the basis of the GMC's jurisdiction will be a finding that the doctor's fitness to practise is impaired. Impairment of fitness to practise can be demonstrated only by evidence of misconduct, deficient professional performance, convictions or cautions, adverse health or a determination by another regulatory body that the doctor's fitness to practise is impaired.

133. The term 'impairment of fitness to practise' is, in my view, non-specific and, although the statute limits the ways in which impairment may be demonstrated, it does not define the term or set any standard by which doctors are to be judged. The problems of definition and recognition, which beset the GMC in its decisions based on SPM, will, in my view, be not only perpetuated but increased. There is an urgent need for the GMC to formulate standards, criteria and thresholds by which impairment of fitness to practise is to be judged. Failure to provide such standards will result in inconsistency of decision-making, unfairness, lack of transparency and a failure to provide adequate protection for patients.

I have made recommendations with regard to the formulation of such standards, criteria and thresholds.

134. The preliminary stages of the FTP procedures have been simplified. The GMC staff will carry out the preliminary sift to remove cases which do not fall within the GMC's jurisdiction. It appears that some of the defects of the old procedures at this stage have been removed, although careful audit of the closure of cases will be required to ensure that this is so. In particular, it appears that the GMC will not close allegations made by private individuals just because the local complaints procedures have not been exhausted. Also, the GMC is now willing to make enquiries of employers and PCOs before deciding whether a case should be rejected at the initial stage.

135. When a case has been accepted into the FTP procedures, there should now be a greatly improved investigation of the facts. The GMC has recruited a team of investigators to work on the initial evidence-gathering process. They will have the advantage of advice from a team of in-house lawyers. It will be possible at this stage to order a medical examination (if health issues arise) and/or a performance assessment. When the evidence has been gathered, the case will be submitted for decision at what is called the 'investigation stage'. The purpose of the process is to decide whether the case should proceed to a hearing before a FTP panel. The case will be submitted to two case examiners, who are contracted to work for the GMC on a part-time basis. One case examiner will be medically qualified; one will be a lay person. If the case examiners agree that the case should proceed to a hearing, they can so direct. If they agree that the case should be closed, they can so direct. If they disagree as to the outcome, the case will be referred to a panel of the Investigation Committee (IC). Case examiners and IC panels will also have powers to issue warnings. The procedures proposed for the issuing of warnings are complex and less than satisfactory. I have recommended that they should be reconsidered.

136. There has unfortunately been some confusion of thought about the formulation of the test (the investigation stage test) to be applied by case examiners and IC panels when deciding whether a case should be referred to a FTP panel. Whereas the jurisdiction of the GMC is based upon an impairment of fitness to practise, the investigation stage test, which is a preliminary sifting test, is said to be 'whether there is a realistic prospect of establishing that the doctor's fitness to practise is impaired to a degree justifying action on registration'. This test is obviously set inappropriately high for a preliminary test. I have made recommendations that I hope will assist in the resolution of this problem.

137. When it first resolved to introduce new FTP procedures, the GMC recognised that it would be desirable to separate the 'investigation function' (that is, the stage up to and including the taking of the investigation stage decision) from the 'adjudication function', which will comprise the FTP panel hearing and any preparations for it. It was recognised that, since the passage of the Human Rights Act 1998, the GMC might be vulnerable to criticism if it appeared to be both the prosecutor and the judge in the same case. It considered hiving off one or other of the two functions. In the event, it decided not to hive off either. It considers that it has provided a sufficient separation of function by ensuring that the FTP panels in the adjudication stage will comprise non-members of the GMC.

138. However, in my view, that will not suffice. The GMC will select the FTP panellists, train them, appraise them, call them in for advice if their decisions do not meet with approval and, in the final analysis, dismiss them if unsatisfactory. In short, FTP panellists will not be at all independent of the GMC. I have recommended that some mechanism should be found for the appointment, training and management of both lay and medically qualified FTP panellists, as well as for the administration of FTP panel hearings, by a body independent of the GMC. By that means, there will be effective separation of the investigation and adjudication functions.

139. In Chapter 27, I have made a large number of other recommendations in relation to the new procedures. My overall conclusion is that, with the amendments I have suggested, they are capable of providing a much improved method of protecting patients from doctors who might harm them. The success of the new procedures depends to a large extent upon the will and determination of the GMC to make them operate for the benefit of patients rather than, as the old procedures often operated, for the benefit of doctors.

Revalidation

140. In 2000, in the wake of a number of medical scandals and tragedies, of which the case of Shipman was one, the GMC resolved to introduce a quite revolutionary method of monitoring doctors. It issued a Consultation Paper setting out its visionary ideas. Instead of reacting to complaints made by patients and employers, the GMC was going to take proactive steps to ensure that all doctors on the medical register remained up to date and fit to practise. This would give an assurance to the public that any doctor whose performance was substandard or whose conduct was dysfunctional would be detected as early as possible. Doctors who wished to practise medicine would, in addition to being on the medical register, have to hold a licence to practise. That licence would have to be 'revalidated' every five years. This would be achieved by requiring the doctor to undergo an evaluation of his/her fitness to practise. I have described the development of the GMC's plans for revalidation in Chapter 26.

141. The Consultation Paper was well received and the GMC commissioned work on the development of plans for implementation. The plans were based on the preparation by each doctor of a folder of evidence which would demonstrate how s/he was practising. The preparation of these folders, it was thought, would not impose an undue burden on doctors because, under the new clinical governance arrangements to be introduced within the NHS, all doctors would have to keep such folders for the purpose of their annual appraisal. The folders would serve both purposes. For revalidation, the folders would be examined by a 'local revalidation group', which would apply standards appropriate to the doctor's specialty, approved by the GMC. The implementation plans, which included the conduct of a pilot scheme in 2001, went quite well.

142. In April 2002, a second pilot scheme was conducted, the purpose of which was to see whether the forms used in doctors' appraisals might be used instead of their folders of evidence. That pilot scheme was less successful. It became apparent that revalidation as then envisaged would be an expensive process and would impose a considerable administrative burden on the GMC. It also emerged that the proposals were unpopular

with important sections of the medical profession. Nonetheless, the amendment to the Medical Act 1983 which would require the GMC to undertake revalidation was passed in December 2002; it was to come into force at a later date. Under the new legislative provision, revalidation was defined as an 'evaluation of a medical practitioner's fitness to practise'.

143. In early 2003, the GMC abandoned its plans for evaluation by a revalidation group of an individual doctor's fitness to practise by means of examination of evidence. Instead, the GMC decided that the mere fact that the doctor had taken part in appraisal was to be deemed sufficient to justify revalidation. Evidence received by the Inquiry suggested that appraisal for GPs was a purely formative process, not capable of providing an evaluation of fitness to practise. Moreover, it had been only recently introduced and the standards to which it was being carried out were variable. Many witnesses expressed the view that it was not a satisfactory basis for revalidation. Appraisal clearly did not involve an evaluation of fitness to practise. In my view, the GMC's change of direction was made, not for reasons of principle but of expediency.

144. In November 2003, the GMC announced that, in addition to showing that s/he had successfully taken part in appraisal, the doctor would have to produce a 'clinical governance certificate' by which the doctor's employer or PCO would certify that the doctor had been appraised and that there were no (or no significant) unresolved concerns arising from clinical governance activity. In my view, the addition of this certificate was an improvement on the previous position but revalidation would still not involve an evaluation of the doctor's fitness to practise. A doctor would be appraised 'successfully' unless serious concerns about his/her fitness to practise were noticed. Also, the clinical governance certificate was to be a negative certificate, saying only that nothing adverse was known. In short, the process still would not provide the positive evaluation of fitness to practise required by the legislation and which the GMC had said that it would provide.

145. That was the position at the time of the Inquiry's seminars in January 2004. The Inquiry has continued to receive written evidence since then. During the spring and summer of 2004, it appeared that proposals were being discussed between the various interest groups (including the GMC and the NHS) which might result in some strengthening of the revalidation proposals. However, on 11th November 2004, the Inquiry received a letter from the Chief Medical Officer, from which it is clear that the DoH and the GMC have agreed that revalidation will depend upon participation in appraisal and a clinical governance certificate which is essentially negative. The certificate will confirm the doctor's participation in appraisal and will state (if appropriate) that there are no locally known concerns about the doctor's health or probity, no local disciplinary procedures in progress and that there have been no relevant disciplinary findings since the last revalidation. The certificate will contain no general statement that the doctor is the subject of 'no concerns' or 'no significant unresolved concerns' locally. The arrangements will not provide an evaluation of fitness to practise. It is important that the public should appreciate this and should realise that revalidation will not provide the assurance that was hoped for. I have made recommendations which would, if adopted, ensure that revalidation does provide an evaluation of fitness to practise.

146. I have a further concern about the revalidation proposals. Any doctor who 'fails' to be revalidated at the first stage of the process will be subjected to additional scrutiny within the GMC. At the moment, it is not clear exactly how the second stage of the process will work. The proposals lack transparency. However, what is clear is that no doctor will be deprived of his/her licence to practise unless a FTP panel finds that his/her fitness to practise is impaired to a degree justifying suspension or erasure from the medical register. Thus, even a doctor whose fitness to practise is sufficiently impaired to warrant the imposition of conditions upon his/her registration will be revalidated. In general, doctors who have failed revalidation at the first two stages will be referred to a FTP panel if it appears, on assessment, that their professional performance is deficient or that there are conduct or health problems. Under the standards of the old procedures, professional performance had to be seriously deficient before any action would be taken on registration. Those standards were very low; the President of the GMC, Professor Sir Graeme Catto, described them in evidence to the Inquiry as 'remarkably low'. Thus, the bottom line is that a doctor will fail to be revalidated only if his/her professional performance is 'remarkably' poor. I do not think that this is a satisfactory state of affairs.

The Culture within the General Medical Council

147. As I have already said, the culture within the GMC and its attitude towards its duty to act in the public interest and to protect patients lies at the heart of the future success of the new FTP procedures. Indeed, it lies at the heart of the even more fundamental question of whether the GMC should retain responsibility for the conduct of the FTP procedures. With these procedures, the GMC should protect patients from dysfunctional doctors, who, by reason of their misconduct, ill health or poor performance, put patients at risk of harm. The Inquiry has received evidence and submissions from some quarters suggesting that the GMC should no longer carry out that function. It has been suggested that the GMC does not have the protection of patients as its first priority; its priority is the interests of the medical profession. I have decided not to recommend that the GMC should be deprived of its FTP function. I wish to explain my reasons for reaching that conclusion.

148. Having examined the evidence, I have been driven to the conclusion that the GMC has not, in the past, succeeded in its primary purpose of protecting patients. Instead it has, to a very significant degree, acted in the interests of doctors. Of course, I accept that the GMC also has a duty towards doctors; it must be fair in all its dealings with them. But, in the past, the balance has been wrong and, in my view, the imbalance was due to a culture within the GMC, a set of attitudes and an approach that put what was seen as being 'fair to doctors' ahead of protecting patients.

149. Chapters 15 to 24 contain many examples of the way in which this culture operated. I do not propose to repeat them here. Until about five years ago, not only did the GMC fail to operate its FTP procedures in the best interests of patients but it appears that a majority of its members did not even realise that anything was seriously amiss. However, at about that time, there was a recognition of a need for change. If there had not been, and if there had been no significant change during the last five years, I would have had little hesitation in advising the SoS that he must make provision for some other way of dealing with doctors whose fitness to practise was called into question. It is clear that the GMC did not open its

collective eyes to its own shortcomings without some prompting from outside. The emergence into the public domain of a number of medical scandals during the late 1990s must have played a significant part in the development of a resolve to reform. I have no doubt that there were, in the GMC, some who had for many years wished to see a change of culture and practice. The scandals of Bristol, Ledward, Shipman, Green and possibly others had the effect of bringing the majority within the GMC to the view that some reform was necessary. Since that time, the GMC has been in a state of transition.

150. This state of transition included the development of the new FTP procedures, which came into effect on 1st November 2004, and the process of revalidation, which is due to come into effect in April 2005. Those processes of change have, until very recently, been theoretical. They have comprised preparations for the future. However, some practical changes have taken place during the past five years. These were changes that were not dependent upon the introduction of the new procedures. I have listed some of these in Chapter 27. The conclusion that I reach there is that these changes were improvements upon past practice. They improved the position of complainants and the ability of the system to protect patients. To some extent, the GMC is to be congratulated on making those changes. However, the disappointing feature is that all these changes appear to me to have been made as a reaction to some form of external pressure. Those changes do not demonstrate that there has been a change of culture within the GMC.

151. During the same period, the GMC failed to make a number of changes which, in my view, it would have made if it had had patient protection at the forefront of its collective mind. In Chapter 27, I have mentioned four. I shall not describe them here. However, my examination of the events of the last five years leads me to conclude that, although the GMC has been in a state of transition and has made a number of beneficial changes, it has not radically changed its culture.

152. The most important transitions effected in the last few years have been the preparations for the introduction of the new procedures and revalidation. Does the GMC's approach to those important changes demonstrate a change of culture and attitude? In Chapter 25, I examined the development of the proposals for the new FTP procedures in detail in an attempt to understand the thinking behind that development. The GMC's vision for the future procedures was clearly set out in the Consultation Paper published in 2001. That paper demonstrated a firm commitment to FTP procedures that would operate for the protection of patients without compromising the need to be fair to doctors. On the basis of that document, I would have said that there had indeed been a change in the culture of the GMC. However, the translation of the vision into reality has been in some respects disappointing. In my conclusions to Chapter 25, I found that there had been no consistent development from the initial vision to the final product. The major change is the creation of a unified set of procedures. There have been many other changes, some for the better, some for the worse. The GMC has adopted a number of suggestions that have been made in evidence to the Inquiry. It has reacted positively to some of the criticisms and concerns about which the GMC witnesses were asked. But I do not feel confident that the GMC has maintained the clarity of purpose that it exhibited in 2001. I do not feel confident that there is currently a coherent policy that the new procedures will be operated with the primary objective of protecting patients.

153. Examination of the development of the GMC's proposals for revalidation leads to a similar conclusion. I have described those proposals above and have expressed my view that they are not satisfactory. They do not provide adequate protection for patients. In the early days, the GMC had visionary plans but, when it came to implementation, there was a retreat. That retreat caused dissent within the GMC but it was accepted by the majority. I am driven to the conclusion that, for the majority of GMC members, the old culture of protecting the interests of doctors still lingers on.

154. I have reached two conclusions. The first is that the GMC as a body does not seem to be proactive in the interests of patient protection. It will often (although not always) take appropriate action when the need to do so has been pointed out to it but it does not see such things for itself. The second conclusion is that, when there is a conflict between the interests of 'being fair to doctors' or doing 'what the profession thinks is right' and the interests of patient protection, the majority sometimes takes the doctors' view. I am not saying that that is always the case, but revalidation is an important illustration of the point.

155. Why then have I not recommended to the SoS that the GMC should no longer be responsible for the FTP procedures? In fact, I have recommended that responsibility for the adjudication stage should be transferred to an independent organisation. However, I have recommended that because it is inappropriate for the GMC to control both the investigation and adjudication stages of the procedures. I would have made that recommendation even if there had been no suggestion that the GMC's culture could be criticised. I have not recommended that the GMC should cease to be responsible for fitness to practise for four reasons.

156. First, fitness to practise and revalidation are closely linked. Revalidation and registration are closely linked. It is preferable therefore that fitness to practise and registration should be under the control of the same body. I do not consider that my Terms of Reference permit me to consider whether the GMC might lose its responsibility for registration (or indeed for setting the standards for admission and all the educational responsibilities that accompany that function). That would, in effect, be to recommend the abolition of the GMC. I could not do that. This is a Public Inquiry, not a Royal Commission on the regulation of the medical profession. If I were to recommend the detachment of the FTP procedures, it would create practical difficulties for the future, although I do not think they would be insurmountable.

157. Second, the task of creating a body to take over the FTP function would not be an easy one. If improvements to the GMC could be effected, so that it acted more consistently in the interests of patients and the public, that would seem to me to be a preferable course to take.

158. So far, I have given two reasons; both are negative. However, there are some positive reasons for my conclusion. The GMC has changed during the past few years. It has carried through a new set of FTP procedures and it is about to introduce a form of re-licensure called revalidation. My conclusions are that these matters have not been handled as well as the public was entitled to expect, but that does not negate the fact that there has been some change in the right direction. It is important that that direction of change should continue.

159. There is a major reason to expect that change for the better might continue, namely the CRHP/CHRE. This is a new body but it has already made its mark by reason of its power to refer to the High Court any decision of the GMC which it considers to be unduly lenient and which it considers should be reviewed for the protection of members of the public. However, the CRHP/CHRE also has wide powers of oversight of the GMC's FTP function. It can audit outcomes of cases; it can examine processes and require rule changes. Its existence will, I believe, have an important effect on the GMC. The GMC knows that, if it fails to act in the best interests of patients and the public, the CRHP/CHRE will intervene. Moreover, this Inquiry has shed a great deal of light on GMC practices, particularly on those that are not usually open to public scrutiny. I hope that what the Inquiry has revealed will help the CRHP/CHRE in that it will know where to look to see whether or not the GMC is doing its job well. I have recommended that there should in the future be a review of the powers of the CRHP/CHRE with a view to ascertaining whether any extension of its powers and functions is necessary in order to enable it to act effectively to ensure that patients are sufficiently protected by the GMC.

160. How the new FTP procedures will operate in practice it is not possible to say. In my view, it is important in the public interest that, in about three or four years' time, there should be a thorough review of the operation of the new procedures, to be carried out by an independent organisation. I have recommended that that task should be undertaken by or on the instructions of the CRHP/CHRE. The cost should, in my view, be borne by public funds. That review should not be limited to consideration of administrative systems, but should be empowered to examine casework decisions at all levels as well.

161. I would like to believe that the GMC's culture will continue to change in the right direction by virtue of its own momentum. However, I do not feel confident that it will do so. I am sure that there are many people within the GMC, both members and staff, who want to see the regulation of the medical profession based on the principles of 'patient-centred' medicine and public protection. Indeed, I think it is likely that all members are theoretically in favour of those principles. The problem seems to be that, when specific issues arise, opposing views are taken and, as in the past, the balance tends to tip in favour of the interests of doctors.

162. For an organisation like the GMC, issues are bound to arise in which there is a conflict between the interests of doctors and those of patients and of the public. Members have to deal with that conflict. To do their work properly as members of a regulatory body, they have to put the public interest first. That is very difficult for a member who depends for his/her position on an electorate of doctors. I am sure that some manage to do it. I think that others find it more difficult. At present, the GMC is effectively controlled by elected members. It seems to me that one of the fundamental problems for the GMC is the perception, shared by many doctors, that it is supposed to be 'representing' them. It is not; it is regulating them. It may be that this perception goes back to the 1970s, when the profession objected to being asked to pay an annual retention fee and raised the cry of 'no taxation without representation'. If the profession perceives that the GMC is supposed to represent it, that would explain why some GMC members tend to adopt a representative role. In fact, the medical profession has a very effective representative body in the British Medical Association; it does not need – and should not have – two.

163. I have come to the conclusion that one of the reasons why the GMC is not able to rid itself of the old culture lies within its constitution and the overall majority of elected 'representative' members. I think that the GMC should look again at its constitution. I know that the constitution was changed as recently as July 2003. I realise that further upheaval would be unwelcome. However, my considered view is that it is not appropriate that the GMC should be dominated by elected members. It should certainly be dominated by medical members; I am not suggesting that there should be any increase in the proportion of lay members. But I do suggest that there should be more appointed medical members, people who are not beholden to an electorate and who do not see themselves in the position of representatives of the profession. Rather, they should see themselves as servants of the public interest. Accordingly, I have recommended that the GMC's constitution be reconsidered.

164. I have also recommended that medical and lay members that are to be appointed (by the Privy Council) should be selected for nomination to the Privy Council by the Public Appointments Commission following open competition. It would seem sensible for the Universities and medical Royal Colleges to have the right to nominate medically qualified candidates for consideration. However, the competition should also be open to medically qualified persons who wish to put themselves forward. I have seen, from the DoH prospectus inviting applications for the position of lay membership in 2003, the emphasis that was laid – quite rightly – on the lay members' duty to safeguard the public interest. I would like to see the same emphasis on the public interest applied to the appointment of medical members.

165. In the past, the GMC has been accountable to the public only in very general terms. It has had a duty to regulate the medical profession in the best interests of patients and the public. However, there has been no person or body to whom the GMC has been directly accountable. Since April 2003, the CRHP/CHRE has had the power to oversee and correct some aspects of the GMC's work. The GMC itself recognised and drew the Inquiry's attention to the fact that, although the GMC derives its powers from Parliament, it is not directly accountable to Parliament for the way in which it exercises its powers. The GMC suggested that it might be appropriate if it were to be directly accountable. I think that that is a good idea. I have in mind that the GMC should be required to publish an annual report of its activities, which could be scrutinised by a Parliamentary Select Committee. For this to be a worthwhile exercise, the report would have to contain specified categories of information, including statistical information, in a form that was readily understandable and, in effect, transparent.

166. In the course of this long Report, I have on many occasions been critical of the GMC, its procedures and its attitudes. I realise that the fact that this Inquiry has been conducted in public and that my Report will be in the public domain must make those criticisms even more unwelcome than they would have been if made in private. Indeed, I recognise that their effect is likely to be bruising. It has not been my intention to be hurtful or indeed to be critical of any individual at the GMC. My criticisms have been of the corporate body and its collective actions. I have made a large number of recommendations affecting the GMC and I realise that some of them will be unwelcome. However, I hope that it will be accepted

that they have been made in a constructive spirit and with the intention of helping the GMC to achieve its primary purpose of protecting patients.

Conclusions

167. In this Stage of the Inquiry, I have examined the parts that are or could be played by Government, the GMC, the Healthcare Commission, the CRHP/CHRE, NHS organisations, practice staff, patients and members of the public in protecting patients who might be at risk from an aberrant or poorly performing GP. In this Report, I have made a large number of recommendations which, together with the recommendations in my Third and Fourth Reports, are designed to extend and improve the existing framework of protective systems. In this Report, I have suggested improvements to clinical governance systems; in particular I have stressed the need for the proper investigation of complaints and the need for a system of monitoring mortality statistics. I have recommended ways in which the protective role of PCTs can be enhanced, for example by providing them with improved information about the doctors on, or seeking admission to, their lists. I have made recommendations that will provide patients with more information about their doctors and will enable them to exercise some, albeit limited, degree of choice. I have made recommendations designed to ensure that the GMC's new FTP procedures will work effectively for the protection of patients and will also be fair to doctors. Finally, I have suggested a way in which revalidation could be made to comply with the requirements of the Medical Act 1983 and to fulfil the high aspirations of those who have sought to promote it.

168. To some extent, these recommendations are bound to give rise to tension and conflict between the interests of those affected by them. However, I am confident that there is a large body of opinion both within and outside the medical profession that will recognise the need for all those involved to work together and to pull in the same direction. In making these recommendations, I have striven to achieve three things: first, that, if ever there were to be another potential Shipman, he would be detected very quickly; second, that the prospects of detecting all forms of aberrant behaviour or substandard performance by doctors should be enhanced and, third, that the good quality of care provided by the large majority of doctors should have scope and opportunity for continued further improvement.

RECOMMENDATIONS

This Summary contains only a brief statement of each of my recommendations. To understand the reasoning behind each recommendation, the reader must refer to the Chapter(s) in which the evidence relating to it is described and the paragraph(s) of Chapter 27 in which the issues are discussed. The relevant references accompany each recommendation or set of linked recommendations.

Handling Complaints and Concerns

The Lodging of Complaints

1. I endorse the provision contained in the draft National Health Service (Complaints) Regulations (the draft Complaints Regulations), whereby patients and their representatives who wish to make a complaint against a general practitioner (GP) will be permitted to choose whether to lodge that complaint with the GP practice concerned or with the local primary care trust (PCT). I recommend that the time limit for lodging a complaint be extended from six to twelve months.
(Chapter 7, paragraphs 27.15–27.16 and paragraph 27.18)

2. Steps should be taken to improve the standard of complaints handling by GP practices.
(Chapter 7 and paragraph 27.17)

3. Draft regulation 30 of the draft Complaints Regulations, which would require GP practices to provide PCTs with limited information about complaints received by the practice at intervals to be specified by the PCT, should be amended. GP practices should be required to report all complaints to the PCT within, say, two working days of their receipt. The report should comprise the original letter of complaint or, if the complaint was made orally, the practice's record of the complaint. The PCT should log the complaint for clinical governance purposes and, if it considers that the complaint raises clinical governance issues, it should 'call in' the complaint for investigation.
(Chapter 7 and paragraphs 27.19–27.23)

The Investigation of Complaints

4. There should be statutory recognition of the importance of the proper investigation of complaints to the processes of clinical governance and of monitoring the quality of health care. (paragraph 27.26)

The First Triage

5. On receipt by a PCT of a complaint about a GP, a 'triage' (the first triage) of the complaint should be conducted by a member of the PCT's staff who is appropriately trained and experienced and has access to relevant clinical advice. The object of the first triage should be to assess whether the complaint arises from a purely private grievance or raises clinical governance issues. (paragraphs 27.27–27.30)

'Private Grievance Complaints'

6. 'Private grievance complaints' should be dealt with by appropriately trained PCT staff. The objectives in dealing with such complaints should be the satisfaction of the patient and, where possible, restoration of the relationship of trust and confidence between doctor and patient. (paragraph 27.31)

The Second Triage

7. 'Clinical governance complaints' should be investigated with the dual objectives of patient protection and satisfaction and of fairness to doctors. They should be referred for a further triage (the second triage) to a small group comprising two or three people – for example, the Medical Director or Clinical Governance Lead, a senior non-medical officer of the PCT and a lay member of the PCT Board. The object of the second triage should be to decide whether the complaint is to be investigated by or on behalf of the PCT or whether it should instead be referred to some other body, such as the police, the General Medical Council (GMC) or the National Clinical Assessment Authority (NCAA).
(paragraphs 27.32–27.33)

The Investigation of 'Clinical Governance Complaints'

8. The investigation of 'clinical governance complaints' should not be undertaken by PCT staff. Instead, groups of PCTs should set up joint teams of investigators, who should be properly trained in the techniques of investigation and should adopt an objective and analytical approach, keeping their minds open to all possibilities.
(paragraphs 27.35–27.49)

9. All 'clinical governance complaints' (save those which do not involve serious issues of patient safety and where the underlying facts giving rise to the complaint are clear and undisputed) should be referred to the inter-PCT investigation team. The objects of the investigation should be to reach a conclusion as to what happened and to set out the evidence and conclusions in a report which should go to the PCT with responsibility for the doctor. If the investigators are unable to reach a conclusion about what happened because there is an unresolved conflict of evidence, they should say so in their report.
(paragraph 27.50)

Acting on the Investigation Report

10. On receipt of the investigation report, the PCT group which carried out the second triage should consider what action to take. It might be appropriate to refer the matter to another body, such as the GMC or the NCAA. Alternatively, it might be appropriate for the PCT to take action itself, e.g. by invoking its list management powers. If the report of the investigation team is inconclusive, because of a conflict of evidence, the case should be referred to the Commission for Healthcare Audit and Inspection (now known as the Healthcare Commission), under a power which should be included in the amended draft Complaints Regulations when implemented. (paragraphs 27.52–27.54)

The Effect of Concurrent Proceedings

11. Neither an intention on the part of the complainant to take legal proceedings, nor the fact that such proceedings have begun, should be a bar to the investigation by a NHS body of a complaint. In circumstances where the NHS body is taking disciplinary proceedings relating to the subject matter of the complaint against the person complained of, a complainant should be entitled to see the substance of the report of the investigation on which the disciplinary proceedings are to be based and should not merely be informed that the investigation of his/her complaint is to be deferred or discontinued.

12. In some circumstances, it may be necessary for a NHS body to defer or discontinue its own investigation of a complaint if the matter is being investigated by the police, a regulatory body, a statutory inquiry or some other process. However, a NHS body should never lose sight of its duty to find out what has happened and to take whatever action is necessary for the protection of the patients of the doctor concerned. It should also provide such information to the complainant as is consistent with the need, if any, for confidentiality in the public interest. The relevant provisions of the draft Complaints Regulations should be amended to reflect these principles. (paragraphs 27.55–27.61)

The Role of the Healthcare Commission

13. The draft Complaints Regulations, when implemented, should include a power enabling PCTs to refer a complaint to the Healthcare Commission for investigation at any point during the first stage of the complaints procedures. Cases raising difficult or complex issues or involving issues relating to both primary and secondary care might be referred to the Healthcare Commission for investigation at the time of the second triage, or later if the investigation by the inter-PCT investigation team raises more complex issues than were initially apparent. Referral to the Healthcare Commission should also take place in cases where an inter-PCT investigation team has found that it cannot reach a conclusion because there remain unresolved disputes of fact. The purpose of the referral would be for the Healthcare Commission to carry out any further necessary investigation and, if appropriate, to set up a panel to hear oral evidence about the facts in dispute and to decide where the truth lay. (paragraphs 27.52 and 27.62–27.71)

Complaints in the Private Sector

14. Complaints procedures in the private sector should be aligned as closely as possible with those in the NHS, so that a complainant who does not receive a satisfactory response to his/her complaint from a private sector body can proceed to a second stage of the complaints procedures to be conducted by the Healthcare Commission.
(paragraphs 27.72–27.74)

Handling Concerns

15. Concerns expressed about a GP by someone other than a patient or patient's representative (e.g. by a fellow healthcare professional) should be dealt with in the same way as patient complaints. Such concerns should be investigated (where necessary) by

the inter-PCT investigation team or, in a case raising difficult or complex issues, by the Healthcare Commission. Consideration should be given to amending the relevant provisions of the draft Complaints Regulations to permit the Healthcare Commission to accept and investigate concerns referred to it by a PCT or other healthcare body without the need for a reference from the Secretary of State for Health.

(paragraphs 27.77–27.78)

Standards

16. Objective standards, by reference to which complaints can be judged, should be established as a matter of urgency. These standards should be applied by those making the decision whether to uphold or reject a complaint and by PCTs and other NHS bodies when deciding what action to take in respect of a doctor against whom a complaint has been upheld. When established, the standards by reference to which complaints are dealt with must fit together with the threshold by reference to which the GMC will accept and act upon allegations, so as to form a comprehensive framework. (paragraphs 27.79–27.82)

Support for Complainants

The 'Single Portal'

17. In order to ensure that, so far as possible, complaints and concerns about health care reach the appropriate destinations, there should be a 'single portal' by which complaints or concerns can be directed or redirected to the appropriate quarter. This service should also provide information about the various advice services available to persons who are considering whether and/or how to complain or raise a concern, including advice services for persons who are concerned about the legal implications of raising a concern.

(Chapter 11 and paragraphs 27.83–27.88)

The New Arrangements

18. About two years after the Complaints Regulations come into force in their entirety, an independent review should be commissioned into the operation of the new arrangements for advising and supporting patients who wish to make a complaint. Any deficiencies identified by that review should be corrected. (Chapter 7 and paragraphs 27.89–27.90)

Disciplinary Procedures

19. The powers of PCTs should be extended so as to enable them to issue warnings to GPs and to impose financial penalties on GPs in respect of misconduct, deficient professional performance or deficient clinical practice which falls below the thresholds for referral to the GMC or exercise of the PCT's list management powers.

(Chapter 7 and paragraphs 27.91–27.102)

The Use of Prescribing Information as a Clinical Governance Tool

20. Steps should be taken to ensure that every prescription generated by a GP can be accurately attributed to an individual doctor. Only then will the data resulting from the monitoring of prescribing information constitute a reliable clinical governance tool.

21. Regular monitoring of GPs' prescribing should be undertaken by PCTs. Special attention should be paid to the prescribing of controlled drugs. Doctors who have had a problem of drug misuse in the past or who are suspected of having a current problem should be subjected to particularly close scrutiny. When a restriction is placed on a doctor's prescribing powers, this information must be made available (preferably by electronic means) to those who need to know, especially pharmacists.
(Fourth Report, Chapters 5 and 12 of this Report and paragraphs 27.103–27.104)

The Use of Mortality Data as a Clinical Governance Tool

22. The Department of Health (DoH) must take the lead in developing a national system for monitoring GP patient mortality rates. The system should be supported by a well-organised, consistent and objective means of investigating those cases where a GP's patient mortality rates signal as being above the norm.
(Chapter 14 and paragraphs 27.105–27.107)

23. Every GP practice should keep a death register in which particulars of the deaths of patients of the practice should be recorded for use in audit and for other purposes.
(paragraph 27.108)

24. PCTs should undertake reviews of the medical records of deceased patients, either on a routine periodic basis (if resources permit) or on a targeted basis limited to those GPs whose performance gives rise to concern. (paragraph 27.109)

Appraisal in the Context of Clinical Governance

25. The purpose of GP appraisal must be made clear. A decision must be taken as to whether it is intended to be a purely formative (i.e. educational) process or whether it is intended to serve several purposes: part formative, part summative (i.e. pass/fail) and/or part performance management.

26. If appraisal is intended to be a clinical governance tool, it must be 'toughened up'. If that is to be done, the following steps will be necessary. Appraisers should be more thoroughly trained and should be accredited following some form of test or assessment. Appraisers should be trained to evaluate the appraisee's fitness to practise. GPs should be appraised by GPs from another PCT. Standards should be specified, by which a GP 'successfully completes' or 'fails' the appraisal. All appraisals should be based on a nationally agreed core of verifiable information supplied by the PCT to both the appraiser and the appraisee.
(Chapter 12 and paragraphs 27.110–27.116)

The Use by Primary Care Trusts of Their List Management Powers

27. The Family Health Services Appeal Authority (Special Health Authority) or its proposed successor, the NHS Litigation Authority, should collect and analyse information relating to the use made by PCTs of their list management powers. Such analysis would assist the DoH in providing guidance to PCTs about the types of circumstance in which they might properly use their powers. (Chapter 5 and paragraph 27.117)

Practice Accreditation Schemes

28. The Government should consider the feasibility of providing a financial incentive for the achievement of GP practice accreditation by means of an accreditation scheme similar to that operated by the Royal College of General Practitioners in Scotland.

(Chapter 5 and paragraph 27.118)

Support for Single-Handed and Small Practices

29. The policy of the DoH and of PCTs should be to focus on the resolution of the problems inherent in single-handed and small practices. More support and encouragement should be given to GPs running single-handed and small practices. In return, more should be expected of such GPs in terms of group activity and mutual supervision. The DoH should take responsibility for these initiatives.

(Chapters 9 and 13 and paragraphs 27.119–27.120)

The Recruitment and Appointment of General Practitioners

30. PCTs should be willing and able to provide advice to GP practices on good recruitment practice and should also be willing to offer support in drafting job specifications and advertisements. They should be prepared, if requested, to assist in sifting applications (if multiple applications are received) and in making the necessary checks on applicants before the interview stage, so as to exclude in advance any applicants who are unsuitable. However, this latter exercise may be too much of a burden for PCTs unless and until the Inquiry's recommendations for greater information to be placed on the GMC's website and for the creation of a central database of information about doctors (see below) are implemented. (paragraphs 27.121–27.128)

31. A standard reference form should be developed for use in connection with appointments to GP practices. PCTs should insist that a reference is obtained from the doctor's previous employer or PCT. In the case of a PCT, the reference should be signed by the Medical Director or Clinical Governance Lead. (paragraph 27.129)

32. When recruiting a new member, GP practices should canvass and take account of the views of their patients about the kind of doctor the practice needs.

(paragraphs 27.130–27.137)

General Practitioners' Personal Files

33. PCTs should keep a separate file for each individual GP on their lists. That file should hold all material relating to the doctor which could have any possible relevance to clinical governance. If a doctor moves from one PCT to another, the file (or a copy of it) should be sent to the new PCT. It might be helpful if the DoH were to establish national criteria for the content of the files to be kept by PCTs. (paragraph 27.138)

The Raising of Concerns

Facilitating the Raising of Concerns by Staff in General Practice

34. Every GP practice should have a written policy, setting out the procedure to be followed by a member of the practice staff who wishes to raise concerns, in particular concerns

about the clinical practice or conduct of a healthcare professional within the practice. Staff should be encouraged to bring forward any concerns they may have openly, routinely and without fear of criticism. In the event that a member of the staff of a GP practice feels unable to raise his/her concern within the practice, s/he should be able to approach a person designated by the PCT for the purpose. The contact details of that person should appear in the written policy. The designated person should make him/herself known to all practice staff working in the PCT area. PCTs should ensure, through training, that practice staff understand the importance of reporting concerns and know how to do so.

35. The written policy should contain details of organisations from which staff can obtain free independent advice. If the 'single portal' is created, in whatever form, the policy should set out contact details of that also. (Chapter 9 and paragraph 27.139)

Facilitating the Raising of Concerns by Staff in the Private Sector

36. The Healthcare Commission should require all private healthcare organisations to have a clear written policy for the raising of concerns. Steps should be taken to foster in the private sector the same culture of openness that is being encouraged in the NHS. (Chapter 11 and paragraph 27.140)

Support at a National Level for Those Who Wish to Raise Concerns about Health Care

37. Consideration should be given to amending the Public Interest Disclosure Act 1998 in order to give greater protection to persons disclosing information, the disclosure of which is in the public interest.

38. Written policies setting out procedures for raising concerns in the healthcare sector should be capable of being used in relation to persons who do not share a common employment.

39. There should be some national provision (probably a telephone helpline) to enable any person, whether working within health care or not, to obtain advice about the best way to raise a concern about a healthcare matter and about the legal implications of doing so. It might be possible to link this helpline with the 'single portal' previously referred to. (Chapter 11 and paragraph 27.141)

The Availability of Information about Doctors

Information Available to Employers and Primary Care Organisations

40. There should be a central database containing information about every doctor working in the UK. This should be accessible to the officers of NHS bodies and to accredited employers in the private sector, as well as to other bodies with a legitimate interest, such as the Healthcare Commission, the GMC, the NCAA and the DoH.

41. The database would contain, or provide links to, information held by the GMC, the Criminal Records Bureau (CRB) and the NHS Counter Fraud and Security Management Service. It would also contain records of disciplinary action by employers, details of list management action by PCTs, any adverse reports following the investigation of a complaint, any

adverse findings by a Healthcare Commission panel or by the Healthcare Ombudsman and details of any findings of negligence in a clinical negligence action and settlement of a clinical negligence claim above a pre-determined level of damages. It should also contain certain other information. Doctors would be able to access their own entries to check the accuracy of the information held.

42. Private sector employers should be required to provide relevant information as a condition of registration with the Healthcare Commission. Deputising services should also be required to provide information and should be able to access the database through the relevant PCT.

43. Information about unsubstantiated allegations or concerns should not be included on the central database. Instead, the doctor's entry on the database should be flagged to indicate that confidential information is held by a named body. Access to that information would depend on who was asking for it and for what purpose and would have to be determined at a high level. (paragraphs 27.142–27.149)

Further Information to Be Provided to Primary Care Organisations

44. GPs should be required to disclose to the relevant PCO the fact that a clinical negligence claim has been brought against them, the gist of the allegation made and, when the time comes, the outcome of the claim. A failure by a doctor to make full declarations to a PCO as required by the National Health Service (Performers Lists) Regulations 2004 should be regarded as misconduct of sufficient gravity to warrant referral to the GMC.
(paragraphs 27.150–27.154)

Information Available to the Public and Patients

45. The GMC should adopt a policy of tiered disclosure to apply to all persons seeking information about a doctor.

46. The first tier should relate to information which is relevant to the doctor's current registration status, together with certain information about his/her past fitness to practise (FTP) history. First-tier information should be posted on the GMC website and should also be disclosed to anyone who requests information about the doctor's registration. The periods of time for which information should remain at the first tier should depend on the nature of the information. When the relevant period expires, the information should be removed from the website. It should be replaced by a note indicating that there is further information which can be obtained by telephoning the GMC. That information should then be available at the second tier.

47. Disclosure of information at the second tier should be made to any person who makes a request about a doctor's FTP history. All information which has at any time been in the public domain should remain available to enquirers at the second tier for as long as the doctor remains on the register. (paragraphs 27.155–27.197)

Information That Should Be Given to Patients of a Practice

48. In all cases where a GP's registration is subject to conditions, or where s/he has resumed practice after a period of suspension or erasure, patients of any practice in which the GP

works should be told. A letter of explanation which has been approved by the PCT should be sent to all patients. Patients should have the opportunity to refuse to be treated by a doctor who is subject to conditions or who has previously been subject to an order for suspension or erasure. (paragraphs 27.198–27.199)

The General Medical Council

The General Medical Council's Role in the Wider Regulatory Framework

49. The GMC should ensure that its publications contain accurate and readily understandable guidance as to the types of case that do and do not fall within the remit of its FTP procedures. (Chapters 18 and 25 and paragraph 27.201–27.202)

Separation of Functions

50. There must be complete separation of the GMC's casework and governance functions at the investigation stage of the new FTP procedures and this must be reflected in the Rules. (Chapter 25 and paragraph 27.205)

51. The adjudication stage of the FTP procedures must be undertaken by a body independent of the GMC. This body should appoint and train lay and medically qualified panellists and take on the task of appointing case managers, legal assessors (if they are still necessary) and any necessary specialist advisers. It should also provide administrative support for hearings. (Chapter 25 and paragraphs 27.206–27.209)

52. Consideration should be given to appointing a body of full-time, or nearly full-time, panellists who could sit on the FTP panels of all the healthcare regulatory bodies. (Chapter 25 and paragraph 27.207)

The Statutory Tests

53. The GMC should adopt clear, objective tests to be applied by decision-makers at the investigation and adjudication stages of the FTP procedures. The tests that I recommend are set out at paragraphs 25.63 and 25.67–25.68. The tests should be incorporated into the Medical Act 1983 and/or the Rules. The draft Guidance for FTP panellists should be amended so that it is consistent with the provisions of Section 35D of the Medical Act 1983 and rule 17(2)(k) of the General Medical Council (Fitness to Practise) Rules Order of Council 2004 (the November 2004 Rules). (Chapter 25 and paragraphs 27.211 and 27.261)

A New Route to Impairment of Fitness to Practise

54. The Medical Act 1983 should be amended to add a further route by which there might be a finding of impairment of fitness to practise, namely 'deficient clinical practice'. (Chapter 25 and paragraph 27.212)

Standards, Criteria and Thresholds

55. Urgent steps should be taken to develop standards, criteria and thresholds so that decision-makers will be able to reach reasonably consistent decisions at both the

investigation and the adjudication stages of the FTP procedures and on restoration applications. (Chapters 17–25 and paragraphs 27.213–27.229)

56. The Council for the Regulation of Healthcare Professionals (now known as the Council for Healthcare Regulatory Excellence (CRHP/CHRE)) should be invited to set up a panel of professional and lay people (similar in nature to the Sentencing Advisory Panel) which should assist in the process of developing the necessary standards, criteria and thresholds. (Chapter 21 and paragraph 27.230)

57. Steps should be taken to ensure that FTP panels determining cases in which issues of deficient professional performance arise apply a standard which is no lower than that set for admission to general practice. (Chapter 24 and paragraph 27.231)

The Investigation Stage

The Preliminary Sift: the Test for Jurisdiction

58. Rule 4 of the November 2004 Rules, which sets out the test to be applied by the Registrar on receipt of an allegation, should be amended to give greater clarity. The test that I recommend is set out at paragraph 25.115. (Chapter 25 and paragraph 27.232)

Preliminary Discussions with and Disclosure to Employers and Primary Care Organisations

59. The November 2004 Rules should be amended to make formal provision for the GMC routinely to communicate with employers and with primary care organisations (PCOs) before deciding what action should be taken in response to an allegation and giving the GMC power to require from the doctor the necessary details to enable it to make such communication. Communication should take place in all cases other than in the case of an allegation which is so serious that it obviously requires further investigation or in the case of an allegation which is plainly outside the GMC's remit.
(Chapters 18 and 25 and paragraph 27.234)

The Treatment of Convictions

60. Where a doctor has committed a criminal offence in respect of which a court has imposed a conditional discharge, that offence should be dealt with by the GMC in the same way as if it were a criminal conviction. (Chapters 18 and 25 and paragraph 27.232)

The Power to Direct Investigations

61. The November 2004 Rules should be amended so as to give case examiners, and Investigation Committee (IC) panels in cases where the case examiners have disagreed, the power to direct investigations. (Chapter 25 and paragraph 27.235)

Case Examiners

62. Case examiners should be advised that they should not take mitigation into account when making their decisions and that they should consult a lawyer if they are in any doubt as

to whether the available evidence is such that there is a realistic prospect of proving the allegation. (Chapter 25 and paragraph 27.236)

Performance and Health Assessments

63. The November 2004 Rules should be amended to give case examiners, and IC panels in cases where the case examiners have disagreed, the power to direct that an assessment of a doctor's performance and/or health should be carried out.
(Chapter 25 and paragraph 27.237)

64. The GMC should develop an abridged performance assessment to be used as a screening tool in any case in which an allegation is made which potentially calls into question the quality of a doctor's clinical practice. (Chapter 24 and paragraph 27.237)

65. In order to avoid doctors undergoing multiple performance assessments, the GMC should investigate the development of a modular assessment.
(Chapter 24 and paragraph 27.237)

66. The November 2004 Rules should be amended to include a provision whereby reports of performance assessments should be disclosed by the GMC to doctors' employers or PCOs as soon as possible after receipt.
(Chapters 24 and 25 and paragraphs 27.238–239)

Letters of Advice

67. The power to send letters of advice should be incorporated into the Rules and clear criteria for the sending of such letters should be prepared. (Chapter 25 and paragraph 27.240)

The Issuing of Warnings at the Investigation Stage

68. The GMC should reconsider its proposals for the issuing of warnings at the investigation stage. (Chapter 25 and paragraph 27.241)

The Procedure for Cancelling Hearings before a Fitness to Practise Panel

69. Rule 28 of the November 2004 Rules, which provides for the cancellation of hearings before a FTP panel, should be amended so as to provide that a decision to cancel must be taken by an IC panel and that the reasons for the cancellation must be formally recorded. Both the doctor and the maker of the allegation should be notified in advance of the fact that cancellation is being considered and both should have the opportunity to make representations.

70. There should be regular monitoring and audit of the number of applications to cancel FTP panel hearings and of decisions to cancel and the reasons for those applications and decisions. Those reasons should be scrutinised with a view to taking steps to minimise the number of cases in which referrals are subsequently cancelled. The number and reasons should be placed in the public domain on an annual basis.
(Chapters 20 and 25 and paragraph 27.242)

Consensual Procedures

71. If the GMC pursues its present intention to extend the use of voluntary undertakings to cases other than those raising issues of adverse health or deficient performance, the disposal of such cases should take place in public at the adjudication stage and not in private as part of the investigation stage. (Chapter 25 and paragraph 27.243)

Revival of Closed Allegations

72. The November 2004 Rules should be amended to make provision for the revival of closed allegations. The usual 'cut-off' period should be five years but it should be possible, in exceptional circumstances and in the interests of patient protection, to reopen a case at any time. (Chapter 25 and paragraph 27.244)

Review of Investigation Stage Decisions

73. Reviews of investigation stage decisions should be carried out by an independent external commissioner. The circumstances in which a review may take place should be extended to cover decisions of the Registrar to reject an allegation rather than to refer it to a case examiner. (Chapter 25 and paragraph 27.245)

Voluntary Undertakings in Cases with a Health Element

74. The November 2004 Rules should be amended so as to provide that the arrangements for the obtaining and consideration of health assessments and for the management and supervision of doctors who are the subject of voluntary undertakings relating to health should be directed by a medically qualified case examiner, who should fulfil the functions previously carried out by a health screener. If a case is to be closed on the basis of a health assessment, the decision should be taken by two case examiners, one medically qualified and one lay, and, if they disagree, by an IC panel. (Chapter 25 and paragraph 27.246)

Voluntary Undertakings in Cases with a Performance Element

75. The November 2004 Rules should be amended so as to provide that the arrangements for the obtaining and consideration of performance assessments and for the management and supervision of doctors who are the subject of voluntary undertakings relating to performance should be directed by a medically qualified case examiner, who should fulfil the functions previously carried out by a performance case co-ordinator. If a case is to be closed on the basis of a performance assessment, the decision should be taken by two case examiners, one medically qualified and one lay, and, if they disagree, by an IC panel. (Chapter 25 and paragraph 27.248)

The Adjudication Stage

Investigation

76. There should be an explicit power in the Rules to allow the GMC to undertake any further investigations it considers necessary after a case has been referred to a FTP panel and before the panel hearing. (Chapter 25 and paragraph 27.250)

Case Management

77. In the event that the GMC retains control of the adjudication stage, the GMC committee charged with governance of the adjudication stage should audit the work of case managers. Case management should apply to cases with a performance element.
(Chapter 25 and paragraph 27.252)

78. FTP panellists should be warned that they should exercise caution about drawing adverse inferences from a failure to comply with case management orders.
(Chapter 25 and paragraph 27.253)

Legally Qualified Chairmen

79. In the event that the GMC retains control of the adjudication stage, it should appoint a number of legally qualified chairmen who should, as an experiment or pilot, preside over the more complex FTP panel hearings. The results of the pilot scheme should be scrutinised to see whether there are benefits, whether in terms of the improved conduct of hearings, more consistent outcomes, improved reasons and/or fewer appeals.
(Chapter 25 and paragraph 27.254)

Evidence

80. As part of their training, FTP panellists should be advised about their discretion to admit hearsay evidence and other forms of evidence not admissible in a criminal trial. Panellists should also be advised, during training, that it is entirely appropriate for them to intervene during FTP panel hearings and to ask questions if they feel that any issue is not being adequately explored. (Chapters 21 and 25 and paragraph 27.255)

Standard of Proof

81. The GMC should reopen its debate about the standard of proof to be applied by FTP panels. The civil standard of proof is appropriate in a protective jurisdiction. It is arguable that the criminal standard of proof is appropriate in a case where the allegations of misconduct amount to a serious criminal offence.
(Chapters 21 and 25 and paragraph 27.256)

Notification of the Proposed Outcome of a Hearing

82. The GMC should abandon its intention to notify doctors, at the same time as sending notice of referral of their case to a FTP panel, of the outcome it will be seeking at the FTP panel hearing. (Chapter 25 and paragraph 27.257)

Reasons for Findings of Fact

83. FTP panels should be required to give brief reasons for their main findings of fact.
(Chapters 21 and 25 and paragraph 27.258)

Referral of a Case after a Health or Performance Assessment

84. Rule 17(5)(b) of the November 2004 Rules (which permits a FTP panel, on receipt of a report of a health or performance assessment, to refer the allegation back into the investigation stage for consideration of voluntary undertakings) should be revoked.
(Chapter 25 and paragraph 27.259)

Evidence to Be Received

85. Rule 17(2)(j) of the November 2004 Rules should be amended to make clear what types of further evidence should be received before a FTP panel decides whether a doctor's fitness to practise is impaired. That evidence should include the doctor's previous FTP history with the GMC or any other regulatory body. Rule 17(2)(l) should be amended to make clear what categories of evidence might be received after a finding of impairment of fitness to practise but before determination of sanction.
(Chapter 25 and paragraph 27.260)

Warnings

86. The Medical Act 1983 should be amended to permit a FTP panel to issue a warning in a case where it has found that a doctor's fitness to practise is impaired but not to a degree justifying action on registration. (Chapter 25 and paragraph 27.261)

Undertakings

87. Rule 17(2)(m) of the November 2004 Rules, which permits a FTP panel to take into account written undertakings entered into by a doctor when deciding how to deal with the doctor's case, should be revoked. If it is to be retained, the rule should be amended to make clear that undertakings can be taken into account only at the stage of deciding on sanction, after findings of fact and a decision about impairment of fitness to practise have been made. In that event also, provision should be made within the Rules for supervision of the doctor to ensure compliance with undertakings, for the holding of review hearings in cases where a doctor has given undertakings and for dealing with a breach of an undertaking.
(Chapter 25 and paragraphs 27.262–27.263)

The Need for Supervision

88. Throughout the period that a doctor's registration is subject to conditions imposed by a FTP panel or to voluntary undertakings, someone within the GMC (preferably a case examiner) should take responsibility for monitoring the doctor's progress and for ensuring, so far as possible, that s/he is complying with the conditions imposed or undertakings given.

89. In every case where a doctor is continuing to practise subject to conditions or voluntary undertakings, a professional supervisor should be appointed to oversee and report on the doctor's progress and on his/her compliance with the conditions or undertakings. In a case where a doctor's health is an issue, a medical supervisor should be appointed.

90. Any breach of a condition imposed by a FTP panel or of a voluntary undertaking (save for the most minor breach) should result in the doctor being referred back (or referred) to a FTP panel so that consideration can be given to imposing a sanction which affords a greater degree of protection to the public.

(Chapter 25 and paragraphs 27.264–27.266)

Review Hearings

91. The November 2004 Rules should be amended to ensure that there is at least one review hearing in all cases where a period of suspension or conditions on registration have been imposed, unless there are exceptional reasons why no such hearing should take place.

92. The arrangements set out in the draft General Medical Council (Fitness to Practise) Rules 2003 (the 2003 draft Rules), whereby any necessary gathering of evidence in preparation for a review hearing would be undertaken by a specially appointed case examiner, should be reinstated.

93. In all but exceptional cases, a doctor whose registration has been suspended should be required to undergo an objective assessment of his/her fitness to practise before being permitted to return to practice. That assessment should be considered by a FTP panel at a review hearing and a decision should be taken as to the doctor's fitness to practise. A doctor who has been the subject of conditions on his/her registration should be required to go through the same process. Doctors who are the subject of voluntary undertakings should also be required to undergo such an assessment before their undertakings are permitted to lapse.

94. The GMC's primary role should be one, not of remediation of doctors, but of protection of patients. If a doctor who is subject to conditions or voluntary undertakings undergoes an assessment in the circumstances described above, and the assessment reveals that s/he does not meet the required standard, consideration should be given to taking the steps necessary to remove the doctor from practice. He or she should not be permitted to 'limp on' with repeated periods of conditional registration and no real hope of meeting the standard for unrestricted practice.

(Chapters 22, 24 and 25 and paragraphs 27.249 and 27.267–27.274)

Applications for Restoration to the Medical Register

95. The arrangements set out in the 2003 draft Rules, whereby any necessary gathering of evidence in preparation for a restoration hearing should be undertaken by a specially appointed case examiner, should be reinstated.

96. Every doctor whose application for restoration to the register has reached the second stage of the procedure should be required to undergo an objective assessment of every aspect of his/her fitness to practise. The doctor should not be restored to the register unless s/he has met the required standard.

97. Doctors who are restored to the register should be required to have a mentor whose task it will be to monitor, and report to the GMC on, their progress in practice.

(Chapters 24 and 25 and paragraphs 27.275–27.277)

Cases involving Drug Abuse

98. A thorough investigation of the circumstances underlying allegations of misconduct involving drug abuse should be conducted. The full facts should be established, including the circumstances in which the abuse began.

99. The GMC should commission research into drug abusing doctors and the outcomes of their cases following supervision under the health procedures.
(Chapter 23 and paragraph 27.278)

Transparency

100. Every aspect of the FTP procedures in which either doctors or makers of allegations have a direct interest should be set out in the Rules. In addition, the GMC should publish a FTP manual, containing all its relevant Rules and its guidance for panellists, case examiners and staff, together with any relevant Standing Orders.

101. Clear statistical information should be collected and published by the GMC. The GMC should publish an annual report which should amount to a transparent statement of the year's activities in respect of the FTP procedures.
(Chapter 25 and paragraphs 27.279–27.280)

Audit

102. The GMC should carry out audits of various specific aspects of its procedures, in addition to its other routine auditing activities.
(paragraphs 27.203, 27.232, 27.233, 27.240 and 27.241)

Revalidation

103. The arrangements for revalidation should be amended so that revalidation comprises, as required by section 29A of the Medical Act 1983, an evaluation of an individual doctor's fitness to practise. (Chapter 26 and paragraphs 27.281–27.282)

104. The annual report referred to at 101 above should include clear statistical information about the number of applications for revalidation and their outcomes. It should amount to a transparent statement of the year's revalidation activities. (paragraph 27.280).

Independent Review

105. In three to four years' time, there should be a thorough review of the operation of the new FTP procedures, to be carried out by an independent organisation. This task should be undertaken by or on the instructions of the CRHP/CHRE. (paragraph 27.307)

Constitution

106. The GMC's constitution should be reconsidered, with a view to changing its balance, so that elected medical members do not have an overall majority. Medical and lay members who are to be appointed (by the Privy Council) should be selected for nomination to the

Privy Council by the Public Appointments Commission following open competition.
(paragraphs 27.310–27.312)

Public Accountability

107. The GMC should be directly accountable to Parliament and should publish an annual report which should be scrutinised by a Parliamentary Select Committee.
(paragraph 27.314)

The Council for Healthcare Regulatory Excellence

108. Section 29 of the National Health Service Reform and Health Care Professions Act 2002 should be amended so as to clarify that the Act provides for the CRHP/CHRE to appeal against 'acquittals' and findings of 'no impairment of fitness to practise', as well as in respect of sanctions which it believes were unduly lenient.

109. There should in the future be a review of the powers of the CRHP/CHRE with a view to ascertaining whether any extension of its powers and functions is necessary in order to enable it to act effectively to ensure that patients are sufficiently protected by the GMC.
(Chapter 21 and paragraph 27.283)

CHAPTER ONE

Introduction

1.1 At the time this Inquiry was set up in January 2001, it was known that Harold Shipman had murdered 15 women patients during the years 1995 to 1998. It was also suspected that he might have killed others over a much longer period. When, at the end of his trial, it came to light that, in 1976, Shipman had been convicted of offences of forgery and obtaining pethidine by deception, many people, particularly the bereaved, began to ask how it was that Shipman had been able to return to unsupervised general practice in 1977, just over a year later. They also wondered how it was that his repeated killing of patients had escaped the notice of the authorities responsible for general practitioners (GPs) such as him. One of the Inquiry's Terms of Reference required me to look into **'the performance of the functions of those statutory bodies, authorities, other organisations and individuals with responsibility for monitoring primary care provision ... and to recommend what steps, if any, should be taken to protect patients in the future'**. I interpreted the word 'monitoring' in its broadest sense, as I am confident that that was the intention of Parliament.

1.2 By the time the Inquiry was ready to embark upon the hearings in connection with this aspect of its work, in 2003, I had already published the First Report, in which I found that Shipman had killed no fewer than 215 patients over the period from 1975 to 1998. Thus, in order to comply with the Terms of Reference, the Inquiry had to examine the provisions for the monitoring of GPs working in the NHS over a period of 23 years. That included consideration of the operation of the General Medical Council's (GMC's) fitness to practise (FTP) procedures during that period because those procedures are an integral part of the monitoring of all doctors, including GPs working in the NHS. As will be seen from this Report, during almost the whole period of Shipman's practice as a GP, the role of NHS bodies at a local level was primarily that of provider and facilitator of GP services to the population. They did not exercise a supervisory role over GPs, who were not employees but independent contractors. Only in the 1990s did family health services authorities and health authorities begin to exercise a monitoring or quasi-management role in respect of the GPs practising in their area.

1.3 Because the Terms of Reference require me to make recommendations for the better protection of patients in the future, the Inquiry also had to examine the monitoring systems in place at the present time and those that are envisaged for the future. I have found that the changes that began in the early 1990s gathered pace, at first gradually and then at an increasing rate. There must have been many reasons for this, not least a change of Government in 1997. However, a series of medical tragedies and scandals, of which that of Shipman was perhaps the most significant, undoubtedly provided a major impetus for change to the arrangements for monitoring GPs within the NHS. Other changes have taken place within the NHS as a whole, as well as within the GMC. These changes too have occurred, at least in part, as a response to tragedies and scandals and the investigations and inquiries that followed.

1.4 In effect, a revolution has taken place in the last six or seven years. The policy underlying these changes can be summed up very briefly. It has been recognised that, in the

provision of medical services, there must be far greater accountability to patients and to the public in general. There is now, throughout the NHS, a duty to monitor and improve the quality of healthcare provided. Accountability also means that there must be much greater openness with the public and patients.

1.5 The main mechanism by which the duty to provide care of an acceptable quality is fulfilled is known as 'clinical governance', a concept to which I shall return on many occasions in this Report. Local NHS bodies – in England these are called primary care trusts (PCTs) – now have a range of methods by which they can monitor the performance of the doctors within their remit, rewarding those who are doing well, and helping those who are doing less well to do better. Now, in the final analysis, they also have the power to remove from the medical list for the locality those who are unwilling to provide – or are incapable of providing – an adequate service.

1.6 As part of the revolution, a number of new NHS bodies have come into existence in recent years. An example is the National Clinical Assessment Authority, which carries out assessments of doctors who are thought to be performing poorly. It also advises PCTs and hospital trusts that wish to carry out their own assessments of a doctor's performance. The Commission for Health Improvement was formed to monitor the performance of all NHS bodies, such as PCTs. However, after only a brief period of existence, this body has now been disbanded and its functions, somewhat modified, have been assumed by the Commission for Healthcare Audit and Inspection, now known as the Healthcare Commission. The National Patient Safety Agency has been formed with a remit to learn from clinical accidents and errors. These new bodies all have a role to play in the monitoring of doctors and the improvement of the quality of care which is to be provided within the NHS.

1.7 The revolution is not complete and change continues at what seems a dizzying pace. Even within the short period since the Inquiry's hearings in the summer and autumn of 2003, significant changes have been made or announced. The Department of Health has made some changes to the way in which complaints by patients about health service provision are handled; more changes are to be expected after the publication of this Report. The GMC has very recently introduced its new FTP procedures and has announced its proposals for the revalidation of doctors on the UK register of medical practitioners, to be introduced in April 2005.

1.8 If all or most of these changes are designed to bring about improvements that should ensure the better protection of patients in the future, it might be thought that there is no need for an Inquiry such as this to make any further recommendations. Is there anything more that the Inquiry needs to recommend? As will be seen, although it is indeed my view that most of the changes introduced and proposed are for the benefit of patients, there does remain more to be done.

1.9 During the Inquiry, I have received evidence from many doctors and have read quite widely from the medical press. I have become aware that some doctors have welcomed the changes of which I have spoken. Many have not. That does not in the least surprise me. The extent of change and the speed with which it has been effected must have been profoundly unsettling for many. I know that some feel embattled by what they perceive as

over-regulation, loss of professional independence, interference in their clinical work and damage to their relationships with patients. There is resentment that the 'powers that be' have overreacted to the Shipman case; it is said that the profession is being held to blame and will be punished for the actions of 'a murderer who just happened to be a doctor'. I know that, in some quarters of the profession, there is concern and anxiety about the Inquiry. I suppose that it is feared that the Inquiry will recommend yet further demands, restrictions, testing, inspection and general 'shaking-up'. I understand and sympathise with those fears and hope to allay them.

1.10 I think it would be a mistake for the medical profession to regard Shipman as 'a murderer who just happened to be a doctor'. He was a doctor – and in many ways not a bad one – who perverted his skill, knowledge and the trust of his patients to evil ends. It was the fact that he was a doctor that enabled him to do what he did. In his Pioneer Lecture, given to honour Sir Donald Irvine, at the Forum on Quality in Healthcare on 13th January 2004, Professor Richard Baker said:

> **'Since beginning to investigate Shipman in 2000, I have been trying to understand how it was that he could kill so many patients without detection. There were, of course, some system failures, but it has been impossible to avoid the question as to why the system weaknesses were tolerated to the extent that Shipman was able to murder not merely one or two patients, but over 200. The conclusion I have come to is that all doctors, and not general practitioners alone, share responsibility for creating the circumstances that enabled Shipman to be so successful a killer.'**

I think that what Professor Baker had in mind was the culture of mutual self protection within the profession and the attitude of paternalism towards patients and those outside the profession. This culture and attitude are no longer acceptable and are disappearing. They are being replaced by the culture of patient-centred medicine. Nonetheless, they linger on. But, in my opinion, no right-thinking doctor would seek to defend them today.

1.11 I recognise that the overwhelming majority of doctors are trustworthy, competent, hardworking and justly proud of their profession. Shipman was certainly not one of that majority. He breached the trust of his patients and fellow professionals to a greater extent than any other doctor is known ever to have done. Of course, it would be wrong to impose upon the whole profession regulatory requirements designed only to catch a mass murderer. Doctors who murder their patients are, fortunately, extremely rare. Others have been detected and it is not unknown for healthcare professionals, such as nurses, to use their position of trust to kill their patients. It would be folly to assume that there have not been others who have not been detected or that there will never be any similar instances in the future. No right-thinking doctor would wish a colleague who deliberately harms a patient to go undetected or to remain in practice.

1.12 Not all doctors who harm their patients intend to do so, as Shipman did. Some are reckless as to whether they cause harm. Among those, I would include doctors who indecently assault their patients. Such doctors seek their own gratification and, while not positively wishing to harm their patients, are reckless as to whether they in fact do so. One has only

to read the newspapers to see that such cases are by no means uncommon. Another form of recklessness as to patient safety is seen in doctors who continue in practice while under the influence of alcohol or mind-affecting drugs. All right-thinking doctors would agree that such colleagues should be stopped from practising until they have ceased such self-abuse.

1.13 There are also doctors who harm patients because they were inadequately trained or have failed to keep their knowledge up to date or because they have a personal, medical or psychiatric problem which affects their ability to provide safe care for their patients. They may be personally trustworthy and conscientious and yet cause harm unwittingly. Again, all right-thinking members of the profession would agree that steps must be taken to protect patients of such doctors from harm while the doctor undergoes treatment or remediation. I think they would also agree that, if the problem proves intractable, the doctor will have to give up practice or be prevented from continuing.

1.14 It is with these categories of doctor that the Inquiry is concerned, not with the great majority, who, as I have said, are trustworthy, competent and hardworking. Nobody suggests that there are many doctors in these categories, even when all are put together. There is no definitive view as to the extent of the problem. During the Inquiry, various suggestions have been made – some based on research, some little more than guesstimates – as to the proportion of practising doctors whose performance gives rise to an unacceptable risk of harm to patients. It could be as many as 5%; it may be as little as 1%. Professor Sir Graeme Catto, President of the GMC, suggested that there might be up to 10% about whose practice there was cause for some concern. Even if the proportion of unsafe doctors were as low as 1%, that would mean that there would be about 1000 unsafe doctors practising in the UK. Such doctors, if allowed to continue in practice, not only harm patients but do a disproportionate amount of damage to the reputation of the profession. It is primarily upon the weeding out of those unsafe doctors that the recommendations of the Inquiry will focus.

1.15 It may be said that, if the Inquiry is interested only in protecting patients from unsafe doctors, it should have focussed on those doctors alone and should not have considered provisions that affect *all* GPs. In my view, protecting patients from harm must be approached in two ways. There must be measures designed to identify those who are not performing to an acceptable standard and there must also be measures that will help doctors who are performing satisfactorily to improve with time and experience and not slide backwards. The system must seek to ensure that all who enter general practice are competent to do so and that they remain so. At the moment, it cannot be said with confidence that all practising GPs were competent at the time of entry; the overwhelming majority will have been, but only since 1998 have GPs been required to prove their competence by successfully undergoing summative assessment. A GP's standard of practice ought theoretically to rise as s/he progresses, as s/he adds the benefit of experience to his/her basic knowledge and skills. But, the human condition being what it is, as time passes, some doctors' performance goes downhill rather than up. Medicine is a rapidly developing field and not all doctors keep up to date. Others deteriorate owing to a variety of personal and professional difficulties. It seems to me that the best way to prevent doctors from falling below the level of acceptable performance and to improve the

standard of patient care generally is to provide facilities and opportunities for continuous professional development and to require that those opportunities are taken. My view is that those opportunities should be provided in a formative way and not in an atmosphere of criticism or inspection. That does not mean that the process of continuing education should not be challenging. Surely no right-thinking doctor would disagree.

1.16 Although the Inquiry's aim is to protect patients, I do recognise that the measures to be recommended must be proportionate to the importance of the aims. The aims are important. Even so, there are other considerations which also are very important, perhaps, arguably, even more important. The measures must not damage the good and trusting relationships that exist between millions of patients and their doctors. They must not deprive GPs of all independence or seek to impose uniformity; I have not recommended that GPs should lose their self-employed status. Nor must the measures go too far in taking doctors away from their primary function of giving clinical care to patients. I am conscious that many GPs complain about the burden of 'form-filling' which, they say, reduces the time they can give to patients. I can see that the requirements of clinical governance and appraisal entail a good deal of non-clinical work. Many doctors feel that such time is well spent; no doubt others disagree. I have tried to ensure that the proposals I have made will not entail further significant increase in the non-clinical work that GPs have to undertake.

1.17 One of the most important ways in which patients can be protected from unsafe doctors is by the thorough investigation of complaints made by and on behalf of patients and also of concerns expressed by fellow professionals. There has, in the past, been a perception in the minds of some doctors that patients who complain are troublemakers. I know from personal experience that it can be very wounding to receive an unwarranted complaint. It is also natural that the person who is the object of the complaint is likely to see it as unwarranted, even though others might not agree. It is well recognised by complaints handling bodies that there are some habitual or vexatious complainers; the evidence I received suggests that they are a tiny minority. My view, at the end of the Inquiry, is that much can be learned from complaints and expressions of concern from patients and fellow professionals. Not only will unsafe doctors be identified but poor practice can be detected, providing an opportunity for improvement. Systems failures might also be discovered and lessons learned for the future. I recognise that the investigation of complaints and concerns is a very uncomfortable experience. However, I think that all doctors – and all professional people – must accept it, not only because such an investigation is the right of the patient or client but also as a learning experience and as an important means of uncovering substandard care and protecting patients from unsafe doctors.

1.18 I have associated the expression of concern about a doctor by a fellow professional with patient complaints. In my view, they should be so associated because the subject matter might well be the same. I also think that the willingness of one healthcare professional to take responsibility for raising concerns about the conduct, performance or health of another could make a greater potential contribution to the safety of patients than any other single factor. I consider that very few unsafe doctors would escape notice by a fellow professional provided that all healthcare professionals accepted a sense of common responsibility for quality and safety.

1.19 During the Inquiry, the expression 'no-blame culture' has often been used. A current view is that, when a medical mishap occurs, it is more important to learn a lesson so that a repetition of the event may be avoided than to punish the doctor or healthcare professional whose actions have led to the mishap. Put in that way, the principle seems sound. The proponents of this view often claim that most mishaps are due to systems failures rather than personal error. It would be wrong to punish a doctor for the failure of the system in which s/he had to work. Again, put in that way, the principle is sound. However, I do not accept that these views are wholly right. Over the 30 years of my professional life, I have dealt with thousands of cases of accident and injury, suffered on the road, in the workplace and in the course of medical and dental treatment. That wealth of experience leads me to believe that, while some mishaps are caused purely by a personal lack of care or personal incompetence and some are caused purely by a systems failure, the majority are caused by a combination of personal and system factors. Of course, justice requires that no doctor should be held responsible for matters beyond his/her personal control. However, in my view, justice and the safety of patients require that doctors – and other healthcare professionals – should be held to account if they have failed in a respect which lies within their proper sphere. When things go wrong, there must be a proper investigation and identification of the cause. Only then can there be a proper opportunity to learn from the event. A systems failure can only be corrected when it is identified. Only then, if personal error is found, can steps be taken, by disciplinary action or re-education, to safeguard patients in future. Some people call this 'a culture of fair blame'. I would say that what is needed is investigation, justice, learning and protection.

1.20 On a separate but related topic, I am firmly of the view that the profession must accept an even greater degree of openness with patients than has yet been given. The profession and patients have come a long way since the days when the doctor told the patient what was s/he was going to do and the patient accepted it with gratitude but little understanding. As all doctors know, patients have changed. On average, they are better educated and better informed and have greater understanding than ever before. Also, they are less deferential and more questioning. They expect (and deserve) a partnership of equality. Many expect to have full access to their records and to read for themselves the consultant's report on their recent referral. Gone are the days when any doctor would think of writing a personal comment in a patient's record in the belief that it would be seen only by another doctor.

1.21 All these changes are good and most doctors recognise them as such. However, patients are now calling for even greater openness. Although it may be said that there is little opportunity to 'choose' a doctor within the NHS, patients want to make as much of an informed choice as possible and, even if they cannot choose, they want to have their eyes open. Patients want to be able to trust their own doctor implicitly with their health, their welfare and their secrets. Patient surveys show that, in general, they do have that trust, despite the tragedies and scandals of the 1990s. But the same surveys show that the public believes that there are some badly behaved and incompetent doctors who have been allowed to continue practising by the 'powers that be'. Patients want to know that their own doctor is not one of those. They want to know more about their doctor's qualifications, experience and competence. They feel entitled to know if their doctor has

been in trouble with the criminal law or with the GMC. They want to know if their doctor has been found wanting on an assessment of performance and has had conditions placed upon his/her registration. In the USA and Canada, such information is routinely provided to the public on websites supported by either licensing authorities or professional colleges. In my view, more such information should now be made available in this country. It may be that some doctors will feel that publication of such information would entail a loss of privacy and would restrict a doctor's ability to put the problems of the past behind and move on. That may be so. However, my own view is that doctors must demonstrate that they have not acted in such a way as to call into question their patients' trust.

1.22 Those are the ideas and principles which underlie the recommendations in this Report. For those who accept these principles, any changes which might be made as a consequence of my recommendations would cause no surprise, concern or dismay. The Inquiry has been fortunate to hear evidence and receive contributions from many eminent doctors and academics. Most of the ideas and principles I have propounded come from these forward-thinking leaders of the profession. Many of these ideas are already widely accepted within the profession and are seen to bring benefits to patients, the profession and society as a whole. But not all doctors see things in the same way. In a profession as large as medicine, that is not surprising. However, I believe that, with strong and effective leadership, the whole profession will come to accept these ideas as the way to maintain high standards and the trust and confidence of patients.

CHAPTER TWO

The Conduct of Phase Two, Stage Four of the Inquiry

Terms of Reference

2.1 The Terms of Reference of the Inquiry relevant to the subject matter of Phase Two, Stage Four ('Stage Four') are as follows:

> **'(c) by reference to the case of Harold Shipman to enquire into the performance of the functions of those statutory bodies, authorities, other organisations and individuals with responsibility for monitoring primary care provision and the use of controlled drugs; and**
>
> **(d) following those enquiries, to recommend what steps, if any, should be taken to protect patients in the future ...'**.

The Subject Matter

2.2 During Stage Four, the Inquiry examined the arrangements for monitoring general practitioners (GPs) which were in place between 1974 and 1998, when Shipman was in general practice. This examination included consideration of the following:

- the adequacy of the monitoring arrangements operated by primary care oganisations (PCOs) and other bodies, and their efficacy in detecting poor clinical practice or aberrant behaviour
- the role of patient complaints within the monitoring system and the adequacy of the systems for dealing with patient complaints over the relevant period
- the role within the monitoring system of concerns about GPs which are raised by colleagues, by other healthcare professionals and by members of the public, and the adequacy of the steps which have been taken in the past to facilitate the raising of such concerns
- the operation of the regulatory and disciplinary systems which form an integral part of the overall monitoring process and the extent to which those systems have in the past worked effectively to support and reinforce local monitoring arrangements.

The Approach of the Inquiry

2.3 The Inquiry examined these topics in the light of all the information which it has accumulated about Shipman's crimes, about his medical practice, about his previous history of drug abuse and about the complaints made and the disciplinary action taken against him during the course of his career.

2.4 The Inquiry then proceeded to consider the changes to the systems that have occurred since 1998, as well as those planned for the future. Throughout Stage Four, I have approached the task of assessing the effectiveness and adequacy of these various systems – past, present and future – by reference to the duty imposed upon me by the

Inquiry's Terms of Reference to make any recommendations that I regard as being necessary for the future protection of patients. In order to understand the degree of protection afforded by the various systems, it has been necessary to look at the whole regulatory framework governing the work of GPs.

Evidence

2.5 I shall deal separately with the evidence collected by the Inquiry in relation to each of the topics listed above. A total of 386 witness statements and approximately 52,430 pages of documents have been scanned into the Inquiry's image database in connection with Stage Four.

Families

2.6 When providing their Inquiry witness statements for Phase One, the relatives and friends of Shipman's patients were invited to give their suggestions for changes to existing systems which, if effected, might provide additional safeguards for patients in the future. Many responded to this invitation and made helpful and constructive suggestions as to how the various systems might be improved. I have considered all those written suggestions and, during the course of the Stage Four hearings, the Inquiry received further evidence, both oral and written, from a number of relatives and friends of patients whom Shipman had killed.

Monitoring Arrangements

Local Monitoring Arrangements

2.7 The Inquiry's primary purpose in examining local monitoring arrangements was to consider whether there had been any failure on the part of the PCOs which had responsibility for primary care in Tameside during the period for which Shipman was in practice there. This entailed undertaking an examination of the arrangements that were in operation locally and comparing those local arrangements with the arrangements that were in place in other parts of the country during the same period. It also involved assessing whether those arrangements that were in place should have alerted the PCOs to the fact that Shipman's practice was unusual or aberrant in some way or that he was an 'outlier' in any respect.

Primary Care Organisations and Other Local Bodies

2.8 The Inquiry received evidence from officers of the successive PCOs which had responsibility for primary care in Tameside. The PCOs which had this responsibility in the past were the Tameside Family Practitioner Committee (FPC), the Tameside Family Health Services Authority (FHSA) and the West Pennine Health Authority (WPHA). The body with current responsibility is the Tameside and Glossop Primary Care Trust (PCT).

2.9 Written and oral evidence was received from administrative officers and medical advisers who had formerly been employed by the Tameside FPC, the Tameside FHSA and the

WPHA. These witnesses described the monitoring arrangements that were in place during Shipman's career and explained, by reference to contemporaneous documents contained in the files on Shipman held by the PCOs, what the various arrangements had revealed about Shipman's practice. The Inquiry also heard oral evidence from the Chief Executive and Medical Director of the Tameside and Glossop PCT about the monitoring arrangements which are currently in place and the developments which have occurred since 1998, when Shipman ceased practice.

2.10 In order to compare the performance of the various Tameside PCOs with that of their counterparts in other areas, the Inquiry circulated a questionnaire to a number of randomly selected strategic health authorities (SHAs) in England and Wales. The questionnaire asked detailed questions about the monitoring arrangements that had been in place over the previous 25 years. Nineteen responses were received from SHAs and PCOs (to whom the questionnaire had been passed by the relevant SHA) in different areas of England and Wales. Representatives of four of the respondent bodies were invited to provide further evidence and two of those representatives, together with the Medical Director of another local PCT, attended to give oral evidence about past and current monitoring arrangements in their areas.

2.11 In addition, the Inquiry received evidence from representatives of other local organisations, including the West Pennine (formerly Tameside and Glossop) Local Medical Committee (of which Shipman had in the past been secretary), and from doctors who had been employed by the former Regional Medical Service.

Monitoring of Prescribing by General Practitioners

2.12 Shipman acquired drugs to feed his own drug abusing habit in 1974 and 1975 and, virtually throughout his career in general practice, to kill patients. During the later years of his time in practice, some monitoring of GPs' prescribing was carried out locally. The Inquiry examined in detail the results of the monitoring of Shipman's prescribing and heard evidence about this from pharmaceutical advisers who had formerly been employed by the Tameside FHSA and the WPHA as well as from a pharmacy consultant who had been employed by the fundholding consortium of which Shipman was for some time a member.

2.13 In my Fourth Report, written at the conclusion of Phase Two, Stage Three ('Stage Three') of the Inquiry's hearings, I recommended measures which would make it far more difficult for a doctor or other healthcare professional to obtain illicit supplies of controlled drugs, and which would also make it more likely that a doctor who succeeded in obtaining drugs illicitly would be detected. One of the measures which has a valuable role to play is the monitoring of GPs' prescribing of controlled drugs. The evidence that the Inquiry received in Stage Three has informed my views on this topic. During the Stage Four hearings, the Inquiry received a written statement from Mr Barry Lloyd, Prescribing Information Consultant, who is retained by the National Prescribing Centre and the Prescription Pricing Authority (PPA) to develop and provide training in the use of prescribing information systems. Mr Lloyd attended the Inquiry office and gave a demonstration of the use of the ePACT.net system which is now used for the monitoring of prescribing. The Inquiry also heard oral evidence on this topic from Mr Michael Siswick, of the PPA.

The Appointment of General Practitioners

2.14 In 1977, Shipman was appointed to the Donneybrook practice in Hyde. This appointment was made at a time when he had been working outside general practice for over 18 months, following his dismissal from the Abraham Ormerod Medical Centre, Todmorden, in late 1975. His dismissal had occurred after the discovery that he had been illicitly obtaining and abusing controlled drugs. The Inquiry examined the circumstances of Shipman's appointment to the Donneybrook practice and of his admission to the medical list of the Tameside FPC. The Inquiry considered in particular whether the Tameside FPC knew of his previous history and, if not, whether it should have made enquiries which would have revealed that history. The role in the appointment process played by members of the Donneybrook practice was also considered.

2.15 Witness statements were obtained from seven members and former members of the Donneybrook practice, and all but two gave oral evidence. The Inquiry had previously obtained evidence from three of Shipman's former partners at the Abraham Ormerod practice for the purposes of its Phase One investigations. In addition, the Inquiry received evidence from other witnesses who had knowledge of the arrangements for GP appointments that were in operation in 1977. These included the Chairman of the former Medical Practices Committee, the body which was at that time responsible for ensuring an equitable distribution of GPs across the whole of England and Wales. The Inquiry also received written statements from a former administrator of the Calderdale FPC (which had responsibility for primary care in Todmorden at the time Shipman was in practice there), from two inspectors of the Home Office Drugs Branch (who had been involved in the detection of Shipman's drug offences), from a representative of the West Yorkshire Police and from a former employee of the General Medical Council (GMC). These witnesses gave evidence about the information that would have been provided to a person making an enquiry in 1977 to one of those organisations about Shipman's previous history of drug abuse or about the criminal and disciplinary proceedings resulting therefrom.

The Wider Picture

Evidence from National Bodies

2.16 The Inquiry received a detailed witness statement from Sir Nigel Crisp, Permanent Secretary of the Department of Health (DoH) and Chief Executive of the NHS in England, describing the development of the arrangements for the monitoring of GPs from the 1970s to date. Sir Nigel gave oral evidence to the Inquiry and outlined the further changes that were planned for the future. These further changes included those resulting from the new General Medical Services (GMS) Contract (introduced in April 2004), together with a new requirement (to be introduced by the GMC in 2005) that all doctors should undergo periodic revalidation. The DoH provided a considerable amount of further written evidence, both in response to specific requests by the Inquiry and generally. In addition, representatives of the DoH participated in the Inquiry's seminars.

2.17 Dr John Chisholm (Chairman, General Practitioners Committee, British Medical Association (BMA)) and Dr William Reith (former Chairman, Scottish Council of the Royal

College of General Practitioners (RCGP)) attended to give evidence about a range of matters, including the plans for the future revalidation of doctors. Professor Alastair Scotland (Chief Executive and Medical Director, National Clinical Assessment Authority (NCAA)) and Dr Linda Patterson (Medical Director, former Commission for Health Improvement (CHI)) gave evidence about the role and functions of their respective organisations. Dr Reith and Professor Scotland attended some of the Inquiry's seminars, as did Dr John Grenville, representing the BMA. Professor Aidan Halligan, Deputy Chief Medical Officer for England and Director of Clinical Governance for the NHS, also participated in some of the seminars.

2.18 The Inquiry received written statements and other communications in connection with this part of its investigation from a wide variety of organisations, including the National Patient Safety Agency (NPSA), the Audit Commission, the Commission for Healthcare Audit and Inspection (now known as the Healthcare Commission), the Patients Association, Patient Concern, the Association of Community Health Councils, the Commission for Public and Patient Involvement in Health, the Joint Committee on Postgraduate Training for General Practice, Action against Medical Accidents (AvMA), the National Association of Primary Care Educators UK and a number of postgraduate deaneries. Representatives of the Patients Association, of Patient Concern and of AvMA attended those of the Inquiry's seminars at which the topic of monitoring and related issues were discussed. Professor Dame Lesley Southgate, Professor of Primary Care and Medical Education, University College London, former President of the RCGP and the person responsible for designing the assessment instruments used in the GMC's performance procedures, also attended some of the seminars.

Evidence from Academics

2.19 In connection with the topic of monitoring GPs, the Inquiry commissioned two reports from academic experts. The first, written by Professor Richard Baker, Director, Clinical Governance Research and Development Unit, University of Leicester, addressed a number of specific issues identified by the Inquiry. The second, which constituted an overview of past, current and future arrangements for monitoring the quality of care provided by GPs, was written by Professor Martin Roland (Director, National Primary Care Research and Development Centre, University of Manchester), Professor Martin Marshall (Professor of General Practice, University of Manchester), and Dr Jonathan Shapiro (Director, 'Policy. Development. Partnership.' and Senior Fellow, University of Birmingham). Both Professor Baker and Professor Roland attended some of the Inquiry's seminars and Professor Baker also gave oral evidence.

Appraisal

2.20 At the time of the Inquiry's hearings, the new system for appraising GPs had recently come into operation. It was important for the Inquiry to examine how appraisal was being carried out and to examine both its relationship with local monitoring and clinical governance systems and its intended linkage with revalidation. Several witnesses gave evidence about their own experiences of appraisal in general practice or in hospital or other

settings. In addition, the Inquiry received a written statement from Dr Vikram Tanna, Appraisal Lead, Tameside and Glossop PCT, and heard oral evidence from two witnesses who were responsible for organising GP appraisal on behalf of their PCTs; one of the witnesses was himself a GP appraiser. The Inquiry also received from the Tameside and Glossop PCT a number of anonymised completed appraisal forms.

Dealing with Poor Performance and Serious Untoward Incidents

2.21 A further questionnaire, relating to the arrangements made by PCOs for dealing with doctors whose professional performance gives rise to concerns, was circulated to a random selection of 24 PCOs in England and Wales, all of whom responded. The Inquiry also distributed a questionnaire to six SHAs (all of whom responded), seeking information about their systems for dealing with serious untoward incidents.

Single-Handed Practice

2.22 After Shipman's conviction in January 2000, there were many calls for a move away from single-handed practice. It was suggested that Shipman would not have escaped detection over such a long period had he been working in a group practice. It was, therefore, necessary for the Inquiry to consider whether it was easier for Shipman to carry out his crimes because of the arrangements that existed in the practices where he worked and, also, to consider the merits and drawbacks of single-handed practice.

2.23 The Small Practices Association is a national body representing the interests of single-handed and small practices and its Chairman, Dr Michael Taylor, gave oral evidence to the Inquiry. I also heard oral evidence from Dr Hugh Whyte, Senior Medical Officer, Directorate of Health Policy and Planning, Scottish Executive Health Department, about the position of small and single-handed practices in Scotland. The Inquiry also received a statement from Mrs Ann Lloyd, Director of the NHS Wales Department of the National Assembly for Wales, dealing with the Assembly's policy on single-handed medical practitioners.

2.24 Several witnesses called to give evidence on other topics provided their views and experience of small and single-handed practices. The Inquiry sent a questionnaire to 15 randomly chosen PCTs, seeking information about their attitudes towards such practices and about any special arrangements they made to support them. The DoH provided relevant policy and statistical material.

Monitoring Mortality Rates

2.25 One aspect of monitoring which assumed particular significance after the discovery of Shipman's crimes was the monitoring of mortality rates. No monitoring of the mortality rates among Shipman's patients had been carried out prior to his investigation and arrest. The Inquiry received written evidence from a number of former members of staff of the WPHA about the statistical information relating to GP patients and GP patient deaths held by the WPHA during the period of Shipman's practice and about the uses to which that information was put. The evidence also related to the analyses of Shipman's mortality rates

which had been carried out by the WPHA after Shipman's arrest in September 1998. The Inquiry also considered the clinical audit of Shipman's practice which was carried out by Professor Baker. At the conclusion of the report on the results of his clinical audit, Professor Baker had recommended that the systems for monitoring GPs should be reviewed and extended to include routine monitoring of GP patient mortality rates.

2.26 The Inquiry had first to consider whether the successive PCOs with responsibility for Tameside had been at fault in not instituting any monitoring system during the period of Shipman's practice there. In order to discover what, if any, steps PCOs in other parts of the country had taken to monitor mortality rates, the Inquiry distributed a questionnaire to all SHAs in England and health authorities (HAs) in Wales, requesting information. Responses were received from all 33 SHAs and HAs. Following receipt of the responses, the Inquiry sought and obtained further evidence from a number of PCOs which had undertaken analyses of mortality rates in the recent past. The Inquiry also obtained written evidence from NHS bodies in Northern Ireland and Scotland about steps which were being taken to develop monitoring systems in their areas.

2.27 The Inquiry commissioned Dr Paul Aylin, Clinical Senior Lecturer in Epidemiology and Public Health, Imperial College School of Science, Technology and Medicine, to report on the feasibility of setting up a national monitoring system for GPs and to advise on an appropriate method of analysis. Dr Aylin and a team of colleagues from Imperial College carried out the necessary work and prepared a written report. In July 2003, they gave a presentation of their work to the Inquiry.

2.28 In October 2003, Dr Aylin's work, together with wider issues relating to the monitoring of GP patient mortality rates, was discussed at a two-day seminar, which was attended by a number of experts in the field, together with representatives of the BMA, the RCGP and the former CHI. Also participating in the seminars were three representatives from PCOs who had experience of monitoring and/or investigating GP patient mortality rates. Dr Kathryn Booth (Chair, Northern Ireland General Practice Mortality Regional Group) and Dr Mohammed A Mohammed (Senior Research Fellow, Department of Public Health and Epidemiology, University of Birmingham) told the seminar about the pilot project for monitoring mortality rates which was then being undertaken by the Eastern Health and Social Services Board in Northern Ireland.

Patient Complaints and Local Disciplinary Procedures

2.29 The Inquiry's first purpose in considering the patient complaints and disciplinary procedures was to examine Shipman's involvement in those procedures and to consider whether the subject matter of any complaints made against him should have alerted those who operated the procedures to his criminality. It was also necessary to consider the part played by the complaints and disciplinary procedures within the wider context of the arrangements for monitoring and, more recently, for clinical governance. The examination of detailed evidence relating to the operation of these procedures by reference to a number of particular cases was helpful to me when I came to formulate my proposals for change.

2.30 The Inquiry received information from the WPHA relating to the complaints made to the PCOs responsible for Tameside about Shipman between 1977 and 1996. Shipman had twice been disciplined following patient complaints, once by the Tameside FPC in 1990 and once by the Tameside FHSA in 1993. Those two cases were also reported to the GMC. An earlier complaint to the Tameside FPC in 1985 had been dismissed. Mr Steven Rawlinson, a friend of the deceased patient whose death was the subject of the 1985 complaint, gave oral evidence. The mother of the deceased patient provided a written statement. Mr William Greenwood, then Assistant Administrator at Tameside FPC, later Assistant Director of Primary Care, WPHA, gave oral evidence about his experience of the local operation of the procedures, including his involvement in the complaints brought against Shipman. Statements were provided by ten members and former chairmen of the medical service committees that adjudicated on those complaints and five of them – some medical and some lay – gave oral evidence.

2.31 Miss Andrea Horsfall, formerly Deputy Consumer Liaison Manager, WPHA, gave oral evidence about her experience of the procedures that were in place after 1st April 1996. As a result of the changes in procedures, the WPHA had less involvement in the resolution of patient complaints than previously and there were far fewer disciplinary hearings. Mr Geoffrey Lamb, a former senior convenor at the WPHA, provided a statement about his involvement in the procedures that followed unsuccessful local resolution of a complaint.

2.32 Mr David Laverick, former Chief Executive of the Family Health Services Appeals Authority, gave oral evidence and supplied statistical information about the later stages of the disciplinary processes. His evidence on that topic was supplemented by witness statements from Mr Brian Hubbard (a junior colleague of Mr Laverick), Mr Paul Burns (Mr Laverick's successor as Chief Executive) and Dr William Miller (former Chairman of the Medical Advisory Committee).

2.33 The Inquiry also received 14 responses to a questionnaire sent by the Inquiry to a number of healthcare organisations on the subject of complaints, in particular complaints about GPs. The questionnaire asked – among other things – what changes they would like to see made to the existing NHS complaints procedures. Representatives of the RCGP, the BMA, the DoH, the National Care Standards Commission (NCSC, now part of the Healthcare Commission), the Association of Medical Secretaries, Practice Managers, Administrators and Receptionists (AMSPAR), the Consumers' Association (now known as Which?), the Office of the Health Service Ombudsman, the NCAA, the Healthcare Commission and the GMC attended a seminar dealing with patient complaints and the investigation of complaints.

The Raising of Concerns

2.34 The scale and number of Shipman's crimes and the long period over which they were perpetrated raised the possibility that concerns might have been raised about his activities in the past and that those concerns might have gone unheeded by the authorities. The Inquiry set out to discover whether there had been anyone who had felt such concerns and, if so, whether they had made their concerns known. In the event, it was clear that very few people had harboured any suspicion at all about Shipman. In the

case of those few people who had, the Inquiry wished to establish whether they had voiced their concerns and, if so, why those concerns had not been acted on. If there were people who had had concerns, but had not voiced them, I wanted to establish why that was so and to explore ways in which such people could, in the future, be encouraged to come forward.

Concerns about Shipman

2.35 The Inquiry focussed on several specific groups of people who might have had particular reason to become concerned about Shipman's activities.

Families and Friends

2.36 The first of these were the relatives and friends of Shipman's victims. When providing their Inquiry witness statements for Phase One, in connection with the Inquiry's investigation of the deaths of Shipman's patients, relatives and other witnesses were asked whether they had had any concerns about the death in question. In preparation for Stage Four, those witness statements were examined again and the witnesses who had said they had had concerns at the time the death occurred were asked to provide further information. Witnesses were asked to explain why (if such was the case) they had not voiced their concerns at the time. They were asked whether they would have known to whom they should take those concerns. They were also asked to suggest ideas for change which might make it easier for people to bring forward similar concerns in the future.

Members of the Donneybrook Practice

2.37 The next group that the Inquiry considered were the members of the Donneybrook practice, where Shipman killed at least 71 patients between 1977 and 1990. I have already referred to their evidence earlier in this Chapter.

Members of the Practice Staff

2.38 The third group which the Inquiry considered was Shipman's practice staff. They had worked in close proximity to him at the Market Street Surgery and it was clearly important to ascertain whether any members of staff had known or suspected anything of his criminal activities. Members of the practice staff had provided a considerable amount of background evidence to the Inquiry for the purposes of its Phase One investigations. In preparation for Stage Four, they were shown schedules containing details about the deaths of patients of the practice and were asked what, if anything, they could recall about those deaths. Lengthy witness statements were provided by Sister Gillian Morgan (nurse practitioner), Mrs Alison Massey (practice manager), Mrs Carol Chapman (receptionist), and Mrs Judith Cocker (receptionist). Two other members of staff, who had worked at the practice for short periods, also provided witness statements. All these witnesses gave oral evidence to the Inquiry. Mrs Margaret Walker (computer operator) had emigrated by the time of the Inquiry hearings. She had provided a very detailed witness statement before her departure. Another witness, who had worked temporarily as a nurse at the practice, provided a written statement.

Other Healthcare Professionals

2.39 The Inquiry also obtained written evidence from three other healthcare professionals, who had been based part-time at the Market Street Surgery, but had had little involvement with the day-to-day running of the practice. The evidence of Mrs Marion Gilchrist, the district nurse attached to Shipman's practice between 1995 and 1998, was heard by the Inquiry during Stage Three. The evidence of Mrs Ethel Dooley and Mrs Barbara Sunderland, district nurses who occasionally stood in for Mrs Gilchrist, was also heard during that stage.

Others Who Had Concerns

2.40 The Inquiry received evidence, both oral and written, relating to suspicions about Shipman which had arisen in the minds of Mrs Christine Simpson (resident manager of Ogden Court, a sheltered housing development in Hyde), Mr John Shaw (a local taxi driver), Mrs Dorothy Foley and Mrs Elizabeth Shawcross (home helps) and Mrs Shirley Harrison (relative of one of Shipman's victims and neighbour of another). Mr Shaw, Mrs Foley, Mrs Shawcross and Mrs Harrison had told nobody in authority of their concerns. However, Mrs Simpson told the Inquiry that she had informed her line manager, Mrs Janet Schofield, a housing officer employed by the Manchester and District Housing Association (now part of the Harvest Housing Group), of her concerns. Mrs Schofield did not accept that Mrs Simpson had communicated this information and Mrs Schofield gave oral evidence about the matter to the Inquiry.

2.41 During Phase Two, Stage One (which related to the first and unsuccessful police investigation into the deaths of Shipman's patients), the Inquiry heard evidence about the mounting concerns of Mr David Bambroffe and Mrs Deborah Bambroffe, which had led eventually to Mrs Bambroffe communicating those concerns to Dr Susan Booth of the Brooke Practice. That communication had the effect of heightening the concerns already felt by the late Dr Linda Reynolds, another member of the Brooke Practice. In March 1998, she reported her concerns, and those of her partners, to the local Coroner and thus initiated the first police investigation. Mr and Mrs Bambroffe, together with Mr Nigel Reynolds (Dr Reynolds' widower) gave oral evidence in Stage Two; they provided further witness evidence for the purposes of Stage Four, in which they set out their views about steps which might be taken to make it easier for those who had concerns to bring them to the attention of the appropriate authorities.

Concerns of Colleagues

2.42 The case of Mrs Renate Overton, which I deal with in Chapter 10, featured prominently in the First and Third Reports and oral evidence surrounding the circumstances of her death and its aftermath were heard in December 2002. In my Third Report, I found that two consultants at Tameside General Hospital (Dr Ceri Brown and Dr Murtaza Husaini) had been aware in February 1994 that Shipman had administered (they believed negligently, rather than deliberately as I found in my First Report) an overdose of morphine or diamorphine to Mrs Overton such as to cause severe brain damage which led, 14 months later, to her death. They had not reported the matter to anyone in authority. At the time of

writing the Third Report, I deferred the question of whether they were under a duty to report their concerns about Mrs Overton's case and whether they should be criticised for their failure to do so. I decided that I should consider those questions after the Stage Four hearings at which evidence was to be received on wider issues concerning the duty to report, the options for reporting available to the two consultants and the culture within the medical profession at the time. At the same time, I heard some evidence about the change in culture since then.

2.43 I had already heard, during Stage Two, evidence on those topics from the two consultants themselves and from other members of the medical, nursing and administrative staff at the Tameside General Hospital. For the Stage Four hearings, the Inquiry gathered evidence from a variety of other sources. The Medical Directors of three trusts responsible for hospitals comparable in size to Tameside General Hospital gave oral evidence. The solicitors representing the two consultants supplied witness statements from Professor Alan Aitkenhead, Professor of Anaesthesia, Queen's Medical Centre, Nottingham and Dr John Givans, a retired GP who does consultancy work for the Medical Defence Union. Both gave oral evidence. The medical defence organisations and the BMA provided written contributions and Dr Gerard Panting, of the Medical Protection Society, also gave oral evidence. The two consultants declined the opportunity to give further evidence although they were represented at the hearings.

The Wider Picture

Public Concern at Work

2.44 The Inquiry received written and oral evidence from the organisation Public Concern at Work (PCaW), which offers help and encouragement to organisations (in particular NHS organisations) that wish to create and foster a culture in which staff feel safe to raise concerns. It has also set up and administers a telephone helpline that provides free confidential legal advice and practical assistance to individuals who are considering raising concerns. Mr Guy Dehn, Director, PCaW, gave oral evidence to the Inquiry about the development over recent years of measures to encourage people with genuine concerns about malpractice to make their concerns known, and to protect those who take such action from suffering detriment as a result.

Concerns of Practice Staff and Healthcare Professionals

2.45 I wished to understand the difficulties faced by GP practice staff and healthcare professionals who have concerns (in particular, concerns relating to poor clinical practice or other behaviour which might pose a risk to patients) about doctors and other healthcare professionals, and to explore ways of reducing those difficulties. Mr Dehn addressed these issues in his evidence and the Inquiry also heard evidence from Mr Ian Hargreaves, retired Regional Director, Royal College of Nursing (RCN), and Mrs Debra Davies, Counter-fraud and Performance Manager of the former Iechyd Morgannwg HA. Relevant evidence was also received from a number of organisations, including AMSPAR, the British Association of Medical Managers, the Consumers' Association (now known as Which?), the Nursing and Midwifery Council, the Community Practitioners' and Health

Visitors' Association and the Association of Chief Police Officers. Mr Simon Bennett, of the DoH, provided a witness statement dealing with these matters, which were also discussed at a seminar attended by, among others, representatives from PCaW, AMSPAR, the RCN and the DoH.

Concerns of Home Helps, Wardens of Sheltered Housing Developments and Residential Care Assistants

2.46 Home helps, wardens of sheltered housing developments, residential care assistants and those in other similar employment may be in a position to observe poor clinical practice or other behaviour by doctors and other healthcare professionals that might put patients at risk. The Inquiry wished to explore the arrangements in place for the bringing forward of such concerns. The Inquiry obtained from 14 local authorities examples of the 'whistleblowing' policies currently in place for employees in the fields mentioned above. The Inquiry also received written and oral evidence from persons with responsibility for organising home help and warden services in the Tameside area and in other parts of Manchester. Further written evidence was provided by a number of organisations, including the NCSC, the Care Standards Inspectorate for Wales, the Care Commission (Scotland), the Local Government Management Board, UNISON and Age Concern.

The General Medical Council

The Areas of Interest for the Inquiry

2.47 The final topics to be considered by the Inquiry were the fitness to practise (FTP) procedures operated by the GMC, the body which is responsible for the registration of doctors and which plays a central part in the regulation of the profession, and the GMC's future plans for the revalidation of doctors. The Inquiry's interest in the GMC's FTP procedures arose in a number of different ways. First, it was necessary for the Inquiry to examine the GMC's treatment of Shipman in 1976, when his conviction for drug offences was reported to it, and to decide whether that treatment was, by the standards of the time, adequate and appropriate. Many people had expressed the view that to deal with a doctor convicted of drugs offences by means of a warning letter was inappropriate and had not provided adequate protection to patients. I had to consider whether Shipman's case was a 'one-off' or whether it was, in fact, typical of the way in which cases of that kind were dealt with at the time.

2.48 In 1976, the procedures later developed by the GMC for dealing with sick doctors (the health procedures) were not in operation. They were introduced in 1980 and were aimed primarily at the rehabilitation of the doctor concerned. The Inquiry was told that, had they been in force at the time of Shipman's referral to the GMC, Shipman would have been dealt with under those procedures because he had been diagnosed as having a drug dependency. It was, therefore, necessary for the Inquiry to examine the operation of the health procedures from their inception in 1980 to date, in order to ascertain whether the outcome of Shipman's case would have been different if he had been dealt with under the health procedures. I also had to consider whether the way in which the GMC has in the

past dealt with drug abusing doctors like Shipman has afforded adequate protection to patients.

2.49 It was also necessary for the Inquiry to consider whether it would have been more appropriate for drug abusing doctors (particularly those who, like Shipman, had been convicted of serious criminal offences) to have been dealt with by means of the GMC's procedures for disciplining doctors who have, or might have, been guilty of serious professional misconduct (SPM) (the conduct procedures) as an alternative to (or as an adjunct to) dealing with them under the health procedures. This necessarily involved an examination of the operation of the GMC's conduct procedures.

2.50 The regulatory and disciplinary procedures operated by the GMC form an integral part of the overall monitoring system. If a complaint is received by a PCO about a GP's conduct or performance, or if the results of routine local monitoring suggest that s/he is performing poorly, the doctor might be referred to the GMC with a view to action being taken on the doctor's registration. The threat of action on registration provides the 'teeth' for the local monitoring process and the effectiveness or otherwise of the GMC's FTP procedures may be determinative of the success of local monitoring arrangements. If the GMC does not act, or responds inadequately and, as a result, a doctor who presents a risk to patients is permitted to continue in practice, the monitoring process as a whole is undermined. This interdependence of local systems and those of the GMC provided an additional reason for the Inquiry to examine the GMC's health and conduct procedures, and also its performance procedures, into which doctors whose professional performance has been identified locally as deficient may be referred. The Inquiry has also explored the interrelationship between NHS GP complaints and disciplinary procedures and the FTP procedures operated by the GMC. In particular, the Inquiry considered two complaints about Shipman that were reported both to the local NHS authorities and to the GMC and examined how those complaints were handled by those bodies. The Inquiry has considered the need for interlinking standards, criteria and thresholds to be applied by decision-makers locally and by those involved in making decisions at the various stages of the GMC's FTP procedures.

2.51 From 2005, the GMC intends to introduce a requirement for every doctor to undergo periodic revalidation as a condition of continuing to hold a licence to practise. Revalidation is defined in the Medical Act 1983 (as amended) as an **'evaluation of a medical practitioner's fitness to practise'**. The introduction of the requirement for revalidation will give the GMC a direct responsibility for the monitoring of doctors, including GPs. If the effect of revalidation were that every doctor on the register were to be required to demonstrate an acceptable and objectively measurable standard of competence and performance, this would be a highly significant addition to the current monitoring arrangements for GPs. The development of the proposals for revalidation has, therefore, been of considerable interest to the Inquiry. I have considered the different proposals for carrying out the revalidation process which have been put forward by the GMC over recent years, with a view to determining whether the various models proposed would give patients adequate protection against incompetent, poorly performing and aberrant doctors.

2.52 It is intended that those doctors whose fitness to practise is in doubt (and who cannot, therefore, be revalidated in the usual way) will be referred into the GMC's FTP procedures (frequently, but not invariably, in the form of a case with a performance element). Thus, the FTP procedures will underpin the revalidation process. However rigorous the initial process of evaluating doctors for the purposes of revalidation might be, it would be rendered useless if the FTP procedures were to operate so as to allow doctors who had not attained the required standard of competence and performance to remain in practice. The interrelation between revalidation and the FTP procedures, therefore, provided an additional reason for the Inquiry to examine the effectiveness of those procedures.

2.53 The case of Mrs Overton also raised issues relating to the GMC. One of the reasons advanced by Dr Brown for not having reported the incident was that the GMC would not have acted on such a complaint. He did not think he had sufficient information on which to base a complaint. He was also worried that, if he made a report, the GMC might criticise him for disparaging Shipman. In order to enable me properly to assess the weight of this piece of evidence, it was necessary for the Inquiry to examine how cases of serious, apparently 'one off', incidents such as that involving Mrs Overton would have been dealt with by the GMC in the early and mid-1990s. The facts of the case of Mrs Overton were also used by the Inquiry to test how an incident of that type would have been dealt with by the GMC (as well as by local NHS bodies) in the more recent past.

2.54 Two further issues relating to the GMC arose directly in Shipman's case. The first of these was the inability of the GMC, when Shipman was under investigation for murder – and even after his arrest – to take any steps to suspend him from practice. Under the arrangements then in place, the GMC was powerless to take action until he had been convicted of murder, over a year later. The second issue related to the provision of information about Shipman's previous history. The PCOs responsible for the provision of primary care in Tameside remained unaware of Shipman's previous history until the time of the second police investigation in August 1998. Most of his patients had no idea that he had previously been reported to the GMC for drug abuse. These factors have led me to consider whether information of this kind held by the GMC should be made more readily available to NHS bodies and other organisations with an interest in knowing, and also to patients.

2.55 The GMC has recently introduced new FTP procedures. In line with the requirement placed upon me to make any recommendations I believe necessary for the protection of patients, I regarded it as appropriate to examine the proposed new procedures and to consider the extent to which they provide adequate protection for patients.

Witnesses from the General Medical Council

2.56 The Inquiry heard oral evidence from Mr Robert Gray, who was Assistant Registrar of the GMC in 1976 and had been involved in processing the report against Shipman. Another member of the administrative staff at the time provided a written statement. Oral evidence was also given by Dr Derek Llewellyn, a member of the Penal Cases Committee (PeCC) which decided to close Shipman's case and send him a warning letter, rather than referring the case for a public hearing before the Disciplinary Committee. Dr Ronald Bryson, one of the consultant psychiatrists on whose evidence the PeCC relied when making its decision, provided written evidence.

2.57 The witnesses who gave evidence relating to more recent events were in general chosen by the GMC, after consultation with the Inquiry. Two former members of the administrative staff, one of whom had been employed by the GMC between 1977 and 2002, gave oral evidence about practice and procedures in the 1980s and 1990s. Two senior current members of the administrative staff described the practice and procedures which had been in operation more recently. Several former and current members of the GMC, both medically qualified ('medical') and non-medically qualified ('lay'), provided written evidence. Oral evidence was given by Dr Krishna Korlipara (current medical member and former medical screener), Dr Sheila Mann (former medical member and health screener), Mr Stephen Brearley (current medical member, who explained the GMC's plans for revalidation) and Mr Robert Nicholls and Dr Arun Midha (both current lay members). Professor Sir Graeme Catto, current President, and Mr Finlay Scott, Chief Executive and Registrar, also gave evidence, both separately and together. Dr Malcolm Lewis (current medical member and former medical screener) and Mr Robin Macleod (current lay member) represented the GMC at the Inquiry's seminars.

Other Witnesses

2.58 Professor Isobel Allen, Emeritus Professor of Health and Social Policy, University of Westminster Policy Studies Institute, has carried out a considerable amount of research, commissioned by the GMC, into the operation of its FTP procedures, in particular its conduct procedures. With colleagues, she produced two highly detailed Reports based on her research, one in 1996 and one in 2000, together with a further Paper in 2003. She attended the Inquiry to give oral evidence. Sir Donald Irvine, immediate past President of the GMC, provided a considerable amount of written evidence (including his book, 'The Doctors' Tale', published in 2003) and gave oral evidence in relation to the GMC's FTP procedures, its plans for revalidation, and other issues relevant to Stage Four. Several other witnesses gave written statements, among them Miss Isabel Nisbet, then seconded to the Council for the Regulation of Healthcare Professionals (now known as the Council for Healthcare Regulatory Excellence (CRHP/CHRE)). She explained the role of the CRHP/CHRE in overseeing the regulatory functions of the GMC. Mr Sandy Forrest, Director of the CRHP/CHRE, attended two of the Inquiry's seminars. Detective Chief Superintendent Bernard Postles (now retired) and Mrs Jan Forster, formerly Director of Primary Care, WPHA, provided witness statements dealing with their attempts between August and October 1998 to secure Shipman's suspension from practice.

Drug Abusing Doctors

2.59 As I have explained, the Inquiry wished to examine whether the way in which the GMC has dealt with drug abusing doctors in the past provided adequate protection for patients and to consider whether it would be appropriate for it to deal with such doctors differently in the future. The Inquiry commissioned a report from Dr Andrew Johns, Consultant Forensic Psychiatrist, South London and Maudsley NHS Trust, who has special expertise in the subject of substance abuse. The report dealt with the issues of substance misuse by doctors, the risks posed by a rehabilitated doctor, the likelihood of relapse into drug taking and assessing the risk of relapse. Dr Douglas Fowlie, Consultant Psychiatrist, Grampian

Primary Care NHS Trust, provided a witness statement, dealing with his experience of treating and supervising doctors, and of advising the GMC, in cases of substance abuse, Dr Johns, Dr Fowlie, Professor Sir Michael Rawlins (former Chairman, Advisory Council on Drug Misuse), Dr Kit Harling (Director of NHS Plus, DoH) and Dr Jolyon Oxley (Honorary Secretary, National Counselling Service for Sick Doctors) participated in one of the Inquiry's seminars at which this topic was discussed.

Case Files

2.60 In order to compare the handling of Shipman's case in 1976 with that of other similar cases reported to the GMC during the mid- to late 1970s, and subsequently under the health procedures, the Inquiry sought and obtained a large number of files concerning drug-related cases dealt with by the GMC. The Inquiry was primarily concerned with cases where the doctor had obtained drugs for his/her own use, rather than those where there were allegations of irresponsible prescribing, the illicit supply of drugs to others or conduct of that nature. The Inquiry also obtained case files relating to cases (both drug-related and not) where the doctor's honesty had been in issue. In order to examine the way in which the GMC would have dealt with the case of Mrs Overton, had it been reported, the Inquiry obtained some files relating to cases involving allegations of clinical negligence or poor clinical practice in connection with the prescribing and administration of drugs which had been reported to the GMC in the mid-1990s and subsequently. Witnesses from the GMC were asked to comment on the contents of some of the case files both in writing and in their oral evidence.

2.61 The Inquiry also sought and obtained files in a small number of recent cases falling within certain categories and chosen at random. The object of this was to illustrate the working of various aspects of the GMC's FTP procedures as they were in 2003. Relevant witnesses were asked to comment on the contents of the case files both in writing and orally.

2.62 The Inquiry has not undertaken any detailed audit of cases dealt with by the GMC. However, the case files have been used to illustrate the way in which the FTP procedures worked in practice at various times of their operation. They have provided a valuable insight into the operation of the procedures which are not in general open to public scrutiny. I refer to some of the cases in Chapters 16 to 24 of this Report. Also referred to are published decisions of the Professional Conduct Committee and decisions of the Privy Council and the High Court relating to appeals against decisions of the GMC's FTP committees and applications for judicial review of decisions made by the GMC. Where the circumstances of the case under discussion are not in the public domain, the doctors involved have been given code numbers and some details (such as dates) have been omitted so as to preserve confidentiality.

Additional Evidence

2.63 The Inquiry received responses to a questionnaire which had been circulated by Alexander Harris, the solicitors representing the Tameside Families Support Group, to those families and friends of Shipman's patients for whom they act. The questionnaire sought views on, *inter alia*, the GMC's handling of Shipman's case in 1976 and the way in

which doctors convicted of drugs offences should be dealt with. The Inquiry itself wrote to a range of organisations, asking for their views. Thirty one responses were received. In addition, the Inquiry issued questionnaires to a random selection of PCTs, enquiring about their experience of dealing with the GMC; six responded.

Documentary Evidence

2.64 The evidence to which I have referred above does not, of course, represent the whole picture. In addition, I have been able to examine and consider documents from the following sources.

The West Pennine Health Authority and Its Predecessors

2.65 Very shortly after the establishment of the Inquiry in 2001, the WPHA provided files of its documents relating to the monitoring activities of the PCOs during Shipman's time in practice there. Some of these documents were of a general nature and some related specifically to Shipman. Since the initial delivery of documents, the WPHA has responded to requests from the Inquiry to provide further documents and other information.

The Department of Health

2.66 The DoH provided a considerable amount of background material, including consultation documents, Government White Papers, circulars, reports, guidance and directions, covering the period from the 1970s to the time when Shipman ceased practice and beyond. This has enabled me to put in context the various arrangements in place in Tameside, and to understand the development of the arrangements for regulating GPs over the last 30 years or so. The Inquiry also obtained a limited number of documents which survived from the time when the Regional Medical Service had responsibility for visiting GPs.

The Royal College of General Practitioners

2.67 The RCGP provided the Inquiry with documentation recording its involvement in the developments in the arrangements for regulating GPs, which has plainly been extremely significant. Documents relating to the RCGP's various quality awards and markers and to its proposals for the appraisal and revalidation processes have also been supplied.

The General Medical Council

2.68 Annexed to Mr Scott's various witness statements were approximately 9000 pages of documents relating to the operation of the GMC's FTP procedures. Subsequently, the GMC has provided a large amount of further documentation, some at the specific request of the Inquiry and some on its own initiative. Included among these documents have been the briefing papers, minutes and transcripts relating to recent meetings of the Council.

Other Organisations

2.69 In addition, I have received a wealth of documentation from other organisations, notably the NCAA, CHI, the NPSA, the BMA and PCaW.

Academic and Professional Journals and Other Professional Publications

2.70 With the assistance of the Medical Advisor to the Inquiry, Dr Aneez Esmail, the Inquiry team collected, from academic and professional journals and other publications, a large amount of published literature dealing with, *inter alia*, the regulation and disciplinary systems for GPs, tools for the monitoring and evaluation of GPs, GP appraisal, proposals for the revalidation of doctors, the raising of concerns, NHS complaints systems, the monitoring of GP patient mortality rates and the operation of the GMC's FTP procedures. I have referred to some of this literature in the course of this Report.

2.71 The period for which the Inquiry has been considering these topics has been a time of change for the profession, with the introduction of GP appraisal and of the GMC's new FTP procedures, the creation of new bodies (such as the Healthcare Commission and the CRHP/CHRE), the development of recently created organisations (such as the NCAA and the NPSA), the introduction of the new GMS Contract and the impending introduction of revalidation. All these changes have been debated and discussed in the professional publications which are produced regularly. These publications have provided a useful insight into the attitude of members of the profession to the various developments that have been effected or proposed.

The Inquiry's Own Consultations

2.72 In preparing for Stage Four, the Inquiry began by seeking the views of a large number of organisations and individuals who were thought likely to have an interest in some or all of the topics to be considered during Stage Four. As a result of these and subsequent enquiries, the Inquiry was able to identify those persons and organisations who might be able to provide evidence and other material which would assist the Inquiry. In addition, as I have already mentioned, the Inquiry has issued various questionnaires and requests for information and documents.

2.73 During the Stage Four hearings, the Inquiry published a Consultation Paper, 'Safeguarding Patients: Topics for Consideration at the Stage Four Seminars'. The purpose of the Consultation Paper was to provide a focus both for written responses and for discussion at a series of seminars held by the Inquiry in January 2004. The Inquiry received written responses from 95 individuals and organisations. The views expressed in those responses were considered and discussed at the seminars.

2.74 The seminars covered six different topics and extended over eight days. Participating in the seminars were representatives of organisations and individuals with an interest and expertise in the topics under discussion. I have mentioned above many of those who participated. Many of the views expressed during the Inquiry's consultation process are referred to in this Report.

The International Perspective

2.75 One of the seminars, lasting two days, was devoted to a discussion of the systems in five other jurisdictions. Dr Perry Pugno (Director, Division of Medical Education, American Academy of Family Physicians, USA) told the Inquiry about the current arrangements

for the monitoring and recertifying of family doctors in the USA, together with changes to the recertification process planned for the future. He also described the operation of the National Practitioner Data Bank, a publicly accessible database of information about family practitioners. On the second day of the seminar, he described the way in which complaints against family doctors are processed in the USA. Dr André Jacques (Director, Practice Enhancement Division, Collège des Médecins du Québec, Montréal, Canada) told the Inquiry about the systems for monitoring the performance of family practitioners used in the province of Québec. He also described the regulatory role of the College. Dr Rocco Gerace (Registrar, College of Physicians and Surgeons of Ontario, Toronto, Canada) described the systems of monitoring of family physicians in operation in the province of Ontario, together with the plans for the Maintenance and Enhancement of Physician Performance programme, a system of revalidation, to be introduced in the future. Dr Gerace also spoke about the regulatory role of the College. Mr Ronald Paterson (Health and Disability Commissioner, New Zealand) described the system for dealing with patient complaints in New Zealand and, in particular, his own role as an independent investigator of complaints about individual healthcare professionals and healthcare systems. Professor Chris van Weel (Head of Department of General Practice and Social Medicine, University of Nijmegen, The Netherlands) spoke about the arrangements for regulating general practice in his country. Professor Baker and Professor David Newble (Professor of Medical Education, Head of Department of Medical Education, Director of Learning and Teaching, Faculty of Medicine, University of Sheffield) each attended one day of this seminar.

Before the Oral Hearings

The Arrangements for the Distribution of Evidence

2.76 The arrangements for the distribution of evidence were the same for Stage Four as for Phase One. They are described at paragraphs 3.17 and 3.18 of my First Report. As in Phase One, all the evidence available to the Inquiry was released into the public domain by means of the Inquiry website except where material had to be redacted to respect confidentiality or to protect the identity of individuals not directly concerned with Shipman.

The Public Meeting

2.77 On Monday, 17th March 2003, the Inquiry held a Public Meeting, at which I explained the arrangements for Stages Three and Four of Phase Two.

Representation

2.78 Before and after the Public Meeting, I granted leave to various individuals and organisations to be represented before the Inquiry during the Stage Four hearings and, for some, recommended funding for that representation at public expense. A list of participants in Stage Four and their representation can be seen at Appendix A of this Report.

Salmon Letters

2.79 Before the Stage Four hearings began, the Solicitor to the Inquiry, Mr Henry Palin, sent letters (known as 'Salmon letters') to those persons and organisations whose conduct might be the subject of criticism by the Inquiry. The potential criticisms were clearly identified in those letters.

2.80 In the event that any further potential criticisms came to light at or after the hearings, these were the subject of further Salmon letters. Recipients of Salmon letters were given the opportunity to respond to the potential criticisms in writing, as well as in the course of their oral evidence at the hearings.

Broadcasting

2.81 I had given permission for the Stages One, Two and Three hearings to be broadcast in accordance with a protocol which had been prepared by the Inquiry and was designed to ensure that Inquiry material would not be misused. That protocol was slightly amended in September 2002. Those arrangements caused no difficulties during Stages One, Two or Three and I received no representations suggesting that they should be discontinued. I therefore gave permission to recognised organisations to broadcast during Stage Four, provided that they complied with the slightly amended protocol, clarifying the broadcasters' duties in respect of websites. During Stage Four, I received and granted six applications from witnesses that their evidence should not be broadcast. I also directed that certain parts of the evidence relating to the way in which the GMC had handled individual cases should not be broadcast and that the public screens should not be used for the display of documents during those parts of the hearings when those cases were being discussed. This was in order to respect the confidentiality of the doctors who were the subjects of those cases.

The Oral Hearings

2.82 The oral hearings were held in the Council Chamber at Manchester Town Hall. The Stage Four hearings took place between Monday, 14th July 2003 and Thursday, 18th December 2003.

2.83 The arrangements for the oral hearings, and for the publication of evidence, were the same as for the Phase One hearings. They are described at paragraphs 3.28 to 3.36 of my First Report. The public gallery at the Town Hall remained open, and transcripts and other documents were posted on the Inquiry's website after each day's hearing.

2.84 Volunteers from Tameside Victim Support Witness Service attended to assist family witnesses and three other witnesses when they attended to give evidence at the Stage Four hearings, but were not required during the remainder of these hearings. I remain most grateful to Tameside Victim Support Witness Service for all the assistance they have given during the course of the Inquiry.

2.85 In general, witnesses who gave oral evidence during the Stage Four hearings were called by Counsel to the Inquiry. However, in the interests of fairness, those witnesses who had

received Salmon letters were given the opportunity of making an opening statement of their evidence in response to questions by their own counsel or solicitor, before being questioned by Counsel to the Inquiry. None of the recipients of Salmon letters in Stage Four availed themselves of this opportunity.

Submissions

2.86 Following the conclusion of the Stage Four hearings the representatives of those individuals and organisations who had been granted representation made written submissions. Counsel to the Inquiry also produced written submissions relating to certain specific issues. I offered an opportunity to all representatives to make representations that I should hear oral submissions but received no such representations. Although I have not, in the course of this Report, made many direct references to the written submissions received, I have considered them with care and have taken them fully into account when reaching my conclusions.

The Seminars

2.87 The seminars were held in the Council Chamber at Manchester Town Hall on Monday 19th, Tuesday 20th, Thursday 22nd, Friday 23rd, Monday 26th, Tuesday 27th, Thursday 29th and Friday 30th January 2004. A total of 37 participants took part in the discussions at the various seminars. A list of seminar participants can be seen at Appendix B to this Report. Those discussions were led by Leading Counsel to the Inquiry. Although structured, the discussions were significantly less formal than the oral evidence given during the usual Inquiry hearings.

2.88 Participants in the seminars had submitted written responses to the Inquiry's Consultation Paper in advance and expanded on those responses during the course of the seminars. Persons attending the seminars as observers were able to raise points through Counsel for the consideration of seminar participants. After the seminars, the Inquiry received a number of further responses, both from participants who wished to confirm or revise views previously expressed, and from people who had attended the seminars, or who had become aware of the discussions that had taken place, and wanted to contribute their own opinions. A list of respondents to the Consultation Paper appears at Appendix C to this Report.

2.89 I found the seminars, and indeed the whole consultation process undertaken by the Inquiry, extremely valuable in clarifying my thoughts and helping me to formulate my recommendations for the future.

The Structure of This Report

2.90 In Chapters 3 and 4 of this Report, I shall describe the arrangements for administering and monitoring the provision of primary care during the period of Shipman's time in general practice, between 1974 and 1998. I shall also consider the circumstances of Shipman's appointment to the Donneybrook practice and of his move to single-handed practice in

1992. In Chapter 5, I shall consider the changes to the arrangements for administering and monitoring the provision of primary care which have occurred since 1998.

2.91 Chapter 6 will cover the system for dealing with complaints about GPs prior to 1996 and the way in which complaints against Shipman, made in 1985, 1990 and 1992, were handled. In Chapter 7, I shall discuss the patient complaints system which has been in operation since 1996 and the new system which has now been partially introduced.

2.92 The subject of Chapters 8, 9, 10 and 11 is the raising of concerns. Chapter 8 describes the experience of those few people who had concerns about the deaths of Shipman's patients. Chapter 9 examines whether the staff at Shipman's practice knew of, or had reason to suspect, his criminal activities. Chapter 9 also looks at the position of practice staff, and at the difficulties which they may face in bringing forward any concerns they might have about doctors and other healthcare professionals within the practice. Chapter 10 is devoted to issues connected with the death of Mrs Overton. Chapter 11 deals with general issues relating to the raising of concerns in the employment context and in other circumstances and to steps that might be taken to provide further protection for persons who wish to bring forward genuine concerns.

2.93 In Chapter 12, I describe the current arrangements for clinical governance and the limitations of those arrangements. Chapter 13 deals with the position of single-handed practitioners and the steps which should be taken to avoid them becoming professionally isolated.

2.94 Chapter 14 contains a discussion of the feasibility and desirability of the monitoring of GP patient mortality rates, the experience of those bodies which have undertaken such monitoring in the past and the way in which it might be organised in the future.

2.95 Chapter 15 provides an introduction to the section of the Report dealing with the GMC's FTP procedures and its plans for revalidation. In Chapter 16, I shall examine the GMC's handling of the report of Shipman's conviction for drug-related offences in 1976. Chapter 17 deals with the difficulties of defining the concepts of SPM and seriously deficient performance, on which the old conduct and performance procedures were based.

2.96 In Chapter 18, I examine the processing of complaints undertaken by the administrative staff of the GMC which has, in the recent past, resulted in 65% of cases being rejected at that early stage. In Chapters 19 to 22, I examine the screening process, the work of the Preliminary Proceedings Committee and the Professional Conduct Committee and the operation of the GMC's health procedures. In Chapter 23, I consider the way in which the GMC has dealt with drug abusing doctors in the past and the changes which I consider should be made in the future. Chapter 24 contains an examination of the operation of the GMC's performance procedures. Chapter 25 considers the new FTP procedures and, in Chapter 26, I examine the GMC's proposals for the revalidation of doctors. Chapter 27 sets out my proposals for change.

The Effect of the Evidence

2.97 In Stage Four, the Inquiry has covered a wide range of issues and has received an enormous amount of evidence. In this Report, I have set out some parts of the evidence

in detail but, in general, I have recorded only my observations and conclusions based on all that I have heard and read. The evidence is available on the Inquiry's website for those who wish to read it. I am conscious that there are some aspects of the evidence to which I have referred only briefly. For example, I have scarcely mentioned the fascinating presentations received at the international seminars. This does not mean that they have not been of value or that they have not influenced my thinking; they have. It means only that I have had to be selective. This Report is already long and has taken several months to write. I would not have wished to delay its publication any longer.

CHAPTER THREE

The Appointment of General Practitioners and the Administration of General Practice prior to 1980: Shipman's Appointment to the Donneybrook Practice

Introduction

3.1 When Shipman's crimes came to light, there was a general feeling of disbelief that the authorities responsible for the provision of primary health care had not detected his aberrant activities and taken action to remove him from practice years before. The discovery that he had been convicted in 1976 of criminal offences in connection with controlled drugs (a fact which it was understandably assumed must have been known to those authorities) only served to increase that feeling.

3.2 Shipman was in general practice from 1974 until 1998 with a break of two years (from September 1975 to October 1977), following his departure from Todmorden. Over that period of more than 20 years, there were significant changes in the way that general practice was organised. Since 1998, the pace of change has quickened still further. Many new arrangements have been introduced, some as a direct result of the discovery of Shipman's activities and others as part of wider moves to improve the quality of care within the NHS. The framework within which general practice is conducted today is very different from that which existed in the 1970s and 1980s.

3.3 In this Chapter and in Chapter 4, I shall describe the arrangements which were in place for regulating the activities of general practitioners (GPs) during the time when Shipman was in general practice. In Chapter 5, I shall set out the changes which have occurred since he ceased practice in 1998. The details of many of the arrangements that I shall describe were complex. For present purposes, it is necessary only to summarise the position briefly. I shall deal only with the arrangements as they affect England. I shall also consider the actions of those responsible for appointing Shipman to his position in general practice in Hyde in 1977.

The Wider Professional Regulatory Framework

3.4 Today, there are approximately 34,500 GPs in active practice. Most work wholly within the NHS. A few practise privately. Many NHS practitioners perform a small amount of private work in addition to their NHS work. The NHS bodies which, over the years, have had responsibility for the provision of primary health care (and to which I shall refer collectively as 'primary care organisations' (PCOs)) have never had any responsibility for GPs working in the private sector.

The General Medical Council

3.5 Until recently, the only organisation with the power to regulate doctors practising in the private sector was the General Medical Council (GMC). The GMC was established under the Medical Act 1858. In order to be entitled to practise, a doctor must appear on the

medical register held by the GMC. The GMC is required by Parliament to ensure that those admitted to the register are competent. Until November 2004, it was required also to take action on a doctor's registration when, following a complaint, that doctor was shown to have become unfit to practise by reason of serious professional misconduct, serious impairment of health or seriously deficient performance. Under new procedures introduced in November 2004, it will take action on a doctor's registration if it is satisfied that his/her fitness to practise is impaired to a degree justifying action on registration. It is the GMC alone that can remove a doctor's right to practise anywhere in the UK. It can do so whether the doctor practises in the NHS or in the private sector.

Local Medical Committees

3.6 Locally elected committees of GPs (known as local medical committees (LMCs)) have had statutory recognition since 1911. Their original purpose was to give GPs a voice in the administration of general practice. In fact, the wide range of functions exercised by LMCs means that they have more than just a voice. Members of a LMC, in particular the secretary and chairman, can wield considerable power and influence. First and foremost, LMCs are political groupings, which represent the interests of local GPs in consultations and discussions with PCOs. They provide advice and support to local practitioners. LMCs also have a formal statutory role in disciplinary and complaints procedures involving GPs. They have the power to nominate representatives to membership of certain committees, including disciplinary committees. They have a statutory right to be consulted on a wide range of issues affecting GPs. They can also be a valuable source of information and intelligence to the PCOs.

3.7 Members of a LMC may, by virtue of their position, be appointed members of PCOs. Shipman was secretary of the LMC for Tameside between 1981 or 1982 and 1988. As a representative of the LMC, he had a place for some time on the Executive Board of the Tameside Family Practitioner Committee (FPC), the PCO which at that time had responsibility for Tameside.

3.8 Mr William Greenwood, Assistant Administrator (later Deputy General Manager) of the Tameside FPC from 1983 until 1990, gave oral evidence. In the 1970s, he had held more junior posts at the Tameside FPC and acknowledged that his firsthand knowledge of this period was limited. He recalled that, in some circumstances, the LMC and the FPC would work together to resolve matters of mutual concern. However, the LMC was vigilant in protecting GPs against any perceived interference by the FPC in professional matters. On occasions, FPC staff had wished to carry out surveys asking questions of GPs. The LMC would not co-operate in the surveys. It resisted any attempt by the FPC to 'step out of the mould of administrators'.

Before 1974

3.9 The National Health Service Act 1946 placed responsibility for the provision of general medical services (together with pharmaceutical services, dental services and ophthalmic services) with 117 executive councils. For the purpose of this Report, I am concerned only with medical services, which were to be provided by GPs. From the inception of the NHS

in 1948, GPs enjoyed the status of self-employed professionals providing services under a national contract, the General Medical Services (GMS) Contract. As independent contractors, rather than direct employees, their relationship with the NHS was very different from that of doctors employed in secondary care (i.e. hospitals) within the NHS.

3.10 The GMS Contract is an agreement between GPs and the Government about arrangements for the supply of medical services. Until April 2004, the responsibilities of GPs were set out in terms of service, breach of which could result in disciplinary action. Payment for services was governed by the Statement of Fees and Allowances (the 'Red Book'), published by the Secretary of State for Health (SoS) after negotiation with the profession. Both the terms of service and the Red Book were subject to review from time to time.

3.11 In the early years, most GPs were single-handed practitioners. Standards of practice were extremely variable. Practice premises were frequently inadequate. Remuneration was based entirely on the number of patients on a GP's list. This gave rise to competition for patients which did not necessarily lead to an improvement in quality of care.

3.12 In 1966, a new GMS Contract brought major changes to general practice. Under the new Contract, contributions were paid by the NHS towards the cost of providing practice premises and of employing practice staff. A new group practice allowance was introduced, together with payments for out of hours work. The effect of these changes was to encourage GPs to improve the range – and, to some extent at least, the quality – of services provided. Group practices were formed and modern health centres, with improved facilities, were built. The new system of funding for GPs had a significant impact on the relationship between general practice and the NHS. It meant that GPs became to some extent financially reliant on the FPCs. Some say that the 1966 Contract marked the beginning of modern, team-based general practice.

From 1974: the Structure and Functions of the Family Practitioner Committees

3.13 In 1974, the year when Shipman started in practice, the NHS was subjected to the first major structural change since its foundation. Fourteen regional health authorities (RHAs) were established. Their role included responsibility for planning and for the allocation of resources to 90 area health authorities (AHAs). The AHAs had responsibility for establishing FPCs for their areas. These FPCs replaced the executive councils. The AHAs had statutory responsibility for providing family health services, including medical services. The duty of administering those services was given to the FPCs. The authorities with responsibility for Tameside were the North West RHA, the Tameside AHA and the Tameside FPC.

3.14 In general, FPCs were governed by an executive board, comprising a chairman and 30 members, 15 of whom were from the contractor professions (i.e. GPs, dentists, opticians and pharmacists). The eight medical members were nominated by the LMC. There were 15 lay members also. The chairman could be either a lay or a professional member. FPCs had no officer (i.e. employee) members. The most senior member of staff was an administrator, who would have an assistant. Those two members of staff would be

appointed by the Department of Health and Social Security (DHSS). The entire staff of an average FPC would number no more than about 25.

3.15 FPCs were responsible for ensuring access to, and the availability of, medical services to the local population. In addition, they had responsibilities for

(a) maintaining their medical lists

(b) the remuneration of GPs

(c) administering the terms of service for GPs

(d) implementing a mechanism to deal with GPs who breached their terms of service.

3.16 The task of the FPCs was to ensure that the systems prescribed for discharging their various functions were properly implemented. One witness described the FPCs as 'really just pay and rations organisations'. They had no management role. Nor did they have any responsibility for professional competence or quality of care. These were matters left entirely to the profession. The FPCs had no access to independent medical expertise. The LMCs assumed responsibility for maintaining professional standards locally. Nationally, as I have already said, the GMC was responsible for regulating the professional conduct of the doctors on its register.

The Medical List

3.17 Each FPC was required to keep a medical list of doctors in its area who had undertaken to provide general medical services. Applications by doctors for inclusion on a medical list were made in three different circumstances:

- where a member of an existing group practice retired, died or left for other reasons and a replacement was required
- where a single-handed practitioner died or ceased practice, leaving the practice vacant
- where there appeared to be a demand for an additional doctor.

In each case, a decision had to be taken as to whether a vacancy should be declared. The FPC could not itself take that decision. Instead, it was taken by the Medical Practices Committee (MPC), a national body whose function was to ensure an equitable distribution of GPs across the whole of England and Wales.

3.18 When a vacancy was declared in order to replace a member of an existing practice, the role of the FPC in the appointment of a doctor to fill that vacancy was very limited. I shall refer to that role in greater detail at paragraphs 3.51–3.54, when I describe Shipman's appointment to the Donneybrook practice. When a vacancy arose in either of the other two circumstances mentioned above, the FPC was responsible for advertising the vacancy and for shortlisting and interviewing candidates. The FPC would then make recommendations to the MPC, which was responsible for making the final selection.

3.19 The power of a FPC to remove a GP from its list was limited to cases where the GP had died, had ceased to be a registered practitioner, had failed to provide medical services

for a period of six months or where the GP's registration had been erased or suspended by the GMC. In certain circumstances (see paragraph 3.24 below), a FPC could make representations to the NHS Tribunal that a doctor should be removed from its list. The NHS Tribunal was a non-departmental body with judicial powers. Its purpose was to protect family health services from doctors who prejudiced their efficiency. The Tribunal had the power to remove a doctor from a FPC's list or to declare that the doctor should not be employed in any capacity connected with the provision of medical services.

Remuneration

3.20 FPCs were responsible for the payment of GPs, in accordance with the increasingly complex scheme of fees and allowances set out in the Red Book. Some of those allowances (e.g. those for postgraduate and vocational training) were designed to provide an incentive to improve standards. However, they were very limited in scope.

The Terms of Service

3.21 Once a GP was included on the medical list, s/he was subject to terms of service which were set out in the National Health Service (General Medical and Pharmaceutical Services) Regulations 1974 (the 1974 Regulations). The terms of service imposed a number of requirements on GPs, including the following:

- to render to their patients all necessary and appropriate personal medical services of the type usually provided by GPs
- to keep adequate records of the illnesses and treatment of their patients on forms supplied for that purpose by the FPC
- to order, by issuing a prescription, any drugs or appliances which were needed for the patient's treatment.

3.22 Other terms covered such matters as the acceptance and termination of responsibility for patients, responsibility for the provision of deputies and assistants, provision of proper and sufficient accommodation at practice premises and the provision of medical certificates. It was the responsibility of FPCs to administer the terms of service and to take action on any matters arising from such administration.

Failure to Comply with the Terms of Service

3.23 FPCs also had responsibility for putting in place and administering a disciplinary mechanism for dealing with cases where it appeared that a GP had failed to comply with his/her terms of service. Each FPC was required by the National Health Service (Service Committees and Tribunal) Regulations 1974 to establish at least one medical service committee (MSC). The function of the MSC was to hear complaints against GPs of alleged failures to comply with their terms of service. Three lay members of the FPC sat on the MSC, together with three doctors appointed by the LMC and the chairman. The chairman was a lay person, and did not necessarily have to be a member of the FPC.

3.24 The task of processing complaints and providing secretarial and administrative support for the MSC was undertaken by staff of the FPC. However, it was the MSC which took the decision whether or not a GP had breached his/her terms of service and which recommended any further action it thought appropriate. The FPC would then consider the MSC's report and would decide what action to take. It could recommend to the SoS that a warning should be issued or that an amount should be withheld from the GP's remuneration. It could, in certain circumstances (and after consultation with the LMC), impose a limit on the number of patients on a GP's list. In a serious case, the FPC could make representations to the NHS Tribunal that a doctor's continued inclusion on its medical list would be prejudicial to the efficiency of the services it provided. Efficiency could be affected if the GP posed a threat to patients or if the standard of care provided fell far short of that which the NHS and patients had a right to expect. Such representations could result in the GP's removal from the FPC's list and, in an extreme case, from all NHS lists. Referrals to the Tribunal were, however, very rare and the procedure very cumbersome. The FPC had no power itself to remove a doctor from its list (save in the limited circumstances referred to at paragraph 3.19) or to impose conditions on his/her continued inclusion on the list.

3.25 Where, after consultation with the LMC, it appeared to a FPC that a doctor was incapable of carrying out his/her obligations under the terms of service by reason of physical or mental illness, it was open to the FPC to require the doctor to supply a medical report to the LMC. However, the FPC was not able itself to choose the practitioner who prepared the report, to specify the aspects of the doctor's health to be dealt with in the report or to see the report when prepared. All these functions were performed by the LMC. All the FPC was entitled to was a report from the LMC, setting out the views of the LMC about the doctor's fitness to discharge his/her obligations. Even if the report showed that the doctor was unfit to practise, the FPC could not remove him/her from practice, or make alternative arrangements for patient care, without first consulting the LMC and then obtaining the consent of the SoS.

The Limited Role of the Family Practitioner Committees

3.26 In summary, the role of the FPCs was very limited and in some respects rather curious. They were responsible for administering the provision of general medical services, but had little control over the GPs responsible for providing those services. Issues of standards and quality of care were regarded as matters for regulation by the profession itself. FPCs were the recipients of complaints, which might include complaints about the quality of services, but could exert little or no influence over that quality. They had limited opportunity for direct contact with the GPs on their lists and, as I shall go on to explain, little information about them.

3.27 In the 1970s, there was a recognition in some quarters (notably by the Royal College of General Practitioners) that standards of care among GPs were extremely variable and, in the case of some, unacceptably low. Some members of the profession began to take steps aimed at raising standards. At that time, FPCs did not undertake any monitoring of clinical performance or of the quality of the services offered. Insofar as any monitoring of GPs was undertaken, it was done by the Regional Medical Service (RMS).

The Regional Medical Service

3.28 The RMS consisted of medical and supporting administrative staff employed by the DHSS and based in six divisions in England. Each division was headed by a senior medical officer who was designated a divisional medical officer. The divisional medical officer was supported by a number of regional medical officers (RMOs). The RMOs had two distinct functions. First, they provided medical opinions for DHSS benefit schemes. Their other role was to advise and generally to liaise with GPs. They made visits to every GP on a regular basis, usually once every one or two years. These visits were mainly of a routine pastoral nature. A wide range of issues affecting the organisation of general practice in the area was discussed. Visits were also used to carry out inspections of practice premises and to discuss GPs' prescribing habits. RMOs advised GPs on their duties in respect of controlled drugs and were authorised by the SoS to inspect their controlled drugs registers (CDRs) and stocks of controlled drugs. Until the 1960s, RMOs would examine clinical records to ensure that they were being maintained properly. That practice had fallen into disuse by the mid-1960s.

3.29 Since RMOs were, at one time, virtually the only direct link between GPs and the DHSS, the information collected at practice visits provided a potentially valuable insight into the way general practice was functioning on the ground. Information in the form of regular reports (not reports of individual practice visits) was passed by the RMOs to divisional medical officers for dissemination within the DHSS. There was no formal arrangement for communicating this information to the relevant FPC for each area. Some RMOs made a practice of liaising closely with their local FPCs, but this did not always happen.

3.30 In the course of his/her dealings with a GP, a RMO might be alerted to the possibility that the GP was prescribing excessively, or that s/he was failing to exercise reasonable care when issuing medical certificates or that s/he was not keeping proper medical records. In any of those circumstances, disciplinary proceedings could result. If that happened, the SoS would refer the matter for adjudication, not to the FPC, but to the LMC. This was because such issues as medical certification, record keeping and prescribing were regarded as matters to be regulated by the medical profession, not by those responsible for administration. The LMC would then report its findings and recommendations to the SoS, who would decide on an appropriate penalty. If a withholding of remuneration was directed, the SoS would instruct the FPC to put this into effect. Other than this purely administrative action, the FPC had no part to play in these disciplinary processes. The evidence given to the Inquiry suggests that, in fact, these processes were rarely invoked.

Shipman's Appointment to the Donneybrook Practice

3.31 Following his departure from Todmorden, Shipman worked for about 20 months in the Community Child Health Services in Newton Aycliffe, County Durham. There, he conducted clinics and advised on child development. In the summer of 1977, he responded to an advertisement which had been placed in the medical press by doctors practising at Donneybrook House in Hyde. They were seeking a replacement for Dr John Bennett, who had recently left the practice.

Arrangements within the Practice

3.32 The arrangements between the seven doctors of the Donneybrook practice were somewhat unusual. The practice had been formed by the amalgamation of three separate partnerships. Following the amalgamation, two of the doctors who had formed one of the pre-existing partnerships continued to operate a single list of patients. The two doctors shared the care of those patients. The other five members of the practice each operated his own individual list. All seven members of the practice shared staff costs and other expenses. For most purposes, they were treated by the Tameside FPC and its successors as a single partnership.

3.33 Following the departure of Dr John Bennett, six doctors continued to practise at Donneybrook House. They were Dr John Smith (the senior partner), Dr Derek Carroll, Dr Geoffrey Bills, Dr William Bennett, and two relatively new recruits, Dr Geoffrey Roberts and Dr Ian Napier, who had joined in 1975 and 1976 respectively. It was Dr Roberts' first post in general practice. Dr Napier had worked for two or three years in another practice in Stockport before joining the Donneybrook practice. Dr Bills and Dr Carroll continued to operate a shared list. The others worked virtually as single-handed practitioners, save that they organised themselves into two groups for the purpose of providing cover for half days. Dr John Bennett and Dr Roberts had formed one group and Dr Smith, Dr William Bennett and Dr Napier formed the other.

3.34 Dr Smith, Dr Bills, Dr Roberts, Dr Napier and Dr Jeffery Moysey (who joined the practice in 1983) gave oral evidence to the Inquiry. Dr Carroll and Dr William Bennett provided statements.

Preliminary Steps

3.35 Although most of those involved have no clear recollection of this part of the process, it seems that, when Dr John Bennett left, the doctors at the Donneybrook practice must have notified the FPC. The procedure was that the FPC would make a report to the MPC and would obtain approval in principle for the appointment of a replacement doctor. That approval was received in July 1977. It would have been something of a formality. At the time, Tameside was a 'designated' area, which meant that a high level of need for doctors had been identified by the MPC. The Donneybrook practice was a busy practice and a replacement doctor would plainly have been necessary. When the members of the Donneybrook practice received confirmation that they could proceed to select a replacement, they placed advertisements in the press.

3.36 After Shipman's application had been received, a decision was taken to interview him. Dr Roberts' recollection was that recruitment was difficult at that time, there was a poor response to the advertisements and Shipman was the only applicant interviewed. Dr Bills also remembered that this was a difficult time at which to recruit. Dr Napier believed that there were a number of other applicants from whom to choose. Other members of the practice had little recollection of the matter.

The Interview

3.37 There was some difference of recollection also as to whether there was only one interview or a preliminary interview followed by a more formal meeting between Shipman and his

wife, Mrs Primrose Shipman, and members of the practice. Dr Roberts recalled an interview conducted by Dr Smith, Dr Bills and himself. He believed that Mrs Shipman was present for some or all of the time. Dr Bills did not remember Mrs Shipman being there. Dr Smith remembered Mrs Shipman attending. Dr Napier believed that he too attended an interview and, from his description of what was discussed, it appears that this must have been the same occasion as the others described. He said that Mrs Shipman was not there. It may be that, as Dr Roberts has suggested, Mrs Shipman was present for only part of the time. That might account for the different recollections about her presence.

3.38 All those present remembered that Shipman volunteered information about problems he had experienced in Todmorden. Dr Smith said that Shipman referred to himself as 'making a confession' about what had happened there. He told the interviewing panel that he had become depressed as a result of being required to undertake an unfair share of the work at his former practice. Dr Roberts understood that Shipman had resorted first to treating himself with anti-depressant medication and that he had subsequently become addicted to pethidine.

3.39 Other members of the interviewing panel remembered only that he had become addicted to pethidine or a similar drug. Dr Roberts remembered Shipman telling them that he had been convicted of criminal offences in connection with his drug taking. Dr Roberts had understood that these were in contravention of the Misuse of Drugs Act 1971. He had not appreciated that they had involved the forgery of prescriptions and offences of obtaining drugs by deception. Indeed, he was surprised when he read in the Inquiry's First Report the nature of the offences of which Shipman had been convicted. Dr Napier recalled no mention of any involvement with the criminal courts. Dr Roberts said that Shipman also told the interviewing panel that he had received a warning from the GMC and that he had undergone treatment by a psychiatrist. Of the doctors who interviewed Shipman, only Dr Napier gained any impression of how long the conduct had continued. He told the Inquiry that he had in his mind a period of about six months, although he did not know how he had gained that impression. It seems likely that Shipman generally underplayed the seriousness of the events that had occurred in Todmorden and gave a self-serving account of how and why his difficulties had arisen. However, the interviewing panel would not have realised that.

3.40 Despite the problems that Shipman had described to them, it is clear that the impression of him formed by members of the interviewing panel was generally favourable. Shipman seemed enthusiastic and energetic. He had an interest in, and recent experience of, child development (which was an expanding field at the time). He also had an interest in preventive medicine. He appeared to be candid about his past history and to be mature in his approach to it. His story about his treatment at his previous practice was plausible, given the climate at the time. In short, he won the confidence and sympathy of his interviewers.

Subsequent Enquiries

3.41 Following the interview, it was resolved that enquiries should be made of the GMC, of the Home Office (in order to determine whether any restriction had been imposed on his

prescribing) and of the psychiatrist who had treated Shipman. It is not clear whether this was Dr Ronald Bryson, under whose care Shipman had been when an inpatient at The Retreat (a private hospital in York where he was treated following the discovery of his drug abuse), or Dr Hugo Milne, who saw him as an outpatient thereafter. It seems likely to have been the latter, as he would have had more recent knowledge of Shipman. In any event, Shipman provided the necessary details and Dr Roberts was deputed to make the enquiries.

3.42 Dr Roberts ascertained from the GMC that Shipman was registered, with no restrictions on his practice; in fact, the GMC had no power to impose such restrictions at that time, but Dr Roberts would not necessarily have been aware of that. Witnesses from the GMC have confirmed that Dr Roberts would not have been informed that Shipman had a fitness to practise (FTP) history, i.e. that he had been the subject of a warning (in the form of a letter) in respect of convictions which had been reported to the GMC. Warning letters were treated as confidential between the GMC and the doctor concerned. In fact, as I have said, Shipman had told the interviewing panel that he had received a warning from the GMC.

3.43 Dr Roberts then spoke to the Home Office. He said that he was told that there was no restriction on Shipman's ability to prescribe. Mr Frank Eggleston, the Senior Drugs Inspector at the Home Office's Bradford office in 1977, gave oral evidence. He could not remember dealing with Dr Roberts' query and there is no record of it on file. One of the other inspectors may have spoken to Dr Roberts. Their approach would, he believed, have been broadly the same as his own. He would have told the caller whether or not Shipman had been made the subject of a direction restricting his ability to prescribe. He would not have volunteered any further information, even information (e.g. about the circumstances giving rise to a criminal conviction) which was already in the public domain. He would not have wanted to damage Shipman's employment prospects and would, therefore, have been very circumspect in what he said.

3.44 Dr Roberts then spoke to the psychiatrist. He recalled that he was told that Shipman had had an addiction problem, had undergone a period of detoxification, had been treated for depression and had finished his treatment. He recalled no discussion about the underlying cause of Shipman's problems, or about the circumstances of the offences of which he had been convicted. Dr Roberts was concerned to know whether Shipman was fit to take up general practice and he recalled that, put simply, he received the answer 'Yes'. Dr Napier recalled being told subsequently that the psychiatrist had expressed the view that it would be a great loss to medicine if Shipman were unable to practise. That view would have reflected the sentiments contained in the letter written by Dr Milne and submitted by Shipman's solicitors to the GMC at the time that Shipman's case was under consideration in 1976.

3.45 Dr Roberts also remembered speaking to one of Shipman's former partners at Todmorden. He said that he received 'some vitriol' about Shipman at first and was told that Shipman had stolen or misappropriated pethidine from the practice. However, he was also told that, despite his problems, Shipman had been a good GP. Dr Roberts did not recall any discussion about Shipman's addiction and did not think that such a discussion would have been appropriate in the circumstances. Nor had he raised with Shipman's

former partner the suggestions that Shipman had been overworked when at the practice. Dr Roberts believed there would have been little to be gained by doing so since all he would have got would have been a different point of view from that of Shipman. Shipman's account of his experiences at the practice had been convincing and Dr Roberts was prepared to accept it. The impression Dr Roberts was left with was that:

> **'... Shipman had been a man with problems which had led to his leaving the practice but his basic skills as a GP were good'**.

3.46 Dr Roberts believed that he would have spoken to Shipman's employers in County Durham although he had no specific recollection of doing so. That would have accorded with his usual practice. There seems little doubt that Shipman would have received a positive reference from that quarter. In short, the enquiries undertaken by Dr Roberts did nothing to undermine the account that Shipman had given of his problems and the favourable impression that the panel had formed during the interview.

The Decision to Appoint

3.47 Dr Roberts recalled that he imparted the information he had collected to his partners informally, rather than at a practice meeting. Both Dr William Bennett and Dr Carroll remembered being told of Shipman's drug problem, which appeared to have been treated and resolved. Neither remembered being aware that Shipman had been convicted of any criminal offences. Dr Carroll said that he was not aware of Shipman's convictions until the conclusion of the trial in 2000, when they received a good deal of publicity. Even had he known of them, he said, it would not have affected his view that Shipman should be appointed. Dr Bennett was certain that he was unaware that Shipman had forged prescriptions. He said he would have regarded that as a serious matter and would have been uncomfortable having a partner who had been convicted of offences of dishonesty. It is quite likely that the fact of Shipman's criminal convictions was not explained to Dr Bennett or Dr Carroll. Little emphasis appears to have been placed on that aspect by those who interviewed Shipman. It is quite possible, therefore, that they did not regard it as sufficiently significant to pass on to the others.

3.48 Dr Napier told the Inquiry that he had felt some hesitation about appointing Shipman, since there were other applicants for the job and he felt there was a risk that Shipman might relapse into his former habit of drug taking. Dr Smith acknowledged that Dr Napier may have questioned whether it was right to take on Shipman but does not recall any strong opposition to his appointment. None of the other doctors remembered there being any dissent on the issue. In any event, a decision was taken to appoint Shipman for a probationary period of either three or six months. That was the usual basis on which appointments were made as it gave both sides an opportunity to ensure that they were able to work satisfactorily together. During the probationary period, Shipman was to take on the usual duties of a GP principal and to assume responsibility for Dr John Bennett's list of patients. The legal formalities were not concluded until the expiration of the probationary period.

3.49 Dr Roberts explained that, in making their decision, members of the practice took their lead from the GMC. The GMC, which they believed would have had knowledge of all the

facts relating to Shipman's drug taking activities, had found that Shipman was fit to practise. It was not for the practice to go behind that finding. He told the Inquiry that, if Shipman had been subject to restrictions on his practice (e.g. prescribing restrictions), he would not have been taken on, since this would have caused practical difficulties in his day-to-day professional life. Similarly, if he had been subject to professional supervision, this would have been a bar since there was no one available at the practice with the necessary experience to exercise formal supervision over him. If the treating psychiatrist had said that Shipman was not ready for practice or that he required professional supervision, this would also have been a decisive factor. As it was, all the indicators appeared to be positive.

Controlled Drugs

3.50 Several members of the practice recalled that, at some time, Shipman had said he did not intend to keep controlled drugs. It may be that he expressed this intention at interview, although Dr Bills had no recollection of it. Dr Roberts remembered being informed of Shipman's intention and of the name of the drug (Fortral) which he was proposing to use for pain relief in place of a controlled drug. In accordance with their way of running their practices, members of the practice maintained their own supplies of controlled drugs for use in emergencies. There was no supply of drugs available to all members of the practice, as there had been at Todmorden, and no CDR in common use.

Shipman's Application for Inclusion on the Medical List

3.51 Once the practice had made its selection, Shipman applied to join the medical list held by the Tameside FPC. The application form (as prescribed by the 1974 Regulations) required details of his medical qualifications, the practice that he intended to join, the nature of the services (e.g. maternity and contraception services) he was to provide and his current employment. He was required to identify the proposed geographical area of his practice, his practice premises, his surgery hours and telephone details. Shipman also completed a supplementary questionnaire in which he indicated, *inter alia*, that he had been a principal in general practice previously and had practised in the area of the Calderdale FPC. This questionnaire was for statistical purposes only. Shipman was issued with various other forms of an administrative nature which he was required to complete. No information was sought or given about his disciplinary record or about any criminal convictions he might have.

3.52 Having received Shipman's application for inclusion on its list, the FPC checked with the GMC that he was on the register. Without registration, he would not, of course, have been eligible for admission to the list. The FPC would not have enquired of the GMC whether Shipman had a FTP history, i.e. whether he had previously been disciplined by the GMC. As I have said, the GMC would not have provided any further information, even if asked. There was no contact with his previous employers or with the Calderdale FPC. No references were taken up or sought. Having satisfied themselves that Shipman was registered with the GMC, staff at the Tameside FPC sent his application to the MPC, together with the FPC's report supporting his application.

3.53 The MPC granted the application. A vacancy had been declared and the practice had made its choice of candidate. Provided that the relevant procedures had been properly complied with, approval of the application would have been automatic. Once the MPC's approval had been given, Shipman's name was included on the medical list. The fact that he was to serve a probationary period was a matter between him and the other members of the Donneybrook practice. So far as the FPC was concerned, Shipman was free to practise as a GP principal.

Conclusions

The Role of the Tameside Family Practitioner Committee

3.54 The involvement of a FPC in the process of appointing a doctor to replace a member of an existing practice was extremely limited. Its role was purely administrative. The FPC acted as little more than a conduit for the provision of information to the MPC. The function of the MPC was purely to ensure that patients in all parts of the country had reasonable access to a GP. It was not concerned with issues of quality of care. Neither the FPC nor the MPC sought, or would have expected to be provided with, any qualitative evidence about the competence or performance of a GP applying to replace a member of an existing practice. Even when dealing with other types of vacancy – where the FPC and MPC were more actively involved in the selection process – no information about such matters as disciplinary findings or criminal convictions would have been available to them. Those were matters solely between doctors and their regulatory body, the GMC. It was the GMC's task, not that of the FPC, to decide whether a doctor was fit to treat patients. The role of the Tameside FPC in the appointment of Shipman must be viewed in this context.

The Role of the Members of the Donneybrook Practice

3.55 At Shipman's interview, the members of the Donneybrook practice were impressed by his enthusiasm, his energy and his interest in child health. They were (with the possible exception of Dr Napier) disarmed by his apparent frankness about his past history and convinced by his assurances that his problems were now behind him. They had some sympathy with the predicament in which he claimed to have found himself at his former practice.

3.56 Dr Roberts had learned from the GMC that Shipman was registered without restriction. It was clear, therefore, that the GMC, which was assumed to have considered the full facts of his case, took the view that he was fit to practise. It is not, in my view, surprising that the members of the Donneybrook practice should have been prepared to accept the GMC's view without question. From the Home Office, Dr Roberts had ascertained that no restriction had been placed on Shipman's prescribing, as would have been possible following his conviction for drug offences in February 1976. This would have tended to suggest that he was not thought to be at particular risk of misusing controlled drugs in the future. Furthermore, the message from the psychiatrist who had treated Shipman was extremely positive; it was to the effect that Shipman had had a problem which had been satisfactorily resolved. A partner in the practice from which he had been dismissed spoke well of his abilities as a GP. The information provided by his employers, for whom he had

been working for 18 months or so, would also have been encouraging. Those who were aware of Shipman's intention not to carry controlled drugs in the future no doubt found that reassuring.

3.57 In my view, the members of the Donneybrook practice cannot be criticised for their decision to give him a chance by recruiting him. It may be that they were to some extent influenced by the lack of other suitable candidates for the vacancy. However, Dr Roberts emphasised that there was no question of 'making do'; the feeling was that Shipman would be a positive asset to the practice. I note that no one appears to have considered what patients might think about the appointment of a doctor with Shipman's past history. That would have been typical of attitudes at the time.

3.58 It is clear that those members of the Donneybrook practice who were aware of Shipman's previous dishonesty did not focus on that aspect of his conduct. Insofar as they were concerned about his conduct and behaviour in the future, it was the risk of a relapse into drug taking, not a perpetuation of his former dishonest behaviour, that they feared. In my judgement, they cannot be criticised for their failure to attach more significance to the fact that Shipman had been convicted of offences of dishonesty. Even now, dishonest conduct by a doctor, undertaken in order to obtain drugs illicitly, is regarded by many as 'just part of the illness'. In my view, it was reasonable for them to follow the lead given by the GMC in regarding Shipman as fit to practise, notwithstanding his past dishonesty.

Should the Family Practitioner Committee Have Been Told?

3.59 None of the members of the Donneybrook practice considered telling the FPC of Shipman's history, or seeking the advice of the FPC about whether it was wise to appoint a former (albeit apparently reformed) drug addict to the practice. In his capacity as secretary of the LMC, Dr Roberts had regular meetings with the administrator of the FPC, with whom he had a good personal relationship. However, the possibility of consulting the administrator about Shipman's appointment did not occur to him. Dr Roberts considered the role of the FPC to be facilitative only. He would not have seen it as the function of staff at the FPC to advise. He would not have thought to notify them of Shipman's past history. Indeed, he said that he would not have known what the FPC would do with that information, if it had been given. Dr Roberts' attitude accurately reflects the evidence I have heard and read about the somewhat distant relationship between GP practices and FPCs in the 1970s. Mr Greenwood did not seek to criticise members of the Donneybrook practice for not having notified the FPC about Shipman's past. Indeed, his evidence emphasised the limited part which the FPC played in the appointment process. I am satisfied that no criticism can be levelled at members of the Donneybrook practice in respect of their failure to inform the FPC about Shipman's past history.

Should Arrangements Have Been Made for Shipman to Be Supervised?

3.60 Once Shipman started at the Donneybrook practice, no arrangements were made for exercising any form of supervision over him or for monitoring his clinical practice. Should members of the Donneybrook practice be criticised for that failure? Dr Roberts said that this was not the way things were done in 1977. Monitoring and supervision of GPs was not

part of the culture of the time. This assertion derives some support from the fact that the GMC itself had no power to order restrictions or conditions on practice at that time. Supervision of a colleague would undoubtedly have caused practical difficulties since members of the practice were busy, worked independently of each other and had full lists. If they had believed that Shipman required supervision, he would not have been taken on. As I have said, the risk which Shipman's colleagues would have had in mind would be that of a relapse into drug taking. Certainly, Dr Smith, as senior partner and GP to Shipman and his family, was aware of the need to ensure that Shipman did not revert to his drug taking habits. However, Dr Smith observed no sign of renewed drug taking and noted that Shipman was working well and appeared to have plenty of outside interests.

3.61 I think that, insofar as they considered the matter, the members of the practice would have thought that they would be alert to signs of any recurrence of Shipman's drug taking, so that, if it occurred, they would notice and could take appropriate action. In the event, there is no evidence that Shipman ever returned to taking drugs after his time in Todmorden. In my view, the members of the Donneybrook practice cannot be criticised for not having arranged any monitoring or supervision for Shipman. They would have had no idea how to go about this. It had not been suggested by the GMC or Shipman's psychiatrist that supervision was necessary. Such an arrangement might have been construed as showing a lack of confidence in Shipman's rehabilitation. The authorities (the GMC and the Home Office) had decided that Shipman was fit to practise without restrictions on his prescribing. His colleagues relied on that. Judged by the standards of the time, their conduct was, in my view, entirely reasonable.

The Effects of Non-Disclosure

3.62 As I have said, members of the Donneybrook practice did not inform the Tameside FPC about Shipman's past. Nor did the information that Shipman was required to provide in support of his application to join its list include any information about his disciplinary or criminal record. That was not the fault of the FPC, which was merely following the prescribed procedures. It was not thought appropriate or necessary in the 1970s for FPCs to be provided with such information. Given its restricted function, that is perhaps not surprising.

3.63 The effect was that it was not until 1998, when the police investigation into the death of Mrs Kathleen Grundy was underway, that the West Pennine Health Authority, which had by that time succeeded to the responsibilities of the Tameside FPC, became aware of Shipman's convictions. Thus, throughout the 21 years of their association with Shipman, the various bodies responsible for the provision of primary care in Tameside believed that they were dealing with a professional man of probity. They were unaware that there might be special reasons for maintaining a close watch on Shipman and, in particular, on his prescribing of controlled drugs.

3.64 The importance of PCOs having ready access to full information about the past history of GPs who apply to join – or who are already included on – their lists is a matter to which I shall return later in this Report.

CHAPTER FOUR

The Monitoring of General Practitioners from 1980 to 1998: the Arrangements for Monitoring in Tameside

Introduction

4.1 In the 1980s, the primary care organisations (PCOs) began to assume some responsibility for monitoring the operation of certain aspects of general practice. As time went on, they began to take steps directed at improving the quality of care provided by general practitioners (GPs). In this Chapter, I shall examine the arrangements for the monitoring of GPs between 1980 and September 1998, when Shipman ceased to practise. I shall also describe the steps taken by successive PCOs in Tameside to monitor the GPs in their area during the time that Shipman was in practice there. I shall go on to consider whether more should have been done in that respect by those organisations, by reference to the steps being taken at the same time by PCOs in other parts of the country.

From 1980 to 1990

Changes in Structures

4.2 The Health Services Act 1980 gave the Secretary of State for Health and Social Security (SoS) power to dispense with area health authorities (AHAs) in some areas, and to replace them with district health authorities (DHAs). In 1982, the AHAs were abolished and responsibility for the family practitioner committees (FPCs) passed to the DHAs. The Tameside DHA replaced the Tameside and Glossop AHA. In 1985, the FPCs became autonomous authorities, independent of the DHAs and directly accountable, first to the Department of Health and Social Security (DHSS) and, from July 1988, to the Department of Health (DoH). From the late 1980s, the FPCs had a more active role in planning the organisation and development of primary healthcare services.

4.3 From 1985, the FPCs were fully responsible for the provision and management of general medical services in their area, although they had limited tools at their disposal with which to control the quality of those services. Nevertheless, they made use of those they had. Mr William Greenwood, Assistant Administrator (later Deputy General Manager) of the Tameside FPC from 1983 until 1990, told the Inquiry that, by the mid- to late 1980s, he had instituted a system of regular reviews of the log of complaints about GPs kept by the FPC. He recalled one instance when those reviews revealed a pattern of complaints from patients of a certain practice who were having difficulty in getting appointments within a reasonable time. That resulted in Mr Greenwood visiting the practice in question to discuss the problem. Discussions of this type would often result in an agreed solution. However, unless a GP was in breach of his/her terms of service, the FPC was entirely reliant on its powers of influence and persuasion to effect change. It could take no action to compel a GP to comply. The inability of the FPC effectively to control entry to, and removal from, its medical list gave rise to particular frustration, all the more so since members of the public tended to assume that the FPC was capable of exercising a much greater degree of control over GPs than was in fact the case.

'Promoting Better Health'

4.4 In the mid-1980s, the Government carried out a review of primary healthcare services, which culminated in the publication, in November 1987, of a White Paper, 'Promoting Better Health'. The White Paper contained a large number of proposals designed to improve the standard of primary care provision. The Government intended that FPCs should become the means of securing improvements in the level, quality and cost-effectiveness of local services. Their responsibilities were to be extended and their managerial role strengthened. For example, FPCs were to be given a role in encouraging effective and economical prescribing. In addition, FPCs (in collaboration with DHAs) were to set targets for measures (e.g. vaccination, immunisation and screening for cervical cancer) designed to prevent disease. Financial incentives were to be available to GPs who met those targets and who participated in other initiatives designed to promote health. These proposals marked the beginning of the widescale use of financial incentives as a means of persuading GPs to improve the standard and quality of their services. Sir Nigel Crisp, Permanent Secretary of the DoH and Chief Executive of the NHS in England, gave oral evidence to the Inquiry. He described how financial incentives have been used to secure the co-operation of independent contractor GPs, which would not otherwise be forthcoming. As I shall describe in Chapter 5, the new (2004) General Medical Services Contract makes extensive use of financial incentives to encourage improvements in quality.

4.5 From the late 1980s, senior staff at the FPCs were no longer known as 'administrators'. Instead, they became 'managers'. The number of staff employed by the FPCs began to increase. Personnel with a wide variety of skills were recruited to assist FPCs in developing their new management role. Performance reviews of FPCs by Ministers and senior officials of the DoH were introduced. Computerised systems to facilitate the recall of patients for immunisation and screening were installed by FPCs. The scene was set for the start of a process of change which has continued to the present day.

4.6 In April 1990, amendments to the National Health Service (General Medical and Pharmaceutical Services) Regulations 1974 (the 1974 Regulations) came into force. The terms of service set out the framework within which GPs operated. The amendments to the terms of service put into effect many of the proposals which had been contained in 'Promoting Better Health'. In particular:

(a) The general requirement in the 1974 terms of service that GPs should render to their patients 'all necessary and appropriate personal medical services' was expanded to include, *inter alia*, the giving of appropriate advice in connection with general health and the offering of various kinds of vaccination and immunisation.

(b) A new term of service obliged GPs to obtain the approval of the FPC for the times and places they proposed to be available for consultation by patients.

(c) Another new term of service required GPs to answer oral or written enquiries from the FPC about prescribing or referrals to other NHS services. Such enquiries could relate to one prescription or referral, or could be more general in nature. FPCs were required to appoint medical advisers to assist them in carrying out such enquiries. These advisers were to be independent of the local medical profession.

(d) There were requirements for GPs to offer a consultation and examination to newly registered patients, to patients who had not been seen for the last three years and (annually) to patients aged 75 and over.

(e) GPs were placed under an obligation to take reasonable care to satisfy themselves that any person employed to assist them was suitably qualified and competent. FPCs were given power to issue guidance to assist GPs in assessing qualifications, experience and competence. However, the assessment itself was a matter for the GP alone.

(f) There were a number of provisions requiring GPs to provide information (including an Annual Report containing specified information) to FPCs.

(g) As from 1st April 1991, any GP attaining the age of 70 was to be removed from the medical list.

(h) The arrangements for remuneration of GPs were amended to include various types of incentive payments.

'Working for Patients'

4.7 Meanwhile, in January 1989, the Government had published another White Paper, 'Working for Patients', heralding important changes to the arrangements (in particular the funding arrangements) for primary health care. An important objective of the changes was to strengthen the management role of FPCs yet further.

4.8 The 1989 White Paper proposed that the composition of FPCs should be changed significantly. Membership of a FPC was to be reduced from 31 (including the chairman) to 11. The chairman was to be appointed by the SoS. The proportion of professional members was to be reduced, and those professional members who remained were to be appointed by regional health authorities (RHAs) to act in a personal, rather than a representative, capacity. One of the purposes of this change was to distance the FPC from the professionals whose contracts it was responsible for managing. Chief executives (who were also to be members of the FPC) were to be appointed, at a higher salary than had hitherto been paid to the senior staff of a FPC.

4.9 Larger GP practices were to have the option of holding their own budgets ('fundholding'). From those budgets they would have to meet the cost of obtaining a range of hospital services for patients, as well as the cost of employing practice staff and improving practice premises and prescribing costs.

4.10 Changes were proposed also in the arrangements for non-fundholding practices. For the first time, cash limits were introduced for infrastructure costs, i.e. the costs of developing and improving practice premises, employing practice staff and acquiring computer equipment. In addition, non-fundholding practices were to be allocated indicative prescribing amounts (IPAs). These were notional, rather than actual, budgets: hence the term 'indicative'. They were to be calculated by reference to past prescribing costs and to the average costs incurred by practices in similar circumstances. One of the aims

behind these proposals was to make GPs more careful about their use of resources and to encourage savings where possible.

4.11 The 1989 White Paper also expressed the Government's intention of establishing a system of medical audit in general practice.

The Implementation of 'Working for Patients'

4.12 The proposals contained in the 1989 White Paper were substantially brought into effect by the National Health Service and Community Care Act 1990. In September 1990 family health services authorities (FHSAs) replaced FPCs. They were to be accountable to the RHAs. Thus, the new Tameside FHSA was accountable to the North West RHA. The purpose of the change was to relieve the DoH of direct involvement in local management and to bring responsibility for primary health care and hospital services together at a strategic level, thus making it possible to co-ordinate policy initiatives spanning both services.

From 1990 to 1998

Changes on the Ground

4.13 During the early 1990s, the FHSAs began to use the new tools they had been given to develop their management role. They grew in size. Tameside FHSA doubled the number of its staff to about 50. The FHSAs employed medical advisers, many of them from the Regional Medical Service (RMS), which had been part of the new DoH since the latter's creation (it had formerly been part of the DHSS) in 1988. In 1991, the RMS was transferred to the Department of Social Security (DSS) and thereupon ceased to have any general responsibility for GPs.

4.14 The level of prescribing costs incurred by GP practices was a matter of considerable concern to FHSAs. If a fundholding practice overspent on its prescribing budget, the FHSA was responsible for paying the excess. That had an obvious impact on the FHSA's own budget. If a non-fundholding practice failed to keep within its IPA, the excess was met from central funds held by the DoH. However, the FHSA would be under pressure from the RHA to use its influence to modify the activities of high cost prescribers in its area. In practice there was little a FHSA could do if a practice overspent, unless it could successfully establish that a GP was guilty of excessive prescribing: see paragraph 4.21.

4.15 Initially, therefore, the work of medical advisers was primarily concerned with promoting rational and cost-effective prescribing practice. At this time, the main emphasis was on cost factors. Efforts were made to discourage GPs from prescribing expensive proprietary drugs. They were encouraged instead to prescribe cheaper, generic equivalents. The advisers used prescribing data provided by the Prescription Pricing Authority (PPA) to inform their discussions with GPs. The PPA is a special health authority which processes all NHS prescriptions written by GP and nurse prescribers in England. Prescriptions are submitted by community pharmacists and dispensing GPs who receive payment from the PPA. The PPA also collates and disseminates (to GP practices, PCOs and other NHS bodies) data about drugs prescribed and the costs thereof. From April 1991, medical

advisers were also authorised by the SoS to inspect GPs' controlled drugs registers (CDRs) and stocks of controlled drugs, to ensure compliance with the statutory requirements relating to the keeping of controlled drugs.

4.16 The FHSAs also began to recruit pharmaceutical (or prescribing) advisers (usually part-time) to assist with the more technical aspects of prescribing. The pharmaceutical advisers brought with them a higher degree of specialist knowledge about drugs and their properties than was possessed by the medical advisers. Local incentive schemes were set up to promote cost-effective prescribing. If a non-fundholding practice underspent on its IPA, it would receive additional funds to invest in the purchase of equipment or other improvements. Agreed formularies (i.e. lists of drugs to be prescribed) were developed for GPs' use. The emphasis shifted to the promotion of good quality prescribing practice, as well as cost savings. FHSAs began to employ community pharmacists who would discuss with doctors the prescribing needs of individual patients or groups of patients. Pharmaceutical advisers did not possess the same powers to enquire into a GP's prescribing as did medical advisers. Nor did they have any authority to inspect GPs' CDRs or stocks of controlled drugs. If they had any reason for concern about a GP's handling of controlled drugs, they would refer that concern to others for investigation.

4.17 The receipt of a range of incentive payments for the provision of additional services and other activities made it necessary for systems of verification of claims for payment to be developed. GP practices were required to set up systems for collecting data to support their claims for incentive payments. That process was facilitated by the increasing computerisation of GP practices which began at about this time. The collection of this data, together with other information which practices were now obliged to supply to them, enabled FHSAs to build up a more accurate picture of the care being provided by individual practices.

4.18 FHSAs established medical audit advisory groups (MAAGs) to encourage GP practices to carry out audits of their activities. The profession insisted that audit should be led by members of the profession, should be formative (i.e. educational) in nature, should be confidential and should not be linked to management processes. As a consequence, audit results were reported annually to the FHSA in an aggregated, anonymised form. FHSA managers had no access to the results of audits carried out by individual GP practices. These were seen only by GP members of the MAAG and by the staff responsible for supporting the MAAG.

4.19 There was no longer any significant overlap between membership of the FHSAs and that of local medical committees (LMCs). Nevertheless, FHSAs continued to consult closely with LMCs. Tameside FHSA (whose one medical member was not a member of the LMC) instituted routine monthly meetings with the LMC. In general, the two co-operated well, although some difficulties were experienced when the FHSA was called upon to implement Government policies (such as the fundholding arrangements) which were unpopular with some GPs. Relationships with LMCs varied from area to area, depending upon the personalities involved.

Developments in 1992

4.20 The National Health Service (General Medical Services) Regulations 1992 consolidated and amended the 1974 Regulations and included new terms of service (the 1992 terms

of service) which were largely unchanged from those which had been in force previously. The 1992 terms of service (amended over time) remained in force until April 2004.

4.21 Also in 1992, the National Health Service (Service Committees and Tribunal) Regulations 1992 introduced a new procedure for dealing with allegations of excessive prescribing. Prescribing could be excessive by reason of either the quantity or the number of drugs prescribed. FHSAs were given the power to refer such cases to professional committees. Those committees consisted of a doctor with substantial experience of clinical pharmacology (chosen from a panel selected, after consultation, by the SoS) together with two GPs, one of whom had been nominated by the LMC. This procedure replaced the previous arrangement whereby LMCs had been responsible for adjudicating in such cases: see Chapter 3. The professional committees could determine the amount of any financial penalty to be imposed. Dr David Edwards was a former regional medical officer (RMO) and co-Medical Adviser (with Dr David Archer) to a consortium of the Tameside, Wigan and Stockport FHSAs in the early 1990s. He was, he believes, the first adviser to use this procedure successfully. This was after he had left the consortium and moved to Wigan. The evidence received by the Inquiry suggests that it was invoked only on very rare occasions thereafter.

4.22 The LMCs continued to have responsibility for determining issues relating to medical certification and record keeping, as well as for considering complaints made by one GP against another and involving a question of the efficiency of services. The evidence received by the Inquiry suggests that these latter procedures were not used frequently, although Mr Greenwood remembered one occasion when the LMC for Tameside considered concerns reported by the partners of a practice about the clinical activities of one of their colleagues. LMCs also continued to be involved in the procedures for dealing with doctors who appeared unfit to discharge their obligations under the 1992 terms of service by reason of physical or mental illness. In 1980, the General Medical Council (GMC) had introduced its new procedures for dealing with doctors whose fitness to practise was seriously impaired by ill health. The more intractable cases of illness could, therefore, be referred to the GMC.

Shipman's Move to the Market Street Surgery

4.23 In 1992, Shipman moved from the Donneybrook practice to the Market Street Surgery, where he practised single-handed until his arrest in 1998. He was already on Tameside FHSA's medical list. He was merely leaving one practice and setting up another in the same area. No application to the Medical Practices Committee was necessary. All Shipman was required to do was to establish to the satisfaction of the FHSA that he had suitable premises from which to practise, that his arrangements (e.g. his times of availability) would adequately meet the needs of patients and that the other necessary administrative arrangements had been made. The FHSA had no power to prevent the move, although it would have been open to it to withhold funding for infrastructure costs had it chosen to do so.

4.24 Having found the premises at 21 Market Street, Shipman wrote to Mr Barry Thomas, General Manager of the FHSA, asking him to view the premises and give his approval. At

the FHSA's request, he also submitted an outline business plan. Subsequently, Shipman met Mr Thomas, Dr Roger Freedman (the Medical Adviser at the time) and the secretary of the LMC. As a result of that meeting, the premises were approved.

4.25 Mr Greenwood said that the FHSA would have had mixed feelings about Shipman's move. On the one hand, he was the first doctor to move outside the two large practices which operated from Donneybrook House and would thus have provided some welcome diversity in the types of practice on offer. On the other hand, the creation of a new practice involved additional costs to be met by the FHSA. Another factor was that, unusually for the time, the Tameside FHSA had a policy of not supporting single-handed practice unless an applicant could demonstrate that s/he would provide a better quality of services locally. In the event, the FHSA must have been satisfied that that was the case since it supported Shipman's move. Mr Greenwood believed that Shipman's stated intention to hold open surgeries (at a time when patients were experiencing real problems in getting appointments with other practices) might have been a significant factor in the FHSA's decision.

The Mid-1990s

4.26 In the mid-1990s, there were a number of organisational changes in the NHS. In 1994, the number of RHAs was reduced from fourteen to eight. The North West RHA was merged with the Mersey RHA. With effect from 1st April 1996, the RHAs were abolished altogether and their functions were taken over by eight Regional Offices of the NHS Executive. The North West Regional Office covered Tameside. These Regional Offices were responsible for the performance management of primary care as part of their responsibility for the management of healthcare systems in their areas.

4.27 At the same time, the DHAs and FHSAs were abolished and their functions were devolved to a hundred new unitary health authorities (HAs) of which the West Pennine Health Authority (WPHA) was one. The WPHA covered the areas previously administered by the Tameside and Oldham FHSAs, together with the Glossop area, which had previously been part of the Derbyshire FHSA. The primary care team at the WPHA was led by Mrs Jan Forster, Director of Primary Care. The two Medical Advisers, Dr Alan Banks and Dr Frances Bradshaw, shared the position of Assistant Director. Under the HA structure, local GPs were not formally involved in the management of local primary care services. However, there was close co-operation between the WPHA and the LMC.

Complaints and Discipline

4.28 In April 1996, changes were also made to the complaints and disciplinary systems governing GPs. These were separated so that the determination of a patient complaint no longer led automatically to the possibility of disciplinary proceedings. Each practice was required to have a complaints procedure, and patient complaints were initially dealt with at practice level. If that failed, conciliation and, possibly, a hearing by an independent review panel (IRP) could follow. The IRP would produce a report, setting out its findings and, if appropriate, making recommendations for changes to the GP's practice. However,

neither the IRP nor the HA which received the report could compel the compliance of the GP in question. I shall describe these arrangements in detail in Chapter 7.

4.29 All HAs were required to set up medical disciplinary committees, whether alone or jointly with other HAs. If a HA received information which it considered could amount to an allegation that a GP had failed to comply with his/her terms of service, it had a number of options. The HA could:

- take no action or
- refer the matter for investigation by another HA's disciplinary committee and/or
- refer the information to the NHS Tribunal, the GMC or the police.

4.30 If the allegation was being dealt with through the complaints procedure, the HA had to await delivery of the IRP's report or the abandonment/withdrawal of the complaint by the complainant before taking disciplinary action by referring the complaint to another HA's disciplinary committee. The process was cumbersome and lengthy. It is perhaps not surprising that, as I shall explain in Chapter 7, it was little used.

4.31 One effect of the changes to the complaints procedure was that, after 1996, HAs only rarely became aware of the subject matter of individual complaints made about GPs. Practices were obliged to make an annual return to the HA, stating how many complaints had been made to them, but that return did not include information about the nature of the complaint made. Moreover, the system depended on practices being frank about the number of complaints received. HAs did not have a full picture of the complaints being made in their area. This deprived them of a valuable means of monitoring quality of care and services. It ran counter to the increased role which, in other respects, they were playing in the management of primary health care.

The Position in 1998

4.32 By 1998, considerable progress had been made by HAs in the collection of data about GP practices and in the encouragement of practices, by means of financial incentives, to improve the range and quality of their services. Nevertheless, there were still considerable limitations on the ability of the HAs to deal with those GPs who were not amenable to change. The medical advisers had powers only to enquire about prescriptions and referrals and to inspect GPs' arrangements for keeping controlled drugs. Otherwise, they had no right to enter practice premises. They had to proceed by means of persuasion and the use of influence. Ultimately, they had no sanction against a GP who overspent his/her IPA, provided that s/he was not guilty of 'excessive prescribing'. Dr Banks, former Medical Adviser to the Tameside FHSA/WPHA, told the Inquiry that prescribing was 'a very powerful tool' available to GPs. If they became alienated, they could spend a lot of money on prescribing and, by so doing, have an adverse effect on the FHSA/HA's budget. Because of that, he said, he was anxious not to alienate Shipman. At first consideration, Dr Banks' attitude to Shipman might seem rather pusillanimous. For a doctor deliberately to increase his spending on drugs as part of a 'power game' would be quite unacceptable. However, I have much sympathy with Dr Banks' position and attitude. A doctor's right to prescribe as s/he thinks fit in the patient's interest has always been jealously guarded and

it could be very difficult to demonstrate that a doctor was prescribing expensive drugs for improper reasons. The evidence suggests that Shipman would have been well able to quote published papers to justify his prescribing decisions. Moreover, he was a very prickly, difficult and sometimes arrogant personality. I can understand why Dr Banks thought that a confrontation might be counter-productive.

4.33 Following the changes of 1996, HAs had less involvement with patient complaints. Indeed, as I have said, they received incomplete information about complaints which were made and consequently had less opportunity to gain intelligence about poor practice. Disciplinary action for breach of a GP's terms of service was taken rarely and referrals to the NHS Tribunal became even less common. HAs still had only a very limited power to remove a doctor from their lists. Their only recourse, if dissatisfied about some aspect of the GP's practice that did not amount to a potential breach of his/her terms of service, was to refer the doctor to the GMC. Dr Banks told the Inquiry that, in his view, matters of clinical competence were for the GMC and could not be dealt with at local level.

The Problem of the Poorly Performing Doctor

4.34 During the late 1980s and early 1990s, there was mounting awareness of, and concern about, doctors whose conduct, competence and/or quality of care was substandard. It was recognised that by no means all these doctors were being brought to the attention of the authorities. Even if they did, they could not readily be dealt with by the existing procedures.

4.35 The only mechanism by which such problems could be tackled at that time was by invoking an informal procedure whereby the LMC would appoint 'Three Wise Men' to enquire into a GP's performance and would attempt to resolve any problems which were identified. Every HA was advised to enter into an agreement with the LMC for the setting up of such a procedure. However, the procedure had no statutory basis and the GP could not be compelled to co-operate. Not surprisingly, the procedure frequently failed to resolve the problem.

4.36 The Medical (Professional Performance) Act 1995 (the 1995 Act) introduced what became known as the GMC's performance procedures. Prior to the introduction of these procedures, the GMC had been able to take action only if a doctor had been found guilty of serious professional misconduct or was suffering from a serious impairment of health. The 1995 Act, which came into effect on 1st July 1997, gave the GMC power to suspend or impose conditions upon the registration of a doctor whose professional performance was found to be seriously deficient. The aim was to enable the GMC to take action where complaints about a doctor's clinical performance over time suggested a pattern of serious deficiency.

4.37 Local arrangements were to be put in place to assist in identifying doctors (both GPs and hospital doctors) who were performing poorly and to ensure that, wherever possible, action was taken at a local level to remedy their failings. Only when that remedial action failed should a referral to the GMC become necessary.

4.38 Around the time of the introduction of the new GMC procedures, a considerable amount of guidance was issued to HAs concerning the arrangements which they should put in

place to deal with poorly performing doctors. I shall describe those arrangements in Chapter 5. It took time for the necessary arrangements to be put in place. In most areas, the procedures did not come into operation until 1998 or later. When eventually they were in operation, they represented a very significant adjunct to the complaints and disciplinary mechanisms previously available to the PCOs.

The Arrangements in Tameside

4.39 I shall now turn to consider the arrangements for monitoring GPs which were in place in Tameside during the period of Shipman's practice there. Could and should those arrangements have led to his earlier detection or, at any rate, should they have alerted the authorities to the fact that he was aberrant in some way? Were there effective mechanisms which could have been put in place but were not? How did the arrangements in Tameside compare with those elsewhere?

4.40 As I have already explained, the bodies successively responsible for organising primary care in Tameside did not know until 1998 that Shipman had criminal convictions (including convictions for forging prescriptions) associated with the misuse of controlled drugs. They were therefore unaware that he posed any particular risk, in relation to his prescribing practices or otherwise. Their conduct must be viewed in that light. It has been suggested to the Inquiry that the Tameside FPC and its successors should be criticised for failing to 'unearth' information about Shipman's past history. I shall deal with that suggestion later in this Chapter.

4.41 Shipman was, in many respects, a competent doctor. He kept abreast of current medical literature and of developments within the field of general practice. He was an enthusiastic proponent of preventive medicine. When target payments for vaccination, immunisation and cervical cytology were introduced, he consistently attained those targets. His Market Street practice established sound systems for monitoring and treating patients suffering from chronic disease, such as asthma. It is possible (as some have suggested) that Shipman created an appearance of greater professional competence than he in fact possessed. In any event, it is unlikely that routine examination of the limited amount of data available to the Tameside FHSA/WPHA about his practice activity would have raised any concerns about his competence or professional conduct. The routine checks which were carried out by the WPHA in later years to verify Shipman's claims for payment for items of service showed no significant discrepancies. Inspections of his practice premises found them to be in good order. Moreover, as I shall explain in Chapter 6, although complaints were made against Shipman, they were not such as would have raised serious concerns about his conduct or competence. Most conventional monitoring techniques would, therefore, have failed to identify him as a potential source of problems.

4.42 I intend to focus on those aspects of Shipman's practice which, had they been subject to specific enquiry, might have been identified as abnormal in some way, and as meriting further investigation. Those aspects are the number of deaths among his patients and the circumstances surrounding those deaths, his prescribing (in particular, his prescribing of opiates) and the quality of his medical records. I shall also consider other information

which, during the later years, was held by the Tameside FHSA/WPHA and which might have contained significant material.

The Number and Circumstances of Patient Deaths

4.43 Before Shipman's arrest, it had not been the practice of PCOs to monitor the death rates among patients of individual GPs. There were a number of reasons for this which I shall explain in Chapter 14. There can be no criticism of the PCOs in Tameside for the fact that they did not undertake any monitoring of this kind.

4.44 At present, there is no system for collecting and analysing information about the circumstances of deaths. Thus, no one in authority was alerted to the abnormally high proportion of Shipman's patients who had died at home, or who had suffered sudden, unexpected deaths or who had died (on Shipman's own admission) in his presence or shortly after a visit from him or whom he had 'found' dead. No one in authority was aware of the fact that six deaths had occurred on his surgery premises. None of the PCOs responsible for Tameside over the years held such data or had any means of obtaining it. They cannot, therefore, be criticised for being unaware of it.

4.45 Under the new coroner system proposed in my Third Report, all deaths would be reported to the coroner, and far more information would be available about the circumstances surrounding each death. That information would come from the person (usually a healthcare professional) who confirmed that death had occurred, from the doctor who gave an account of the deceased's medical history and from a member of the deceased's family or someone else with knowledge of the deceased. Information from these various sources would be cross-checked. The coroner system would hold all the relevant data. It would be possible to monitor that data and investigate any apparently unusual patterns or other features. At present, this exercise just cannot be done.

The Period from 1977 to 1990: the Tameside Family Practitioner Committee

4.46 As I explained in Chapter 3, the role of the FPCs prior to the mid-1980s was extremely limited. It was concerned with matters of administration, rather than professional conduct or clinical practice. FPCs carried out no form of activity that could be described as the 'monitoring' of the GPs on their lists. Nor, during this period, could a FPC expect to receive expressions of concerns from one doctor about another. As I shall describe in Chapter 10, the culture at that time was such that few doctors would have regarded it as their professional duty to report a colleague, even if they had had concerns about his/her fitness to practise. On the rare occasions when a concern was expressed, it would be dealt with by the LMC rather than the FPC: see paragraph 4.22.

4.47 Virtually the only source of information which might have led to the identification of a 'problem doctor' would be complaints from patients or their representatives. It is significant, therefore, that Mr Greenwood had, by the mid- to late 1980s, instituted a system of reviews of the complaints log held by Tameside FPC. As I have explained, Mr Greenwood recalled that his review revealed the existence of an administrative problem affecting one practice. It would not have revealed a problem with Shipman. At no

time during his career did a complaint or pattern of complaints emerge, such as would have led to wider suspicions about his activities. As I shall describe in Chapter 6, some complaints were made about him. However, they gave no indication of his criminality.

The Period from 1977 to 1990: the Regional Medical Service

4.48 As I have said, the RMOs made regular visits to GPs during this period. The Inquiry received evidence from three former RMOs. Dr Jack Edwards, a former GP, was a RMO from 1965 until 1992 and covered the Tameside, Trafford and Stockport areas. Dr Archer, another former GP, joined the RMS in 1987 and was based in Manchester, covering four FPC areas, including Tameside. In January 1988, he was seconded to the Trafford FPC and did not thereafter visit GPs in Tameside until he returned there as Medical Adviser to the Consortium of the Tameside, Wigan and Stockport FHSAs. Dr David Edwards, who left general practice in 1986 to join the RMS, covered the Wirral and Cheshire areas (excluding Stockport). In June 1990, he left the RMS and joined the consortium of the Tameside, Wigan and Stockport FHSAs as co-Medical Adviser with Dr Archer.

Shipman's Prescribing

4.49 No reports of practice visits by RMOs to GPs in Tameside have survived. Dr Archer was, however, able to refer to notes of visits (including visits to the Donneybrook practice) recorded in his diary. All the witnesses agreed that one of the topics discussed at their meetings with GPs was prescribing. Dr Archer said that the topic would be discussed in general terms. He would stress the need for economy in prescribing. He would advise GPs to take care when prescribing new drugs. He would encourage them to report adverse reactions to drugs.

4.50 In general, RMOs would have only basic information about the prescribing costs of each practice. More detailed data was made available to them only if the practice had been identified by RMS Headquarters as a high cost prescriber. The usual rule was that, if a practice's prescribing costs were more than 25% above the average, the RMO would be required to visit the practice to discuss ways in which the GP(s) in question might modify their prescribing habits.

4.51 None of the RMOs who provided evidence to the Inquiry remembered Shipman having been identified by (or to) them as a high prescriber. Dr Archer's notes of visits to Donneybrook House in December 1987 and January 1991 contain no mention of any concerns about him. This may well have been because Shipman's prescribing costs at that time formed part of the prescribing costs for the whole Donneybrook practice. Prescribing data available to the RMOs would have related to the practice, not to individual doctors within the practice. If the Donneybrook practice had not been identified as having high prescribing costs, more detailed data would not have been obtained. Thus, the RMOs would not have been aware of Shipman's prescribing costs relative to those of his colleagues at the practice.

4.52 Between 1977 and 1990, Shipman killed 71 patients. Although the Inquiry has no information about his acquisition of opiates during this period, I have no doubt that he was

diverting diamorphine, which had been prescribed in the names of patients, for his own purposes. He had done that in Todmorden (with pethidine) and was to do it again (with diamorphine) when at the Market Street Surgery. The basic prescribing information generally available to RMOs would not have shown that Shipman was prescribing opiates. Indeed, as I have explained, it would not have shown details of Shipman's prescribing at all.

Enquiries into Shipman's Keeping of Controlled Drugs

4.53 The RMOs were responsible for checking GPs' CDRs and stocks. Four members of the Donneybrook practice recalled their CDRs being inspected. Only one (Dr Ian Napier) remembered a RMO inspecting his stock of controlled drugs. Dr David Edwards told the Inquiry that Shipman had informed him that he did not keep controlled drugs and did not have a CDR. He does not remember whether Shipman gave a reason for this. It was not unusual. A significant proportion of GPs did not keep stocks of controlled drugs. Dr Edwards would therefore have had no reason to doubt what Shipman said. There seems little doubt that, whichever of the RMOs had asked about his arrangements for controlled drugs, the answer would have been the same.

4.54 It should also be noted that, during this period, regular inspections of pharmacists' CDRs were carried out by police chemist inspection officers (CIOs). They would have been focussing their attention solely on controlled drugs and had, by virtue of their position, a considerable amount of knowledge and experience about their use. They noticed nothing suspicious about Shipman's prescribing. That being the case, it would appear unrealistic to suggest that the RMOs should have done so from the information contained in the practice prescribing data.

Shipman's Record Keeping

4.55 The Inquiry was told that, until the 1960s, the practice had been for RMOs to inspect GPs' medical records to ensure that they were being maintained in accordance with the terms of service. That practice had ceased (certainly in Hyde) well before Shipman arrived. The Inquiry has been unable to ascertain why the practice fell into disuse. Inspecting records is a time-consuming process and it may be that it had been discontinued for that reason. It is possible that it had come to an end as a result of resistance within the medical profession to inspection of its records. It was certainly unpopular. Dr Geoffrey Roberts, formerly secretary of the LMC for Tameside, told the Inquiry that he had tried to institute a system of inspections of surgery premises in 1980. He made one inspection, which included looking at records, but said that the GP in question 'took great exception' to this. It may be that the RMOs met with a similar reaction when they carried out their inspections. Be that as it may, it is clear that, by 1977, the practice had long been discontinued.

4.56 Had Shipman's medical records been subjected to critical scrutiny, two features might have emerged. First, the quality of his records might have been observed to be poor. That was certainly the general view of those doctors who subsequently examined his records for the purposes of the Inquiry. I say that the records 'might have been' considered poor because Dr Napier, one of Shipman's colleagues at the Donneybrook practice, was

candid enough to tell the Inquiry that the records of all the doctors at the Donneybrook practice, including his own, were 'fairly terrible, if not pathetic' at the time Shipman left. They had subsequently been greatly improved with the advent of computerisation. It may be, therefore, that the overall quality of Shipman's notes would not have attracted particular attention.

4.57 The other feature would have been the nature of the entries made in connection with the deaths of patients. Sometimes, those entries were extremely sparse and information about the circumstances of deaths, the diagnosis of the cause of death and the basis for the diagnosis was plainly inadequate. Sometimes, the records were much more detailed but revealed unusual circumstances surrounding the death. Many examples of such entries (some dating from the 1980s) are discussed in my First Report. Whether or not the unusual features of the entries would have been noticed would have depended first on whether the RMO had elected to inspect the records of a deceased patient whom Shipman had killed. The chances of that are perhaps small, as most such records would have been sent back to the FPC shortly after the patient's death. Even if they had been returned to Shipman subsequently, they are likely to have been stored at his home, where many records were found after his arrest. It would also have depended on whether the content of the notes was considered critically. If the purpose of the inspection was to ascertain whether the notes were arranged in chronological order, whether proper summaries had been prepared and other matters of that kind, the odd features might have been missed.

The Period from 1990 to 1998: the Tameside Family Health Services Authority and the West Pennine Health Authority

4.58 In 1991, as I have explained, the FPCs were replaced by FHSAs. The FHSAs took over all the responsibilities which had previously lain with the RMS, save for those relating to certification for the purpose of DSS benefits. The independent medical advisers whom the FHSAs were required to employ took over responsibility for monitoring GPs' prescribing and for assisting in the introduction of the new IPAs. From 1990, Dr Archer and Dr David Edwards, both former GPs and RMOs, were co-Medical Advisers to a consortium of the Tameside, Wigan and Stockport FHSAs. They were succeeded, in November 1991, by Dr Freedman, a former GP. In August 1993, he became Medical Director of the Manchester FHSA and his place at Tameside was taken by Dr Banks, another former GP.

4.59 From April 1991, the advisers also took over responsibility for inspecting GPs' CDRs and their stocks of controlled drugs. It seems that, from that time, fewer inspections of CDRs and stocks of controlled drugs took place than previously. Dr Jim Smith, Chief Pharmaceutical Officer for England at the DoH, conceded that that was the case. He said that, in the early 1990s, controlled drugs were not a priority. He thought this was because they were not perceived as a problem. The other systems of control (operated by the Home Office and the police) were thought to be sufficiently robust. He acknowledged that that view had been proved wrong. A team which included Professor Richard Baker, Director, Clinical Governance Research and Development Unit, University of Leicester, undertook a study, the results of which were reported in a paper entitled 'Reducing Leakage of Prescribed Drugs' in January 2002. In the course of the study, the team identified 59 GP practices in Leicestershire and Rutland that kept stocks of controlled

drugs. Thirty one of those practices had undergone no inspection of their CDRs or controlled drug stocks for a period of more than ten years prior to the study. Only six practices had been inspected within the previous 12 months. It appears, however, that the advisers in Tameside did question GPs about their arrangements for keeping controlled drugs. I shall refer to Shipman's responses to such questions later in this Chapter.

4.60 Tameside FHSA also appointed a pharmaceutical adviser. Mrs Rosalyn Anderson was the pharmaceutical adviser to the Tameside FHSA (later the WPHA) from September 1992 until April 1996. Mrs Bernice Abrahams (then Miss Bernice Caden) stood in for a year in early 1993 while Mrs Anderson was on maternity leave. Mr Peter Welsby overlapped with Mrs Anderson for about six months before taking over from her.

Prescribing Data

4.61 By the early 1990s, more informative prescribing data had become available from the PPA. Prescribing analysis and cost (PACT) data was available in paper form. It had certain limitations. The standard eight-page PACT report gave information about prescribing by GP practice, not individual GP, unless the GP practised single-handed. It did not contain information about private prescriptions. It did not identify the patient for whom a drug or appliance had been prescribed. In fact, then – as now – no patient-specific data was collected by the PPA.

4.62 The data was presented by reference to the British National Formulary (BNF). The BNF is divided into chapters, each setting out details of drugs that act on a specific therapeutic area. Each chapter is divided into sections dealing with the types of drug which act on that therapeutic area. The sections are further broken down into paragraphs and sub-paragraphs, providing highly specific details of the drugs of each type. Sub-paragraphs are further broken down into details of drugs, products and individual formulations.

4.63 Using the prescribing of a diamorphine 100mg injection by way of illustration, the information contained within the BNF is as follows:

BNF Chapter 4:	Central nervous system
BNF Section:	Analgesics
BNF Paragraph:	Opioid analgesics
BNF Sub-paragraph:	Opioid analgesics (i.e. the same as the BNF paragraph)
BNF Chemical substance:	Diamorphine
BNF Product:	Diamorphine HCl (systemic)
BNF Presentation:	Diamorphine HCl injection 100mg ampoule

4.64 PACT reports in paper format were available to GP practices and PCOs. Each report covered a period of three months and compared practice data with FHSA/HA national averages. A standard PACT report would show the practice prescribing costs for the BNF section. Using the example of diamorphine, it would show the practice prescribing costs

for analgesics but would not distinguish between the different types of analgesic (still less the chemical substances, products or presentations) prescribed. Thus, it would not be evident from the PACT report that a doctor had prescribed diamorphine. Although the reports identified the 20 leading drugs in the practice by cost and frequency of prescribing, the fact that opiates are inexpensive meant that even large quantities of diamorphine would not have appeared, particularly if a practice was a high cost prescriber in other areas. An exception would be if a number of high dose (100mg or 500mg) ampoules of diamorphine had been prescribed. The high dose ampoules are significantly more expensive than the lower dose ampoules. Usually, the high dose ampoules are prescribed for a terminally ill patient for a short period immediately prior to death. Paper PACT reports have remained essentially the same since they first became available.

4.65 PACT catalogues were also available to PCOs and, on request, to GP practices. In general, they covered a period of three months, although catalogues containing as much as two years' data could be requested. The catalogues were very bulky, anything from 70 to 250 pages for a three-month period. They contained a detailed inventory of every drug prescribed by the practice at BNF presentation level. The catalogue would show the number of times a drug was prescribed, the quantity of the drug prescribed and the total cost. It would not show for how many patients the drug had been prescribed. PACT catalogues contained raw data and offered no means of analysing trends or comparing prescribing between practices.

4.66 Since 1992, electronic PACT systems have been available to PCOs and other NHS bodies. The first of these, PACTLINE, provided data for only the previous year's prescribing. Analysis could be performed down to the level of BNF section (e.g. analgesics) only. Further analysis had to be performed using the paper PACT catalogue. The FEPACT (later known as HAEPACT) system, introduced during 1994 and 1995, enabled PCOs to send requests to the PPA mainframe for analysis of drug and presentation level data. This was used to obtain a more detailed analysis of the information already available from PACTLINE. Theoretically, it would have been possible to request an analysis of Shipman's prescribing of diamorphine injections by means of this system. In practice, however, such a query would not have been made without a prompt suggesting that something was amiss. In general, the FEPACT/HAEPACT systems were used to obtain further data about problem areas identified by PACTLINE. Had the Tameside FHSA/WPHA obtained information from elsewhere that Shipman was misusing diamorphine, it could have interrogated the PPA system to explore that possibility. It would, however, have had to have been alerted to a potential problem in order to make the enquiry in the first place. Only two years' historical data was available on the electronic systems. In April 1997, a new EPACT system replaced PACTLINE and HAEPACT. EPACT permitted more sophisticated analysis and reporting. However, the system was not straightforward and required a degree of expertise.

4.67 In April 1999, a new system, ePACT.net, was introduced. Training in the use of the system was available. Initially, the training course did not cover techniques for analysing the prescribing of controlled drugs. As a result of Shipman's conviction, however, appropriate training was started in May 2000. Since then, many PCOs have instituted a system of

regular monitoring of the prescribing of controlled drugs by GP practices in their area. The ePACT.net system has three significant advantages over its predecessors. First, it is much easier to use. Second, the system permits interrogation of the system on-line, so that the results are available immediately. The third advantage of ePACT.net is that data for the previous three years is available for analysis. This gives a greater opportunity to see the emergence of a pattern.

Shipman's Prescribing

4.68 It is clear that, from at least March 1992, Shipman was identified by the Tameside FHSA as a high cost prescriber. The problem was caused by his tendency to prescribe expensive drugs, in particular lipid-lowering drugs. He favoured branded drugs over the less costly generic variety. In 1993, he was the lowest prescriber of generic drugs in the area. As a high cost prescriber, Shipman received regular visits from the FHSA's medical and pharmaceutical advisers. They tried to persuade him to modify his prescribing habits.

4.69 When challenged about the high cost of his prescribing, Shipman was always able to justify himself, by reference to current research or his own patient data. He would claim to have a low death rate among his asthmatic patients and no suicides among depressive patients, and would cite this as evidence of his successful use of anti-asthmatic and anti-depressant medication. He would explain and justify his belief in the prophylactic effect of lipid-lowering drugs. GPs had clinical freedom to prescribe as they believed appropriate for their patients. Advisers could only encourage and attempt to persuade them to change their prescribing habits. They were powerless to do more unless a GP was guilty of prescribing so excessively as to contravene his/her terms of service. Dr Freedman recalled that, at one time, before he left the Tameside FHSA in August 1993, there was some discussion as to whether it would be appropriate to refer Shipman to a professional committee on the grounds of his expensive, and low generic, prescribing. He believed that the FHSA took advice from one of the regional pharmaceutical advisers. The view was that the new procedures could not be applied to Shipman since his prescribing patterns did not fall into the appropriate categories. It was decided that it was better to pursue an 'educational approach'.

4.70 In 1993, Shipman acquired a computer system with software designed to encourage the use of generic drugs wherever possible. Whether because of that or (as Dr Banks suggested) in response to the introduction by the FHSA of financial incentives for generic prescribing, Shipman increased his generic prescribing markedly. From that time, he became one of the highest prescribers of generic drugs in the FHSA. However, his overall prescribing costs continued to be the highest in the area. In 1995, Shipman joined a fundholding consortium with a shared prescribing budget. The consortium engaged the services of Ms Carol Abdulezer, an independent pharmacy consultant, to prepare a formulary for use by the consortium. In the course of that work, she reviewed the PACT data of all the GPs in that consortium, including Shipman.

4.71 Shipman did not modify his prescribing costs, even when he was subjected to pressure from colleagues within the consortium. In June 1998, three months before his arrest, his prescribing costs exceeded the HA equivalent by 75% and the national equivalent by

88%. Throughout this period, Shipman's prescribing was a matter of real concern to the Tameside FHSA/WPHA and to the North West Regional Office of the NHS Executive. However, that concern did not relate to the quality of his prescribing. It was not felt that he was prescribing inappropriately or inadequately. He was not prescribing drugs which had been superseded by more effective preparations or drugs known to be of limited therapeutic value. On the contrary, he favoured modern, newly developed drugs. The sole reason for concern about Shipman's prescribing habits was their cost.

Shipman's Prescribing of Opiates

4.72 The Inquiry heard oral evidence from Dr Archer, Dr David Edwards, Dr Freedman, Dr Banks, Mrs Abrahams and Mr Welsby, whose joint employment as advisers to the Tameside FHSA/WPHA spanned the period with which I am concerned. The Inquiry also heard evidence from Ms Abdulezer. Mrs Anderson was prevented by family difficulties from attending to give evidence but provided two statements. Notes and letters relating to prescribing visits, some of the prescribing data used to prepare for those visits and other relevant documents were made available to the Inquiry. None of the Tameside FHSA/WPHA advisers had ever had occasion for concern over Shipman's prescribing of diamorphine. Ms Abdulezer had had occasion to speak to him about it once in circumstances which I shall relate shortly.

4.73 As I have explained, the standard paper PACT reports were not sufficiently detailed to show that diamorphine had been prescribed. When the advisers obtained the more detailed PACT catalogues, their attention would have been focussed on the areas of high cost. These would not usually include opiates which, as I have explained, are relatively inexpensive save for the high dose ampoules of diamorphine.

4.74 If an examination of a PACT catalogue had revealed that a large quantity of diamorphine had been prescribed during the period (usually three months) covered by the catalogue, it would be assumed that this was attributable to pain relief prescribed for a terminally ill patient in the last stages of his/her life. Such patients often need very large quantities of diamorphine to relieve their pain. The Inquiry was told that the advisers would not want to appear to be 'penny pinching' in such a sensitive area. Accordingly, they would be reluctant to question the amount of diamorphine prescribed in these circumstances. Mrs Anderson said that she would not have looked at a GP's use of controlled drugs in detail unless she had been alerted to a potential problem.

4.75 In March 1992, Shipman prescribed two 30mg ampoules of diamorphine. He prescribed no more that year. The prescription would have attracted no attention. Between February and August 1993, he prescribed 14 single 30mg ampoules of diamorphine, in the names of 13 different patients. These would not have been evident from the electronic PACTLINE system or the standard paper PACT reports. They would, however, have appeared in the PACT catalogues for the three quarters during which the prescriptions were issued. Prescription of a 30mg ampoule of diamorphine as a 'one-off' means of treating a patient would be unusual. A series of such prescriptions would be even more unusual. If noticed by someone with knowledge about the use of opiates, this pattern of prescribing should have raised questions and concerns. In my Fourth Report, I was critical of the pharmacist

and the CIO who failed to notice the unusual nature of these prescriptions from the entries in the CDR kept at the pharmacy at which the prescriptions were dispensed. However, I am not critical of the FHSA advisers responsible for examining the PACT data for the periods covering these prescriptions. I have already explained that the information contained within the PACT catalogues would not have told a reader how many patients had received the diamorphine. That fact, and the fact that the reader would be examining one quarter's catalogue at a time, would mean that the information, even if noticed, would have had very little impact. The total amount and cost of the diamorphine prescribed over a single quarter would have been relatively small. The information would have appeared in a bulky document containing a great deal of data about the drugs, including high cost drugs, prescribed by Shipman over the same three-month period. It is not surprising that these single 30mg ampoules of diamorphine were not noticed.

4.76 In November 1993, Shipman's method of obtaining diamorphine changed. He took possession of two or three boxes, each containing ten 100mg ampoules of diamorphine, after the death of a patient. He said that he intended to destroy them. The diamorphine had been prescribed for administration by means of a syringe driver to a terminally ill patient who had died at home. Thereafter, Shipman obtained diamorphine in large quantities by prescribing it for cancer patients who did not in reality require it, by removing it from the houses of patients who had died of cancer or by collecting it on behalf of a terminally ill patient and keeping some or all of the drug for himself.

4.77 As I have said, Ms Abdulezer did have occasion to ask Shipman about his prescribing of diamorphine. She told the Inquiry that, when examining the prescribing data of the fundholding consortium of which Shipman was a member, she discovered that his diamorphine prescribing for the quarter had increased. She immediately assumed that the reason for the increase was that Shipman was prescribing for a terminally ill patient. Her purpose in speaking to him was not to investigate the reason for his prescribing or to seek to persuade him to reduce it, but to ascertain for how long the need for the drug was likely to continue. She wanted to know whether she should request the Tameside FHSA/WPHA to take it into account when setting the consortium's prescribing budget. Shipman immediately identified the patient concerned, retrieved his/her medical records and showed Ms Abdulezer a letter from the hospital setting out the dosage of diamorphine to be given. He told Ms Abdulezer that the drug would not be required for long as the patient was in the end stages of a terminal illness. The following quarter, the costs had returned to their previous level so Ms Abdulezer did not query them further. She cannot remember the name of the patient but thought that the incident had occurred in 1995 or early 1996. She had no reason to doubt Shipman's word.

4.78 During those two years, Shipman had several patients who suffered from cancer and were in genuine need of large quantities of diamorphine. In fact, we now know that he diverted some of their diamorphine for his own purposes. That would not have been evident to an adviser, armed only with the PACT data and reliant upon Shipman for any additional information. The PACT data did not identify the patient(s) for whom the drug was prescribed, nor of course did it give any information about what had happened to the drug once it was prescribed and dispensed. It would have been easy for Shipman to convince

an adviser, as he did Ms Abdulezer, that the diamorphine had been legally prescribed to a patient and used by him/her.

4.79 For the reasons I have explained above, I do not find it surprising that the monitoring of prescribing which was carried out by the Tameside FHSA/WPHA advisers did not reveal cause for concern about Shipman's prescribing of diamorphine. Even if it had, I have little doubt that Shipman would have been able to allay any concerns which arose.

4.80 Meanwhile, over the same period, the police CIOs were carrying out inspections of the CDR held by the Norwest Co-op Pharmacy, from where most of Shipman's diamorphine prescriptions were dispensed. They too saw nothing to cause them concern. As I have explained in my Fourth Report, they are not to be criticised on that account save in respect of the records relating to the 30mg ampoules of diamorphine dispensed in 1993. The prescriptions were all made out correctly in the names of real patients who were suffering from cancer. It was not apparent to the CIOs – or indeed to the dispensing pharmacist – that Shipman was prescribing more than the patients actually needed. Nor could they know what a detailed interrogation of the PACT data would have revealed, namely that Shipman was a high prescriber of diamorphine, although not the highest in the area. Nor were the CIOs aware that Shipman sometimes collected the drugs on his patients' behalf. That information was not recorded in the CDR, although if my recommendations are accepted, it will be in future. In the Fourth Report, I have also recommended that a single agency should have the function of inspecting the CDRs and examining the PACT data. In that way, the officers of one body would have a complete picture of a doctor's practice in relation to the prescribing and collecting of controlled drugs.

Enquiries about Shipman's Possession and Prescribing of Controlled Drugs

4.81 I have already said that Dr David Edwards had been told by Shipman that he did not keep controlled drugs and did not have a CDR. That was when Dr Edwards was a RMO. Later, he became one of the Tameside FHSA's first Medical Advisers. Dr Archer, Dr Edwards' co-Adviser, did not say in his statement to the Inquiry whether or not he had discussed the matter with Shipman but, if he had done so, no doubt he would have received the same answer.

4.82 Dr Freedman told the Inquiry that when, on one of his prescribing visits, he asked Shipman whether he had a CDR, Shipman answered that he did not keep controlled drugs. He said that he was afraid they might be stolen. When asked what he would do in an emergency, he told Dr Freedman that it was not his practice to visit patients who telephoned the surgery with the symptoms of a heart attack. He said that, when this happened, he would immediately ring for an ambulance and get them straight into hospital where they could be more promptly treated. As it happens, Shipman frequently claimed that his victims had died of a heart attack after he had failed in an attempt to treat or resuscitate them but Dr Freedman was not to know that. There seems little doubt that Shipman would have given the same answer to anyone who put the question to him. It was not an unusual stance for a GP to take. No adviser would have had any reason to doubt Shipman's word.

4.83 In October 1998, following Shipman's arrest, Dr Banks, then Medical Adviser to the WPHA, asked the PPA to analyse Shipman's prescribing of 100mg diamorphine injections.

Because of the restrictions on the available data (see paragraph 4.66 above), it was possible to look at only the previous two years' data. Two points emerged from this analysis. The first was that Shipman was not, as might have been expected, the highest prescriber of this dosage of diamorphine in the area of the WPHA. In fact, he was the sixth highest prescriber over the two-year period. He might well have been found to be the highest if a longer period could have been examined; he prescribed heavily and stole a very large amount in the first half of 1996. The second point was that, although Shipman's pattern of prescribing 100mg ampoules of diamorphine was unusual (in that there was more frequent relatively low level prescribing than would be expected), the prescribing patterns of the other high prescribing doctors were not all conventional either.

4.84 If this unusual pattern had come to the attention of the authorities and Shipman had been asked about it, he would have been able, on each occasion, to produce evidence of a patient (whether terminally ill or recently dead) for whom the diamorphine had been prescribed. The records of most of those patients would have confirmed that they were in genuine need of large quantities of diamorphine for pain relief. The district nurses who were caring for the patients would, if asked, have confirmed that no more of the drug was being prescribed than was necessary. They would have been unaware of those drugs which Shipman had collected from the pharmacy and diverted for his own ourposes. Even on the occasions when he had prescribed diamorphine for a patient who was not in genuine need of it, Shipman would no doubt have given a plausible reason, associated with the patient's cancer, for prescribing the drug. It would have required an in-depth investigation, of the kind that would be undertaken only if real concerns or suspicions had arisen, to reveal Shipman's practice of collecting and keeping drugs for himself.

Record Keeping

4.85 During the period from 1991 until 1998, no routine inspections of medical records were conducted in Tameside. Dr David Edwards told the Inquiry that, when he was co-Medical Adviser, from 1990 until 1991, he sometimes received requests from patients' relatives to view medical records in connection with a complaint or following the death of a patient. He would seek the permission of the patient's GP and of the LMC before showing the records to the relatives and explaining their contents. If Dr Edwards noticed that records were substandard, he would speak to the GP concerned.

4.86 Dr Banks agreed that individual sets of patient medical records might be examined in connection with the investigation of a complaint against a GP. However if, on examination, the records appeared inadequate, he said this would not lead to any wider inspection of the GP's records.

4.87 The view held by Tameside FHSA/WPHA was that they had no right to inspect records save in the limited circumstances described above. This view is not shared by the DoH. Its view is that, pursuant to paragraph 36 of the 1992 terms of service (which required GPs to keep adequate medical records and to forward them to the FHSA (later the HA) on request as soon as possible), a PCO could request to see the medical records at any time. However, Dr Banks said that any attempt to carry out random inspections of GPs' records would have been resisted by the profession. In the past, there had been problems in

gaining access to records for the purpose of verifying financial claims made by GPs in respect of treatment given to patients. The WPHA had succeeded in reaching an agreement with local GPs that staff should have such access for the limited purpose of financial audit. Not every HA in the country had achieved the same success. Dr Banks said that, if the WPHA had attempted to carry out random inspections of records, 'the BMA (*British Medical Association*) would have been on our backs immediately'. Dr Banks did, of course, examine 15 sets of Shipman's deceased patients' records in the course of the abortive police investigation of March 1998. He thought that the records lacked information but assumed, not that Shipman was a poor record keeper, but that the records must be incomplete.

4.88 The introduction of medical audit revealed problems with the records kept by some GPs in Tameside. Records which were incomplete or disorganised or which lacked a detailed summary card caused difficulty in retrieving information for the purpose of audit. In order to tackle this problem, the Tameside FHSA instituted a scheme (subsequently continued by the WPHA) whereby teams of trained, non-medical staff went into GP practices to summarise and reorganise medical records. There was no compulsion on a practice to accept this service. The work of the team did not involve any clinical assessment of the records and it was in no sense a process of monitoring. Shipman never availed himself of this service.

Other Sources of Information

4.89 In the early 1990s, the Tameside FHSA introduced a system of 'practice profiling'. There was no requirement upon it to do so. The profiling was an additional exercise which it chose to perform. It involved using the available information about list sizes, prescribing and referral activity, chronic disease management and financial matters such as payments for items of service in order to compare the performance of individual GP practices. Each practice was sent a copy of a profile which showed its performance compared with other (anonymised) practices. The profiles became more sophisticated over the years and incorporated a wider range of information.

4.90 Mr Greenwood said that the purpose of the exercise was to identify trends which might assist in planning services in the future. He said that the FHSA was also trying to identify outliers with a view to offering help and support to them and to bringing them more into line with their peer group. The profile also provided a means by which GP practices (which operated to some extent in isolation) could compare their performance with that of other practices. In the early years, senior managers from the FHSA visited all the GP practices in the district annually to discuss their profiles. Over time, it was felt that this did not represent an effective use of resources and the visits were discontinued.

4.91 The Inquiry has the practice profiles compiled in respect of the Market Street practice in March 1996, 1997 and 1998. The profiles show a high level of practice activity in such areas as childhood immunisations and cytology. They also show evidence of Shipman's high prescribing costs. The only additional data which might have been significant related to the low level of hospital activity among his elderly patients (i.e. those over 65). In both 1996 and 1997, Shipman's practice had the lowest level of hospital activity in the district

among patients of that age. In the light of what we know now, this factor has some significance. No figures for hospital activity appeared in the 1998 profile.

4.92 Both Mr Greenwood and Dr Banks explained that the data for hospital activity was regarded as very unreliable. Dr Banks said that, in any event, hospital activity was not a matter within the remit of medical advisers. The use of hospital services tended, he said, to be regarded as a public health issue to be considered in conjunction with those providing the services. Mr Greenwood said that the advisers would look at the correlation between hospital activity and prescribing (e.g. to see whether practices that prescribed a high level of anti-asthmatic medication had fewer admissions to hospital). Otherwise, hospital activity was regarded as a planning and funding issue. Even if it had attracted attention, the low level of hospital activity among Shipman's older patients would no doubt have been attributed to his declared policy of keeping his elderly patients at home for as long as possible.

4.93 The Tameside MAAG was set up in October 1990. It was a sub-committee of the FHSA. It included among its members GPs (some nominated by the LMC), a postgraduate tutor, a representative from secondary care and the FHSA's medical adviser. The FHSA employed a former nurse manager, Ms Heather Harrisson, as audit facilitator, and another member of staff as secretary. The task of the MAAG was to facilitate audit activity by offering advice, education, training and support in audit. GPs were encouraged to participate and the MAAG would suggest suitable topics for audit with a view to obtaining data which could be used to improve patient health. The MAAG co-ordinated district-wide audits which offered a degree of comparative feedback. Every GP practice was offered an annual visit by members of the MAAG. The practice would be invited to make available the written results of its audits for discussion with GP members of the visiting team.

4.94 Audits were carried out by GP practices themselves. They were not obliged to submit their results to the MAAG although most did. If submitted, the reports were discussed at a MAAG meeting at which only GP members (and one member of the staff) were present. The full MAAG would discuss only aggregated and anonymised audit results. The FHSA did not have access to audit results relating to individual practices.

4.95 In April 1996, the Tameside and Oldham MAAGs merged to form the West Pennine Primary Care Clinical Audit Group (WPPCCAG). The Glossop practices joined the WPPCCAG in 1997. At that time, HAs were given specific management responsibilities for clinical audit. It was intended that audit should be closely linked with improvements in the quality of clinical care. The HAs were to have a part in determining what audits should be done. They had to monitor the range and extent of participation in audit by practices and to secure the increasing involvement of patients in the audit process. However, HAs still did not see individual practice audit results and had no opportunity to assess their quality. Nor would they become aware of any signs of substandard practice that the audits might reveal.

4.96 From the time of his entry into single-handed practice, Shipman was an enthusiastic participant in audit. His practice nurse, Sister Gillian Morgan, and practice manager, Mrs Alison Massey, also participated in audit. Shipman submitted to the MAAG (later the WPPCCAG) a number of audits dealing with a wide range of topics. None disclosed any

substandard practice. A few practices in the district had conducted audits of their patient deaths. Shipman never did so although, as I related in my Second Report, he claimed untruthfully to Dr Banks in July 1998 that he and Sister Morgan had carried out an audit into patient deaths that had occurred in the early part of 1998. In November 1997, Mrs Massey conducted an audit of patients who had left the practice in the preceding six months. She discovered at least 29 cases in which the patient had died. This was a high number. The average mortality rate for GP practices is about ten patients per thousand per annum. Given Shipman's practice list of just over 3000, about 15 deaths in six months could have been expected. However, the audit expressed the number as a percentage (27.9%) of patients leaving the practice. The total number of patients leaving was not stated. Those who saw the audit would not have been aware of the underlying number of deaths.

4.97 In general, Shipman's audit activity reinforced the impression of a well-run and enthusiastic practice. In November 1997, a letter from the audit administrator observed that Shipman's practice **'has been identified as one of a number who undertake a high level of audit activity, and are well advanced with practice development'**.

The Arrangements Elsewhere

4.98 I have described the arrangements for monitoring GPs which were in place in Tameside during the period when Shipman practised there. In order to discover how those arrangements compared with those in force elsewhere, the Inquiry sent questionnaires to a number of strategic health authorities in England and Wales, chosen at random, requesting detailed information about the systems which were in place in their areas during the time Shipman was in practice.

4.99 The responses to these questionnaires revealed that the arrangements in Tameside were very typical of those implemented in the majority of areas from which responses were received. The approach to the monitoring of prescribing was similar in most areas. In general, PCOs relied chiefly on patient complaints and expressions of concern to reveal poor practice. Many of the responses referred to the fact that FHSA/HA managers had no access to the audits performed by individual practices. A few managers had developed protocols whereby serious concerns arising out of audit activity would be notified to them. Only one of the PCOs which responded to the questionnaire reported that it had carried out routine inspections of GPs' medical records. Most said that, as in Tameside, records were examined only when a complaint was being investigated. As I have said, most HAs began to operate the new local performance procedures from 1998 onwards.

4.100 A few HAs had developed additional strategies aimed at improving the quality of care and identifying problem GPs. Starting in about 1996, some areas had developed performance indicators against which practices were measured. Some (e.g. Sheffield FHSA/HA) carried out regular audits of chronic disease management, which the Inquiry was told were helpful in identifying doctors who were performing poorly. One PCO reported carrying out examinations of deceased patients' records in order to investigate concerns which had arisen about GPs' performance. One HA monitored the numbers of patients transferring from one GP practice to another while continuing to live at the same address.

Such a move might well indicate dissatisfaction with the patient's original practice. If a spate of such transfers was observed, this would suggest that there was a problem with the practice which required investigation.

4.101 Many of the responses stressed the limitations which were placed on the ability of FHSAs and HAs to monitor and manage GPs as a result of GPs' independent contractor status and the need to prove a breach of the terms of service before any local disciplinary action could be taken.

Conclusions

The Tameside Family Practitioner Committee

4.102 It seems to me that, during the period from 1997 to 1990, Tameside FPC was doing all that it could – within the very limited ambit of activity available to it – to identify and deal with concerns which might arise about the GPs on its list. It had neither the power nor the resources to do more. The information that the Inquiry has obtained from other areas confirms this view.

The Regional Medical Service

4.103 As I have already indicated, I do not consider that any criticism can be made of the RMOs responsible for visiting the Donneybrook practice between 1977 and 1990. There is no reason to believe that they would have been aware of Shipman's prescribing of opiates. Nor can any criticism be attached to their failure to inspect his medical records. The practice of inspecting medical records had fallen into disuse well before Shipman arrived in Hyde. Even if the records had been inspected, it is, on balance, unlikely that they would have revealed anything other than the fact that Shipman was not a particularly diligent record keeper.

The Tameside Family Health Services Authority and the West Pennine Health Authority

4.104 It is clear from the evidence that the Tameside FHSA/WPHA discharged its duties in relation to the control and supervision of GPs conscientiously and properly. I am confident that the members of its staff had a genuine desire to improve the quality of GP practice in its area and made good use of the powers given to them in furtherance of this objective. It seems from the responses to the Inquiry's questionnaire that the performance of the Tameside FHSA/WPHA was typical of that of most PCOs up and down the country. There were areas (South Yorkshire was one) where the HA had taken innovative steps in an attempt to raise standards and identify doctors who were performing poorly. However, the PCOs in Tameside cannot be criticised for not having been in the vanguard. They were doing all that was required of them.

4.105 In many respects, the data collected about Shipman's practice would have given a positive picture of his competence and performance. Only in the area of prescribing was Shipman perceived as an outlier. Even then, the problem arose from his rigid views (which he was able to justify) about the beneficial effects of certain expensive drugs. There was no question of his prescribing being substandard in any way. Unless his prescribing of

diamorphine was high enough to show up amidst his other prescribing (as it plainly was when Ms Abdulezer spoke to him), it would not have been detected in the absence of routine monitoring of the prescribing of controlled drugs. Such routine monitoring was not carried out widely, if at all. It is significant in that context that no training was given nationally on this topic until after Shipman's conviction in 2000.

4.106 Tameside FHSA/WPHA was typical in examining GPs' medical records only in connection with complaints about a GP. Other than that, there would have been no occasion to inspect Shipman's records. Examination of the records of some of Shipman's living patients might have shown little of note, save that the records were of generally poor quality. Careful inspection of his deceased patients' notes might have raised concerns. Tameside FHSA/WPHA was entirely typical in not having a system of examining deceased patients' notes in the absence of specific concerns.

4.107 Tameside FHSA/WPHA appears to have made arrangements for clinical audit which were entirely typical of those of other PCOs. In particular, it had no powers to compel a practice to conduct audits, let alone an audit of any particular activity. An audit of the deaths of Shipman's patients in 1995, 1996 or 1997 would have revealed a real cause for concern and might have led to the discovery of his crimes. However, WPHA is not to be criticised for the fact that this did not happen.

4.108 I have referred to the criticism made of the Tameside FPC and its successors that it failed to unearth and act upon proper and full information as to the true nature and extent of Shipman's criminal past. It is difficult to see how the PCOs could have gone about obtaining this information. First of all, they were unaware that there was anything to find out in Shipman's case. They would therefore have had to institute a system of investigating the past history of every GP on their medical list. This would have been fiercely resisted by the profession and would have been unlikely to have the support of the DHSS/DoH. So far as the Inquiry is aware, this was not an exercise that was undertaken anywhere else. In my view, those responsible for the provision of primary care in Tameside cannot be criticised for failing to undertake it.

4.109 In its written submission to the Inquiry, the Tameside Families Support Group referred to the bewilderment of its members that, during the period when Shipman practised in Hyde, the State should have abdicated its responsibility for monitoring GPs. I can understand that sentiment. Viewed through today's eyes, it seems extraordinary that, until less than a decade ago, the PCOs should have had so few powers to regulate GPs' behaviour.

4.110 The explanation lies, I think, in the historical status of GPs as independent contractors. That status has imposed constraints on attempts by successive PCOs to control and supervise GPs effectively. Until recently, GPs could be compelled to comply with their terms of service but no more. GP practices are small businesses providing services for which the PCOs pay. During the early part of the period with which we are concerned, there was a strong belief, apparently shared by Government, that the profession provided the best (indeed the only) means of imposing high standards of clinical care and professional conduct on doctors and of monitoring those standards. It was believed that it would do so rigorously. Hence, matters of professional concern arising locally were left to be determined by LMCs with the GMC as the ultimate arbiter of fitness to practise. This

belief, which was fostered by the profession, was difficult to challenge in an area involving the need for professional expertise.

4.111 It is clear that, by the 1980s (possibly before), there was a realisation that, if consistency of service and standards among GP practices was to be achieved, some element of management by PCOs must be introduced. The matter could no longer be left to the profession. The process of change began in the mid-1980s and has continued ever since. It has been accompanied by a growing recognition of the importance of tackling poor performance among GPs. As I shall describe in Chapter 5, there have been considerable developments in the arrangements for monitoring GPs since 1998. Until that time, progress was slow and, in retrospect, it is natural to wish that the process of change had started sooner. However, the fact that it did not cannot, in my view, be attributed to fault on the part of any person or organisation.

CHAPTER FIVE

Developments in the Arrangements for Monitoring General Practitioners since 1998

Introduction

5.1 In May 1997, a new Government came into office. These were difficult times for the NHS. Concerns about the high mortality rate among children undergoing complex heart surgery at the Bristol Royal Infirmary had become public knowledge by 1995. It was known too that senior staff at the hospital had been aware of problems for some time and had taken no action. Three doctors were charged by the General Medical Council (GMC) with serious professional misconduct (SPM). Hearings began in October 1997 and ended with all three being found guilty of SPM in June 1998.

5.2 In December 1996, Rodney Ledward, a consultant gynaecologist, whose lack of skill had caused injury to many of his patients over a period of 15 years or so, had been dismissed from the hospital at which he worked. His case came before the GMC in September 1998. He too was found guilty of SPM. There had been complaints and concerns about his conduct and competence over a long period, yet he had been allowed to continue in practice. Also in September 1998, Shipman was arrested and it soon became clear that he might well have killed a large number of his patients over many years.

5.3 These events, and other less high profile incidents, focussed public attention on the adequacy of the arrangements then in place for identifying and eliminating incompetent or aberrant clinical practice. Those arrangements had patently failed to protect the patients of Ledward and Shipman, and the children who had undergone surgery at Bristol. It was evident that change was urgently needed.

5.4 The subsequent years have been a period of great change for the medical profession and the NHS. In the field of general practice, there have been significant developments in the role of primary care organisations (PCOs). They have been given additional powers which should enable them to exercise a far greater degree of control than before over the general practitioners (GPs) on their lists. In addition, they have been developing ways to improve the quality of care and to deal with doctors who are not providing an acceptable standard of care. In this Chapter, I shall describe the developments that have occurred and consider how they are working in practice.

The Devolution of Power to the Primary Care Trusts

5.5 The publication of a White Paper, 'The New NHS', in December 1997 heralded a fundamental re-organisation of the NHS. There was to be a greater emphasis on quality of care. Clearly defined standards of care were to be produced, against which the performance of NHS organisations would be measured. Responsibility for meeting those standards was to be devolved locally, with doctors and nurses playing a key role in making decisions about the services to be provided in their areas.

5.6 GP fundholding had encouraged some GP practices to extend the range of their services and to develop different ways of commissioning services so as to benefit patients. In the

White Paper, the Government signalled its intention to do away with fundholding by individual GP practices. However, the intention was to build on, and develop further, the work which had already been started by local clinicians.

5.7 Practice-based fundholding was abolished by the Health Act 1999. In July 2001, in a publication entitled 'Shifting the Balance of Power within the NHS', the Government announced that responsibility for the management, development and integration of all primary care services (medical, dental, pharmaceutical and optical) in England was to pass from the health authorities (HAs) to a network of newly created primary care trusts (PCTs), covering the whole of the country.

5.8 From 1st April 2002, the 95 existing HAs were abolished and 28 new HAs were created in their place. The area covered by the former West Pennine Health Authority (WPHA) became part of the new Greater Manchester HA. Shortly afterwards, HAs were renamed strategic health authorities (SHAs).

5.9 Also in April 2002, 302 (now increased to 303) new PCTs were created. From that time, the PCTs have had responsibility for improving the health of the community in their areas and for commissioning secondary (i.e. hospital) care, as well as for the provision of primary care services. Meanwhile, the SHAs have been made responsible for creating a coherent strategic framework for the development of NHS services in their areas. They are also responsible for managing the performance of PCTs and NHS trusts against agreed business plans and a national set of priorities. In turn, SHAs account to the Secretary of State for Health (SoS) for the performance of the NHS in their areas.

Quality

5.10 I have already mentioned that the 1997 White Paper promised that greater emphasis would be placed in the future on quality of care. One manifestation of this new emphasis was to be a new statutory duty of quality.

The Duty of Quality

5.11 Section 18 of the Health Act 1999 imposed a duty upon every HA, PCT and NHS trust:

> **'... to put and keep in place arrangements for the purpose of monitoring and improving the quality of health care which it provides to individuals'**.

The words 'health care' were defined by the Act (as amended) as:

> **'... services for or in connection with the prevention, diagnosis or treatment of illness and the environment in which such services are provided'**.

5.12 It was intended that the 'duty of quality' should have the effect of focussing the attention of PCTs on devising ways in which to monitor and improve the quality of care provided by GPs in their areas.

Clinical Governance

5.13 The means by which the duty of quality was to be discharged was 'clinical governance', a new concept which essentially involved the setting up of structures and systems designed to secure and improve the quality of care. It was to apply to all NHS bodies. I shall discuss the concept of clinical governance at greater length in Chapter 12.

5.14 As part of their clinical governance arrangements, PCTs continue to monitor GPs' prescribing and continue also to encourage and facilitate audit by GP practices. In addition, all GPs practising in the NHS are now required to participate in annual appraisals. These are organised by their PCTs and conducted in the main by fellow GPs, usually practising within the same PCT. I shall deal with the monitoring of prescribing, audit and appraisal, together with other steps that have been taken by PCTs to implement clinical governance, in Chapter 12.

Standards and Guidelines

5.15 Following the publication of the 1997 White Paper, there was for the first time an attempt to define national clinical standards, by means of National Service Frameworks (NSFs) and by the establishment, in 1999, of the National Institute for Clinical Excellence (NICE). NSFs were developed with the aim of identifying the essential ingredients of good clinical service provision for certain disease groups and patient populations (e.g. for cancer, mental health, coronary heart disease, etc.). The aim was to reduce unacceptable variations in care and standards of treatment across the country. The role of NICE was to develop evidence-based clinical guidelines for the care and treatment of patients with specific diseases or conditions, and to assess and evaluate new and existing medicines, treatment and interventional procedures by reference to cost and clinical effectiveness.

5.16 More recently, in February 2004, the Department of Health (DoH) published a Consultation Paper, 'Standards for Better Health', seeking views on a set of proposed core standards governing the quality of health care provided by all NHS bodies in England. The paper also set out proposed developmental standards designed to encourage a rise in the overall quality of health care in the long term. In July 2004, the DoH published its proposals in a document entitled 'National Standards, Local Action: Health and Social Care Standards and Planning'. This document is aimed primarily at those who have responsibility for planning and commissioning the delivery of services in the years 2005–2008. It sets out the standards that must be achieved immediately as 'core standards' and the 'developmental standards' which should be achieved during the coming years.

The Commission for Health Improvement

5.17 The Health Act 1999 also established the Commission for Health Improvement (CHI), a non-departmental public body, independent of the NHS. CHI assumed full powers in April 2000. It was given responsibility for reviewing and reporting on the clinical governance arrangements made by NHS trusts and PCTs. It was also given the task of monitoring arrangements for national services, including compliance with NSFs. CHI was abolished

by the Health and Social Care (Community Health and Standards) Act 2003 and, with effect from April 2004, its functions have been subsumed into those of its successor the Commission for Healthcare Audit and Inspection (now known as the Healthcare Commission). I shall describe the role of CHI and of the Healthcare Commission in Chapter 12.

Changes in the Arrangements for General Practice

5.18 In the past, GPs have usually practised as principals (i.e. with their own lists of patients) within group practices or single-handed. They have been independent contractors, providing general medical services (GMS) in accordance with a standard national contract. A new GMS Contract came into force in April 2004. There have, of course, always been GP non-principals, who have provided locum services on a full-time or a part-time basis. In addition, over recent years, many GPs have been employed (again on both a full-time and a part-time basis) by deputising services to provide care outside the usual GP surgery hours.

5.19 As a result of provisions contained in the National Health Service (Primary Care) Act 1997, it has become possible for GPs to work within a variety of more flexible arrangements. Now, a significant proportion – approximately 40% – of all GPs provide services under contracts for personal medical services (PMS). The advantage of PMS contracts is that they are individually negotiated and can be tailored to suit the GP practice concerned, as well as the needs of the PCT. It is open to a PCT (subject, of course, to negotiation with the practice) to insert terms into a PMS contract, setting quality standards and giving the PCT additional control over the way in which services are provided.

5.20 Many GPs who do not wish to take on the risks, responsibilities and/or commitment of partnership or single-handed practice are now employed by GP practices or by PCTs. The latter arrangement has advantages for a PCT, which is able to deploy a GP in its employment to practices or areas in need of an additional doctor on a temporary or long-term basis. PCTs have a greater degree of control over the activities and quality of practice of a directly employed doctor than they can exert upon a doctor providing GMS.

The Primary Care Trusts

Organisation

5.21 Each PCT is governed by a board, which has responsibility for the statutory functions of the PCT. It takes decisions on committing financial resources, on policy and strategy and on human resources issues. The board consists of the chairman of the PCT and between ten and fourteen members, not more than seven of whom may be officers of the PCT. The number of officer members of the board may never exceed the number of non-officer members. The non-officer members are lay people, in the sense that they are not practising healthcare professionals or employees of certain specified NHS bodies. The non-officer members are drawn from the locality and are appointed by the SoS, as advised by the NHS Appointments Commission. The officer members must include:

(a) the chief executive, the director of finance and the director of public health of the PCT

(b) the chairman of the professional executive committee (PEC) of the PCT: see paragraph 5.23. He or she is deemed to be an 'officer' of the PCT for these purposes

(c) between one and three persons (at least two of whom must be members of the PEC) appointed by the chairman of the PEC following nomination by the PEC. All such persons are deemed to be 'officers' of the PCT for these purposes.

5.22 At least one of the officer members in categories (b) or (c) must be a GP and one (from the same categories) must be a nurse. The officer members may include officers other than those specified at (a) above. The chairman must be a lay member of the board.

5.23 The PEC is responsible for driving the activities of the PCT. Sir Nigel Crisp, Permanent Secretary of the DoH and Chief Executive of the NHS in England, observed in his statement to the Inquiry that the PEC is the 'engine room' of the PCT. It is dominated by clinicians, the objective being that professionals providing services locally should play a real part in shaping policy and developing services for their area. The PEC sets policy for the implementation of the functions of the PCT and exercises a management function. It has between seven and eighteen members, including the chief executive and director of finance of the PCT. Membership of the PEC also includes local professionals (including at least one GP and one nurse, together with such other professional members as reflect the functions carried out by the PCT), one or two representatives from Social Services and one member with particular expertise in public health. GPs usually form the majority of the PEC and the chairman of the PEC is almost invariably a GP.

5.24 PCTs vary in size. An average-sized PCT will be responsible for about 100 GPs. That is significantly fewer than were covered by the former HAs. The size of the PCTs should mean that their staff are in a good position to acquire a real knowledge of the GPs and other professionals responsible for providing health care in their areas. However, the size of the PCTs also has its disadvantages. It is not practicable for an individual PCT to employ staff who possess all the specialist skills that it will at times require. Many do not have a medical director. This is, no doubt, one of the reasons why PCTs were given the power to join together in order to discharge some of their functions. Many PCTs are making use of this power and are developing ways of increasing the range of skills open to them by sharing services. The Inquiry heard from Dr Robert Queenborough, Medical Director, Trafford North and Trafford South PCTs. His PCTs share a single management team while retaining separate boards, PECs and finances. As time goes on, it may be that the pooling of resources between PCTs will become more widespread.

Operation

5.25 The functions of the PCTs are wide-ranging. Like their predecessors, they have responsibility, not only for the provision of primary medical services, but also for pharmaceutical, ophthalmic (now termed 'optical') and dental services. They also have responsibilities for such matters as the improvement of health in their community, the commissioning of secondary care, and co-ordination with other organisations to provide integrated health and social services. As I shall describe, their management powers in relation to their lists of GPs have now been extended considerably. This places additional responsibilities upon them. The PCTs must also act on concerns about doctors who are

providing an unacceptable standard of practice. A number of witnesses and participants at the Inquiry's seminars drew attention to the considerable determination and resources (both human and financial) required of a PCT when dealing with a doctor who is performing poorly or who is otherwise giving cause for concern. The administrative work associated with the new GMS Contract also represents a formidable challenge for PCTs. All these various functions and responsibilities place a heavy burden on what are, as I have said, small organisations. Not surprisingly, the evidence shows that their efforts to cope with the demands made upon them are meeting with variable degrees of success.

5.26 Another set of problems faced by PCTs arises as a result of their newness. The disbanding of the former HAs and the creation of the 303 new PCTs resulted in the dispersal of a large number of staff with considerable expertise in the field of primary care. In particular, many medical advisers, with an intimate knowledge of the doctors in their areas, have been lost. A number of witnesses have spoken of the loss of 'corporate knowledge' or 'corporate memory' in some areas. It will take time to accumulate that knowledge (or memory) once again. It is to be hoped that the present structures will be left in place long enough for the PCTs' members and staff to develop that knowledge and memory.

5.27 I have already observed that one of the perceived strengths of the new PCTs is that they are led by local professionals. While this has obvious benefits, there are also potential drawbacks. Most PEC chairmen (who are automatically on the board of the PCT) are local GPs. They may also be officers (e.g. secretary or chairman) of the local medical committee (LMC). PCTs are still obliged to consult with LMCs on a wide range of issues. It is easy to imagine circumstances (e.g. when a PCT is in discussions with a LMC about a controversial issue affecting the interests of local GPs) where a conflict of interest may arise. Even when no actual conflict exists, it may be difficult for the doctor concerned to adopt the objective approach that might be expected of a governing member of a public organisation. Mr William Greenwood, formerly Assistant Director of Primary Care at the WPHA, now Director in Chief, Manchester Shared Services Agency (employed by the Central Manchester PCT), mentioned potential tensions about budget management and priorities which might arise. The position becomes even more difficult when a complaint is made or a concern is expressed about the professional practice or conduct of a close professional colleague of a PEC member or chairman or, as has already happened in some areas, the member or chairman him/herself.

5.28 Dr Queenborough said that there was a degree of confusion about the role of the PECs and, in particular, about the accountability of individual members of PECs. He would like to see members of the PEC independent of the LMC. However, he said that, in his area, there were just not enough GPs prepared to take an active role in local medical affairs to make that possible. Mrs Chris Page, Head of Service Redesign, Bebington and West Wirral PCT, told the Inquiry that her PCT had come to an agreement with the LMC that any officer of the LMC who was appointed to the PEC would stand down from his/her position on the LMC. Dr John Chisholm, Chairman of the General Practitioners Committee of the British Medical Association, said that similar agreements had been reached in only a minority of PCTs. He did not support such a division of roles. It was his view that any potential conflict of interest could be managed. He, like Dr Queenborough, was conscious that there was only a small number of doctors willing to take on an active role and to work

on behalf of PCTs. Also, he believed that an overlap of membership between the two organisations could be positively advantageous. He did not, however, regard it as 'ideal' for the chairman of a PEC to be an officer of the LMC.

5.29 Despite the strong professional presence on PCTs, the PCTs do not always enjoy a good relationship with local GPs. Professor Martin Roland, Director, National Primary Care Research and Development Centre and Professor of General Practice, University of Manchester, himself a practising GP, told the Inquiry that it would be wrong to assume that GPs, as a body, regarded PCTs in a positive light as friendly, helpful and supportive towards the profession. On the contrary, some view their PCTs very negatively. Dr Michael Taylor, Chairman of the Small Practices Association, said that the perception of single-handed practices tended to be that PCTs were hostile, rather than supportive, towards them. There is no doubt a good deal of concern and suspicion about how the PCTs will choose to exercise their recently acquired powers to manage their lists. There is also a continuing tension between independent contractor GPs and the PCTs who are seeking to 'manage' them.

The Ability of Primary Care Trusts to Manage Their Lists

5.30 PCTs do not, in general, employ GPs. They do not, therefore, have the usual power of an employer to 'hire and fire'. In the past, they had little say over who was admitted to their lists and no power to remove a doctor who was performing unsatisfactorily. This has now changed.

The Lists

The Medical List

5.31 In Chapter 3, I explained that PCOs were required to maintain a medical list of doctors in their areas who had undertaken to perform GMS. The medical list related to GP principals only. There was no requirement for non-principals, or those providing medical services under PMS contracts, to be included on a PCO's list. In practice, some PCOs maintained lists of non-principals. They did this as a service to GP practices, which were seeking to employ locums or deputies. This was an informal, local arrangement. If no list of non-principals was kept, PCOs had little idea of who was practising in their areas. This remained the position until comparatively recently.

The Medical Supplementary List

5.32 From June 2002, all GP non-principals (except those working under PMS contracts) were required to be included on the medical supplementary list of a PCT. The term 'non-principals' covers locums, deputies, associates, retainers and GP registrars (i.e. trainees). Some non-principals (e.g. locums) may operate in an area covered by several different PCTs. They are required to be on the list of only one of the PCTs in whose area they work. A non-principal must maintain a connection with the area of the PCT on whose list s/he appears. If s/he does not, the PCT is entitled to remove him/her from its list.

5.33 As from April 2002, GP principals were prohibited from engaging as a deputy or employing any doctor (save for a doctor performing PMS) who was not included on (or the subject of an outstanding application for inclusion on) a medical supplementary or medical list. The requirement for non-principals to be on the PCT's list is now covered by the new GMS Contract. DoH guidance makes it clear that any person employing or engaging a non-principal who is included on a PCT's list bears responsibility for satisfying him/herself that the non-principal has the necessary clinical skills and experience to undertake the tasks s/he is recruited to perform. The non-principals must provide clinical references, which should be checked. Inclusion on the PCT's list is no warranty. Once again, this is covered by the new GMS Contract.

5.34 From the time of the introduction of supplementary lists, PCTs have had the same powers relating to admission to and suspension or removal from the supplementary list as for the medical list.

The Services List

5.35 Until recently, doctors performing PMS were not, in general, included on a PCT list. Some might be on the medical supplementary list. However, as from February 2004, all doctors performing PMS (other than those already included on a supplementary list) were required to be on a PCT services list. Applicants had to produce satisfactory evidence of their intention to provide PMS in the area of the relevant PCT.

The Medical Performers List

5.36 Since April 2004, a new medical performers list has replaced the three types of list described above. All GPs performing medical services, whether under GMS or PMS contracts, must appear on the list. The Health and Social Care (Community Health and Standards) Act 2003 provides for regulations to be made in the future prohibiting certain healthcare professionals (e.g. practice nurses) from working in a GP practice unless they are on a PCT list. If such regulations are made, and lists of nurses and other healthcare professionals are created, this will enable PCTs to apply the same rules for inclusion and continuance on the list to other healthcare professionals as are currently applicable to GPs.

Admission to a List

5.37 I have described in Chapter 3 the procedure, as it was in 1977, for the appointment of a replacement member of an existing GP practice and the very limited part played in the process by the PCO (then the family practitioner committee (FPC)). I explained also that the FPC played a greater role in the selection and appointment of a doctor to fill a single-handed practice vacancy or where a vacancy arose for an additional GP in its area.

5.38 Between 1977 and 1998, there were changes to the arrangements for dealing with applications for inclusion on the medical list and to fill vacancies. It is not necessary for me to enumerate the various changes in detail. In essence, however, the powers of the PCO remained much the same. There was still no requirement for applicants for inclusion on the list to provide information about previous disciplinary proceedings or criminal convictions.

The Introduction of Statutory Criteria

5.39 In December 1998, the National Health Service (General Medical Services) Amendment (No. 2) Regulations 1998 made significant changes to the arrangements. Again, there is no need for me to describe these in detail. However, an important development was that the Regulations introduced statutory criteria to be applied by PCOs (then the HAs) when deciding whether to approve for inclusion on their lists a candidate who had been selected by an existing practice and when itself selecting a candidate to fill a vacancy. The Regulations also gave HAs power to determine (within certain limits) their own criteria, against which applicants would be judged. This power gave HAs more flexibility in planning for the future. For example, they could require that applicants for a vacancy should have specific language skills or a particular expertise in caring for children. Despite these changes, the power of a HA to influence a practice in its selection of a replacement doctor remained limited. DoH guidance at the time stated that, if the selected candidate did not meet the criteria set out by the HA, the HA should have discussions with the practice with a view to reaching an **'acceptable compromise'**. If no agreement could be reached, the HA should consider whether to appoint the practice's selected candidate or to decline to do so and require the practice to select another candidate. The guidance warned:

> **'Refusal to appoint a doctor in these circumstances should be an exception and HAs will need to have strong reasons for doing so.'**

5.40 This guidance was not likely to encourage HAs to raise opposition to a candidate selected by a practice. Moreover, there was still no requirement for applicants to declare – or HAs to seek – information about previous disciplinary proceedings or criminal convictions.

Declarations by Applicants

5.41 That changed on 4th February 2000, four days after Shipman's conviction for murder. The National Health Service (General Medical Services) Regulations 1992 (the 1992 Regulations) were amended to require applicants to declare whether they had been convicted of any criminal offence or had been bound over or cautioned and whether they were or had been the subject of any disciplinary proceedings by their professional or regulatory body, in the UK or elsewhere. HAs were given the power to reject an application if, having considered the content of his/her declaration, they regarded the applicant as unsuitable for inclusion on their medical list.

The Abolition of the Medical Practices Committee

5.42 The Health and Social Care Act 2001 abolished the Medical Practices Committee (MPC). From that time, PCOs were given the power to decide whether there was a need for a replacement or additional GP in their area.

Pre-Admission Checks

5.43 The National Health Service (General Medical Services) Amendment (No. 4) Regulations 2001 (the 2001 Amendment Regulations) made it obligatory for a PCO (then the HA) to

carry out certain checks before admitting a doctor to its list. HAs were required to check, as far as practicable:

- the references provided by the applicant
- the information given by the applicant relating to his/her medical qualifications and his/her registration
- the contents of his/her declaration about any past criminal or disciplinary record. This declaration was now required to be significantly fuller than previously: see paragraph 5.60
- whether there was any past or ongoing fraud investigation involving the doctor.

5.44 The HA was also required to take up and consider two references.

5.45 These checks are now carried out by PCTs. At present, there is no requirement that a PCT should carry out checks with the Criminal Records Bureau (CRB) before taking a decision as to whether to admit a doctor to its list. The DoH has left this to the discretion of individual PCTs. Dr Anne Rothery, Medical Director of the Tameside and Glossop PCT, told the Inquiry that her PCT chooses to make such checks. It is a time-consuming operation, taking about half a day for each check. The CRB has, of course, been under considerable pressure since it was established and there have been long delays in completing checks. Since April 2004, all GPs applying to join a PCT's list have been required to provide an enhanced criminal record certificate as part of their application. This should provide information about unproven allegations, criminal charges which were not proceeded with and acquittals. However, the extent of the information contained on the record is dependent upon the applicant giving all relevant addresses and his/her correct names.

5.46 The Family Health Services Appeal Authority (Special Health Authority) (FHSAA (SHA)) (formerly known as the Family Health Services Appeal Authority) is the body which used to hear appeals from the former medical service committees and, after that, the medical disciplinary committees. It maintains, on behalf of the SoS, a record of doctors who have been refused admission or conditionally admitted to, or suspended, removed or contingently removed from, the list of a PCT. The completeness of the information held by the FHSAA (SHA) is entirely dependent upon PCTs notifying it of relevant decisions. Although PCTs are required to do this, it does not always happen. Since November 2003, it has been mandatory for PCTs to make a check with the FHSAA (SHA) before admitting a doctor to their lists. The Government has recently announced its intention to abolish the FHSAA (SHA) and to transfer its functions to the NHS Litigation Authority.

5.47 Dr Sarah Wilson, Director of Public Health and Medical Director, Trent SHA, said at the Inquiry's seminars that the checks which PCTs are required to carry out involve 'a real chase-round'. Their completeness depends on people knowing what checks are to be made and with whom. The clerical staff who carry out the checks do not always have this knowledge. The suggestion was raised during the Inquiry hearings that it might be possible to simplify the process and Sir Nigel Crisp said that the suggestion would be considered.

Non-principals

5.48 Non-principals are required to make the same declarations on their applications to join a PCT's list and have the same ongoing duty to declare criminal and disciplinary proceedings. PCTs are responsible for making checks on their qualifications etc., on an application to join the list. DoH guidance refers to the impracticability of making detailed enquiries about a non-principal's employment history and suggests that attention should be concentrated on any significant breaks in the career history.

Personal Medical Services Providers

5.49 Until the introduction of the new services lists, PCTs did not receive declarations from many doctors working under PMS contracts about criminal or disciplinary proceedings in which they had been involved. Nor could PCTs take action to remove or suspend a doctor performing PMS, a *lacuna* which could cause considerable difficulty. Such action was possible only if appropriate provisions were contained in the local PMS contract. Since February 2004, doctors providing PMS have been obliged to make the same declarations, and are subject to the same sanctions of removal and suspension from the list, as GMS providers.

Refusal to Admit

5.50 The 2001 Amendment Regulations also extended the grounds on which a HA could refuse to admit a doctor to its list. Previously, these had been very limited. A HA had been required to refuse entry to its list if the applicant lacked suitable experience, did not speak the English language sufficiently well, was 70 or over or had been disqualified by the NHS Tribunal. In addition, HAs had discretion to refuse admission to a doctor who had had conditions imposed on his/her registration by the GMC or who did not fulfil the criteria for the post. HAs could also refuse admission if they considered that, in the light of his/her declaration about past or ongoing criminal or disciplinary proceedings, a doctor was unsuitable: see paragraph 5.41

5.51 The 2001 Amendment Regulations made it mandatory for a HA to refuse to admit a doctor to its list in certain circumstances, the most important of which were:

- where s/he had been convicted in the UK of murder
- where s/he had (after 13th December 2001) been convicted of a criminal offence and sentenced to a term of imprisonment of over six months
- where s/he was the subject of a national disqualification by the Family Health Services Appeal Authority (FHSAA) in England or a comparable body elsewhere in the UK: see paragraph 5.54.

5.52 In addition, HAs were given discretionary powers to refuse entry to their lists if:

(a) they considered that the doctor was unsuitable for inclusion on the list by reason not only of the contents of his/her declaration about past or ongoing criminal and disciplinary proceedings but also by reason of any other information in the

possession of the HA, or by reason of the results of the checks made on his/her qualifications and/or registration

(b) having contacted referees, they were not satisfied with the doctor's references

(c) the facts relating to past or current fraud investigations by the NHS Counter Fraud Service (now the NHS Counter Fraud and Security Management Service) and any fraud case involving or relating to the doctor justified it

(d) they had grounds for considering that admitting the doctor to the list would be prejudicial to the efficiency of the service that s/he would undertake.

Statutory criteria, to be taken into account before reaching a decision on these issues, were set out. HAs were given the power to defer a decision in certain circumstances or to impose conditions on a doctor's inclusion on the list.

5.53 These powers are now exercised by the PCTs, which are required to notify to the FHSAA (SHA) all decisions to refuse admission or conditionally admit a doctor to their list.

The Family Health Services Appeal Authority

5.54 In December 2001, the NHS Tribunal was abolished and the FHSAA was created. Despite the similarity of name, the FHSAA is a different body from the FHSAA (SHA) (formerly the FHSAA), to which I referred at paragraph 5.46. The FHSAA is an independent tribunal, whose President and members are appointed by the Lord Chancellor. Appeals against the refusal of a PCT to admit a doctor to its list (save when the refusal was on mandatory grounds) are determined by the FHSAA. PCTs which refuse a doctor admission to their lists are advised to consider approaching the FHSAA, with a view to the FHSAA imposing a national disqualification on the doctor. In the past, a national disqualification did not necessarily mean that a doctor was disqualified from inclusion on all PCT lists. It was possible, for example, for the FHSAA to disqualify a doctor from all supplementary lists, but not other lists. In practice, this was rarely (if ever) done. Since the introduction of the medical performers list, the position has changed and any national disqualification (whether imposed before or after April 2004) applies to all medical performers lists.

The Effect of the Changes

5.55 The changes which I have described have enabled the PCOs (now the PCTs) to exercise real control over who is and who is not admitted to their lists. It is now the PCT (not the MPC) which determines whether there is a need for a new doctor or practice in its area. It is the PCT (after consultation with the LMC and any practice involved) which sets the criteria by which applicants for a vacancy are to be judged. These new powers have enabled some PCTs to develop a strategy for recruitment, tailored to the needs of their population and of GP applicants. This can be of particular assistance in deprived areas where recruitment is difficult.

5.56 The new system of declarations by applicants, and the requirement for PCTs to carry out more comprehensive checks on the information provided by applicants, should mean that PCTs are much better informed about any adverse past history of doctors applying for

inclusion on their lists. If a PCT decides to admit to its list a doctor with a criminal or disciplinary record, it can do so conditionally, and can design suitable conditions to be imposed on the doctor for the protection of patients. Where appropriate, it can refuse admission. Had Shipman's application to join the list in Tameside been made now, with these new provisions in place, the PCT would have been fully aware from the first about his criminal convictions. It could have enquired into the circumstances of them and into his progress since leaving Todmorden. It could have made its own decision as to whether it thought it appropriate to admit him to its list. If the PCT had decided to do so, it could have made special arrangements to monitor his prescribing. It could have advised the local police chemist inspection officer to scrutinise with care any relevant entries in pharmacists' controlled drugs registers. Above all, from the very start, it would have known far more about the person with whom it was dealing.

5.57 I described in Chapter 4 how, in 1992, Shipman was able to move easily to single-handed practice. He was already on the medical list, so few formalities were required. If the HA had been wholly opposed to the move, it could have refused the necessary funding. However, it might have had inadequate information about the doctor concerned (in this case, Shipman) on which to base an informed decision. Now, however, it would be open to the PCT to give careful consideration to the need for, and the desirability of, the formation of an additional single-handed practice and to the suitability of the applicant doctor. If the PCT was aware that the doctor concerned had a criminal and/or disciplinary record like Shipman's, it might be unwilling to enter into a contract with him as a single-handed practitioner. It would not be open to him, under the provisions of the new GMS Contract, to take with him his list of patients as Shipman did from the Donneybrook practice. It seems doubtful whether, if the present arrangements had been in place in 1992, Shipman's move to the Market Street Surgery would have taken place.

Doctors Already Included on a Primary Care Trust's List

5.58 The new provisions governing declarations by applicants for inclusion on PCOs' lists about any past criminal or disciplinary proceedings did not, of course, cover doctors who were already on the lists. It was evident that there might be doctors who, like Shipman, had criminal convictions or disciplinary findings against them of which the PCO was unaware. Therefore, the 2001 Amendment Regulations also contained a 'catch-up provision', requiring every doctor on a medical list to supply to the relevant HA by 31st March 2002 written information as to whether s/he:

(a) had any criminal convictions in the UK

(b) had been bound over following a criminal conviction in the UK

(c) had accepted a police caution in the UK

(d) had been convicted elsewhere of an offence, or what would have constituted a criminal offence if committed in England and Wales, or was subject to a penalty which would be the equivalent of being bound over or cautioned

(e) was currently the subject of any proceedings which might lead to such a conviction, and which had not yet been notified to the HA

(f) had been the subject of any investigation into his/her professional conduct by any licensing, regulatory or other body anywhere in the world, the outcome of which was adverse

(g) was currently the subject of any investigation into his/her professional conduct by any licensing, regulatory or other body anywhere in the world

(h) was, to his/her knowledge, or had been where the outcome was adverse, the subject of any investigation by the NHS Counter Fraud Service in relation to any fraud case

(i) was the subject of any investigation by another HA, or equivalent body, which might lead to his/her removal from any of that HA's lists, or any equivalent lists

(j) was, or had been where the outcome was adverse, subjected to an investigation into his/her professional conduct in respect of any current or previous employment

(k) had been removed from, contingently removed from, refused admission to, or conditionally included in any list or equivalent list kept by another HA, or equivalent body, or was currently suspended from such a list.

5.59 It will be appreciated that this declaration was more comprehensive than that which had been required since February 2000 to be made by applicants for inclusion on a list. In particular, it included action taken by a previous employer or PCO. At the same time, the declarations to be made before admission to the list were extended. If any of the above circumstances were declared, the applicant had to give details of the relevant investigation or proceedings. Doctors already on the medical list and new applicants to the list were required to give similar details in respect of any body corporate of which they were directors. The 2001 Amendment Regulations also required doctors to consent to the HA seeking information from third parties about any investigations into their conduct where the outcome had been adverse.

5.60 In addition, the 2001 Amendment Regulations imposed an ongoing requirement on doctors to inform the HA within seven days of a conviction, caution or binding over, or of the start of any proceedings or investigations of the type specified in paragraph 5.58(e)–(j) and any action by a HA of the type specified at paragraph 5.58(k).

5.61 Such declarations are now made to PCTs. There is to be a 'catch-up exercise', requiring all GPs already on a PCT's list to provide an enhanced criminal record certificate, unless one has already been provided. PCTs will require all GPs on their lists to apply to the CRB by 1st February 2005. Any GP who fails to comply with the requirement will be removed from the PCT's list. However, as it is expected that there may be some delay in processing the large number of applications, PCTs may allow an extension of time. At present, PCTs may require a GP to provide such a certificate if they have reason to believe that his/her declaration was not complete, but it is not a general requirement.

5.62 As from November 2003, GPs were required by their terms of service to report to the PCT any death occurring on their surgery premises. This duty is now placed on practices entering into the new GMS Contract. Since March 2004, GP practices have been required to keep registers of gifts with a value in excess of £100 given to members of the practice and doctors and other persons employed in the practice, together with their spouses or

partners, by patients, patients' families and business associates or potential business associates. Both these provisions were plainly designed with Shipman in mind.

Removal, Suspension and Contingent Removal from a List

5.63 I have already mentioned in Chapter 3 that, in 1977, the powers of a FPC to remove a GP from its list were very limited. That remained the position until 4th February 2000 when the 1992 Regulations were amended to make it mandatory for a PCO (then the HA) to remove from its list a doctor who had been convicted in the UK of murder, or had been convicted of a criminal offence and sentenced to a term of imprisonment of at least six months. This latter provision was later changed to a period of more than six months. In his supplementary statement to the Inquiry, Sir Nigel Crisp said that the original intention had been to limit mandatory removal from the list to those cases in which a sentence was passed exceeding the maximum sentence for an individual offence which could be imposed by a Magistrates' Court, i.e. to reflect the view taken by the judicial system of the seriousness of a particular offence. These provisions for mandatory removal were similar to those referred to in paragraph 5.51, governing the admission of doctors to the list.

5.64 The Health and Social Care Act 2001 conferred powers (and, in some circumstances, an obligation) upon HAs to remove a doctor from their list on the grounds that:

- the doctor's continued presence on the list would be prejudicial to the efficiency of the medical services which doctors on the list undertook to provide (an 'efficiency case')
- the doctor had been involved in an incident of fraud or attempted fraud (a 'fraud case')
- the doctor was unsuitable to remain on the list (an 'unsuitability case').

5.65 In an efficiency case or a fraud case (but not an unsuitability case), HAs were also given power to impose conditions on a doctor's continued inclusion on the list. If the conditions were subsequently breached, the doctor could be removed from the list. Thus, the imposition of conditions was termed 'contingent removal'. Conditions could be subject to a review. HAs were also given power to suspend doctors in certain limited circumstances, namely when it was necessary to do so for the protection of members of the public or was otherwise in the public interest.

5.66 A decision to remove a doctor from the list, or to impose conditions on his/her continued inclusion on the list, might be taken for a number of reasons. Those reasons might relate to prejudice to efficiency arising from the doctor's poor performance. They might relate to financial dishonesty or addiction to drink or drugs. A PCO might also decide to remove a doctor from its list by reason of information about a recent involvement in criminal or disciplinary proceedings which had been disclosed pursuant to the provisions described at paragraph 5.58. The 2001 Amendment Regulations set out criteria to be applied when removal was being considered on the grounds of unsuitability, fraud or prejudice to efficiency. One of the criteria to be applied in all cases is **'the likely risk to patients'** posed by the doctor's past conduct.

5.67 Appeal against a removal from a list went to the FHSAA. HAs were advised, if they took a decision to remove a doctor from their list, to consider approaching the FHSAA with a view to the imposition of a national disqualification. A provision was introduced whereby a doctor could not, except with the consent of the SoS, have his/her name removed from a medical list until any action by the HA on whose list his/her name appeared had been determined. This was to prevent a doctor from evading action by a HA by voluntarily removing his/her name from its list.

5.68 These powers have now devolved to the PCTs. They are now required to report to the FHSAA (SHA) (soon, the NHS Litigation Authority) decisions to remove, suspend or contingently remove a doctor from their lists.

The Effect of the Changes

5.69 The new powers available to control their lists represented a considerable advance in the ability of the PCOs (now the PCTs) to deal with problem doctors. No longer do they have to rely on other bodies (in particular, the GMC) to take action. If the protection of patients requires it, they can take urgent steps to suspend a doctor. If the problem is less acute, they can place conditions on his/her continued inclusion on the list, so as to secure patient safety and ensure the efficient delivery of services. Mr Greenwood said that the new provisions had 'transformed the system'. They had equipped PCTs with new powers and new sources of information. He believed these were essential if PCTs were to increase their ability to monitor GPs in the future.

5.70 Use of these new powers can, however, lead to the loss or restriction of a doctor's livelihood, and can damage his/her professional and personal reputation. They must be used responsibly and any action taken by a PCT must be based on sound and reliable evidence obtained in the course of a thorough and objective investigation. Otherwise, injustice may be done and decisions taken under the powers will be constantly subject to appeal and to challenge in the courts. That said, it is vital that PCTs develop the confidence and the skills to use the new powers when the situation demands it.

5.71 DoH figures show that, between 14th December 2001 (when GP list management was first introduced) and March 2003, PCTs reported to the FHSAA (SHA) 37 suspensions and nine removals from their lists, together with 16 contingent removals. Three of these removals followed the conviction of the GP concerned for criminal offences. No reasons for the action taken were available in the other cases. In addition, PCTs reported that they had refused 33 doctors inclusion on their lists and imposed conditions on inclusion in 49 cases. One refusal related to the fact that the doctor concerned had served a sentence of imprisonment. Other than in that case, no information is available about the circumstances giving rise to the refusals or the imposition of conditions.

5.72 Between 1st April 2003 and 31st March 2004, a further 22 suspensions were notified to the FHSAA (SHA). Including those extant from previous periods, there were 25 suspensions still in force as at 31st March 2004. In addition, there had been 25 removals from PCT lists and two contingent removals. Doctors had been refused admission to a PCT list on 21 occasions and had been included conditionally in 28 cases. There had been five successful appeals against PCT action and a further seven appeals remained

outstanding. No information is available to the Inquiry about the reasons for the actions taken by PCTs during the year to 31st March 2004. PCTs are not required to notify this level of detail to the FHSAA (SHA). It seems to me unfortunate that this information is not collected and analysed. It would assist in providing guidance to PCTs about the sorts of circumstances in which they should exercise their management powers. It would also enable evaluations to be carried out to discover whether PCTs are making adequate and appropriate use of their new powers. As of 31st March 2004, there were nine national disqualifications in force.

5.73 Unverified figures supplied by the FHSAA(SHA) for the six-month period to 30th September 2004 reveal that there were a further 27 suspensions during that period with 46 suspensions extant on 30th September.

Gaps Remaining in the Information Available to the Primary Care Trusts

5.74 There are still significant gaps in the information available to a PCT about GPs applying to, or already included on, its list. In particular, a PCT will not usually be aware of:

- complaints (even complaints of a serious nature) made by patients or others about a GP while s/he was on the list of another PCT or in employment elsewhere in the NHS or in the private sector. A PCT would be aware of such complaints only if they had been determined and had resulted in list management action by the PCT, or disciplinary action by the GMC or an employer. For example, an applicant GP who had been the subject of a series of unproven complaints of indecently assaulting patients would not have to declare that fact. The only circumstances in which the PCT might learn of his/her history would be if it were told informally, or if the police had investigated and a CRB check revealed that information.
- concerns about the doctor's performance expressed by colleagues, healthcare professionals or others. A PCT would be aware of such concerns only if they had resulted in list management action by another PCT, or disciplinary action by the GMC or an employer.
- under the GMC's 'old' fitness to practise procedures complaints made to the GMC about the doctor, unless the GMC took a decision to proceed with the complaint beyond the screening stage. Since August 2000, the GMC has been required to inform employers and PCOs about such complaints once that decision has been taken; that decision may be taken some time after the complaint is received by the GMC. If the complaint is not pursued, no notification will be given. The arrangements under the 'new' procedures should result in earlier notification of allegations made to the GMC. In addition, since May 2004, the GMC has adopted the practice of having early discussions with a doctor's PCO in some cases. Thus, the gap here is now not as great as it was.
- the past or ongoing involvement of the doctor in clinical negligence proceedings, whatever the outcome.
- complaints made to the GP's practice. Until April 2004, a practice was obliged only to inform a PCT of the numbers of complaints made. Under the draft Complaints

Regulations to be implemented shortly (see Chapter 7), there will be an obligation to inform the PCT of the subject matter of complaints. However, the PCT will not see the complaint itself and is reliant upon the honesty of practices in reporting complaints to it.

5.75 These gaps mean that PCTs may be unaware of information about GPs which is highly relevant to the protection of patients. If PCTs are to comply with their duty of quality and provide safe and effective local medical services, it is imperative that they be placed in possession of all available information about the GPs on their lists. In future, if and when PCTs are required to participate in the process of revalidation, by signing a certificate warranting that there are no unresolved significant concerns about the doctor, it may become even more important for PCTs to have full information about the GPs on their list. I shall describe the proposals for revalidation in Chapter 26.

Dealing with Poor Performance

The Development of Local Performance Procedures

5.76 I mentioned in Chapter 4 the introduction, in July 1997, of the GMC's performance procedures and the power which the GMC then acquired to suspend or impose conditions upon the registration of a doctor whose professional performance was found to be seriously deficient. The GMC would take action only in respect of those doctors whose performance was so seriously deficient as to call into question the doctor's registration. This was a very high threshold. It was recognised from the first that there would be doctors performing at an unacceptable standard who would not reach the GMC threshold but who nevertheless represented a real risk to patients. Local procedures had to be developed, therefore, to enable PCOs (then the HAs) to deal with such doctors.

5.77 In addition, the GMC would invoke its performance procedures only in respect of performance after 1st July 1997. Evidence of performance before that date, however unacceptable, could not be relied upon. The effect of this provision was that HAs were unable to refer to the GMC those GPs whose performance had been causing problems for years. Instead, they had to wait until sufficient post-July 1997 evidence could be accumulated. In the meantime, they were left to deal with poor standards of care by means of their own local procedures.

5.78 In 1997, the DoH commissioned the School of Health and Related Research at Sheffield University (ScHARR) to formulate guidance to assist HAs in developing arrangements for supporting GPs whose performance was giving cause for concern. The ScHARR guidance was published in September 1997. It was directed primarily at assisting HAs in tackling performance which was giving rise to some concerns, but not to concerns of such magnitude that a referral to the GMC was obviously appropriate. Unlike the GMC procedures, the guidance covered concerns about the performance of GP practices, as well as about that of individual GPs. The guidance recognised that there would be a few GPs whose performance was so poor that referral to the GMC would be necessary. However, it stressed that a HA making a referral to the GMC would have to demonstrate that it had first done all in its power to improve performance through the giving of appropriate support.

5.79 The ScHARR guidance gave advice about how, once a GP had been identified as under-performing, a HA could best support and assist him/her to raise his/her standard of performance to an acceptable level. The guidance emphasised, *inter alia*, the need:

- properly to diagnose the underlying problems which were causing the GP to perform poorly, and to address them
- to consider a wide range of possible interventions. These might include remedial or additional education and/or training, mentoring, measures to improve practice infrastructure (e.g. the provision of additional support staff, staff training or improved facilities), together with measures to address any health problems the doctor might have.
- to set up a clear management process, led by a senior manager, for responding to concerns about possible under-performance and for co-ordinating the response to those concerns, together with any necessary intervention or other action.

5.80 With the assistance of the ScHARR, pilot procedures for identifying and managing poor performance among GPs were developed and tested at six sites in the North West of England. One of these pilots was established by what was then the Manchester HA. A 'performance panel' was set up, comprising representatives from the HA, the LMC, the local community health councils and the local postgraduate education department. The panel considered cases where the HA had received expressions of concern about a GP from a minimum of three sources. The panel defined a 'concern' as a statement made by or on behalf of a patient, or by a professional, which suggested that a doctor's performance might fall below acceptable standards. Concerns might also come from HA staff as a result of information which was in their possession. The panel would then consider the concerns alongside background information about the doctor held by the HA. It would decide whether the evidence satisfied its criteria for poor performance. If the criteria were satisfied, two members of the panel would visit the GP by prior arrangement to discuss the concerns. The visiting team would then report back to the panel and a decision would be taken as to what, if any, action was necessary.

5.81 Action, if taken, would usually involve the preparation of a 'contract', incorporating a practice development plan and a timetable for implementation. The HA would arrange and fund a trained GP mentor to give support to the doctor if s/he wanted it. The HA might also provide administrative support and assistance if this were required. If a serious deficiency were identified, if the doctor failed to co-operate or if no improvement were effected, the doctor would be referred to the GMC.

5.82 From 1998, in the wake of the pilot projects, HAs began to set up similar arrangements. They approached their task in different ways. For example, some HAs responded (like the Manchester panel) to concerns brought to them by third parties. Others sought to identify doctors who might be performing poorly from the data routinely available to them. Not surprisingly, HAs experienced problems in investigating and assessing concerns about poor performance and in devising and implementing remedial measures once poor performance had been identified. This was new territory for the PCOs and there was uncertainty about how to operate the new procedures.

The National Clinical Assessment Authority

5.83 These problems were addressed in a Consultation Paper, 'Supporting doctors, protecting patients', published by the DoH in 1999. The paper proposed the establishment of a number of assessment and support centres, run jointly by the NHS and the profession. The centres would provide advice to NHS bodies on handling concerns about doctors (both hospital doctors and GPs), would carry out assessments with a view to identifying the nature and seriousness of any problem and would make recommendations for action. It would then be for the local employer (or the HA, in the case of a GP) to implement the recommendations and to provide any support and take any remedial action required. It was hoped that the development of assessment and support centres would allow specialist expertise to be developed and would replace the need for individual NHS bodies to carry out their own assessments of performance. In the past, these local assessments (mainly performed by NHS trusts) had proved very variable in quality.

5.84 The National Clinical Assessment Authority (NCAA) was set up in April 2001. Its form was different in some respects from the model described in 'Supporting doctors, protecting patients'. In particular, the proposal for local centres (which had been opposed by the profession on the grounds that they would resemble 'boot camps') was dropped. Instead, there was to be an administrative centre in London (there is now also one in Wales), with personnel located around the country. The NCAA is at present a special health authority, covering England and Wales, but not Scotland or (currently at least) Northern Ireland. It now deals with dental, as well as medical, practice in the NHS and in the prison and defence medical services. It does not cover the private sector. Under new arrangements, announced by the Government in the summer of 2004, the NCAA is to be subsumed into the National Patient Safety Agency, of which it will be a separate division.

5.85 Although its form was not as planned, the purpose of the NCAA remained similar to that originally envisaged. It was to provide a performance assessment and support service to assist NHS employers and HAs in resolving problems of poor performance. It receives referrals from a variety of sources, mainly NHS trusts and PCTs. As at the end of September 2004, the NCAA had received 1438 referrals. Since 2001, many PCOs have sought the advice of the NCAA. That advice is provided by a team of advisers. The advisers are senior clinicians or managers, located around the country, each covering certain SHA areas. The advisers liaise directly with the PCO and advise on the management of individual cases. If local resolution of the concerns cannot be achieved, the NCAA may agree to undertake an assessment of the doctor's performance. The decision whether or not to undertake such an assessment is for the NCAA to make. A PCO cannot compel the NCAA to intervene. From December 2001, GPs' terms of service were amended to impose a duty on a doctor to co-operate with an assessment by the NCAA when requested to do so by his/her PCO (now the PCT). Under the National Health Service (General Medical Services Contracts) Regulations 2004 (the 2004 Regulations), it is the duty of a practice entering into a GMS Contract to ensure that a doctor working in the practice co-operates with an assessment by the NCAA when requested to do so by the PCT.

5.86 The NCAA assessment is formative (i.e. educational), not summative (i.e. 'pass or fail'). Assessments are directed at ascertaining whether the doctor is 'fit for purpose', i.e. fit for

work in the setting in which s/he is currently working. If a doctor is not 'fit for purpose', s/he may nevertheless be competent to work in a different setting. The problem may, for example, be that s/he does not fit into the team at his/her place of work. Professor Alastair Scotland, Chief Executive and Medical Director of the NCAA, emphasised that 'fitness for purpose' is a very different concept from that of 'fitness to practise', i.e. fitness to practise as a doctor in any setting. Performance assessments carried out by the GMC are directed at fitness to practise, not fitness to practise in a specific setting. NCAA assessments are carried out by trained medical and lay assessors. The Inquiry has been provided with a report of a specimen assessment for information purposes. The first element of every assessment is an occupational health assessment. Its purpose is to ensure that the doctor is fit to go through the rest of the assessment. It also addresses the question of whether there are any features of the doctor's health which might impact on his/her ability to practise effectively in his/her current setting, or which might have an effect on his/her general wellbeing. The second element is an occupational psychology assessment, directed at exploring the doctor's preferred behaviours at work. Professor Scotland said that this was a particularly valuable exercise. It is his experience that, when a doctor is performing poorly, there is invariably a behavioural element which is playing a part. The assessment for GPs includes an assessment of basic knowledge, using a test developed by the Royal College of General Practitioners (RCGP). There is also a day's practice visit, which includes inspection of a sample of medical records and observation of the doctor in consultation.

5.87 A full report of the assessment, with recommendations, is sent to the doctor and the referring PCT. The NCAA will then work with both to assist in the development of a practical action plan to address the assessors' findings. The NCAA cannot compel compliance with its recommendations but, if a PCT neglects to implement them, the NCAA can raise the matter with the relevant SHA or with the DoH. It can also refer a doctor to the GMC if his/her performance appears to be putting patients at risk. Occasionally, the NCAA has felt it necessary to suspend an assessment in order to make an urgent referral to the GMC.

5.88 The PCT retains responsibility for resolving the problem and for putting in place any necessary remedial or supportive measures. This is usually done in conjunction with the postgraduate deans who are responsible for the provision of postgraduate medical education in their areas. Funding for such measures can be a problem, especially given the small size of PCTs. Professor Scotland told the Inquiry about steps which were being taken in an attempt to obtain funding from other sources to assist the PCTs in discharging this responsibility.

Current Local Procedures

5.89 Since PCTs replaced the HAs, responsibility for local performance procedures has devolved upon them. It is now customary for PCTs to adopt a two-stage process. The first stage is usually conducted by a committee or group of persons, including officers, managers and board members of the PCT and at least one representative of the LMC. Other people with appropriate expertise (e.g. a pharmaceutical adviser) may be co-opted as necessary. In Tameside and Glossop PCT, the relevant body is known as the Contractor Monitoring Group. The Group's function has been to discuss and consider the

reports of independent review panels (which were abolished in July 2004), together with complaints and expressions of concern about GPs and GP practices, and to consider these against a background of 'hard' information available to the PCT. Dr Jeffery Moysey, one of Shipman's former colleagues at the Donneybrook practice and vice-chairman of the LMC which serves Tameside, is a member of the Contractor Monitoring Group. He described how the Group discussed 'often rather intuitive, and often subjective concerns' about the performance of practitioners. He felt this was important as, in the future, this information might fit together and 'build up a jigsaw puzzle' which would alert the Group to aberrant behaviour by a GP. Having considered all the relevant information, the Group will then devise local action plans to support the GP and to assist him/her in achieving a higher standard of performance. If these efforts prove unsuccessful, or if there is a history of poor performance which has not been addressed, the doctor will be referred to a performance panel. Tameside and Glossop PCT also has a 'fast track' procedure for use when there are immediate and urgent issues of concern.

5.90 A PCT will either have its own performance panel or will share a panel with one or more other PCTs. Tameside and Glossop PCT has a panel comprising its Chief Executive, Clinical Governance Lead and Medical Director, three LMC representatives and a lay board member. The PEC Chairman also chairs the performance panel. The panel makes a preliminary visit to a doctor about whom concerns have been raised. Following that visit, the panel will decide whether an assessment is necessary. If an assessment takes place, it will result in a report and recommendations. The panel will then seek the doctor's co-operation in complying with the recommendations. If that co-operation is not forthcoming or if the remedial action recommended has no effect, the doctor will be referred to the NCAA or the GMC.

Problems with the Current System

5.91 Concerns have been expressed (for example, by Professor Roland and his colleagues in their report to the Inquiry) that panels serving only one PCT may see performance cases only rarely and may, therefore, be unable to accumulate sufficient expertise in dealing with such cases. There is also the problem of lack of independence and potential conflict of interest. Professor Roland advocates that performance panels should cover a larger area than that of one PCT or that there should be cross-cover between PCTs. There is also scope for inconsistency between panels in different areas of the country. Mr Michael Newton, Head of Performance Management, South Yorkshire SHA, and a NCAA adviser, told the Inquiry that the quality of local assessors and assessments was variable. There are no common standards against which local assessments are carried out. He believes that issues of performance are better and more quickly dealt with by small groups than by large performance panels. He favoured the establishment of teams of properly trained assessors who would carry out assessments on behalf of a number of PCTs. They would carry out assessments to a common protocol to ensure consistency. Mr Newton has been involved in the establishment of a local assessment service available to PCTs in South Yorkshire. A protocol has been produced and the scheme has been adopted in other areas. Mr Newton emphasised that an assessment team should provide a technical, professional service, which identifies concerns and makes recommendations for remedial

action. It is then for the PCT to decide what action should follow. Moreover, he said that it was essential for a PCT to satisfy itself about the evidence of poor performance. It might, at some future date, have to take a decision to remove or contingently remove a doctor from its list on the basis of that evidence. It is essential, therefore, that it has confidence in the evidence on which it is to rely.

5.92 The NCAA has carried out work with the aim of developing a method for local assessment of a doctor about whom there is a concern. In doing so, the NCAA has responded to requests from PCTs for guidance on how to set about conducting assessments themselves or in conjunction with other PCTs. The NCAA has reservations about whether it is practical for PCTs to carry out such assessments. It points out that the process of evidence gathering is complex and time-consuming. Assessors must be of a high calibre, carefully selected and well trained. There must be a system of quality assurance. If an assessment is not done to a high standard, it may not achieve its objective and may be open to challenge. The NCAA believes that the process of setting up and managing local assessments **'poses formidable and perhaps insurmountable challenges for a single PCT, or small groupings of PCTs, undertaking an assessment only very rarely'**. It advises that any PCT considering undertaking local assessment should seek advice from the NCAA before proceeding. It may be that an assessment is inappropriate and that a local investigation, or referral to the GMC, is required.

5.93 An alternative to a local assessment is an assessment by the NCAA. In fact, the NCAA has carried out relatively few assessments during the period of its existence. In the three and a half years between April 2001 and September 2004, the NCAA carried out 87 full assessments. Of those, 36 were assessments of GPs. Much of the NCAA's activity during this period was focussed on problems with hospital doctors, particularly those under suspension. Most requests for help from PCTs have been dealt with by giving advice, by supporting PCTs in the use of their local procedures and by assisting in resolving disputes. I have no doubt that the NCAA is a valuable source of advice and assistance to PCTs. One of its real strengths is its independence from PCTs and other NHS bodies, as well as from the doctor about whom concerns have been raised. Another is the enthusiasm and commitment of its Medical Director, Professor Scotland.

5.94 There has been disappointment on the part of some that the NCAA has not carried out more assessments. However, Professor Scotland said that the fact that comparatively few assessments had been carried out was not related to lack of time or resources. He said that the NCAA had carried out assessments in all those cases in which it considered that an assessment would be useful and appropriate. In the vast majority of cases, it had been possible to deal with the problem without the need for a full assessment.

5.95 It is theoretically possible for a GP who is eventually referred to the GMC to undergo three separate assessments – one conducted locally, one by the NCAA and a third by the GMC. This may not occur frequently, but it is certainly not unusual for a doctor to be assessed twice. This is wasteful of resources, as well as being unduly demanding and stressful for the doctor. Moreover, it can lead to very substantial delays, during which the doctor may continue in practice, with consequent risk to patient safety. Professor Dame Lesley Southgate, Professor of Primary Care and Medical Education, University College London,

drew attention to this problem. She emphasised the need for systematic collection of evidence locally. She said that local assessments should be carried out with the assistance of the deaneries and a decision taken as to whether remedial action seemed possible. She felt that the NCAA could assist with these local processes and could set national standards for the way evidence was gathered. If a judgement were taken that remedial action was likely to be unsuccessful, the GMC or some other body with the requisite experience could undertake a full assessment.

5.96 I shall deal with the potential for duplication between assessments by the NCAA and the GMC later in this Report. As for duplication with local procedures, there seems to be a move towards supporting and improving local performance procedures in order to enable PCTs to resolve their problems themselves, with advice – but not necessarily intervention – from the NCAA. Whether that move will produce assessments of a sufficiently high and consistent standard remains to be seen.

5.97 Particular problems arise with locum doctors. They may operate in the area of more than one PCT. They may not work in one place long enough for a pattern of substandard practice to be recognised and acted upon. The results of substandard practice may not be discovered until after their departure. If problems are experienced with a locum, a practice may not be inclined to employ him/her again. Having taken that decision, members of the practice may be inclined not to bring the locum's performance to the attention of the PCT. Even if they do, the PCT may be unwilling to take on the difficult task of investigating the doctor's poor performance. It may have little evidence on which to do so, especially if the locum has moved on to another area. If the matter is investigated and a need for remedial action is identified, it may be difficult for the PCT to arrange the necessary action. Problems of funding may also arise.

Maintaining Quality

5.98 The recent emphasis on quality of care has given rise to a corresponding increase of interest in ways of securing and maintaining good standards of medical practice. This has resulted in a number of initiatives aimed at assuring the quality of services provided by individual doctors and GP practices.

Individual Mechanisms

Summative Assessment

5.99 In the past, GPs underwent no specific training to equip them for their work in general practice. Qualification for inclusion on the medical register was considered sufficient preparation for their future role. Over time, some individuals began to undertake voluntary vocational training. However, it was not until 1981 that vocational training, consisting of at least a year spent as a GP trainee in an approved training practice, together with up to two years in educationally approved posts within a number of defined specialties, became mandatory.

5.100 Even after 1981, there was no formal assessment at the conclusion of vocational training by which the competence of the trainee could be tested and a decision taken as to

whether s/he was suitable to enter general practice. A certificate of satisfactory completion of training was all that was required. Between 1989 and 1992, only 0.26% of trainees failed to obtain such certificates. Entry to general practice was more or less guaranteed, therefore, upon completion of vocational training. Some doctors elected to take the RCGP's Membership examination within a short time of starting in practice. However, there was no obligation to do so.

5.101 For training purposes, the UK is divided on a regional basis into 22 deaneries. The deaneries are responsible for commissioning postgraduate medical education. They are based around each UK medical school. Responsibility for the provision and organisation of training within each deanery rests with the director of postgraduate general practice education. The organisation of training includes the accreditation of training practices which are subjected to detailed assessment visits every three years, together with continuous monitoring of the quality of the training provided. In England, just under 25% of GP practices have at least one approved trainer. Nearly 4000 GPs are approved trainers. Responsibility for overseeing the training of GPs currently lies with the Joint Committee on Postgraduate Training for General Practice, which conducts three-yearly monitoring visits to the deaneries. These visits include detailed assessments of training practices (conducted jointly with the RCGP) to ensure that standards of accreditation are being maintained. In the future (currently expected to be September 2005), responsibility for overseeing the training of GPs will be transferred to the Postgraduate Medical Educational and Training Board (PMETB), which also has responsibility for the training of hospital doctors.

5.102 In 1996, summative assessment for all GP trainees (now known as GP registrars) was introduced throughout the UK. This became mandatory on 30th January 1998 for all GPs practising in the NHS. There is no requirement that a GP practising in the private sector should have undergone vocational training or summative assessment. The components on which candidates for summative assessment are judged are:

(a) an assessment of knowledge and problem solving

(b) an assessment of consultation skills, judged by means of a videotape or simulated surgery

(c) a written submission of practical work, usually an audit

(d) a trainer's report.

The four components of the assessment are designed to reflect tasks which any independent principal in general practice should be able to perform competently. If a candidate fails one or more components of the assessment, s/he is given extra training to assist him/her to pass on the next occasion. There is no limit on the number of attempts a candidate can make, although funding may not be available for indefinite further training.

5.103 The knowledge and problem solving tests are administered and marked nationally. The trainer's report is compiled within the training practice. The other two components of the assessment are judged by trained assessors and calibrated by the deaneries. The National Summative Assessment Office carries out quality control of assessment results.

A recent review of summative assessments carried out between 1996 and 2001 revealed a disparity in the failure rates between deaneries, with rates varying between 1.1% and 10.1%. The system of summative assessment was designed to give patients the protection of knowing that all GPs completing vocational training would have had their competence assessed to a national standard. The disparity demonstrated in the review is worrying since it suggests that standards differ significantly from area to area. The authors of the review (representatives of two deaneries and of the National Summative Assessment Office) calculated that, if the failure rate in the deaneries with the lowest failure rates had been in line with the average, a further 40 GP registrars would have failed. That suggested that there might be 40 GPs from that period currently in practice who should not have been assessed as competent. The authors suggested that action was required to make standards more consistent.

5.104 At the Inquiry seminars, Dame Lesley Southgate, who is a member of the PMETB and the chair of its Statutory Assessment Committee, expressed the view that summative assessment in its present form was very likely to be abolished in future and that entry to a new GPs' specialist register would be governed by an assessment similar to that required for Membership of the RCGP: see below. She expected that this would lead to a raising of standards but also expressed the concern that the change might lead to tensions between the PMETB and the Government as the latter would be concerned about the provision of sufficient numbers of GPs to staff the NHS.

Membership of the Royal College of General Practitioners

5.105 The RCGP has developed a number of awards to mark excellence in individual doctors. Membership of the College by examination is usually undertaken just before or just after the end of a GP's vocational training. I have already explained that a GP registrar must undergo a summative assessment at the conclusion of his/her vocational training. Dr William Reith of the RCGP said that it was widely accepted that the level of attainment needed to pass the summative assessment was less than that required to secure Membership of the College. He attributed this primarily to the fact that the Membership examiners are a small group of well-trained individuals who impose consistent standards. He drew attention to particular differences between the two procedures in the assessment of the video recording of a candidate's consulting skills, an element common to both summative assessment and the Membership examination. The criteria applied by the RCGP are different from those for summative assessment. In addition, for the Membership examination, assessment of the video recording is carried out by trained individuals who specialise in that part of the examination. For the summative assessment, assessment of the video recording is carried out in the deaneries by a large number of doctors applying less consistent standards.

5.106 It is difficult to establish a precise pass rate for the Membership examination because it is modular in form and candidates can sit modules at different times. Historically, the pass rate was about 90% although, following the recent introduction of the modular format in place of the previous 'all or nothing' approach, one would expect the pass rate to have increased (as it is now possible for a candidate to fail a module and retake it). Also, the introduction of Membership by assessment of performance (see paragraph 5.109) means

that GP principals seeking Membership are likely to opt for that route, rather than for Membership by examination. These more experienced candidates tended to have slightly lower pass rates in the examination than their more junior colleagues, probably as a result of difficulties with examination technique. The fact that fewer of them are taking the examination will have tended to cause the pass rate to increase.

5.107 Of course, in comparing the pass rates for summative assessment and Membership of the RCGP, one is not comparing like with like. Candidates for the Membership examination are self-selecting. It is perhaps unlikely that the weaker recruits to general practice would choose to sit the examination. If all those who underwent summative assessment also sat the Membership examination, the gap between the pass rates for each would no doubt be considerably wider.

5.108 Dame Lesley told the Inquiry that the issue of the difference between the standard for summative assessment and the standard for the Membership examination had been debated over the years. The purpose of the two processes is different. Summative assessment is intended to establish that the candidate has attained a minimum standard for practice. The Membership examination is intended to establish the standard for high quality performance and entry to the RCGP. It is more academic in nature. One element of summative assessment is a report from the GP registrar's trainers, based on his/her observations of the GP registrar or practice. This is not a feature of the Membership examination.

5.109 Membership of the College by assessment of performance was introduced in 1999. It involves a searching assessment of a doctor's clinical abilities and practice. He or she must submit a video recording of consultations and some audit work and undergo a practice visit, including an inspection of medical records. By October 2004, 79 GPs had successfully completed Membership by assessment of performance and 194 were officially registered as working towards the qualification.

Fellowship of the Royal College of General Practitioners

5.110 Fellowship of the RCGP by assessment was introduced about a decade earlier than Membership by assessment. This is a very demanding qualification, requiring the demonstration of extremely high standards of care. Candidates must have been Members of the RCGP for at least five years before embarking upon their Fellowship. By October 2004, 289 GPs had successfully completed the Fellowship, and a further 16 were in the process of doing so. Because the qualification is so demanding, it has not attracted as many applicants as the College initially expected.

Practice-Based Mechanisms

Practice Accreditation

5.111 Practice accreditation is a process by which GP practices submit themselves to assessment of various aspects of their organisation by a visiting team. In England, it is a wholly voluntary process. There is no link between practice accreditation and GP appraisal.

5.112 Methods of practice accreditation began to be developed in the 1990s. Mr Newton told the Inquiry that, in 1998, the Sheffield HA, together with the Leicestershire HA, developed a practice accreditation scheme, the Commitment to Quality Programme (CQP). This scheme has been continued by the PCTs within the area of the South Yorkshire SHA, working in conjunction with PCTs from Leicestershire and Lincolnshire. After wide consultation, a number of standards of good practice were set. GP practices are required to meet these standards in order to secure accreditation. A senior PCT manager works with practices to assist them in preparing for their assessments. The formal assessment is carried out by a team of trained assessors who systematically audit all aspects of a practice's activity against the CQP standards. The teams may consist of two doctors or a nurse and a manager. A representative from the PCT accompanies the team on the assessment visit and has access to the assessment report. The assessment is practice-based and is not directed at assessing the performance of individual doctors. It does, however, include an examination of medical records, protocols and the personal development plans of GPs working in the practice. Reciprocal arrangements between PCTs mean that the assessment team can be drawn from outside the area of the practice being assessed. Accreditation lasts for three years, after which a further assessment is required in order to secure re-accreditation.

5.113 Mr Newton said that good GP practices have found the scheme very helpful. They use the standards as a checklist to ensure that they have proper systems in place. Even more encouraging, however, is the fact that many practices in deprived areas have joined the scheme. The PCTs provide support for practices to assist them in meeting the standards for accreditation and in making any necessary improvements. They operate a website from which practices can obtain *pro formas* for documents needed to comply with the standards (e.g. staff contracts of employment, confidentiality agreements, etc.) and other assistance. Mr Newton said that the CQP provides an excellent opportunity for PCTs to get to know the practices in their areas.

5.114 The RCGP has devised a programme, known as the Quality Team Development Programme, which is used by some PCTs and is similar in some respects to the CQP. Under the programme, PCTs carry out a preliminary audit of GP practices to see whether they meet the required standards. They then assist and support practices to improve in those areas where they fall below standard. There is no final assessment visit and no 'pass or fail'. The programme is intended to promote continuous quality improvement and, once again, is entirely voluntary.

5.115 During the time that the Quality Team Development Programme was being developed in England, the Clinical Standards Board for Scotland (now part of NHS Quality Improvement Scotland) had identified a need for a similar programme in Scotland, but with the added element of a formal assessment in order to secure accreditation. The Quality Team Development Programme was modified for use as a practice accreditation scheme, and the Clinical Standards Board endorsed the scheme as its preferred method of assuring quality in general practices in Scotland. The scheme is operated by RCGP Scotland.

5.116 Like the South Yorkshire scheme, the Scottish practice accreditation scheme is pitched at a level that any reasonable GP practice should be able to achieve. According to

Dr Hugh Whyte, Senior Medical Officer, Directorate of Health Policy and Planning, Scottish Executive Health Department, assessors look for evidence of, *inter alia*, clinical audit, critical incident analysis and clinical effectiveness. Assessors are trained and approved by the RCGP. They may be clinicians, practice managers, nurses or lay people. The assessment includes a random inspection of records and (unlike the South Yorkshire scheme) interviews with the doctors working in the practice. It also examines practice organisation. The assessors produce a report which is submitted to the relevant PCO. The report identifies strengths and weaknesses and makes recommendations for change. PCOs use these reports as part of their clinical governance strategy.

5.117 At present, the Scottish practice accreditation scheme is voluntary. By October 2004, 586 of the 1052 GP practices in Scotland had attained some form of accreditation (or were about to do so), either by means of this scheme or under the system for approving practices as suitable for training GP registrars. The latter system is more demanding than the practice accreditation scheme. All practices approved for training purposes should be able to attain accreditation comfortably under the practice accreditation scheme. The two schemes have now been linked, so that assessments for both are carried out simultaneously. The practice accreditation scheme is also linked with the system of appraisal in Scotland. GPs working in practices which have achieved accreditation will automatically be taken to have completed certain aspects of appraisal. There was a Ministerial commitment in Scotland that all practices would have achieved accreditation by the end of 2004. Whether this will be achieved (albeit later than originally envisaged), and what will happen if some GP practices decline to undergo the accreditation process, is not yet clear. There is no mechanism to compel co-operation. But it does not appear that there was any great resistance to the proposal. I think that this must be attributable to the determination and enthusiasm of the leaders of the profession and at Government level in Scotland. I am sure that there is also real enthusiasm within the RCGP in England but, as yet, this has not resulted in the same commitment by the profession as a whole. It may be that the difference is one of scale and that it is much more difficult to motivate a large body of professional people than a relatively small one. However, it seems to me that it would be very valuable if all GP practices in England could also be encouraged to meet the standards necessary for accreditation.

5.118 The RCGP also operates a Quality Practice Award which was described to the Inquiry as the 'gold standard' for accreditation. It was launched in 1997. As its name suggests, the Award is directed at the achievements of GP practices, not individual doctors. It demands high standards and culminates in a formal assessment to ensure that those standards are met. Dr Reith explained that the Quality Practice Award gives practices more opportunity to be creative. They are able to choose certain aspects of care, or special interests, and to provide more detailed evidence of expertise in those areas. By October 2004, 118 practices had attained it and 31 were working towards it.

5.119 To some extent, practice accreditation may have been overtaken by the terms of the new GMS Contract: see paragraphs 5.123–5.134. Under the Contract, practices will earn 'points' (and therefore additional remuneration) for meeting certain quality standards. Some of those standards are similar to those which must be attained in order to secure practice accreditation. It is possible that the need for separate accreditation schemes will

diminish in the future. For the present, however, the new Contract provides that GP practices accredited under the Quality Practice Award will be excused from providing evidence about certain aspects of their activities. It is intended that, in the future, other organisational quality schemes may be approved for a similar purpose.

The Value of Quality Markers

5.120 As several witnesses pointed out, practice accreditation schemes have limitations. They are directed at practices, not individuals. They focus on organisational factors, on systems of care and on measurable aspects of care. They do not test the skills of the doctor in the consulting room. Nevertheless, accreditation contains some elements relevant to the practice of individual doctors. Records are reviewed and staff are interviewed. Under the Scottish model, doctors are interviewed also. All these aspects may well reveal problems with a doctor's competence or performance, if such problems exist. In single-handed or small practices, the weakness of an individual doctor may be evident. In a large group, it may be more easily obscured. The evidence shows that poor practice organisation can frequently be symptomatic or causative of poor performance. Dr Reith pointed out also that practices and doctors may be performing poorly because they lack resources, are under-staffed or are operating in deprived areas. They may need help and support to provide a proper service. An assessment for the purposes of practice accreditation may reveal these types of problem and result in the necessary support being provided. Perhaps the most valuable aspect of an accreditation scheme, however, is that it provides an opportunity for assessors – whether from the PCT or elsewhere – to go into practices and observe at first hand how they are run and whether there are obvious problems with organisation, facilities or relationships. There are considerable benefits for practices also. Professor Richard Baker, Director, Clinical Governance Research and Development Unit, University of Leicester, observed that even the process of sitting down as a team and working out how to achieve the standard is a useful exercise. The problem is that, in England, participation in practice accreditation is entirely voluntary and has not had the boost of Ministerial commitment as in Scotland. Those practices that do not choose to participate can avoid the close scrutiny to which practices applying for accreditation are subjected.

5.121 Individual markers of quality are of real value in assessing the standard of a doctor's practice. Membership of the RCGP by examination indicates the attainment of a standard higher than that required by the compulsory summative assessment at the conclusion of GP vocational training. Membership by assessment of performance, which can be undertaken at any point in a GP's career, requires evidence of a high standard of clinical care. Fellowship of the RCGP by assessment demands real excellence. There is, however, no requirement for GPs to submit themselves to these examinations or assessments and a sizeable proportion (well over a third) of GPs do not. No financial reward is available for those acquiring these quality markers.

5.122 It is interesting to note that, despite his much-vaunted professional prowess, Shipman did not seek an optional qualification. He did not take the Membership examination. By contrast, he encouraged his practice staff to obtain appropriate qualifications and expressed pride when they did so. There was no practice accreditation scheme in

operation in the Tameside area during the time he practised there. Even if there had been, it seems highly unlikely that he would have participated. I do not think that he could have taken the risk that a random inspection of his records might cause someone to question the care of his patients. His staff, if interviewed, might have spoken about the high level of deaths among patients in the practice or about deaths which had occurred in the surgery. While accreditation is not directed at detecting aberrant behaviour by individual doctors, it is possible that, if accreditation were compulsory, the mere knowledge that their practice would be placed under close scrutiny would serve to some as a deterrent against such behaviour and to others as an incentive to improve.

The 2004 General Medical Services Contract

5.123 The new 2004 GMS Contract was implemented on 1st April 2004. From that date, PCTs were placed under a new duty to secure the provision of primary medical services. These services can be commissioned by four routes: by GMS, by PMS, by alternative providers (e.g. the voluntary sector, commercial providers, NHS trusts or other PCTs) or by direct provision by the PCT itself.

5.124 A contract to provide GMS is made between a PCT and a practice with at least one GP provider of services. A contract is no longer between a PCT and an individual GP. The contracting practice may be a single-handed practice, a partnership or a certain type of limited company. Patients now register with a practice, rather than with an individual GP. At the time of registration, they are asked to name a preferred practitioner within the practice.

5.125 Contracting practices are under an obligation to provide 'essential services' during 'core hours'. They can opt out from providing 'additional services' (i.e. cervical screening, contraceptive services, adult and childhood vaccinations and immunisations, child health surveillance, maternity medical services and minor surgery). From 1st January 2005, practices can also opt out from providing out of hours services. Where a practice chooses not to provide certain additional services, or out of hours services, it is the responsibility of the PCT to commission others to provide those services.

5.126 The new Contract is designed to encourage practices to develop different ways of working, using an increased mix of professional skills. For example, a practice may decide to employ more nurses to carry out some of the functions previously carried out by doctors. Practices might also make greater use of employed (possibly part-time) GPs. It is no doubt hoped that this will ease, to some extent, the problem of inadequate GP numbers. The opportunity to opt out of providing out of hours services is intended to make the job of a GP more attractive and thereby to help GP recruitment and retention.

5.127 From 1st April 2004, the GP terms of service, and the disciplinary mechanisms invoked (rarely) in the event of a breach of those terms of service, ceased to have effect. The new Contract arrangements are governed by the 2004 Regulations. The Schedules to the Regulations set out the obligations on practices that enter into the Contract. Under Schedule 6, such a practice is obliged, *inter alia*:

- to have in place an effective system of clinical governance

- to carry out its obligations under the Contract with 'reasonable skill and care'
- to operate a complaints procedure in accordance with the NHS complaints procedure and to provide the PCT at such intervals as required with information about the number of complaints received
- to co-operate with any investigation of a complaint by a PCT or the Healthcare Commission
- to hold adequate professional indemnity insurance
- to ensure that those performing services within the practice are suitably qualified, are competent, have the necessary clinical experience and training and are registered (where appropriate) on the PCT's list
- to ensure that those performing services within the practice have arrangements in place to maintain and update skills and knowledge
- to ensure that GP performers participate in appraisal
- to ensure compliance with a NCAA assessment when required to do so by the PCT
- to provide suitable premises
- to allow persons authorised by the PCT to enter and inspect the practice premises
- to keep adequate patient records and ensure patient lists are kept up to date
- to have arrangements in place for effective infection control and decontamination.

5.128 The sanctions available to a PCT where a contracting practice fails to discharge its obligations are set out in the 2004 Regulations. In certain circumstances, a PCT can terminate a GMS Contract. If a contracting practice breaches the terms of the Contract and the breach is capable of remedy, the PCT can give notice to the practice, requiring it to remedy the breach within a certain period. Where a breach is not capable of remedy, the PCT may serve a notice, requiring the practice not to repeat the breach. If the breach is repeated, or further breaches occur, the PCT may terminate the Contract. A PCT can do this only if satisfied that the cumulative effect of the breaches is such that it would be prejudicial to the efficiency of the services provided to allow the Contract to continue. Other sanctions (e.g. termination or suspension of specified obligations under the Contract, or the withholding or deducting of monies payable under the Contract) are also available.

5.129 The significant difference under the new mechanism is that such sanctions as the withholding of payments can be applied only to the contracting party and not (unless s/he is a single-handed practitioner) to individual GPs. However, it is perhaps reasonable to suppose that a doctor whose conduct causes, or might cause, the practice as a whole to suffer a financial or other type of penalty may be under a certain amount of pressure from his/her colleagues to mend his/her ways. The DoH points out that, under the GMS Contract, a contractor is fully responsible for any failure to exercise reasonable care and skill by any person performing services under the Contract. Any contractor who does not deal appropriately with a failure by a doctor employed by the practice could therefore

place at risk the entire Contract. PCTs will also retain their powers to remove, contingently remove and suspend practitioners from their lists.

5.130 The new Contract introduced a new quality and outcomes framework (QOF), a system of financial incentives designed to encourage practices to achieve certain quality standards. A significant amount of a practice's remuneration will potentially be linked with the QOF. The Contract contains 146 indicators, which, if attained, carry 'points' which represent additional payments. Practices can select indicators that they will attempt to attain. The indicators relate to:

- the clinical domain (covering such areas as the prevention of coronary heart disease, treatment of diabetes, etc.)
- the organisational domain (covering such areas as patient records and practice management)
- the patient experience domain (covering length of consultations and patient surveys)
- the additional services domain (covering cervical screening, child health surveillance, maternity services and contraceptive services).

5.131 Data on 'quality achievement' is communicated by practices to PCTs by means of computer links. The operation of the QOF is reliant largely on the honesty of the contracting practice. Some checks will be made to prevent fraud, but there will be a large element of trust in the operation of the system. PCTs will undertake annual reviews of all contracting practices, using trained assessors. Among the assessors will be GPs, PCT managers and patient representatives. ScHARR has advised the DoH on the procedures to be followed at such reviews. The DoH has issued preliminary guidance to PCTs on the recruitment of assessors. Practices will be required to submit evidence in advance of the review. Assessors will have access to medical records in order to check achievement against the QOF. Inspection of the records will be subject to a code of practice. It seems likely that the inspection will be limited in extent and purpose, as was the case with post-payment verification, which I referred to in Chapter 4. It is not intended that concerns about a doctor's performance should be dealt with at an annual review.

5.132 The linking of payment to indicators of quality modifies the previous system whereby payment was more closely related to the number of patients on a GP's list. The change will not, however, result in any loss of income (in the short term at least) for practices which retain large lists and do not participate in the QOF. The DoH has guaranteed that no practice will suffer a loss of income as a result of the changes to the GMS Contract.

5.133 The Contract is in its early days and it is impossible to assess with any confidence the impact it is likely to have on the quality of patient care. There is some concern that the fact that practices will be encouraged to concentrate their efforts on meeting the quality indicators identified in the Contract might lead to neglect of important aspects of care (such as continuity of care) that are not included. Moreover, the quality indicators do not cover some of the most important aspects of 'doctoring' such as consultation skills and accuracy of diagnosis. The Contract should have the effect of increasing significantly the amount of data available to PCTs about practices which participate in the QOF. It remains

to be seen whether that data will be of real use in assessing the quality of care given to patients. The annual review will provide an opportunity for PCTs to get inside GP practices and to examine certain aspects of them. The value of this exercise will depend on the precise form the reviews take and on the skills and expertise of the assessors concerned. It is not clear at present how closely practices will be scrutinised. Another unknown factor is the extent, if any, to which practices where the standards of care may be poor will choose to participate in the QOF and the provision of additional services.

5.134 It is expected that PCTs will seek to measure performance on PMS contracts by reference to the same framework as under the new GMS Contract. Since PMS contracts will continue to be negotiated locally, the effect of this remains to be seen.

Conclusions

5.135 In this Chapter, I have described briefly some of the major developments in the arrangements for monitoring GPs that have occurred since Shipman's arrest in September 1998. There have been other changes too, which I shall refer to later in this Report. Some of these developments have occurred as a direct result of Shipman's crimes, although their application extends much further than an attempt to protect patients against a murderous doctor. It is clear that the landscape in which general practice is conducted now is significantly different from that of six years ago. There have also been alterations in the way that many GPs work. The increase in the number of GPs in direct employment with PCTs and working under PMS contracts has given PCTs more ability to 'manage' them. How successfully that will be achieved remains uncertain. In any event, there is still a large population of GPs working as independent contractors and not readily susceptible to the management or control of the PCT. It remains to be seen whether the new GMS Contract will give PCTs greater opportunities for monitoring and regulating the quality of primary medical care and, if it does, whether those opportunities will be used effectively. PCTs now have access to more information about GPs and are more likely to be aware of doctors who are aberrant in some way. In an extreme case, they can remove a doctor from their list. It seems to me that, at least in theory, all these changes are for the good. However, they impose an immense burden upon PCTs, which are, as I have said, small and 'young' organisations. It is likely, in my view, that the success attending these new measures will be variable.

5.136 If these new measures had been in operation during the time when Shipman was practising, would he have been prevented or deterred from killing patients or would he have been detected if he had done so? Certainly, the PCT would have known about his background and could have refused him admission to the list. It could have imposed conditions upon his inclusion which would have allowed close supervision of his practice in respect of controlled drugs. However, I do not think it likely that such arrangements would have deterred Shipman from killing. Nor would the current arrangements have greatly enhanced the prospects of his detection. In subsequent Chapters, I shall consider whether there are other measures which should be taken to monitor GPs. In particular, I shall consider how a complaint or concern about a doctor should be investigated and whether, once an aberrant doctor has been identified, adequate steps are being taken to

restrict his/her professional activities or remove him/her from practice, and thus to prevent unacceptable risk to patients.

CHAPTER SIX

Complaints and Discipline prior to April 1996

Introduction

6.1 I have already observed that one element of the local governance of general practitioners (GPs) was the disciplinary process initiated and executed at local level. Soon after the inception of the Inquiry, I learned that, following complaints by patients, Shipman had been disciplined on two occasions by the primary care organisations responsible for Tameside, in 1990 and 1993. Before describing the circumstances giving rise to those complaints and the disciplinary proceedings that followed, I shall explain the legislative and procedural background at the relevant time.

General Practitioners' Terms of Service

6.2 As I have explained in Chapters 3 and 4, between 1974 and September 1990, family practitioner committees (FPCs) were responsible for administering the arrangements for primary care. In September 1990, FPCs were replaced by family health services authorities (FHSAs). GPs were not in a direct contractual relationship with the FPC or FHSA but operated instead under the General Medical Services (GMS) Contract, a national agreement with Government. The FPC/FHSA administered the local operation of the GMS Contract. Under the provisions of the National Health Service (General Medical and Pharmaceutical Services) Regulations 1974 (the 1974 Regulations), the arrangements made by FPCs (later the FHSAs) with doctors for the provision of general medical services had to incorporate the GPs' terms of service.

6.3 The GPs' terms of service covered a wide range of topics, but in the specific context of complaints they provided as follows:

> **'General**
>
> **3. Where a decision whether any, and if so what, action is to be taken under these terms of service requires the exercise of professional judgement, a doctor shall in reaching that decision not be expected to exercise a higher degree of skill, knowledge and care than general practitioners as a class may reasonably be expected to exercise.'**

This paragraph set the standard by which the doctor's conduct was to be judged as that reasonably to be expected of the reasonably competent GP.

6.4 The terms of service relevant to the subject matter of the complaints made against Shipman were as follows:

> **'Service to Patients**
>
> **13. Subject to paragraph 3, a doctor shall render to his patients all necessary and appropriate personal medical services of the type usually provided by general medical practitioners. He shall do so at his practice premises or, if the condition of the patient so requires,**

elsewhere in his practice area or at the place where the patient was residing when accepted by the doctor ... the doctor shall not be required to visit and treat the patient at any other place. Such services include arrangements for referring patients as necessary to any other services provided under the Health Service Acts and advice to enable them to take advantage of the local authority social services ...

14. A doctor shall, unless prevented by an emergency, attend and treat any patient who attends for the purpose at the places and during the hours for the time being approved by the Committee ...'

and

'Records

30. A doctor shall –
(a) keep adequate records of the illnesses and treatment of his patients on forms supplied to him for the purpose by the Committee, and

(b) forward such records to the Committee on request as soon as possible, and

(c) within 14 days of being informed by the Committee of the death of a person on his list and in any case not later than one month of otherwise learning of such a death, forward the records relating to that person to the Committee.'

6.5 The wording above is taken from the 1974 Regulations but it remained essentially unchanged in the later Regulations. In April 1990, some changes were made to the 1974 Regulations upon the coming into force of the National Health Service (General Medical and Pharmaceutical Services) Amendment (No. 2) Regulations 1989. However, these changes were not of significance for the purposes of this Chapter. The National Health Service (General Medical Services) Regulations 1992 consolidated and amended the 1974 Regulations and set out new terms of service which were also largely unchanged.

The Framework of the Complaints and Disciplinary System

6.6 By the National Health Service (Service Committees and Tribunal) Regulations 1974 (the 1974 Service Committees Regulations), FPCs (and later FHSAs) were required to set up service committees for each contractor service to investigate complaints of alleged failures to comply with the terms of service. The 1974 Service Committees Regulations were the subject of numerous amendments, particularly by the National Health Service (Service Committees and Tribunal) Amendment Regulations 1990. The National Health Service (Service Committees and Tribunal) Regulations 1992 consolidated the earlier Regulations and amendments and made further amendments. These Regulations governed complaints received after 1st April 1992 and continued in force until 1996.

Informal Procedures

6.7 Not every complaint received by a FPC/FHSA contained an allegation capable of amounting to a breach of a GP's terms of service. Complaints not containing such allegations could not be referred to a service committee but they might be amenable to informal resolution, by discussion between the parties, which would have the effect of restoring the relationship of trust and confidence between doctor and patient. Some complaints, even those which might amount to an allegation of a breach of terms of service, were not apparently very serious and it might appear inappropriate for them to lead to formal disciplinary proceedings. In such cases, an officer of the FPC/FHSA might seek to resolve the complaint informally through discussion, provided that the complainant consented. Prior to 1990, there were no centrally or officially directed informal complaints procedures. Different areas had different arrangements which had evolved locally.

6.8 The position changed in 1990. On 7th March 1990, the Secretary of State for Health (SoS) gave directions to FPCs to establish conciliation processes. The procedure to be followed depended on the apparent seriousness of the patient's complaint. For less serious matters, an officer of the FPC (after September 1990, the FHSA) would try to resolve the problem in correspondence. For more serious cases, the matter could be referred to conciliation. Lay conciliators were appointed who were accountable to the FPC/FHSA, and each FPC/FHSA, after consultation with the local medical committee (LMC) for its area, drew up a list of professional advisers to whom the lay conciliators would have access. Guidance was given as to the types of case that were not suitable for these informal procedures and should be dealt with by the more formal medical service committee (MSC) procedure. Potentially serious breaches of terms of service were to go to the MSC. These included such complaints as an allegation of a failure to respond to a patient's repeated requests to visit, an allegation that the doctor had failed to relieve severe pain in terminal illness or a complaint that the patient had been unable to contact the doctor.

Formal Procedures

Dealing with a Complaint

6.9 If a complaint against a GP was received from, or related to, a patient who was or had been entitled to receive general medical services from a GP on the FPC/FHSA's list, and if the complaint appeared to amount to a potential breach of the GP's terms of service, it would be referred to the chairman of the FPC/FHSA's MSC. As a rule, the complaint had to be made by the patient or by another with the patient's authority. However, if the patient had died or was under the age of 16 or was incapable, by reason of old age, sickness or other infirmity, of making the complaint him/herself, a complaint could be made by another person. Complaints had to be made within eight weeks (from 1990, 13 weeks) of the event giving rise to the complaint, unless the MSC was satisfied that the failure to give notice of the complaint in time was occasioned by illness or other reasonable cause and provided also that the GP or the SoS consented to the investigation of the complaint out of time. From 1992, the functions of the SoS were delegated to the Family Health Services Appeal Unit (FHSAU).

6.10 Although no such specific procedure existed before 1990, if, after 1990, the substance of the complaint did not sufficiently appear from the written statement of the complainant, the FPC/FHSA had to request the complainant to provide such further particulars as the FPC/FHSA reasonably required.

6.11 The MSC consisted of a chairman, three lay members of the FPC/FHSA and three practitioner members appointed by the LMC for the area. In practice, in Tameside, the LMC nominees were LMC members. The position of chairman could not be filled by a doctor, so, in practice, chairmen were lay members of the FPC. Another lay member of the committee would be designated as deputy chairman.

6.12 A decision whether a complaint should be accepted for investigation was taken by the chairman of the MSC. If s/he decided that the complaint disclosed reasonable grounds to believe that the doctor had breached his/her terms of service, an officer of the FPC/FHSA would send to the GP the written statements of complaint and (after 1990) details of the terms of service alleged to have been breached. The GP had to submit his/her written response within four weeks, or longer if agreed by the MSC. Where a response was received from the GP, the FPC/FHSA copied this to the complainant and invited his/her written observations within 14 days, or longer if agreed.

6.13 The chairman of the MSC would then decide whether an oral hearing should take place. In general, an oral hearing would be directed where there was an apparent conflict of evidence between the complainant and the GP. If there was no such conflict, the chairman could direct that the matter be considered by the MSC without an oral hearing. An officer of the FPC/FHSA would usually seek to ensure that any relevant medical records were available. He or she would also give notice to the parties (i.e. the complainant and the GP) of the meeting of the MSC at which the matter was to be considered and of particulars of the breaches alleged. If there was to be an oral hearing, the parties were required to submit any documentary evidence and the names of any witnesses. It was a matter for the parties what evidence was adduced.

The Medical Service Committee Hearing

6.14 A meeting of the MSC would be convened to deal with the consideration of one or more complaints. All members of the committee might attend but often this proved impossible. After 1990, the quorum required to hear a complaint was a chairman (or deputy), two lay members and two medical members. Before 1990, three members could constitute a quorum, provided that there was at least one lay and one medical member present. A duly authorised officer of the LMC could attend. One or two authorised officers of the FPC/FHSA would attend to assist the committee. The complaint might be dealt with on the papers or after an oral hearing. Oral hearings were conducted on an adversarial basis and followed the procedure of a civil trial. They were held in private but the parties could attend until the deliberation stage was reached. A party could be accompanied by someone to assist in the presentation of the case but, if that other person was a barrister or a solicitor, s/he could not address the committee or question witnesses. Usually, a representative of the GP's medical defence organisation would appear on his/her behalf. Sometimes, the complainant had the assistance of someone from the local Community Health Council

(CHC). The role of advising and supporting complainants throughout the whole complaints process, was an adjunct to the CHCs' main function, which was to provide a focus for public consultation on a wide range of health issues. However, it was a role that many CHCs appear to have filled very effectively.

6.15 If a new allegation, relevant to the complaint under consideration, was introduced in the course of the hearing, the chairman had to decide whether it should be admitted. Such a new complaint could be admitted only if it had been made within the time limit. If a new complaint was admitted out of time, the whole proceedings were liable to be declared void on appeal.

6.16 After the evidence and the submissions of the parties (if any), the committee would deliberate on its findings of fact and conclusions as to whether there had been a breach. Until this stage, members of the committee would have been told nothing of the GP's past disciplinary record. If they found that a breach had occurred, they would be told of any breaches found against the doctor in any MSC report made within the preceding six years before being asked to consider what penalty to recommend to the FPC/FHSA. At the end of the proceedings, the committee would instruct an officer of the FPC/FHSA to write a report on the evidence, findings and recommendation as to penalty, if any.

6.17 If a party failed to attend, the case might be adjourned but it could be concluded without a hearing. After 1990, if the complainant refused to attend or failed to confirm that s/he intended to attend, the MSC could report on the complaint without holding a hearing. Unless the GP consented to disposal without a hearing, however, the report could not contain any recommendation adverse to him/her.

6.18 For cases in which the FPC/FHSA itself wished to bring a complaint against a GP, the matter could be referred to the MSC of another FPC/FHSA. This would usually arise where the complaint did not affect a specific patient, e.g. in a case of fraud. This arrangement was also available in cases in which it was thought desirable for other reasons. An example would be if the GP complained against was a member of the MSC or was personally known to members of the MSC for the area in which s/he practised.

6.19 The MSC was not bound by the strict rules of evidence. The Department of Health and Social Security (from 1988, the Department of Health (DoH)) issued guidance notes about various matters, including the admissibility and weight of certain types of evidence. In summary, the MSC had a broad discretion as to whether it should hear or look at any particular evidence and what weight to attach to it.

The Medical Service Committee Report and Penalties

6.20 Prior to 1990, the MSC's report had to state its findings of fact and the inferences drawn. From 1990, the report additionally had to provide the committee's reasons for drawing such inferences. The report was presented to the FPC/FHSA. If the MSC found that the doctor was in breach of his/her terms of service, the MSC might recommend that previous breaches of the doctor's terms of service should be taken into account. After 1992, the report also had to contain details of the material evidence received, all findings of fact, the reasons for any inferences drawn and the recommendations for action by the FHSA.

6.21 The FPC/FHSA considered the report. It was bound by the MSC's findings of fact and had to give reasons for any departure from its recommendations. On penalty, the FPC/FHSA could, in accordance with the Regulations:

(a) impose a limit on the number of patients included in the GP's list. This would be recommended where it was concluded that the doctor was, because of his/her large list, unable to give an adequate service to all the patients on his/her list

(b) (before 1990) recommend to the SoS that the GP should pay any expenses incurred by the patient by reason of the breach of terms of service and/or that an amount should be withheld from his/her remuneration; (from 1990) itself determine that the GP should pay any expenses incurred by reason of the breach of terms of service and/or determine that an amount not in excess of £500 should be withheld from the GP; in relation to amounts in excess of £500, even after 1990, the FPC/FHSA could only recommend to the SoS, and could not determine, that there should be a withholding

(c) make representations to the NHS Tribunal that the continued inclusion of the GP in its medical list would be prejudicial to the efficiency of the services in question; in other words, recommend that the GP be removed from the medical list

(d) (before 1990) recommend to the SoS that the GP should receive a warning to comply with his/her terms of service more closely in the future; (from 1990) itself determine that s/he should receive such warning

(e) (from 1992) send any documents connected to the complaint to the General Medical Council (GMC). Prior to 1992, this had been considered unnecessary because the SoS was supposed to report appropriate MSC cases to the GMC on the recommendation of a body known as the Medical Advisory Committee (MAC), which I shall describe below. Guidance notes issued to FHSAs by the DoH had appended to them guidance, previously drawn up for the MAC, as to the types of case that should be reported. The guidance for the MAC referred to the April 1987 edition of the GMC publication 'Professional Conduct and Discipline' (known as the Blue Book; see Chapter 17), but also made clear that any misconduct regarded as **'seriously prejudicial to the medical care of patients'** should be reported.

Appeals to the Secretary of State for Health

6.22 Both the doctor and the complainant had a right of appeal to the SoS in respect of any adverse determination. Thus, either party could appeal against a finding that a breach had or had not occurred, against a decision on the extension of a time limit or against a sanction imposed by the FPC/FHSA. In 1992, the SoS devolved those appellate functions to the FHSAU, which was set up at the Yorkshire Regional Health Authority. This body would also hear cases that were referred to it because the recommended sanction was a withholding of over £500 and required endorsement by the SoS. On 1st April 1995, the FHSAU was established as a Special Health Authority and changed its name to the Family Health Services Appeal Authority (FHSAA); in November 2001 its name changed to the Family Health Services Appeal Authority (Special Health Authority) (FHSAA (SHA)).

6.23 The SoS's delegated functions were exercised by an officer of the FHSAU or, later, the FHSAA and FHSAA (SHA). In practice, therefore, appeals were determined by the Chief Executive or his/her deputy. If the Chief Executive was of the view that it was necessary to resolve conflicts of evidence, s/he could appoint a panel to conduct an oral hearing. The panel would comprise a barrister or solicitor as chairman and two doctors, one from a panel nominated by the British Medical Association (BMA). The panel conducted the oral hearing but reported back with a recommendation as to whether or not there had been a breach; the Chief Executive or his/her deputy made the final decision.

6.24 The Chief Executive had the power to seek advice and a recommendation from the MAC and was specifically required to do so in the case of specified failures to comply with terms of service (broadly speaking, those involving the exercise of clinical judgement). According to Mr David Laverick, who was Chief Executive of the FHSAA from 1st October 1995 until 31st August 2001, it was his practice always to involve the MAC although his predecessors probably did so, according to his evidence, only when specifically required to do so by the Regulations. The MAC comprised six members, who were appointed by the SoS. The Chairman and his/her deputy were to be doctors of no less than ten years' standing, selected by the SoS after consultation with the BMA. Of the remaining five members, three were chosen from a BMA panel of about 24 doctors and the others from a panel selected by the SoS.

6.25 When Mr Laverick arrived in post, he was concerned about what appeared to him to be inconsistencies in the recommendations made by the MAC in apparently comparable cases. He was also concerned that the doctors on the MAC seemed to see themselves as advocates for the GP under review. As a result, Mr Laverick sought to introduce guidance as to the amount to be withheld in different types of case. For a very minor first breach of the terms of service, he suggested that the appropriate penalty would be about £250. Where there was a relatively serious first breach, the figure would be around £750–£1000. In relation to second or third breaches or cases with a clear lack of care or disregard for the NHS, Mr Laverick suggested that the penalty should be a recovery in the range of £1500–£3000 depending on the circumstances. After the introduction of the guidelines, Mr Laverick said that the recommendations of the MAC became more consistent and he felt able to follow them in about 90% of cases.

6.26 In some cases the FHSAU/FHSAA would refer cases to the GMC. Mr Laverick's recollection was that, when he arrived in 1995, there were criteria in place which had originated from the GMC, whereby the FHSAA was to notify the GMC of any finding of a breach of what was then paragraph 12 of the terms of service (the obligation to provide personal medical services of the type usually provided by GPs) and also of any withholding of more than £750. After his arrival, Mr Laverick had discussions with representatives of the GMC at which he sought to enlarge, in the face of some opposition from the doctors' representatives, the categories of case that were being reported beyond those cases where there had been a finding of a breach of terms of service. His view was that a wider range of cases involving clinical shortcomings should be reported. He said that his view prevailed and that, thereafter, the FHSAA reported cases involving such issues as a doctor's failure to recognise the limits of his/her professional competence, to

keep professional skills and knowledge up to date, to keep adequate patient records, to take an adequate history or to perform a competent physical examination.

Appeals to the Health Service Ombudsman

6.27 In 1973, the office of the Health Service Ombudsman (also known as the Health Service Commissioner) was created. The Health Service Ombudsman looks into complaints made by or on behalf of people who have suffered because of unsatisfactory treatment or service by the NHS. He or she is independent of the NHS and the Government and his/her services are free. However, until 1st April 1996, the Ombudsman had no jurisdiction over complaints about GPs.

Complaints Made against Shipman: 1985 to 1993

6.28 The Inquiry investigated complaints made against Shipman primarily in an attempt to see whether the system of complaints in operation at the material times was capable of revealing or providing clues about his criminal activities. As will be seen, I have concluded that none of the complaints that were determined by a MSC provided much of a clue as to Shipman's true nature. However, I have decided to set out the circumstances of these complaints because their examination illustrates some of the shortcomings of the system and also throws light on what is needed in any system for the satisfactory handling of complaints.

6.29 The Inquiry asked the West Pennine Health Authority (WPHA) to provide all its records relating to complaints made against Shipman. The WPHA sent files relating to 18 cases and logs recording the bare details of ten more. However, on examination, most of these were found not to be complaints against Shipman personally. Some were complaints about his staff; some were complaints made by his patients but relating to their treatment by other doctors. One, set out in a letter from Miss Beatrice Clee, was not a complaint at all but a request for advice about the various drugs Shipman had prescribed for her. Of those complaints which were directed against Shipman himself, some were resolved through the informal procedures. There was very little information on file and the Inquiry has not sought to look into those cases. However, there were three complaints against Shipman that had been referred to a MSC, as they related to an alleged breach of his terms of service. I shall describe these three cases below.

The Case of Mr J

6.30 Two related complaints were brought by the mother of a patient of Shipman, Mr J, who had died from pulmonary fibrosis in July 1985 at the age of 29. The first related to the treatment provided by Shipman between 1977 and the patient's death in 1985; the second alleged a breach of patient confidentiality. I shall refer to Mr J's mother as Mrs J.

6.31 In her letter of complaint, dated 16th August 1985, which had been drafted at her request by Mr Steven Rawlinson, Mr J's closest friend, Mrs J said that her son had been registered with Shipman since 1977. Mr J had been a self-employed bricklayer and had enjoyed good health except that he suffered from a troublesome cough, particularly in winter. She

alleged that Mr J consulted Shipman on two occasions in 1984 (once in the summer and once in December), complaining of breathlessness. Shipman had told him that his problem was 'all in his mind'. Her son had consulted Shipman again in February 1985, when a chest x-ray had been arranged. On arrival at the clinic where the x-ray was to be taken, the technician had asked Mr J whether he actually had a chest condition. When Mr J said that he did, the technician remarked that the letter of referral said that it was psychosomatic. Following the x-ray, Shipman had advised Mr J that, apart from a couple of white patches, the lungs were normal. Mrs J said that her son's health had deteriorated from that time; his cough had continued and he had lost weight.

6.32 Mrs J said that, in May 1985, her son had noticed blood in his sputum and had returned to see Shipman, who prescribed an antibiotic and an asthma inhaler. She said that her son had insisted on a more thorough examination and Shipman had reluctantly agreed to refer him to a consultant chest physician at the local hospital. An appointment was offered for 22nd July 1985. In early June, Mrs J, deeply concerned about her son's deteriorating health, had contacted Shipman and it was agreed that a private appointment with the consultant should be arranged. At that appointment, on 20th June, the consultant expressed concern about Mr J, took various samples for tests and, a few days later, admitted Mr J to hospital. Mrs J understood that, at the time of admission, the diagnosis was unclear, but tuberculosis and viral pneumonia were mentioned as possibilities. After a week in hospital, no positive diagnosis had been made but Mr J's condition appeared to have stabilised and he was discharged home on 2nd July. By 9th July, he had relapsed and was readmitted, obviously very ill. Various tests were carried out. On 19th July, Mr J underwent a bronchoscopy and biopsy. He died very shortly afterwards.

6.33 Mrs J expressed the opinion that Shipman had been negligent. She did not provide particulars of that allegation but asked a number of questions from which it is apparent that she was concerned that Shipman had not examined her son sufficiently thoroughly, had underestimated the seriousness of his condition and had regarded it as psychosomatic. This had resulted in a delay in treatment. She was also concerned that, when agreeing to refer her son to a chest physician, Shipman had not asked for an expedited appointment.

6.34 Mrs J also alleged that, on a social occasion while her son was in hospital, Shipman had divulged confidential information about his condition to a couple – I shall call them Mr and Mrs G – who were patients of his and also friends of Mr J. The allegation was that Shipman had told Mr and Mrs G that Mr J might have tuberculosis. Mrs G was pregnant and had visited Mr J in hospital. Mrs J said that she thought Mr and Mrs G would be unwilling to provide evidence of this, as they remained on Shipman's list. This complaint, which Shipman later denied, fell outside the remit of the MSC; its proper destination was the GMC. I shall say no more about it, save to observe that it is not satisfactory for a complainant to have to take two related complaints to two different bodies.

6.35 On 3rd September 1985, the Chairman of the Tameside MSC considered the papers and decided that they disclosed reasonable grounds for complaint. An officer of the FPC sent the complaint to Shipman for his response. Shipman responded by letter dated 10th September 1985. Papers recovered by the Inquiry from Shipman's surgery show that, before submitting his response, Shipman had taken the advice of his regional Medical

Defence Union representative on the content of his draft response. He was warned that, in view of the conflicts of evidence between his account and that of Mr J's mother, he should expect to be summoned to an oral hearing.

6.36 Shipman's response began with a brief account of past history. He referred to consultations in January and March 1979, and on 13th June and 26th September 1980. None of those consultations related to a chest condition. He then recounted the history of the chest condition, beginning with a consultation on 15th April 1985. This was a detailed account and gives every appearance of having been extracted from clinical records. The account was silent as to whether there had been any consultations at all between 1980 and 1984 or one in February 1985, but the implication was that there had not been.

6.37 Shipman said that, on 15th April 1985, Mr J had complained of breathlessness. A diagnosis of bronchitis was made and an antibiotic prescribed. Shipman arranged a chest x-ray for the next day. It would appear that this was the consultation which Mr J's mother thought had taken place in the February. Shipman denied that he had said that Mr J's condition was 'psychosomatic' but agreed that he did sometimes advise patients that wheeziness could be exacerbated by anxiety. Shipman said that the x-ray showed active infection and a further course of antibiotics was prescribed on 7th May. On review on 21st May, Shipman found that Mr J was wheezy, had a cough and had lost a stone in weight in three months. Lung function testing showed a peak flow rate (PFR) of 300 litres per minute (which is very poor for a man of Mr J's age). Shipman prescribed a Ventolin inhaler and arranged various tests for 24th May. In his response, Shipman described the results of these tests, which appeared to include blood and urine tests but no further x-ray, and claimed that the results were very suggestive of a chest infection; he said that he had wondered whether Mr J had tuberculosis.

6.38 Shipman said that Mr J attended again on 4th June and, because he was no better, Shipman decided to refer him to a chest physician. The referral letter, dated 6th June, said that Mr J had presented early the previous month (that would be in May) with a tight wheezy chest and a cough productive of green phlegm. On review after a course of antibiotics, the finding was of wheezy expiratory rhonchi and a PFR of only 300. (There was no mention of the weight loss.) He had prescribed Ventolin and said that he had arranged an x-ray, the result of which was compatible with active chest infection. (That was misleading; the x-ray had been taken in April.) He said that at the **'recent'** review, the PFR had **'crept'** up to 500 litres per minute but, he wrote, **'the obvious question is have we got a young man who has asthma or is this the remains of a chest infection?'** I note three interesting features of this letter. Shipman misled the consultant as to the history, stating that he had first seen Mr J in early May and had arranged the x-ray in late May. He had not; those events occurred in April. Second, he made no reference to weight loss, which might well have been a sign of a progressive condition. Third, there was no hint in the letter that Shipman suspected tuberculosis or any other condition requiring urgent attention. The letter positively suggested a non-urgent situation.

6.39 Shipman then stated that on 14th June 1985, at the request of Mr J's mother, he had arranged a private consultation with a consultant. In fact, he used the same (misleading) referral letter as before. The consultation took place on 20th June and, on that day, the

consultant notified Shipman that his diagnosis was that Mr J had bronchiectasis with minimal airway obstruction. The consultant prescribed a broad-spectrum antibiotic and advised Mr J to continue with the inhaler. A fuller letter from the consultant followed, dated 2nd July, recording complaints of breathlessness over seven years, with copious expectoration, worse during the winter months. The letter also mentioned the loss of two stone in weight. From the letter, it appears that, after the consultation, the consultant examined a chest x-ray (probably the one taken on 16th April) and thought that its appearance raised a diagnosis of pulmonary tuberculosis. Mr J was to be admitted for further investigation.

6.40 Shipman's response completed the history by reference to two hospital discharge letters. The first, dated 8th July, reported that Mr J's diagnosis remained unclear, although it was believed that he had a chronic bronchiectasis. His symptoms had improved while he was in hospital and he had been discharged home. However, Mr J had relapsed a few days after discharge and had been readmitted on 11th July. The second hospital discharge letter, written after Mr J's death, informed Shipman that Mr J had died of diffuse idiopathic pulmonary fibrosis. The letter showed that no firm diagnosis had been made until after a biopsy had been carried out.

6.41 Shipman's response included the suggestion that Mr J had been considered as a possible AIDS sufferer and implied that barrier nursing techniques had been put into effect for that reason. The inclusion of this reference to AIDS appears to me to be wholly unnecessary and can only have been designed to cause distress or offence. The discharge letter makes it plain that the tests for AIDS were negative. There is no reference to barrier nursing techniques in the discharge letter, and it appears from elsewhere in his response that Shipman himself believed that, if barrier nursing was in use, it was on account of the possibility of tuberculosis and not AIDS. In any event, barrier nursing was not used for patients with AIDS, even in 1985.

6.42 Finally, Shipman said that he had fulfilled his terms of service. He had examined Mr J on a number of occasions. He had arranged a chest x-ray, made a working diagnosis and given treatment; subsequently, when the patient had not improved, he had referred appropriately. He pointed out that the serious and terminal nature of Mr J's illness had not been apparent until his second admission to hospital. Shipman appended a description of diffuse idiopathic pulmonary fibrosis, the condition from which Mr J had died.

6.43 In response to Shipman's letter, Mrs J sent a lengthy reply, again drafted by Mr Rawlinson. For present purposes, I need only refer to a few points from it to make it clear that she felt that there were issues to be tried. She repeated that her son had consulted Shipman about his chest before 15th April and suggested that the MSC should obtain not only her son's clinical records, but also the surgery appointments sheets. She repeated that it was Shipman's opinion that her son's problems were 'all in his mind'; this had been a running joke between him and Mr Rawlinson. She drew attention to Shipman's claim that he had suspected tuberculosis in late May and yet had not requested an urgent appointment with the consultant. She noted the inaccuracy of Shipman's claim to the consultant that he had first seen Mr J in early May when, by his own account, he had first seen him on 15th April. She appended a report from the consultant, which outlined the history and the autopsy

findings and expressed the opinion that Mr J's idiopathic pulmonary fibrosis had developed over a few years. The consultant said that it was a very rare condition in the young; in his long career, he had never seen a case in one so young. He said that there was no satisfactory treatment for the condition, although steroids had been tried.

6.44 The Chairman of the MSC then considered all the available correspondence and gave his opinion that a hearing of the case was not necessary. He was not required to give reasons for that decision and it appears that he did not do so. Unfortunately, the full FPC file is no longer available and it has not been possible for the Inquiry to see what issues were drawn to the Chairman's attention. In particular, it is not clear whether or not any consideration was given to the fact that some of the allegations related to a period more than eight weeks before the lodging of the complaint or whether that fact influenced the decision reached.

6.45 At some time after that, but before the case came before the MSC for decision, Mr J's mother sent a further letter in which she said that it would be **'interesting'** to know what had happened to her son's medical records for the period September 1980 to April 1985 (about which period Shipman's response had been silent).

6.46 At the meeting of the MSC on 4th December 1985, the Committee comprised Mr Jack Millin (its acting chairman), Mrs Joyce Howarth, Mr Peter Jackson, Dr Thomas Cooksey, Dr Terry Hughes (who was not a medical doctor but an engineer), Dr Winston Jackson and Dr Dennis Milner. The minutes of the meeting record that three cases were considered, two (including that of Mr J) without an oral hearing and one after a full oral hearing. The minute of Mr J's case said that the MSC received the correspondence relating to the complaint, considered the case and resolved that a report be prepared for the FPC, recommending that the complaint be dismissed.

6.47 The report, which was drafted by Mr William Greenwood, then Assistant Administrator at the Tameside FPC, listed all the material before the Committee. At paragraph 17, the report stated that the Committee had had available the patient's medical records. It was recorded that after **'very careful'** consideration of all these items, the MSC had agreed with the previous decision of the Chairman of the MSC that a hearing of the case was not necessary. No reasons were given for that conclusion.

6.48 Mr Greenwood then accurately set out the test to be applied in considering the main complaint, saying that the MSC had to consider whether or not Shipman had exercised due skill and care in arriving at a diagnosis and whether he had placed himself in a position where he could reasonably exercise that skill. The report then recorded the findings of fact. The MSC recorded the periods for which Mr J had been Shipman's patient but made no reference to any consultations in 1984 or 1985, prior to 15th April 1985, despite Mrs J's insistence that he had consulted Shipman during this time. The report then set out a brief résumé of the history, taken, it was said, from the medical records. The account followed that given in Shipman's response. The conclusion was that there had been no unreasonable delay in Shipman's treatment of Mr J. There was no reference to Mr J's failure to improve with treatment or to his weight loss. Nor was it mentioned that Shipman had not asked for an urgent appointment although he apparently suspected tuberculosis. The Committee found that Shipman had exercised reasonable judgement; he had arranged an x-ray and had referred the patient for a consultant opinion. The Committee

plainly regarded the unusual nature of the condition and the difficulty of diagnosis as important factors. It was said that there was no mention in the notes that Shipman considered the illness to be psychosomatic in nature. The Committee concluded that there had been no breach of terms of service.

Evidence at the Inquiry

6.49 Mr Rawlinson gave evidence to the Inquiry. He said that he had been dissatisfied with the result of the complaint and thought that it should have been upheld. He agreed that, at the time, he had been very distressed about the death and very angry. He now realises that helping Mrs J to make her complaint was a means of venting his anger. He is an intelligent man and I think he recognises that he might not have been as objective at that time as he would normally be. He expressed his opinion, held at the time, that the MSC was a closed club, which would protect the doctors from criticism. He added that, on re-reading the papers at the time of the Inquiry, he still had the same impression.

6.50 Mr Rawlinson went through what he now remembered of the details of his friend's illness and confirmed the accuracy of what had been stated in the original complaint. He repeated his concern about Shipman's apparent unwillingness to take Mr J's condition seriously and the delay in obtaining a consultant's appointment and setting in train further investigations.

6.51 He was asked whether he was aware of the time limits that meant that, unless special permission had been given, the MSC would have been unable to look into matters that had occurred more than eight weeks before the date of the complaint. He said that he was not and he now thinks that he and Mrs J were not told about that rule. However, it is not possible to check whether he is right about that, as the only parts of the FPC file to have survived are those documents provided to the MSC.

6.52 Mr Rawlinson also expressed the view that Mrs J and he were not kept sufficiently abreast of what was going on. They did not know how the complaints procedure worked. They did not know what medical records were available and to what extent they were looked at. There was no attempt to clarify the issues; the process seemed to be: complaint – response – reply. They had expected that the MSC would itself investigate what had happened. Mr Rawlinson had made suggestions about the conduct of the investigation (including obtaining the surgery appointments sheets and Mr J's medical records) and had not realised that investigation was left to the parties. He felt it would have been valuable to have had an oral hearing. He also said that he did not know that it would have been possible to appeal against the MSC's decision. However, I think it is likely that he would have been made aware of that. I think it likely that Mrs J was advised of that at the time she was informed of the decision. That would be the usual procedure and I think it likely that Mr Greenwood would have followed it. It is not possible to check this point because part of the file is no longer available.

Evidence from Members of the Medical Service Committee

6.53 The Inquiry sought to find out why the Chairman of the MSC had decided not to hold an oral hearing and why the Committee sitting on 4th December had decided to ratify that

decision. The official report threw no light on those issues. The Inquiry also sought to discover more about the Committee's reasoning and the way in which it had handled the case.

6.54 It seems likely that the Chairman of the Tameside FPC, Mr Basil Sabine, who was also the Chairman of the MSC, probably took the initial decision not to order an oral hearing. Mr Sabine is now deceased. He was not able to attend the MSC meeting on 4th December and, in his absence, the meeting was chaired by Mr Millin (who was too unwell to provide evidence to the Inquiry). Of the other members of the MSC, the Inquiry was able to locate Mr Jackson, Mrs Howarth, Dr Jackson, Dr Milner and Dr Cooksey. All five provided witness statements; Mr Jackson and Dr Cooksey gave oral evidence.

6.55 Dr Cooksey said that there was usually an oral hearing if there were disputes of fact. In his written evidence, he said that, on reading this case, it appeared to him that the issues were clear and it would not have surprised him that the Chairman had decided not to hold an oral hearing. When giving oral evidence to the Inquiry, he accepted that there was an issue between the parties as to whether Shipman had seen Mr J with reference to his chest complaint before April 1985. He also appeared to accept that there was an issue about whether, if Shipman suspected that Mr J might have tuberculosis, it was reasonable to refer him to a consultant on a non-urgent basis. However, he said that he thought that the Committee had taken the view that, whatever had been done, it would not have made any difference to the outcome. This, he thought, might have had a bearing on its decision. If that were so, it would mean that the Committee had addressed its mind to the wrong question, as the test was whether what Shipman had done was reasonable, not whether reasonable treatment would have made any difference to the outcome. When asked about the degree of care with which the MSC had considered the non-oral cases (of which there were two on 4th December as well as an oral hearing), Dr Cooksey said that the MSC was 'supporting the decision of the Chairman who had decided that this was the right course of action'. He accepted that the main business of the day was the third case, which was to have an oral hearing. I feel bound to observe that I myself would have found it difficult, in one day's work (and it is not clear whether the Committee sat for the whole day or only half), to give **'very careful'** consideration to all the material and records in this case, another one like it and yet another in which there was to be an oral hearing, even if I had read the papers in advance.

6.56 Mr Jackson, a solicitor, was a lay member of the MSC. He said he did not know why the Chairman had decided in advance not to hold an oral hearing. However, he did say that the MSC would not look at allegations relating to events occurring more than eight weeks before the date of complaint, unless an application to extend time had been agreed or granted. He made the point that the Committee's report stated that there were no entries in the records showing that Shipman thought the problem was psychosomatic. That is so, but it was pointed out to him that the report did not deal with the question of whether there were any entries at all during the earlier period. Mr Jackson's response to that was that any consultations in the earlier period were 'out of time'. He also pointed out the difficulty of deciding the case on hearsay evidence. He explained that the mother would not have been able to give direct evidence of what Shipman had said; Shipman had denied saying that he had treated the condition as psychosomatic. However, hearsay evidence of what

a deceased person has been heard to say is often received; to refuse to hear it might cause real injustice. The weight to be attached to it must be carefully considered. If the records had contained entries in 1984 relating to a cough or shortness of breath, and if there was no sufficient record of examination and observations, the Committee might have inferred that the hearsay evidence was correct. There was no bar to receiving such evidence and, indeed, the DoH notes of guidance, to which I have already referred, specifically mentioned that hearsay evidence could be admitted, subject to warnings about the weight that should be attached to it.

6.57 Dr Jackson, one of the medical members, said in his statement to the Inquiry that he did not know why it had been decided not to hold an oral hearing. Most cases had one. He speculated that the decision might have been taken to avoid further distress for the mother. Dr Milner said in his witness statement that he was unable to say why the decision had been taken.

6.58 In her statement to the Inquiry, Mrs Howarth said that she could not remember the case but, from reading the papers, she thought there were several reasons why the MSC would have decided to ratify the previous decision not to hold an oral hearing and to dismiss the complaint. She thought that the evidence about what had happened at earlier consultations would have been regarded as hearsay. The notes contained no reference to Shipman's belief that the problem was psychosomatic. I have already commented on those points. She also thought that it appeared that there were no consultations during the earlier period (although, in fact, it is not clear whether there were or were not). She pointed out that it appeared that Mr J had been able to continue at work and therefore it was reasonable to infer that he had not been seriously ill until towards the end, when Shipman's actions, as recorded in the notes, were clear and seemed appropriate. She mentioned that the condition was very rare and difficult to diagnose. That may have been so but the question for the MSC was not whether Shipman should have diagnosed the condition but whether he had provided proper medical care on each occasion when he had seen the patient.

Observations

6.59 Given the incomplete information and material available to me, I cannot reach any conclusion as to whether this complaint was, in fact, properly handled. However, I am left with a number of concerns. I do not know whether Mrs J was advised about the time limits. In my view, she should have been so advised and told of the possibility of applying for leave to extend the scope of the complaint. It may be that she was advised and decided not to apply or that she applied and permission was not granted. It is possible that she applied, permission was granted and the complaint included the events of 1984. If so, the decision did not deal adequately with this earlier period. It seems to me that there should have been an oral hearing, even though some of the evidence would have been hearsay. There were clear conflicts of evidence about Shipman's attitude and his reluctance to refer Mr J to a consultant. If an oral hearing had been held, the Committee might have paid more attention to the allegation that Shipman claimed to have suspected tuberculosis in late May but did not seek an urgent appointment with the consultant. It appears that at least one member of the Committee (possibly more) regarded his role as one of supporting the

Chairman's decision. It may be that some members of the MSC did not understand the question they should have been asking and that they took into account irrelevant considerations.

6.60 Mrs J and Mr Rawlinson were dissatisfied with the process and the outcome and, so far as the process is concerned, this is understandable. In criticising the process, I am not criticising the individuals concerned. They were doing things in the usual way. But the process does not seem to have been designed to provide the complainant with an understanding of what had happened. There was no investigation of this complaint and no attempt to sort out the issues and see what evidence was required or available to deal with each issue. If someone had asked Mr Rawlinson what delay he was complaining about, he would have included his concern about the alleged inactivity during 1984 and early 1985. Someone would have had to explain that, under the rules, the MSC could not look into that unless leave was sought and granted. I would have expected it to be granted. Someone should have looked at the records and made plain in the decision what entries, if any, there were in 1984. If there were none, and Mrs J continued to say that her son had visited Shipman in that year, the surgery appointments sheets could surely have been obtained. At the end of the day, the whole question of whether Mr J consulted Shipman at all in 1984 was left in the air.

6.61 Mr Rawlinson also felt there was a lack of independence on the part of the MSC. At the time of this complaint, Shipman was secretary of the LMC and he had held that position since about 1981. As secretary, he was automatically a member of the FPC. In Tameside at that time (although this was not a requirement of the Regulations), all members of the MSC were also members of the FPC. Thus, Shipman was a colleague of all of the members of the FPC and the MSC, both lay and medical. Dr Cooksey said that he served on the LMC from the late 1960s until 1994 and was chairman from 1977 until 1983. During his term as chairman, he worked with Shipman as secretary. Dr Jackson said that he was chairman of the LMC for two years in the 1980s, although he was not sure whether he still held that position in December 1985. In view of the dates of Dr Cooksey's chairmanship, it seems entirely possible that Dr Jackson was indeed chairman of the LMC at the time of the hearing. Mr Greenwood told the Inquiry that he had thought it inappropriate that the conduct of a local GP should be reviewed by his/her local colleagues. I agree. It is not surprising that Mr Rawlinson felt that the MSC was a closed shop. Even if the members were scrupulously fair, there was no appearance of independence.

The Case of Mr W

6.62 In 1990, a complaint was made about Shipman's treatment of a patient whom I shall call Mr W. He was aged 39 and suffered from epilepsy. He also had learning difficulties although he lived an independent life. No doubt it was on account of those difficulties that the complaint was brought on his behalf by his sister, Mrs L. By letter dated 6th January 1990, Mrs L reported that her brother had been diagnosed with epilepsy and had been advised by a consultant at the local hospital in 1986 that he should take ten tablets a day of Epilim 200mg. It appears that Shipman had, in fact, always prescribed eight tablets a day but nothing turns on that point. On 14th November 1989, Shipman had issued a repeat prescription for Epilim but, instead of prescribing 200mg tablets, he had prescribed

500mg tablets, to be taken at the usual rate of eight per day. On 7th or 8th December, having consumed 76 of the 500mg tablets, apparently over a period of nine days, Mr W fell downstairs. Some days later, Mrs L found him in a very poorly state, sitting in a chair. It appears that he had become incontinent and had developed 'bedsores'. He and his partner, who also had learning difficulties, had been unable to summon help. He was admitted to hospital where he still remained three weeks later.

6.63 The complaint was directed to the Tameside FPC. In September 1990, the FPC's functions were transferred to the Tameside FHSA which continued to deal with the complaint. The Chairman of the MSC instructed the FPC to seek Shipman's response to the complaint. Shipman responded in July 1990. He admitted that he had made an error and said that he could not understand how it had happened; he had had Mr W's notes in front of him when writing the prescription. He thought perhaps he had been distracted. He drew attention to the failure of the dispensing pharmacist to notice the error. He reported that Mr W had now recovered from the episode and had been transferred to sheltered accommodation, which was more suited to his needs. He also explained that the practice had recently become fully computerised and that, in future, once the correct dosage had been entered, errors of this type should not occur, as the repeat prescription would be prepared from data within the system.

6.64 Shipman's response was sent to Mrs L's solicitor who replied, challenging various aspects of Shipman's response, although none of the areas of dispute was material to the determination of the complaint. Although, initially, the Chairman of the MSC was of the view that there would have to be an oral hearing, in the end it was agreed that this would not be necessary. On 12th December 1990, the case was dealt with at a meeting of the MSC which was not attended by either party. Inevitably, Shipman was found to be in breach of paragraph 13 of the terms of service. The report of the hearing concluded with a recommendation that Shipman should be warned to comply with his terms of service more closely in the future but there was no recommendation for a withholding of remuneration. This was the first time that Shipman had been found in breach of his terms of service. This finding and recommendation were accepted by the FHSA. Shipman did not appeal against the finding or the warning. The SoS was notified and endorsed the steps taken by the FHSA. Shipman was notified to this effect on 20th March 1991. The case was not reported to the GMC.

6.65 I make only two comments about this very simple case. First, it took almost a year to bring the matter to a conclusion. That is longer than is desirable. Second, it shows how, if steps have to be taken to discipline a doctor, an adversarial system that focusses on standards that have to be met by a doctor has the potential to provide a suitable means of discovering the facts on which disciplinary action is to be based.

6.66 In view of Mr Rawlinson's complaint that, in 1985, the MSC seemed to be a closed shop, I have considered the degree of independence of the MSC from Shipman in 1990. I note that, in the letters informing the members of the Committee of the date on which the complaint would be dealt with, members were warned to consider whether they ought to disqualify themselves. They were told not to sit if they had an interest in the question to be determined or had some association with any of the parties. The letter advised that

'personal friendship or close business or social relations would disqualify but not – by themselves – mere acquaintance or official contacts'. In 1990, Shipman was no longer secretary of the LMC; he had resigned in 1988. He was no longer a member of the FPC which had, in any event, been replaced by the FHSA. However, he had been secretary of the LMC and on the FPC for about seven years and he must have been well known to many current members of the FHSA and MSC. Major Robin Tarr, a member of the MSC which heard the complaint in respect of Mr W, said that he knew Shipman from the FPC and that, when they first met, Shipman had invited him to look round the Donneybrook practice, to see how a general practice worked. He had found the visit very useful. He said that his acquaintance with Shipman had not affected his decision in the case. Mr Jackson, who chaired the MSC, said that Shipman had a good reputation in the area and was not regarded as careless. He had known Shipman through sitting on another FPC committee of which they were both members and, although he regarded him as a bit of a maverick, he and other lay committee members had been impressed by him.

6.67 In the light of the advice they were given, I do not criticise the members of the MSC who decided not to disqualify themselves. However, I think that, in the interests of ensuring that justice was done and seen to be done, it would have been preferable if there had been a policy that, when a GP member (or recent former member) of the FPC/FHSA was due to come before the MSC, the case should be transferred to the MSC of a neighbouring FPC/FHSA. Indeed, one might go further and say that it would be preferable that any disciplinary action against a GP should be determined by people from another district who have no personal knowledge of him/her. Such a policy would avoid the danger that any dissatisfaction on the part of a disappointed complainant might focus on the lack of impartiality of the tribunal. In this case, the complainant might have taken the view that the penalty was too lenient.

The Case of Mrs B

6.68 On 4th March 1992, Mr B made a complaint in respect of medical services provided to his wife on Wednesday, 26th February 1992. Mrs B was an elderly woman and a patient of Dr Jeffery Moysey, a colleague of Shipman at the Donneybrook practice. Dr Moysey and Shipman had an arrangement whereby they covered for each other on half days. On Wednesdays, Dr Moysey worked until about 10.30am, after which time Shipman covered for him.

6.69 In the letter of complaint, Mr B said that his wife had been ill on Sunday, 23rd February. Dr Moysey had visited on the Monday and had diagnosed a stroke. He had promised to call back 'in a couple of days'. He had also promised to arrange for a consultant domiciliary visit and for district nurses to attend. A nurse had attended on 24th, 25th and 26th February. On Wednesday, 26th February, Mrs B's condition had worsened and the family had expected a visit from Dr Moysey. When he had not arrived by midday, her son (Mr B's stepson) had telephoned the surgery to ask for a visit. He had told the receptionist that Mrs B's condition was worse; he was to say at the MSC hearing that he thought she had had another stroke. The receptionist had said that it was Dr Moysey's half day but that Shipman was covering for him, and that a message would be passed to him as soon as he came in. A short while later, the receptionist had telephoned Mrs B's home and told

Mrs B's son that Shipman had returned but had said that it was not necessary to visit, as Dr Moysey had seen Mrs B two days before. Mrs B's son had repeated his request for a visit, stressing (as he was to say at the hearing) that his mother's condition had deteriorated. He also was to say at the hearing that he had mentioned that she was a heavy woman and was incontinent and that they were having difficulty in lifting her. The receptionist went to speak to Shipman again but reported to Mrs B's son that he refused to come out as it would not be right for him to 'go over' Dr Moysey's decision that there was no need for Mrs B to be admitted to hospital. A while later, the family had called an ambulance and Mrs B was taken to hospital.

6.70 Shipman's response to the complaint was robust. He agreed that he had been deputising for Dr Moysey on the day in question and that he had received a request to visit Mrs B. However, he said that he had made a careful note of the request and the action he took. He enclosed a copy of the note, said to have been made at the time, which read:

> **'Telephone message request for visit.**
>
> **Seen JOM** (*Dr Moysey*) **23.2 92 CVA**
>
> **Domiciliary Arranged**
>
> **Dr Moysey to visit 48 hours ? today**
>
> **Visit because husband unable to cope as elderly**
>
> **NO worse than seen by Dr Moysey**
>
> **Visit arranged for mane** (*the next morning*)
>
> **For Dr Moysey to reassess'**.

6.71 Shipman asserted that he had not been told that Mrs B's condition had deteriorated. In his view, the complaint had arisen because there had been a misunderstanding about when Dr Moysey would revisit. He denied that he was in breach of his terms of service.

6.72 Dr Moysey's response, so far as is relevant for present purposes, was that, when visiting on 24th February, he had found that Mrs B had had a slight stroke from which she appeared to be recovering. He had made suitable arrangements for her care at home. He had not made any definite arrangement to revisit but had said he would call later in the week. On the Thursday after his half day, one of the receptionists had informed him that Mrs B had been taken into hospital and that there was no need to visit her at home. He denied that he was in breach of his terms of service.

6.73 After some initial clarification of the issues, the complaint was transferred to the MSC of the Manchester FHSA because Dr Moysey was a member of the Tameside MSC. A hearing was ordered and took place on 8th September 1993. Both doctors were alleged to be in breach of paragraph 13 of their terms of service. Mr B was represented by the secretary of the Tameside and Glossop CHC.

6.74 Mr B gave evidence and expanded upon his written complaint. In particular, he provided a clear description of the deterioration in his wife's condition that had occurred on the morning of 26th February. He also explained how it was that the family had not telephoned

the surgery until shortly after noon. They had been expecting Dr Moysey to attend; he had said he would call 'in a couple of days'. Mr S, Mrs B's son, also gave evidence and provided more detail of the conversations he had had with the receptionist on 26th February. He asserted that his mother's condition had deteriorated that day and that he had explained that to the receptionist. He said that the receptionist had reported back that Shipman would not come out because Dr Moysey had seen Mrs B two days earlier and it would not be right to 'go over' his opinion that she did not need to be admitted to hospital.

6.75 Dr Moysey gave evidence. He confirmed his written statement. He gave a very full account of his examination of Mrs B and the reasons why he had decided on the Monday that Mrs B should remain at home. He explained the arrangements he had made and his plans for her future management. He described the arrangement he had with Shipman and said that he had never sought to restrict the way in which Shipman treated his (Dr Moysey's) patients.

6.76 Shipman gave evidence. He confirmed his written statement and said that he could not remember the incident at all. He was dependent upon the note he had made. He said that he had not spoken directly to Mr S because the reception staff were very experienced; he had felt he could rely on the receptionist to report accurately what had been said. He said that it was his usual practice to ask the receptionist to find out whether or not there had been any deterioration in a patient's condition. He said that, according to what he had heard from the receptionist, there had been no deterioration in Mrs B's condition. He suggested that the receptionist might have 'overstepped the mark and misinterpreted' the family's request for a visit and said that he would accept responsibility for that. He said that he had not been able to ask the receptionist to attend the hearing because he had been unable to identify which receptionist had taken the message and, in any event, once the message was passed to the doctor, it became his responsibility. He had not produced the practice visits book, in which requests for visits were recorded, and said that he was not sure whether it was still available, 18 months after the event. He was unable to explain why the receptionist should have quoted medical ethics to Mr S. He agreed that, if a relative said there was a deterioration in the patient's condition, the doctor should visit. He said that he believed he had put himself in a position to make a clinical judgement but agreed that, if the evidence of the family was to be believed, he had not done so. He declined to make a closing submission.

6.77 The MSC found that Dr Moysey was not in breach of his terms of service. In the case of Shipman, they preferred the evidence of Mr B and Mr S to that of Shipman. The MSC noted Shipman's failure to produce the visits book (which they thought should have been kept safe as soon as the complaint was received) or to call the receptionist to give evidence before the MSC. The MSC found that Shipman had twice refused to attend Mrs B on 26th February and, before doing so, had not placed himself in a position to make a proper professional judgement. He was in breach of paragraph 13 of his terms of service. After hearing about the previous breach in the case of Mr W, in 1989, the MSC recommended that £800 remuneration should be withheld and that Shipman should be warned to comply more closely with his terms of service in future.

6.78 In its decision, the Committee mentioned Shipman's written note in connection with Mrs B (which by implication they had found was not accurate) but did not comment on whether

it might be deliberately misleading, as opposed to genuinely mistaken. Shipman had claimed that he had made the note contemporaneously. It stated unequivocally that there had been no deterioration. With the benefit of hindsight, it is clear that Shipman had done, in this case, what he is now known to have done in many cases; he had made a false and self-serving record. At first, it seemed to me that the MSC must have regarded the note as false. However, on further reflection, it appears likely that it might have thought that Shipman genuinely misheard or misunderstood what the receptionist said to him and that the fault on his part was not to speak either to Dr Moysey, to ascertain whether he intended to visit later that day, or to Mr S directly, so as to put himself in a position to make a judgement as to the need for a visit. In other words, it seems that the Committee did not necessarily find him guilty of a deliberate refusal to visit or of a deliberate fabrication of a false note.

6.79 Mrs Elsie Gilliland, the Chairman of the MSC, who presided at the hearing, remembered that her view was that Shipman had made no attempt to assess the patient. She said that the Committee had been sceptical of Shipman's failure to call the receptionist or to produce the visits book, and thought his excuses for not doing so were not very satisfactory. She also said that members of the Committee were conscious of the possibility that Shipman had looked at the visits book and knew that it did not support his case. She could not go so far as to say that she thought he was being dishonest. I can well understand her thought processes.

6.80 The recommendations of the Manchester MSC were accepted by the Tameside FHSA. Shipman did not appeal against the finding or the penalty. On 22nd October 1993, notice of the result was sent to the FHSAU and, on 26th May 1994, the penalty was confirmed by the Chief Executive on behalf of the SoS. In accordance with the powers, conferred by the National Health Service (Service Committees and Tribunal) Regulations 1992, that I mentioned earlier in this Chapter, the case of Mrs B was sent to the GMC, together with the papers in the case of Mr W.

6.81 The GMC papers show that the GMC decided to take no action. It was of the view that the case of Mr W was too old to reopen and that the case of Mrs B would be difficult to investigate because Shipman had not made an admission. The GMC seems to have thought that it would not be possible to make a finding as to Shipman's conduct, despite the fact that the MSC had been able to do so. The view was that the case demonstrated only poor performance rather than serious professional misconduct. I shall deal in detail with the GMC's handling of this case in Chapter 19.

6.82 I note that the proceedings took 18 months to be brought to a hearing. No doubt some of this delay was due to the need to transfer the case from Tameside to Manchester. But, even so, the delay was far too long. This case is a good example of the weakness of the MSC system, in which the Committee had no power to call for documents or summon witnesses. The system did not provide for an independent investigation of the facts but left the parties to carry out their own investigation, to the extent that they were either willing or able to do so. In this case, an independent investigator would have been able to take possession of the visits book, which was likely to have contained the best contemporaneous record of what Mr S had said to the receptionist. Also, such an

investigator would have been able to identify the receptionist. It is inconceivable that the receptionists would not have recognised the writing in the visits book.

6.83 In the event, I am confident that the MSC reached the right conclusion. However, it did not, for understandable reasons, detect that Shipman had made a false record in an attempt to pass off his own shortcoming as a misunderstanding by the receptionist or between him and the receptionist. Had all the evidence been available, greater insight into Shipman's conduct would have been gained.

Observations on the Three Complaints

6.84 Bearing in mind that Shipman was an established serial killer of his patients, it seems remarkable that such complaints as were made about him in the years between 1977 and 1996 were not of a more serious nature. No complaint was received about his treatment or failure to treat any patient whom he had in fact killed. Even if they had been investigated in great detail, the three complaints that I have just described would not have thrown any light on Shipman's true character as a murderer. With the benefit of my knowledge of Shipman's habitual dishonesty, I have detected signs of dishonest behaviour in the cases of Mr J and Mrs B. However, such signs were by no means obvious and it is not surprising that they were not detected at the time.

6.85 The only case of which I am aware which could have led to a complaint that might have resulted in the detection of Shipman's true nature was that of Mrs Renate Overton. Shipman injected her with an overdose of diamorphine in February 1994 but she survived, in a persistent vegetative state, until April 1995. As I have already recorded in the First and Third Reports and as I shall mention again in Chapter 10 of this Report, the medical staff at Tameside General Hospital were aware that Shipman had administered a dangerous dose of opiate. It was not suspected that he had acted deliberately. Mrs Overton's family was alerted to the possibility that Shipman had been negligent. However, no complaint was made.

6.86 The handling of the three complaints illustrates some of the shortcomings of the system in operation during the years before 1996. First, they show that, at least where there was to be an oral hearing, there might well be unacceptable delay. Second, the case of Mr J illustrates the difficulties that could arise from the imposition of time limits. Third, the cases illustrate the problems which could occur when it was left to the parties to investigate and prepare the case and to decide what evidence should be presented. Doctors had the benefit of assistance from skilled advisers from their medical defence organisation but complainants did not. They might have the advice of a representative of the CHC but, if not, they would be seriously disadvantaged. Even with such advice, a complainant might well feel disadvantaged in presenting the case. More serious than that was the complainant's lack of resources of investigation. Mrs J suggested the production of documents that might help her to prove her case but had neither the power nor the resources to obtain them. Finally, the case of Mrs J and Mr W illustrate the problems that can arise where the composition of the committee does not give the appearance of complete impartiality.

6.87 As I shall explain, it was not only complainants who felt a degree of dissatisfaction with the pre-1996 procedures. Many doctors found the proceedings very stressful, particularly as they were disciplinary proceedings which might well result in punishment or even referral to the GMC. It is possible that Shipman found them stressful and it does appear that, during the currency of the cases of Mr J and Mr W, Shipman reduced the frequency with which he killed patients. In the 12 months before September 1985 when he was notified of the complaint against him in the case of Mr J, Shipman killed 13 patients and I suspect him of killing a further five. He did not kill at all during the four months between notification and the conclusion of the case on 4th December 1985. In the following month, between 17th December 1985 and 7th January 1986, he killed four patients. Similarly, in connection with the case of Mr W, Shipman killed only one patient during the period of about ten months of the currency of the proceedings. He killed again very soon after they had been concluded. The proceedings in the case of Mrs B were very protracted. In the remaining nine months of 1992 after notification of the complaint, Shipman killed only one patient. However, in the first eight months of 1993, before the hearing in September, Shipman killed 13 patients and I suspect him in respect of another.

6.88 I do not know whether this change in the pattern of Shipman's killing was in any way related to the currency of disciplinary proceedings. I mention the possibility because, in my First Report, I suggested other possible reasons for the variations in the rate of killings. The Inquiry had not then fully investigated the complaints against Shipman and I had not appreciated that the proceedings might have had a deterrent effect.

Recognition of the Need for Change

6.89 In considering these three complaints, I have drawn attention to a number of shortcomings in the MSC system. These shortcomings are typical of the kind of criticism that was being widely expressed about the complaints system in the early 1990s. In June 1993, the SoS appointed an Independent Review Committee under the chairmanship of Professor (later Sir) Alan Wilson, Vice-Chancellor of Leeds University. Its Terms of Reference were:

> **'To review the procedures for the making and handling of complaints by NHS patients and their families in the United Kingdom, and the costs and benefits of alternatives to current procedures, and to make recommendations to the Secretary of State for Health and other health ministers.'**

6.90 The Wilson Report, entitled 'Being Heard', was published in May 1994. It said that the existing arrangements for handling complaints were too complex, too lengthy and too confrontational. MSC reports often failed to give a satisfactory explanation of the decision reached. The requirement that a complaint must constitute a breach of the terms of service was too restrictive. The system appeared to be biased in favour of the GP. The time bars were too technical and restrictive.

6.91 The Report recommended radical changes. The Government invited reactions to and comments upon the Wilson Report before issuing its own response, entitled 'Acting on Complaints', in March 1995. Public response was largely favourable and the Government

accepted virtually all the recommendations of the Wilson Report. It proposed new procedures which were to come into force on 1st April 1996. I shall describe the recommendations of the Wilson Report and the Government's proposals for change in the next Chapter.

CHAPTER SEVEN

Complaints and Discipline after 1996

Introduction

7.1 As I indicated in the last Chapter, the Government's proposals for new procedures for handling patient complaints in the NHS were published in March 1995. The procedures were introduced in April 1996. In this Chapter, I shall describe the 1996 procedures, as they applied to complaints about general practitioners (GPs), and will summarise the evidence received by the Inquiry as to how they worked in practice. I shall also discuss the shortcomings of the 1996 procedures and consider the Government's recent proposals for reform.

7.2 In the last Chapter, I described the operation of three complaints which resulted in disciplinary proceedings being taken against Shipman under the pre-1996 procedures. This Chapter will not contain any similar descriptions. So far as was known to the West Pennine Health Authority (WPHA), only one complaint against Shipman was made in the years 1996 to 1998. The development and operation of the 1996 complaints procedures and the changes to disciplinary procedures that came about after 1996 are of interest to the Inquiry because they form the link between the pre-1996 procedures and a new set of procedures, parts of which have been introduced in July 2004 and parts of which are still under discussion. It is my intention to make recommendations about those aspects of the new procedures that are still to be settled.

The 1996 Complaints Procedures

The Wilson Report

7.3 The Government proposals were based upon the principles expounded in the Wilson Report 'Being Heard', which was published in May 1994, and adopted many of its procedural recommendations. The Report stated that the principles underlying a complaints procedure should be responsiveness, quality enhancement, cost-effectiveness, accessibility, impartiality, simplicity, speed, confidentiality and accountability. The Report stressed that there was a need to draw a clear distinction between complaints and disciplinary procedures. Complaints should not necessarily result in disciplinary action although, if a disciplinary issue emerged, the issue should be passed to family health services authority (FHSA) management for it to determine whether disciplinary action was appropriate. It was said that the degree of investigation into a complaint ought to be governed by the wishes of the complainant but that those responsible for the management of the doctor concerned might need to undertake further investigation for management or disciplinary purposes.

7.4 The Report recommended that every complaint should be handled first by the organisation against which it was made and second, if necessary, by an external body. Every organisation should have a complaints manager, who would be responsible for handling the complaint. In general practice, this person would most often be the practice manager or a partner in the practice. An initial response to the complaint should be made

very quickly, within 48 hours of receipt, and would be aimed at satisfying the complainant by providing either an explanation or an apology, as appropriate. If necessary, that should be followed by an investigation and/or an offer of conciliation, following which a written response would be provided. If the complainant was dissatisfied with that response, the complaint should be considered by a senior officer of the responsible trust. That person should have a range of options available, such as conciliation, personal discussion with the complainant, further more detailed investigation, taking independent advice on clinical matters or, in effect as a last resort, establishing an independent inquiry.

The Government Proposals

7.5 In announcing its proposals, the Government stated that it wished to ensure **'maximum commonality'** of procedures throughout the NHS. The philosophy underlying the complaints process was that it was to be a **'learning process'**. To that end, complaints were to be completely separated from disciplinary proceedings. If it appeared that disciplinary action was appropriate in relation to the circumstances underlying a complaint made by or on behalf of a patient, the disciplinary proceedings would begin only after the complaints procedures were completed.

7.6 The 1996 complaints procedures were to have two stages within the NHS. The first stage would be conducted by the NHS body that had provided the service from which the complaint arose. Complaints against GPs were to be handled, at the first stage, by the practice. Conciliation was to be available as an adjunct to the first stage of the complaints process. If a complainant was dissatisfied with the outcome of a complaint about a GP, s/he could move to the second stage and seek an independent review. He or she would apply to a 'convenor', who would usually be a non-executive director of the health authority (HA), who would decide whether to grant a review. If a review was granted, it would be heard by a panel of three non-medical persons. The report of the panel would be sent to the chief executive of the HA, who would send copies to various involved parties, including the chairman of the HA. A complainant who had exhausted these two stages but remained dissatisfied could resort to the Health Service Ombudsman (also known as the Health Service Commissioner). Advance guidance on the implementation of the new procedures was distributed to all NHS bodies in October 1995.

The Legislation and Guidance

7.7 The legislation governing the 1996 complaints procedures came into force on 1st April 1996, the same date as the creation of the unitary HAs which combined the functions of the district HAs (which previously had responsibility for secondary care) and the FHSAs (which previously had responsibility for the provision of primary care). The requirements for GPs to operate practice-based procedures were brought into effect by amendment of the GPs' terms of service in the National Health Service (General Medical Services) Amendment Regulations 1996. The arrangements that HAs were required to make for the provision of conciliation services and for the appointment of convenors and independent review panels (IRPs) were set out in directions issued by the Secretary of State for Health (SoS). The new disciplinary arrangements were to be found in the National Health Service

(Service Committees and Tribunal) Amendment Regulations 1996. At the outset, guidance was issued to HAs, convenors and GPs as to the way in which they were to carry out their new functions.

The First Stage

7.8 For complaints against GPs, each practice was to develop its own practice-based complaints procedures. The way in which the complaint was to be handled was left largely to the discretion of the practice. The only mandatory provisions were that the practice had to nominate a person to administer the procedures; it had to provide information for patients about how the procedures operated; and it had to acknowledge a complaint within two working days and provide an **'explanation'** within ten working days of receipt of the complaint. In all other respects, the detailed operation of the procedures was for the practice to decide. The written guidance provided advice on best practice and GPs were encouraged to seek the assistance of the HA if in doubt. The policy was to encourage practices to devise procedures that would work well for them and their patients. It was stressed that every member of the practice team involved in the circumstances giving rise to the complaint had also to be involved in responding to the complaint and had to be prepared to co-operate in handling a complaint. It seems to have been assumed that all GPs would take their duties seriously and in the spirit of **'learning'** that underlay the new procedures.

7.9 The guidance suggested that the person nominated to be in charge should be the practice manager or one of the partners, although some other person might be appointed. If the complaints manager was not a doctor, one of the doctors should be an **'overseeing partner'**. Advice was given as to the information to be made available to patients. Standard letters and forms for record keeping were proposed for adoption or adaptation. Practices were advised of the need to keep good records of complaints. It was intended that these would enable the practice to ensure that it was using the resolution of complaints as a learning process. The practice might be required to provide information to the HA in the event that a complaint was not resolved at practice level, but practices were assured that they would not be required to produce their records to the HA.

7.10 The practice's initial response to a complaint should be to arrange an interview, either face to face or by telephone, between the complaints manager and the complainant. Much good advice was given about the right approach. The complaints manager should then **'investigate'** the complaint. The guidance said that this **'may include establishing the facts by talking to practitioners or staff involved'**. That was all the advice given on this crucial aspect of the process. It was suggested that, if necessary, advice might be sought from the practitioner's defence organisation, the local medical committee (LMC) or the HA's complaints manager. The practice complaints manager should then discuss his/her **'findings'** with the overseeing partner to decide upon the response, which might be a letter of explanation or an offer of a meeting. If it was thought that conciliation might be appropriate, the HA should be approached. Advice was given as to the tone and content of a letter of explanation. This should include information about the next stage of the complaints procedure. Finally, suggestions were made about how practices should learn from the complaints received.

7.11 Under the heading **'Helpful Hints'**, practices were advised to encourage patients who intended to complain to do so within a reasonable time after the relevant events, but it was suggested that practices should adopt a flexible approach to late complaints. If a complainant appeared unwilling to lodge his/her complaint with the practice, s/he should be given information about the appropriate contact at the HA and the Community Health Council (CHC). I have described the role of the CHC in Chapter 6.

7.12 It was thought that small or single-handed practices might have difficulty in setting up an adequate complaints handling process. Several possible solutions to this problem were suggested. The practice might join with other practices to operate the complaints system together or a practice might ask the LMC to nominate a member who would assist with the process. A further possible solution would be to offer complainants the services of a HA lay conciliator. I mention in passing that Shipman did not take up any of those suggestions. He appointed himself as complaints manager and the practice nurse, Sister Gillian Morgan, as his deputy. The practice's written complaints procedure said that clinical complaints would be handled by Shipman **'or by another GP'**. However, there was no other GP in the practice and Sister Morgan was not aware of any arrangement with another practice for the handling of complaints.

The Second Stage

7.13 If a complainant remained dissatisfied at the end of the first stage, s/he could apply, within 28 days, for an independent review. In considering whether to grant a review, the convenor would establish the precise nature of the complainant's remaining grievances. The convenor had first to consider whether the initial complaint had been made within the time allowed. Complaints were to be made within six months of the events complained of, or within six months of the discovery of the facts to be complained of and, in any case, within 12 months of the occurrence of the events. However, convenors could exercise discretion to allow a complaint to proceed if the delay was not unreasonable and if it was still possible to investigate the complaint satisfactorily. Before reaching a decision, the convenor had to consult with the person who would be the chairman of the review panel (IRP) if the application was granted. The chairman was a lay person selected from a list nominated by the SoS. If the complaint involved issues of clinical judgement, the convenor was supposed to seek the advice of a suitably qualified clinical adviser. It should be noted that, although the convenor had to consult with the proposed chairman, and possibly with a suitably qualified clinical adviser, s/he did not actually investigate the complaint.

7.14 Guidance was issued as to the approach convenors should take. An application should be refused if it appeared that the local resolution process had achieved all that could be hoped for and that a panel could add no further value, if further conciliation seemed appropriate or if the complainant had begun or had expressed an intention to begin a claim for damages. In practice, only a small proportion of applications for independent review were granted. According to national figures provided by the Department of Health (DoH), in the years between 1996 and 2001, there were between 1040 and 1430 applications made annually, of which between 219 and 341 were granted. The overall percentage allowed was between 22% and 23%. In Tameside, where between 14 and 24 requests were made annually over the same period, the percentages were not dissimilar,

although in one year, only one request was granted out of 23 requests made. Any complainant who was dissatisfied by the refusal to grant a review could ask the Health Service Ombudsman to consider the matter.

7.15 If the application for independent review was granted, the convenor would establish the terms of reference for the panel. A panel would be convened by an officer of the HA. The independent lay Chairman would already have been identified. Another independent lay person would be selected from the list of SoS nominees. The convenor would be the third member. If the complaint related to matters of clinical judgement, two independent clinical assessors selected from a list nominated by the SoS would be appointed to advise the panel.

7.16 Miss Andrea Horsfall was Deputy Consumer Liaison Manager for the WPHA and is now Complaints Manager for the Oldham Primary Care Trust (PCT). She told the Inquiry that she was responsible for making the practical arrangements for IRP hearings and would prepare a bundle of relevant documents on the instructions of the Chairman. Asked whether any further investigation ever took place in advance of the hearing, Miss Horsfall said that, on occasion, the Chairman would direct that a particular witness should be asked to attend to give evidence (although no witness could be compelled to attend). The witness would not be interviewed in advance but would be sent an explanation of what the case was about so that s/he would know what s/he would be asked about. It appears that, although relevant documents were assembled and witnesses invited, there was no investigation of the issues raised by the complaint.

7.17 The hearing before the IRP took place in private. The procedure to be followed was not laid down. The intention was that it should be informal, flexible and non-confrontational. The procedure should be adapted to suit the occasion and the issues to be considered. Sometimes the complainant would be accompanied by a friend or (until the abolition of CHCs in December 2003) a representative of the CHC. The doctor would usually be accompanied by a representative of his/her defence organisation. Either participant could be accompanied by a lawyer, but the lawyer was not permitted to act as an advocate. It appears that many panels chose to interview witnesses in the absence of the opposing party, although this was a matter for the discretion of the panel. Miss Horsfall said that, in her experience, it was usual for the complainant to be asked first to give his/her account of events and to explain why s/he remained dissatisfied with the outcome of the complaint. The panel would ask questions. Then any witnesses the complainant had brought would give their accounts and be questioned. After that, the complainant and his/her witnesses would leave the room and the doctor complained against would come in to give his/her account, followed by any witnesses s/he had brought. Any witnesses asked to attend by the Chairman would then give evidence. A full note of the evidence given would be taken by an administrator from the HA – Miss Horsfall often attended for this purpose – and the proceedings were recorded 'as a back-up'. At the end of the evidence, there would be a brief discussion between the panel members and possibly the assessors, if any. The assessors would then retire to write their report(s) on the clinical issues. The panel would disband.

7.18 The assessors' report(s) (if any) and the notes of evidence would be supplied to the Chairman, who would write a draft report to be circulated to the other members for

agreement or amendment. The report had to contain the relevant findings of fact and the panel's opinion (with reasons) on the complaint, having regard to the findings of fact. The panel was not obliged to accept the report of the assessors on clinical issues but, if it did not, it had to give reasons for its disagreement. The report could contain suggestions for improvements in the services provided by the practitioner concerned. It could not include any recommendation that disciplinary proceedings should be taken. However, Miss Horsfall said that, sometimes, panels expressed themselves quite strongly and their views would be clear. The report was sent to the Chief Executive of the HA, who had to distribute it to a list of interested parties.

7.19 If the complainant was dissatisfied with the IRP's report, s/he could apply to the Health Service Ombudsman, whose powers were extended in 1996 to include the investigation of complaints against GPs and complaints involving the exercise of clinical judgement.

7.20 From April 2002, PCTs took over responsibility for primary care from HAs and assumed the relevant functions under the complaints procedures. The procedures that came into effect in 1996 remained in operation until the coming into force of the National Health Service (Complaints) Regulations 2004 (the 2004 Complaints Regulations) on 30th July 2004.

Reactions to the 1996 Complaints Procedures

The Medical Law Review

7.21 Some criticisms of the 1996 complaints procedures were voiced at an early stage after their introduction. In 1997, Ms Diane Longley wrote an article in the Medical Law Review[1]. She recognised that the new procedures had not been in force for long and that teething troubles were to be expected. However, her main criticism was that the new system was flawed because it was not sufficiently independent of the NHS. First, she noted that convenors were non-executive directors of the HAs and not therefore independent of them. Moreover, their role was not an easy one; they had a wide element of discretion, to be exercised in consultation with the person selected to be the chairman of the IRP. If the application was granted, the IRP was formally a committee of the HA and the presence of the convenor on the panel might give rise to an appearance of in-built bias.

7.22 Ms Longley also drew attention to the need for a complaints system that covered all aspects of the health service, as, she observed, many complaints arose out of the interaction of several different agencies. Although the new procedures for primary and secondary care were similar, they were not connected. It would be difficult for a patient to complain about treatment that spanned more than one NHS body.

7.23 Ms Longley extolled the virtues of the systems operated in the Australian state of New South Wales and in New Zealand, suggesting that they offered a holistic approach to healthcare complaints and true independence from healthcare providers. The New Zealand system is based upon a statutory code of patients' rights. This provides broadly stated standards for the provision of services against which complaints can be assessed

[1] Longley D (1997) 'Complaints after Wilson; another case of too little too late?', Medical Law Review, 5, Summer 1997, pp. 172–192.

and judged by the Health and Disability Commissioner. I was able to read some of the decisions of the current Commissioner, Mr Ronald Paterson, who attended the Inquiry seminars. Because he gives fully reasoned decisions, it has been possible to develop certain standards to be applied in specific types of case or situation. His decisions can, where appropriate, be referred to the relevant professional disciplinary body.

Evidence to the Inquiry of Reactions to the New Procedures

7.24 The Inquiry heard evidence that the 1996 procedures did not bring complete satisfaction. Miss Horsfall was responsible, among other things, for advising general practices about complaints, for arranging conciliation services and for administering the independent reviews. She said that she thought that the 1996 complaints procedures were much better than the previous ones. They were far less stressful for everyone, largely because they were no longer linked to discipline. However, she became aware that complainants were reluctant to complain about their GP directly to the practice. She thought that some were deterred from complaining at all on account of this. Some feared that they might be removed from the doctor's list if they lodged a complaint. If a complainant contacted the HA, the staff had to advise the complainant to make the complaint to the practice. Usually, staff would try to smooth the path for the complainant, possibly by suggesting that the complaint be put in writing or by proposing conciliation. Miss Horsfall had found that conciliation was extremely useful in a wide range of complaints, including some involving issues relating to clinical treatment, as many complainants were only seeking an apology.

7.25 Miss Horsfall also expressed concern that the new system was still 'patient driven', as the old one had been. It was up to the complainant to take matters forward to the second stage. There was no one who would take the complaint over and advance it, if the complainant did not want to pursue it. She thought that some complainants gave up, even though they were not satisfied. This was so even where the allegation was of a nature which could raise serious concerns about the competence of the doctor.

7.26 One of Miss Horsfall's major concerns related to the information that was available to the HA. The HA regarded complaints as an important source of knowledge about the GPs in its area. Under the old system, all complaints came direct to the FHSA. Under the new system most complaints were made direct to the GP practice. The practice only had to inform the HA how many complaints had been received in the past year. It did not have to give any information about the subject matter of a complaint or the way in which it had been resolved. The HA found out about few complaints. If a complainant contacted the HA, s/he might or might not tell Miss Horsfall what the complaint was about. Only in a few cases did Miss Horsfall find out at that stage whom the complaint was against and what it was about. If Miss Horsfall was asked to arrange conciliation, she would find out whom the complaint was against and would receive the practice's records relating to the complaint for transmission to the conciliator but, officially, she was not allowed to use that information. If the complainant proceeded to the second stage, the HA would find out what the complaint was about. Miss Horsfall's concern was that the HA did not have a complete picture of complaints in the area. Since 2002, when PCTs took over responsibility for the provision of primary care and the administration of the second stage of complaints procedures in their area, the same problems have remained. Miss Horsfall said that,

nowadays, the collection of information about complaints is an important aspect of clinical governance. She thought that practices should be required to provide information about complaints to PCTs much more frequently than annually and should have to include copies of the complaint and the final letter of explanation.

7.27 Miss Horsfall also had reservations about the criteria for determining whether or not there should be an independent review. She thought they were too narrow and that this resulted in dissatisfaction on the part of complainants. She was particularly unhappy about the effect of the rule that complainants were not allowed to proceed to the second stage if they intended to sue for damages. Her instructions were to ask complainants about this. If a complainant said s/he intended to sue, the application would be refused.

7.28 The Inquiry also heard evidence that there was dissatisfaction in some places (although not in Tameside) with the way in which convenors carried out their duties. The question was also raised at the Inquiry about whether convenors might be influenced against the convening of an IRP by the knowledge that it would put the HA of which they were directors to some expense. I was told that a review would cost the HA about £1500 to £2000. The guidance that was issued recognised that cost might operate as a disincentive to recommending independent review, expressly stating that cost should not be taken into account.

7.29 Miss Horsfall told the Inquiry that although she had reservations about the rules and guidance under which the convenors had to operate, she considered that Mr Geoffrey Lamb, the convenor for the WPHA, applied the guidelines fairly and with the utmost care. There was no suspicion in her mind that he might ever have rejected an application because of the expense that would be incurred by the HA if it were granted.

7.30 Miss Horsfall thought that complainants were generally satisfied with the conduct of IRP hearings. Complainants often said that they had found the experience less stressful than they had expected. Dr John Givans, who had considerable experience of representing GPs at panel hearings on behalf of the Medical Defence Union, said that many of his clients were dissatisfied because they did not have the opportunity to hear the complainant's evidence. This was particularly unsatisfactory in cases where there was a conflict of evidence about what had happened and the panel had to decide between one version and another. He understood that many complainants also expressed a similar view.

7.31 Miss Horsfall said that some complainants were pleased with the outcome of their reviews and some were disappointed. Some were dissatisfied because there had been no sanction against the doctor, even though the complaint had been upheld.

7.32 Miss Horsfall said that it was not always possible to complete the IRP process within the target timescale of three months. Examination of data published by the DoH in September 2003 shows that, in the year 2002–2003, IRP action was concluded outside target times in about 55% of cases.

7.33 When the IRP's report was received, the HA (and later the PCT) would decide what action, if any, should be taken to remedy any problems identified by the panel. However, the IRP

had no power to insist that the HA/PCT take any action to implement the recommendations or to deal with the GP's shortcomings in any way.

7.34 It is interesting to note that, for the two and a half year period during which Shipman practised while the 1996 complaints procedures were in place, the WPHA became aware of only one complaint made against him and, in line with practice at the time, no details of that were supplied by him. The evidence suggests that, in fact, at least three complaints were made to the practice over that period. Forms described as 'Complaint Control Sheets' relating to two complaints were stapled into Shipman's complaints book, which was recovered from the surgery after his arrest. The first was an oral complaint about the wording used by Shipman in a hospital referral letter. The Complaint Control Sheet described Shipman as the **'Investigating Officer'** and recorded that, after a meeting, the complainant had been happy with the outcome. The second was a detailed oral complaint about a member of the practice staff refusing to provide information about surgery times. The complainant had subsequently declined to be seen and it was recorded that the complaint would be dealt with as and when a formal complaint was received. A third complaint was not recorded on a Complaint Control Sheet at all. All that is available is a copy of a letter sent by Shipman from which it is possible to glean that the patient had complained about his refusal to undertake her maternity care if she wanted a home delivery. The outcome of the complaint is not known.

7.35 It is a matter of some concern that, if there is no external supervision of complaints, a practitioner might be able to mollify a complainant on a false basis, for example, by claiming that what had happened was an unfortunate outcome but was something that did happen from time to time. Another possibility is that a doctor might make an apparently sincere apology for, say, a prescribing error, which satisfied the patient but did nothing to correct the doctor's poor practice. Or, as apparently happened with Shipman, the information supplied by the practice to the HA or PCT about the number of complaints received could be inaccurate.

The 1996 Disciplinary Procedures

7.36 As I have explained, whereas, under the pre-1996 procedures, complaints that amounted to a breach of the GP's terms of service were directly linked to disciplinary procedures before a medical service committee, from April 1996 this was no longer the case. The National Health Service (Service Committees and Tribunal) Amendment Regulations 1996 came into force at the same time as the 1996 complaints procedures. HAs (and later PCTs) could arrange disciplinary proceedings in any matter (apparently amounting to a breach of the GP's terms of service) that, in their opinion, was serious enough to warrant disciplinary action. From 1996, decisions on whether to initiate proceedings were taken by a committee of the HA or PCT, usually known as the reference committee. If it became necessary to hold a disciplinary hearing, a medical disciplinary committee would be provided by an adjacent HA or PCT so as to provide a degree of independence from the HA or PCT which was, in effect, the complainant or prosecutor. A rather cumbersome adversarial procedure would be followed. However, in practice, such proceedings became very rare. Miss Horsfall told the Inquiry that, over a period of seven years, only one doctor had been referred to a disciplinary panel in Tameside, and he and one other

doctor had been reported directly to the General Medical Council (GMC). Nationally, there was a dramatic reduction in the number of disciplinary proceedings held. Whereas, in the latter years of the old regime, annually there had been between 325 and 552 GPs found in breach of their terms of service, between 1997 and 2003 the corresponding figures were between three and twelve. This reduction was in no way foreseen. Mr David Laverick, who was Chief Executive of the Family Health Services Appeal Authority (FHSAA) at the time of the transition, told the Inquiry that it had been anticipated that the numbers would remain the same as before, and that the FHSAA had planned for about 400 findings annually. The 2002/2003 Annual Report of the Council on Tribunals described many substantive and procedural shortcomings that had been revealed by their observations of the working of medical disciplinary committees. Several of these originated from the fact that so few hearings were in fact being held. Specifically, inconsistencies in the rules were exploited by medical defence organisations, and deliberation and decision-making were often laboured and unstructured.

7.37 There seem to be at least two reasons for the marked reduction in numbers of hearings. First, it was not possible for a HA or PCT to take disciplinary proceedings in respect of any matter arising from a patient complaint unless and until the complaints procedures had been completed. If a complaint went to independent review or to the Health Service Ombudsman, the process could take a long time. When it was completed, the HA or PCT could not use the evidence already given to the IRP but had to ask the complainant and his/her witnesses, if any, to give evidence again. Not all were willing to co-operate so long after the event. This procedure was necessary out of fairness to the doctor who, previously, might not even have heard the complainant's evidence, let alone had the opportunity to challenge it directly.

7.38 The second, and perhaps more important, reason for the decline in disciplinary proceedings was that there had been a change of culture. There is now a general view that it is preferable that a doctor whose conduct or performance has been in some way unacceptable should be helped to improve rather than be subjected to punishment. In Chapter 5, I described the ways in which HAs (and more recently PCTs) developed committees or groups whose function was to ensure that any concern about a practitioner, however it was brought to the notice of the HA, was adequately addressed. To a very large extent, the activities of such committees or groups had replaced disciplinary proceedings at local level even before the introduction of the list management procedures that PCTs can now invoke to deal with more serious or intractable problems with GPs. In Chapter 5, I also described the list management powers that PCTs have had since April 2002. These enable (and in some limited circumstances require) a PCT to suspend or remove a doctor from the PCT's list or to impose conditions on the doctor's continuing inclusion.

7.39 It was an inevitable consequence of the sharp reduction in disciplinary proceedings that very few appeals were made to the FHSAA and, later, the FHSAA (Special Health Authority) and, in consequence of that reduction, very few doctors have been reported by that body to the GMC. After 1996, the usual mechanism for the reporting of a doctor to the GMC was either by means of a direct complaint by a patient or representative or by the HA or PCT itself if it took the view that remedial measures it had itself applied had not been, and were not likely to be, successful. Among those responsible for the administration of

disciplinary measures, their demise does not appear to have given rise to significant dissatisfaction. However, it does appear that some patients or their representatives who pursued a complaint against a doctor remained dissatisfied even though their complaints may have been upheld, because their perception was that the doctor had not been held accountable. To some extent, this problem arose because complainants were not entitled to be informed (and, in practice, were not informed) about any remedial measures that the doctor might have been required to undergo as the result of an IRP's report. However, it may be that there is a fundamental problem with the 1996 complaints procedures in that they do not provide any clear focus or objective. Before 1996, the objective was at least clear, unsatisfactory though it may have been: it was to punish the doctor who breached his/her terms of service. Since 1996, the objectives have been to **'satisfy the complainant'** and to learn from mistakes. So far as the complainant is concerned, there is no redress other than perhaps an apology. I shall return to the issue of redress later in this Chapter.

The Power to Suspend a General Practitioner from NHS Practice

7.40 One unsatisfactory aspect of the 1996 disciplinary procedures was brought into sharp focus in 1998, when the WPHA was advised by the Greater Manchester Police (GMP) that Shipman was under investigation for the murder of a patient, Mrs Kathleen Grundy, that a number of other sudden deaths gave rise to suspicion and that Shipman was thought to be a risk to his patients. Shipman had not at that stage been arrested or charged with any offence. He was practising, as usual, from 21 Market Street, Hyde. On 14th August 1998, Detective Superintendent Bernard Postles (later Detective Chief Superintendent), the officer in charge of the investigation into Shipman, requested that the WPHA take steps to suspend Shipman from practice. He also contacted the GMC but was informed that that body had no power to suspend a doctor during the investigation of a criminal offence.

7.41 The WPHA itself did not have the power to suspend Shipman either. The procedure under the National Health Service (Service Committees and Tribunals) Regulations 1992, as amended, was for the WPHA to apply to the NHS Tribunal, which did have the power to impose interim suspension, pending the hearing of an application by the WPHA for removal of Shipman's name from their list. Liaison between the WPHA's solicitor and the Clerk to the NHS Tribunal revealed that the NHS Tribunal would require a written application supported by evidence from the police, including witness statements. The police were unwilling to reveal such information at that time, as disclosure to Shipman might prejudice their investigations. Further communications between the WPHA and the Clerk to the NHS Tribunal resulted in a formal application being made on 21st August, supported by a summary of the position and letters in which the GMP explained the reasons for its **'mounting concerns'** about the safety of Shipman's patients. The procedure required a hearing before the Tribunal. Shipman had to be given 14 days' notice of a hearing; in fact the hearing was fixed for 29th September.

7.42 The police decided to act and arrested Shipman on 7th September. He was charged with murder and forgery and was remanded in custody. His patients were now safe, although the GMP feared that an application for bail might succeed. In any event, the WPHA wished to take over the management of Shipman's practice, as the consortium to which Shipman

belonged was having difficulty in finding locum doctors to provide services to patients. Both the GMP and the WPHA wished to pursue the application to the NHS Tribunal. Further evidence was lodged, on affidavit.

7.43 A hearing took place before the Tribunal in London on 29th September. An application to adjourn the proceedings, made on Shipman's behalf, was refused. The Tribunal's decision was reserved and was delivered, in writing, on 15th October. The Tribunal had decided to suspend Shipman from the list of practitioners providing general medical services to the WPHA. However, the decision did not take legal effect until the expiry of a further 14 days, during which time Shipman was entitled to lodge an appeal. In fact, he did not do so and the order took effect from 29th October 1998. Both the WPHA and the GMP were deeply dissatisfied that it had taken ten weeks to obtain an effective order.

7.44 The difficulties experienced by the WPHA and the GMP in this case led directly to a decision by the GMC to seek extended powers of interim suspension, which it now has. Also, the Health and Social Care Act 2001 abolished the NHS Tribunal and granted to HAs (later PCTs) the power to suspend and remove a GP from their lists. A PCT can take action only in respect of its own list. If appropriate, a PCT can refer a case to the FHSAA (a new body created in December 2001), which can impose national disqualification.

Research into the Operation of the 1996 Complaints Procedures

The Public Law Project

7.45 In July 1997, the Public Law Project commenced research into the operation of the 1996 complaints procedures from the perspective of health service users. Its report, entitled 'Cause for Complaint? An evaluation of the effectiveness of the NHS complaints procedure', was published in September 1999.

7.46 Local resolution was reported to be generally satisfactory in practices that were committed to the process but less good with defensive practitioners who merely **'played the game'**. A number of concerns were expressed. First, it was apparent from an examination of the decisions of convenors that many practices did not operate fair procedures; many failed to investigate the complaint adequately or to give an adequate explanation at the end of the process. In 47% of the cases examined, the convenor had sent the case back for a further attempt at local resolution. There were also more fundamental concerns. The local procedures failed to take account of the imbalance of power inherent in the relationship between healthcare professional and patient. It was very difficult for patients to challenge the organisation that had treated them. The procedures whereby an organisation investigated its own conduct or performance were unlikely to be impartial. Local NHS complaints procedures were not accountable to any external body. These problems were particularly acute in the primary care sector, where the need to bring the complaint directly to the practice acted as a deterrent to complaining. The handling of a complaint by a small organisation could become uncomfortably personalised. Patients feared retribution such as being removed from the practice list. Some were sceptical about whether they would receive honest or impartial explanations. It was felt that there was a need for complainants to be able to take their grievances to an independent authority which would assume responsibility for overseeing any investigation.

7.47 Concern was expressed about the inability of the new procedures (particularly at a local level) to deal adequately with complaints that raised serious questions about performance, conduct or competence, such as might place patients at risk. One of the major problems was the inadequacy of the investigation of the complaint. Not only did the complaints manager not always have the necessary skills, there was often a defensive attitude which amounted to **'collective back-covering'**. It was in this area in particular that there was a need for independence and competence in the handling of complaints.

7.48 Convenors were seen to be less than independent and were perceived as **'insiders'** of the NHS. Nearly 50% of all the convenors interviewed said that they felt compromised by their role as a non-executive director of the HA. Some had insufficient experience or training to fulfil their functions satisfactorily.

7.49 The conduct of IRP hearings was also unsatisfactory. It was reported that most panels opted to hear the participants separately. Many complainants felt dissatisfied that they had not been able to hear the doctor's explanation. There was also a feeling that some panels and assessors were biased towards the NHS. Sometimes, IRP chairmen lacked the necessary skills to function well.

7.50 The report highlighted the problem, mentioned by Miss Horsfall in evidence to the Inquiry, that HAs and PCTs were unable to monitor the handling of primary care complaints because they had little information about them. This had led to a loss of accountability of practitioners. The authors also reported that the commitment of NHS organisations to using the complaints process as an instrument of change was variable. Not all made much effort to implement IRP recommendations. Concern was expressed about the effect of the dissociation of discipline and complaints procedures. It was noted that there had been a marked decline in the number of disciplinary proceedings taken in primary care. It appeared that there was a preference for dealing with shortcomings by retraining and skill improvement. It was suggested that the drawback to this was the lack of any sanction. There was an appearance that healthcare professionals were not accountable.

7.51 The report concluded with a number of recommendations. I shall highlight five. First, it was said that primary care patients should be able to complain directly to an officer who was independent of the practice and who would have responsibility for overseeing the investigation of the complaint. Second, it was suggested that the DoH should develop a framework for fast tracking complaints that raised serious questions about performance, conduct or competence which put patients at risk. Such complaints should be considered by a 'screener' who would decide whether they should be referred immediately to more formal investigatory or remedial processes. Third, the second stage of the process should be conducted under the auspices of a regional, rather than a local, NHS body, to increase independence and efficiency. Fourth, guidance should be disseminated for the conduct of IRPs to improve fairness and transparency. Finally, accountability should be improved by the provision of information about primary care complaints to HAs, by permitting IRPs to recommend disciplinary action and by keeping complainants informed of the outcome of disciplinary action.

7.52 In my view, this research was well conducted, reached careful conclusions and recommended sensible measures. Although it did not result in any immediate action, it

may well have stimulated the commissioning of further research and may have influenced Government thinking.

Report on the Research Undertaken by the York Health Economics Consortium

7.53 In 1999, the Government commissioned the York Health Economics Consortium to undertake research into the operation of the NHS complaints procedures. The Consortium published its report (the York Report) in March 2001. As with the work of the Public Law Project, this research appears to have been well conducted. It was, however, more widely based and surveyed the experience of all types of people who operated the procedures as well as those who used them. The findings bear a remarkable similarity to those of 'Cause for Complaint? An evaluation of the effectiveness of the NHS complaints procedure', although, as I shall explain, the recommendations were far less radical.

7.54 Among complainants, there was a high level of dissatisfaction in respect of local resolution and the second stage. At local level, only about one third of complainants were satisfied with the process. Dissatisfaction related to the handling of the complaints, the time taken, unfairness and bias, stressfulness and outcome. Patient interest groups emphasised the difficulty that many patients experienced in complaining directly to a service provider. There were reports of patients being removed from a practice list following a complaint. Specific criticisms related to unhelpful, aggressive or arrogant attitudes of staff, poor communication and lack of information and support. At the second stage, only a quarter were satisfied. Dissatisfaction again related to delay, unfairness and bias, stressfulness and outcome. Only 13% were satisfied with outcome. The main complaint about the second stage was of lack of independence.

7.55 Among NHS staff who had been the subject of a complaint, there was a high level of satisfaction. Most thought the complaint against them had been handled well and that the process had been fair and unbiased. Some complained that they had not been kept sufficiently informed of progress. In my view, the stark difference between the satisfaction levels of those complaining and those complained against is very significant. It strongly suggests that the procedures were weighted against complainants.

7.56 In the eyes of most of those involved in the operation of the procedures the view was that they were superior to those in force before 1996. However, the need for improvement was recognised, in particular in respect of the independence of those involved in the second stage. Some of those involved thought that the second stage procedures were too time-consuming and expensive. Some thought that the performance targets were difficult to meet. IRP members wanted better training and feedback.

7.57 The York Report discussed the policy implications of the findings and made many specific recommendations. In relation to primary care services, the recommendations were developmental rather than radical. The main thrust of the proposals was to ensure that complaints handling at local level was given a higher priority. It was suggested that complainants must be offered the opportunity to complain otherwise than directly to the practice. This was to be achieved by encouraging practices to work together to share information and to offer support in providing acceptable procedures. There should be less discretion afforded to practice complaints managers about how complaints should be

handled. Wider use should be made of conciliation. There should be a named individual in each PCT, to whom complainants would have access, with responsibility to **'handle complaints about member practices'**. Also it was proposed that PCTs should receive more information about complaints, including the causes of complaints and the action taken or proposed to prevent a recurrence. PCT boards should receive a quarterly report on complaints and should take responsibility for ensuring that agreed actions were implemented. The quarterly report should be disseminated to local patients' organisations. Consideration should be given to the development of a National Service Framework for the management of complaints.

7.58 Proposals for improvement of the second stage related mainly to increased independence of convenors and panels. The second stage should be conducted at a regional or sub-regional level. Consideration should be given to increased powers for panels, for example to summon witnesses and take evidence. Improved training should be provided for all those operating the second stage. The Health Service Ombudsman should be asked to consider how to operate a fast track procedure whereby, in appropriate cases, the second stage would be conducted by the Ombudsman. The board of the relevant NHS body should take active responsibility for ensuring that, following the receipt of an IRP report, an action plan was produced and the action implemented.

Report of the Commission for Health Improvement into the Case of Peter Green

7.59 In August 2001, the Commission for Health Improvement (CHI) published a report of its investigation into the conduct of a GP, Peter Green, who had been convicted in July 2000 of sexual assaults on a number of patients. The report criticised **'an NHS culture that did not listen to complaints or treat them inquisitively'** and **'an NHS complaints system failing to detect issues of professional misconduct or criminal activity'** over a number of years. Concerns about Green's conduct had been raised with a variety of different bodies on no fewer than 23 occasions between 1985 and 1997. These included the FHSA, doctors at Green's practice, the GMC and the police. The complaints had not been logged or cross-referenced and the pattern had not been noticed.

7.60 The CHI report focussed on the systems failures and did not make specific recommendations for the reform of the complaints procedures. However, it described a telling example of the way in which local procedures can fail completely if the attitude of the practice is not open and fair. One of Green's victims made a complaint to the practice in 1996. After **'investigation'**, the official response was that there was **'no evidence that Dr Green was guilty of any professional misconduct or that he had motives other than to benefit you** (*the complainant*) **in his treatment of you'**. Of course, there was evidence of professional misconduct – from the complainant – but the practice had not taken it sufficiently seriously and had apparently accepted Green's explanation of what had occurred.

Commitment to Reform: Consultation

Statements of Intent

7.61 In July 2000, the Government published 'The NHS Plan, A plan for investment, A plan for reform' (the NHS Plan), which contained its proposals for the modernisation of all aspects

of the health service. The NHS Plan included an undertaking to reform the complaints procedures and also to improve the information and assistance to be available to patients. It announced the future formation of the Patient Advocacy (later to be changed to 'Advice') and Liaison Service (PALS), which, it was said, would **'steer patients and families towards the complaints process where necessary'** and would take over the functions then performed by the CHCs in supporting complainants. CHCs provided free advice and support for complainants at all stages of the complaints procedures. CHCs would draft and deal with correspondence, would advise about the issues raised and would accompany the complainant at any hearing. The evidence received by the Inquiry suggests that many did their work well and that their services were much appreciated, not only by complainants but also by those with responsibility for administering the procedures, such as Miss Horsfall.

7.62 In September 2001, the Government published a Consultation Paper entitled 'Reforming the NHS Complaints Procedure: a listening document'. The consultation took place shortly after the publication of the Report of the Public Inquiry into children's heart surgery at the Bristol Royal Infirmary 1984–1995. The Consultation Paper explained that it was the Government's intention to improve the accountability of the NHS and to give patients and the public a greater role in shaping health care. The Consultation Paper summarised the findings of the York Report and sought views on its recommendations. Some specific questions were posed for discussion. The Government promised to listen to patients' views. Consultation closed in October 2001.

7.63 Also in September 2001, a second Consultation Paper was published, entitled 'Involving Patients and the Public in Healthcare. A Discussion Document'. The principal measures proposed were the formation of the Commission for Patient and Public Involvement in Health (CPPIH), which would have an overarching and co-ordinating responsibility for patient involvement in the health service. Two new bodies would be formed, PALS and a locally based Independent Complaints Advocacy Service (ICAS). A Patients Forum would be set up in every NHS trust. The remit of the Patients Forums would be to monitor and review the quality of local services from the perspective of patients. CHCs would be abolished. The two new services, PALS and ICAS, would, in the words of the Consultation Paper, **'be a key means of ensuring that patients' concerns would be dealt with rapidly and to everyone's satisfaction'**. The intention was that PALS would be able to provide on-the-spot advice and help to patients in the resolution of a wide variety of problems. ICAS would provide assistance to patients in advancing a complaint. The proposal to abolish the CHCs was met with widespread expressions of dismay, particularly from organisations representing patients' interests.

7.64 In 'Delivering the NHS Plan', published in April 2002, the Government announced its intention to form the Commission for Healthcare Audit and Inspection (now known as the Healthcare Commission), which would, among many other functions, have responsibility for the independent scrutiny of healthcare complaints.

After the Community Health Councils

7.65 The abolition of the CHCs proceeded more or less as planned and a branch of PALS was set up in each area. PALS advisers are NHS employees; they may be employed by a

hospital trust or a PCT and, in some areas, PALS may serve both the primary and the secondary sectors. PALS is intended to give advice about a wide range of problems that a patient might encounter within the NHS; it is not limited to advice about complaints. A PALS adviser might tell a patient how to go about lodging a complaint and might advise him/her how to obtain the support of ICAS. PALS does not provide independent support for a complainant. It would be inappropriate for it to do so, as those who run the service are NHS employees.

7.66 In May 2003, the Association of CHCs published a preliminary survey of the accessibility and efficacy of PALS. I recognise at the outset that this survey was undertaken by one of the bodies that was being supplanted by PALS. It might reasonably be said that the Association had a point of view to promote. However, I have no reason to suppose that its data is inaccurate. The survey showed that the provision of the new service was very patchy. Of 100 sample calls made to the switchboards of 100 different NHS trusts, requesting access to PALS, only 51 calls resulted in a personal response. The rest were either not connected to PALS or were met by an answerphone response. This survey was conducted in the early days after PALS was set up. It is to be hoped that there has been some improvement during the last 18 months.

7.67 ICAS has taken a little longer to set up. As its name implies, ICAS is intended to be independent of the NHS. Contracts for ICAS provision were being signed when Sir Nigel Crisp, Chief Executive of the NHS in England, gave evidence to the Inquiry in July 2003. ICAS services are currently commissioned centrally by the CPPIH and are provided by Citizens' Advice or similar organisations. In July 2004, the Government announced its intention to abolish the CPPIH and, at present, it is not clear to me who will be responsible for the commissioning of ICAS services. When the Inquiry was hearing oral evidence, ICAS was in its infancy and the precise ambit of its functions was not yet clear. In July 2004, however, according to the CPPIH website, ICAS could offer to **'help clients identify the options for taking forward their complaint/s about NHS services'** and **'make sure lessons from users' experiences of the NHS are fed back into the service and to those responsible for scrutinising the NHS'**. It cannot, however, help with complaints about private healthcare treatment or services that arise outside the NHS, nor can it assist complainants who are pursuing or intend to pursue litigation concerning a complaint about NHS services.

7.68 The Inquiry has not received evidence as to how ICAS is functioning. It seems likely from information currently on its website that it will in fact provide support for complainants throughout the complaints process. There is a need for complainants to have access to free, independent and well-informed advice. It is not sufficient that a complainant is told how to proceed. He or she needs someone with whom to discuss the issues and the merits of the complaint. He or she needs advice about whether, and exactly how, to proceed. He or she needs someone to support him/her at a hearing, if any. If ICAS is indeed able to provide such advice and support, its work is to be very much encouraged.

The Government Proposals for Complaints Procedures

7.69 In February 2003, the Government's proposals for reform of the complaints procedures were published in 'NHS Complaints Reform: Making Things Right'. This document

acknowledged all the defects of the existing system that had been highlighted in the research and which had, apparently, been confirmed during the consultation exercise. These included difficulty in pursuing complaints, delays, negative attitudes by those operating the procedures, lack of fairness, lack of support, lack of independence at the review stage, lack of redress and a failure to use feedback from complaints to improve services.

7.70 The essential proposals were to improve the operation of the local procedures, to reform the second stage radically and to improve the mechanisms for learning from complaints. It was recognised that, if local procedures were to be improved, there would have to be a change of attitude in some of those operating the procedures. In particular, it was said that complaints should be valued as an aid to learning and improving the quality of service; they should be dealt with positively and willingly, not defensively. The proposal was to bring about this change of attitude by improved training and development programmes. Also, patients who wished to complain were to be given improved information and greater support.

7.71 I feel bound to observe that it would be a fine thing if attitudes towards complaints could readily be changed by training and education. I think that they can be improved but that change will be a long and gradual process. First, I have the impression that, for many doctors, a hostile attitude to complaints is deeply embedded. In the medical press, it is not uncommon to find opinions that most complainants are obsessive and their complaints unfounded. Second, it is human nature to be defensive when criticised. Being on the receiving end of a complaint can be distressing, irritating and very time-consuming. That is not to say that the effort to bring about change in attitudes is not worth making. I think it is. In respect of the second stage, 'NHS Complaints Reform: Making Things Right' proposed that the independent review should be carried out, not under the auspices of the local PCT, but by what is now the Healthcare Commission. This organisation would be seen to be independent and efficient. It would be able to identify what was required to put matters right and would also ensure that lessons were learned where mistakes had been made. Third, complaints and their resolution should become an integral part of the systems of quality control in the NHS. Overall responsibility for complaints handling would rest with senior management. Information derived from complaints would be used for clinical governance purposes.

Proposals to Include the Provision of Redress for Justified Complaints

7.72 I referred earlier to the lack of any redress for complainants whose complaint is found to have been justified. At present, and indeed under the draft National Health Service (Complaints) Regulations (the draft Complaints Regulations) setting out the proposed new complaints procedures, if a complaint is upheld, the complainant should receive an apology and an explanation of what has occurred. There is no possibility of even limited financial redress. Historically in this country, there has been a complete separation between the making of a complaint and the seeking of financial redress. Financial redress can be obtained only by legal action in the courts and, consequently, only in cases in which the claimant can prove damage due to a breach of the legal duty of care owed to the patient by the doctor or the organisation. As I mentioned earlier, any patient who

decides to take legal action is, at present, barred from pursuing a complaint to the second stage and can expect no assistance from ICAS.

Consolatory Payments

7.73 A complaints procedure that cannot provide any financial redress is unlikely to give satisfaction in many cases. Indeed, it is my understanding that some financial redress is usual nowadays for complaints against other professionals; certainly the procedures operated by both solicitors and barristers provide limited financial compensation. When a patient complains about a doctor, there will be times when all that s/he wants is an apology or to find out what has happened or reassurance that steps have been taken to prevent the recurrence of the problem that gave rise to the complaint. Sometimes, a complainant will feel that that reassurance can be provided only if the doctor complained of is subjected to some disciplinary process, possibly even amounting to erasure from the medical register. Sometimes, a complainant will want – and should be entitled to – an apology, an explanation, or a reassurance that lessons have been learned, and some, albeit modest, redress.

7.74 In his Annual Report for 2000–2001, the Health Service Ombudsman reported that NHS bodies had found themselves in difficulty when they wished to make a small consolatory payment, for example, to a person who had suffered some injustice, because they could not do so under NHS rules. A payment could be made only if the person involved was able to demonstrate financial loss, or if the NHS body was found guilty of maladministration. The Ombudsman suggested that the rules should permit the payment of a modest sum in acknowledgement of delay or **'botheration'** and make plain that such a payment does not amount to an admission of liability. Such a rule would, in his view, be more in keeping with a modern NHS. The Ombudsman said that he had raised this point with the SoS in connection with a particular complaint but the SoS was apparently unwilling to consider any change on the basis that consolatory payments would divert funds from patient care. The Ombudsman pointed out that, in principle, the rule against consolatory payments applies not only to the NHS, but also to central and local Government, both of which, the Ombudsman claimed, were willing to make consolatory payments. In my view, the opinion of the Health Service Ombudsman was interesting and valuable. He was in a uniquely good position to estimate the value of consolatory payments in achieving satisfaction for complainants.

'Making Amends'

7.75 In June 2003, the Chief Medical Officer published 'Making Amends', a Consultation Paper setting out proposals for reforming the approach to clinical negligence in the NHS. I do not intend to describe the content of the Paper in any detail. In essence, it sets out a long-term strategy to improve health care by learning from mistakes and to provide a holistic response to patients who complain about an adverse event in health care. The paper recognises the need for patients who have suffered an adverse consequence as the result of something 'going wrong' to receive an apology, a frank explanation of what has happened, remedial treatment and care and, where appropriate, financial

compensation. My understanding is that the financial compensation envisaged would be much larger than a consolatory payment but much less than the damages that would be awarded by the courts.

7.76 The thinking behind the proposals is that a system that provides these four elements will, in the long term, ensure that the NHS focusses on the prevention of harm and the reduction of risks so that the quality of care is improved and the level of medical error is reduced. Also, the proposals should lead to a better co-ordinated response to harm resulting from inadequate health care. A reduction in the level of medical error would mean that fewer patients would have cause to sue the NHS and a better response to harm would mean that fewer patients would wish to sue, because their complaints would have been properly dealt with without recourse to action in the civil courts. Not unnaturally, there is a hope that the high cost of clinical negligence claims will eventually be reduced.

7.77 The Consultation Paper focusses mainly on the suggestion for a NHS redress scheme, which is described in some detail, although it also suggests some changes in the law of tort in relation to clinical negligence claims. The scheme for redress would be available in cases where harm has been suffered as the result of serious shortcomings in the standard of care, where the harm could have been avoided and where the adverse outcome was not the result of the natural progression of an illness. At present, the proposal relates only to the secondary care sector, although, if successful, it is hoped to extend it to primary care.

7.78 The Consultation Paper stresses the need for the thorough investigation of all adverse events and the duty on healthcare professionals and managers to provide an honest explanation to patients about what has gone wrong. One particular recommendation relates to a **'duty of candour'** of healthcare professionals. It is suggested that there should be a legal duty upon such professionals to inform patients where they become aware of a possible negligent act or omission. The paper also suggests that, concomitant with the duty of candour, there should be an exemption from disciplinary action by employers or professional regulatory bodies for those reporting adverse events, **'except where the healthcare professional has committed a criminal offence or it would not be safe for the professional to continue to treat patients'**.

7.79 In its response to 'Making Amends' the GMC pointed out that doctors are already under a professional duty to give patients a frank explanation when things have gone wrong. This is wider than the suggested duty to tell patients when the doctor thinks there might have been negligence. Also, the GMC suggested that a legal duty would be difficult to police and would, therefore, be undesirable. The GMC would prefer a professional duty. As for the suggested exemption from disciplinary action, the GMC reminded the Government of the policy enunciated in 'A Commitment to Quality, A Quest for Excellence: A statement on behalf of the Government, the medical profession and the NHS', published in June 2001. In that document, the Government and the profession had agreed that, without lessening the commitment to quality and the accountability to the public, honest failure by a healthcare professional should not be dealt with primarily by blame and retribution but by learning from mistakes. However, as the GMC pointed out in its response, the exemption from disciplinary action now being proposed went beyond the commitment in

the joint statement of policy and would be incompatible with the GMC's own statutory duty to take appropriate action (possibly including disciplinary action) when a complaint is received. Mr Ian Hargreaves, retired Regional Director, Royal College of Nursing, also told the Inquiry that he considered the idea of exemption from disciplinary action undesirable in the case of any healthcare professional.

7.80 The consultation period allowed in 'Making Amends' expired in October 2003 but, at the time of writing in late 2004, the Government has not announced how it intends to proceed.

Proposals for Reform of the 1996 Complaints Procedures

7.81 In July 2003, when the Inquiry embarked upon the Stage Four hearings, which covered all issues relating to the monitoring of GPs, the Government had not yet produced any firm proposals for change to the complaints procedures. The Stage Four hearings included an investigation of the operation of the complaints handling system. In October 2003, the Inquiry published a Consultation Paper, entitled 'Safeguarding Patients: Topics for Consideration at the Stage Four Seminars', which was designed to elicit responses to, and provoke discussion of, ideas that had occurred to the Inquiry team during the investigative stage and the first few weeks of the hearings. The issues and responses were to form the basis for discussion at the seminars to be held in January 2004. Five of the topics raised in the Consultation Paper related to patient complaints.

7.82 In December 2003, the DoH published detailed proposals for change in the form of the draft Complaints Regulations. By this time, the Inquiry had already heard evidence about patient complaints but, fortunately, the draft Complaints Regulations were published before the seminars took place. It appears that the Government had continued to 'listen' to reactions to its outline proposals, because the detailed proposals in the draft Complaints Regulations contained some important developments. The major reform presaged in 'NHS Complaints Reform: Making Things Right' (i.e. the transfer of the second stage review to the Healthcare Commission) was provided for in Part IV of the draft Complaints Regulations. However, in respect of the first stage, it appears to have been recognised that negative attitudes towards complaints prevalent in some NHS organisations could not be changed within a reasonable timespan by education and training alone.

7.83 The Health and Social Care (Community Health and Standards) Act 2003 was passed and provided for the creation of the Healthcare Commission, which came into existence in April 2004. As the proposal to transfer the second stage of the complaints procedure to the Healthcare Commission had been widely welcomed and it was becoming increasingly difficult to operate the IRP system, the Government was anxious to bring the provisions governing the second stage into effect. However, the proposals for the first stage of the procedures had not met with such wide and complete approval. In particular, some reservations about them were expressed at the Inquiry's seminars and it was known that this Inquiry would make relevant recommendations. The Government also wished to await the Reports of two other Inquiries (the Neale and Ayling Inquiries) that would have a direct bearing on complaints issues. Accordingly, in April 2004, the DoH informed this Inquiry that regulations governing the transfer of the second stage to the Healthcare Commission would be made in July 2004. It was also stated that the implementation of any changes to

the first stage of the procedures would be deferred pending the Reports of all three Inquiries. The regulations made would consolidate and rationalise the various existing Regulations governing the first stage. I am grateful for the opportunity to have my recommendations taken into account before the forthcoming legislation is finalised. I shall discuss the issues raised in greater detail in Chapter 27. The reports of the Neale and Ayling Inquiries were published in September 2004.

7.84 As I have explained, the 2004 Complaints Regulations came into force on 30th July 2004. There are two main parts to the Regulations. The first part covers the handling and consideration of complaints (i.e. the first stage) by NHS bodies but it does not cover providers of primary care (where the previous Regulations therefore still apply). A 'NHS body' means a strategic health authority, a NHS trust, a PCT or a special health authority. In the context of this Report, a 'primary care provider' means a GP practice. The second part covers the handling and consideration of complaints by the Healthcare Commission (i.e. the second stage) and applies to complaints about providers of primary care as well as complaints about other bodies. I shall discuss the second part in detail in Chapter 27.

7.85 The draft Complaints Regulations would require primary care providers, as before, to appoint a complaints manager to take responsibility for the investigation of any complaint received by that body. However, in the context of primary care, the proposal now is that patients should have the option of complaining either to the PCT or to the primary care provider. Complaints made to the practice would be investigated by the practice, as now. Complaints made to the PCT would be investigated by the PCT. I think the introduction of this choice would be welcomed by many patients for the reasons already discussed. Most patients would find it easier to complain to the PCT, particularly in respect of matters involving personal criticism of a doctor.

7.86 A number of other changes were proposed in the draft Complaints Regulations and some, though not all, have been introduced for NHS bodies by the 2004 Complaints Regulations. The time limits for making a complaint were to be extended from six months to one year but they have been kept at six months for NHS bodies. I am not sure whether this preservation of the *status quo* was intended to be temporary, pending publication of the Reports of the three Inquiries. As I shall explain in Chapter 27, it is my view that the period should be 12 months. Some of the restrictive rules, which provided that complaints could not in certain circumstances proceed, were to be modified under the draft Complaints Regulations, but these modifications have not been made by the 2004 Complaints Regulations. First, under the 1996 procedures, a complainant who intended to take legal proceedings could not be granted an independent review. Under the draft Complaints Regulations, the complaints manager of the NHS body to whom the complaint was made was to consider, in consultation with the complainant, how the complaint should be handled. He or she could investigate the complaint provided that s/he considered that the NHS investigation would not compromise or prejudice the concurrent proceedings. Under the 2004 Complaints Regulations, however, any complaint against a NHS body about which the complainant has stated that s/he intends to take legal proceedings is excluded from the operation of the Regulations. Similarly, the fact that a NHS body was taking disciplinary proceedings against a doctor would not, under the draft Regulations, have precluded the furtherance of the patient's complaint; however, the existence of proposed

or actual disciplinary proceedings in relation to the substance of the complaint will, under the 2004 Complaints Regulations, now cause that complaint to be excluded from the operation of the Regulations. In my view that is not satisfactory and I shall make recommendations on this topic in Chapter 27.

7.87 One welcome change proposed in the draft Complaints Regulations has been introduced covering the application of the first stage to complaints about NHS bodies. The categories of person allowed to complain have been extended under the 2004 Complaints Regulations. Formerly, the only persons permitted to complain were patients, former patients and such other persons as could properly represent the interests of patients and former patients who could not pursue a complaint for themselves. Now, any person (or the representative of such a person) who is affected by or likely to be affected by the action, omission or decision of a NHS body or primary care provider would be able to lodge a complaint. This is a welcome change.

7.88 Another proposed change that I welcome is the provision to be made for 'complex' complaints. Nowadays, many complaints involve more than one NHS body. Until now, it has not been possible to make a single complaint about the conduct or performance of more than one NHS body or indeed the liaison – or lack of it – between two NHS bodies. This problem was highlighted in Ms Longley's article in the Medical Law Review in 1996 referred to earlier in this Chapter.

7.89 The 2004 Complaints Regulations impose upon the complaints manager of the NHS body who receives the complaint the duty to investigate it **'to the extent necessary and in the manner which appears to him most appropriate to resolve it speedily and efficiently'**. The draft Complaints Regulations would impose the same obligation on the primary care provider. If some complaints about a primary care provider are to be directed to the PCT (as I hope they will be), the proposal gives rise to potential difficulties owing to the lack of training, expertise and resources of PCTs to handle complaints well. I shall discuss these difficulties in more detail in Chapter 27. To some extent these potential difficulties seemed to have been recognised by Government, as the draft Complaints Regulations provided that, where it appeared appropriate, the complaints manager of the NHS body or primary care provider handling the complaint could refer it directly to the Healthcare Commission or to the Health Service Ombudsman. Such a referral could be made only with the consent of the complainant and of the Healthcare Commission or the Health Service Ombudsman. This provision seemed also to be designed to meet the concern expressed in the Public Law Project report that there has, in the past, been inadequate provision for the rapid resolution of complaints that gave rise to serious concerns about conduct or performance and that might bring about the risk of harm to patients. In effect, this provision would have allowed for a complaint to be fast tracked to and investigated by the Healthcare Commission or the Health Service Ombudsman. This seemed to be a welcome proposal, although I was concerned to hear from Mrs Elizabeth Dimond, Complaints and Helpline Project Lead at the Healthcare Commission, that this provision was, in fact, intended primarily to allow a referral in cases in which the complainant had 'lost faith' in the NHS procedures. I note that it is not in the 2004 Complaints Regulations. I will discuss this further in Chapter 27.

Disciplinary Procedures after April 2004

7.90 In paragraphs 7.36–7.38, I explained why in 1996 disciplinary proceedings against GPs at local level fell into disuse immediately after the introduction of the new complaints procedures. They were still used occasionally, however, and their operation still depended upon establishing a breach of the GP's terms of service. As I have explained in Chapter 5 with the introduction of the new General Medical Services Contract in April 2004, terms of service have ceased to exist. In their place, the National Health Service (General Medical Services Contracts) Regulations 2004 (the 2004 Regulations) have introduced a wide range of contractual conditions and obligations. Services will be provided under a contract between the PCT and the practice, not between the PCT and the individual doctor. There are conditions relating to the constitution of the practice. Obligations on the practice include, for example, a requirement that the practice carries out its duties with reasonable skill and care, and practices must co-operate with the investigation of complaints.

7.91 Paragraphs 110 to 120 of Schedule 6 to the 2004 Regulations provide powers for the PCT to deal with breaches of conditions or obligations. These are quite separate powers from the list management powers I have already described in Chapter 5. Under the 2004 Regulations, the PCT may, in some circumstances, terminate the contract with the practice. For example, it may do so if it finds that the practice provided false information in respect of certain important matters when entering into the contract. Also, the PCT may terminate the contract if the practice's financial situation puts the PCT at risk of material financial loss. The PCT has the power to issue a remedial notice if the practice breaches an obligation which is capable of being remedied and is not of such importance as to warrant termination. For example, a failure to provide a practice leaflet might be dealt with by a remedial notice. In the case of a breach which has occurred and cannot now be remedied (such as a failure to visit a patient in circumstances in which a visit was required), the PCT may serve a notice on the practice requiring it not to repeat the breach. The PCT may terminate the contract for repeated breaches or repeated failures to heed notices if it is satisfied that the cumulative effect of the breaches is such that it would be prejudicial to the efficiency of the services for the contract to continue. The PCT also has the power, where appropriate, to impose sanctions on a practice. For example, it might terminate or suspend the provision by a practice of certain specific services, such as, for example, child health surveillance. It may also withhold or deduct monies payable under the contract.

7.92 There is no formal procedure laid down which must be followed before a contract can be terminated or a sanction imposed. However, if it is reasonably practicable to do so, the PCT must consult with the LMC when it is considering termination of a contract or the imposition of a sanction. Also, the PCT must give notice in writing of its intention to terminate the contract or impose a sanction and the practice then has 28 days in which to invoke the NHS disputes resolution procedure before the termination or sanction takes effect. If the disputes resolution procedure is invoked, the termination or sanction would not normally take effect until the conclusion of that procedure. However, the PCT can terminate the contract or impose the sanction before that stage is reached if it is satisfied

that it is necessary to do so to protect the safety of patients or to protect itself from material financial loss.

7.93 These powers, combined with their list management powers, mean that PCTs do now have quite extensive powers, at least on paper, to insist on the provision of appropriate services and to dispense with the services of practices that cannot provide them. It is too early to say how these new powers will work in practice. I do fear that there will be some tension between a PCT's wish to dispense with services that are not up to standard and the need to provide GP services to the population at a time when there is a shortage of GPs. The problem is likely to be particularly acute in areas which are not attractive to or popular with GPs. However, in my view, it is better that the powers are in place, even if they are not used as effectively as the PCT might wish, than that they do not exist at all.

Conclusions

7.94 So far as complaints procedures are concerned, it has been recognised that the arrangements that have existed since 1996 were in need of change. From the perspective of this Inquiry, it appears to me that there are several vital improvements to be made. One is that PCTs should have full information about all complaints received about a GP, not only those that proceed to the second stage of the procedure. Such information is a vital component of clinical governance. Another is that complainants should have the option of making a complaint about their GP or the practice to the PCT and should not be obliged to 'face' the doctor or the practice staff directly. Third, there is a real need to ensure that PCTs have the responsibility and the resources to investigate the more serious complaints adequately, including those involving an allegation of substandard clinical care. It seems to me that, in the past, complaints have not been 'bottomed' because there has been no one responsible for and capable of conducting an independent investigation. Complainants have lacked resources and know-how and it is not always in the doctors' interests to ensure the production of all the available evidence. I welcome the decision to transfer the conduct of the second stage of a complaint to the Healthcare Commission, which is setting up a team of investigators. I hope that the Healthcare Commission will develop real expertise in investigation. However, the existence of an investigative team at the Healthcare Commission will not remove the need for PCTs to have their own facilities available. Finally, I am convinced of the need for the provision of appropriate support for complainants at all stages of the process. I shall make my recommendations for change to the complaints procedures in Chapter 27.

CHAPTER EIGHT

Raising Concerns about Shipman

Introduction

8.1 The scale of Shipman's crimes and the long period over which they were perpetrated suggest, at first sight, that his behaviour must inevitably have raised concerns and suspicions among those who worked closely with him. Surely such people as medical colleagues, other healthcare professionals and members of his practice staff must have realised that something was wrong and reported it? What about those lay people – friends, families and neighbours – who had been involved in the aftermath of the deaths? Previous inquiries that have investigated criminal or other wrongful conduct by an individual or organisation have often heard evidence about complaints which had been made or concerns which had been expressed over the years and had gone unheeded, as a result of which the offending conduct was permitted to continue without check.

8.2 Surprisingly, however, this Inquiry's investigations revealed no long history of complaints or concerns in Shipman's case. That they did not is an indication both of the high regard in which Shipman was generally held and of his extraordinary ability to lie his way convincingly out of the most compromising situations.

8.3 In this Chapter, I shall consider the position of Shipman's colleagues at the Donneybrook practice and examine whether they had any reason to suspect Shipman. The Inquiry has of course heard that, in 1998, a member of another practice, the late Dr Linda Reynolds, became suspicious about the number of deaths among Shipman's patients. She and her colleagues at the Brooke Practice in Hyde decided that she should report their concerns to the Coroner. That report initiated the abortive police investigation of March 1998 which I examined in my Second Report. There were a few other people who also had their suspicions about Shipman. In this Chapter, I shall describe how those suspicions developed and what, if anything, those who had concerns felt able to do about them. I shall deal separately with the position of the practice staff and health professionals who worked with Shipman at the Market Street Surgery in Chapter 9.

The Doctors at the Donneybrook Practice

8.4 I have already described, in Chapter 3, the circumstances in which Shipman came to join the Donneybrook practice in 1977. I have found that no criticism can be levelled against the members of the practice who appointed him, whether in relation to their initial decision to appoint or to the fact that, having been appointed, Shipman was not made the subject of any special supervision.

8.5 Nevertheless, Shipman was a member of the Donneybrook practice for almost 15 years. I have found that, during that time, he killed at least 71 patients. The question must arise as to whether his colleagues should have been alerted to the number and circumstances of the deaths of Shipman's patients or to any other unusual features of his practice.

8.6 The Inquiry heard evidence from Dr John Smith, Dr Geoffrey Bills, Dr Geoffrey Roberts, Dr Ian Napier and Dr Jeffery Moysey. Dr Derek Carroll and Dr William Bennett provided statements.

8.7 The way in which the Donneybrook practice was arranged, with each doctor (save for Dr Bills and Dr Carroll) operating a single list, meant that patients of one doctor would rarely be seen by the other doctors in the practice. It would happen only if the patient's usual doctor was on holiday, if the patient required treatment out of hours, if a consultation was required on the doctor's half day off or at times of illness and in other exceptional circumstances. Therefore, in general, members of the practice neither got to know patients registered with their colleagues, nor their medical histories. When a colleague's patient died, this would not have had the same impact on other members of the practice as if the care of that patient had been shared.

8.8 Moreover, there were no formal means by which members of the practice were informed about the deaths of patients registered with other members. They would have no involvement in the certification of the cause of death or the certification for the purposes of cremation. Each member had his own book of Medical Certificates of Cause of Death (MCCDs), so would not see how many MCCDs Shipman had issued. In general, other members of the practice would become aware of the death of one of Shipman's patients only if the practice staff talked about it or if Shipman specifically mentioned it.

8.9 Nor would members of the practice have any information about the total number of deaths among Shipman's patients or in the practice as a whole. I have found that the annual number of killings during Shipman's period at the Donneybrook practice was variable. I found that, in 1989, he killed 12 patients; in some years (1977, 1980, 1982 and 1991), he may not have killed at all. Certainly he was not killing with the same frequency as in his last years at the Market Street Surgery. Even if they had been aware that a death had occurred, Shipman's colleagues would not have known anything about the circumstances of the death (e.g. whether Shipman had been present or had visited shortly before) unless Shipman had volunteered this information. During Shipman's time at the practice, there was no process of reviewing deaths. An examination of Shipman's killings by the Inquiry revealed that few of the deaths were likely to have come to the attention of his colleagues. None of those cases would have given real cause for concern. None of the doctors remembered the death of Mrs Mary Hamer, which occurred in the surgery of the Donneybrook practice. I found that Shipman killed her. In the past, there had been other deaths at the surgery with which Shipman had not been involved. There was, therefore, no reason for Mrs Hamer's death to be regarded with particular suspicion.

8.10 None of Shipman's former colleagues at the Donneybrook practice had any concerns about the number or circumstances of deaths among Shipman's patients. No such concerns had been expressed to them by others. Dr Roberts, who covered Shipman's patients on his half days, said that he saw nothing odd in Shipman's medical records or his pattern of visiting. He was not aware that a number of patients had died in Shipman's presence. He said that, if he had known that, he would have been surprised. Dr Moysey, who covered Shipman's half days after Dr Roberts left the practice, saw nothing unusual in Shipman's records or prescribed treatments.

8.11 Dr Roberts regarded Shipman as hardworking and observed that he appeared to get on well with patients, colleagues and staff. He exhibited no unusual behaviour. Dr Smith recalled that Shipman had a good medical knowledge and always kept himself up to date.

Dr Napier observed that there were no concerns about Shipman's honesty or competence. He was well regarded by clinicians and proactive in disease prevention. His professional conduct 'seemed exemplary'. None of the doctors felt that Shipman had an especially isolated personality when at the Donneybrook practice.

8.12 There were a few negative comments about Shipman. Dr Moysey and Dr Napier observed that he was 'mercurial'. Dr Smith recalled that he sometimes fell out with the practice staff. Dr Bills felt that he was theatrical, as if always presenting an image. He felt that Shipman exaggerated the seriousness of his patients' illnesses so as to make more of an impression when he was able to 'cure' them. Dr Carroll agreed with this view. Dr Bills also noticed that Shipman was somewhat insensitive when speaking of patients who were terminally ill. He also said that Shipman impressed patients, who 'thought he was marvellous'. He commented that the social workers and health visitors with whom Shipman came into contact were more impressed with his prowess than were the district nurses who worked with him.

8.13 None of the doctors observed any sign of relapse by Shipman into his previous drug taking habits. Nor did they have any recollection of problems with Shipman's prescribing during his time at Donneybrook. In 1989, one of Shipman's colleagues, Dr William Bennett, suffered a coronary thrombosis in the surgery. Shipman administered an injection which Dr Bennett believed to contain 10mg morphine. Dr Bennett did not question where the morphine came from, nor did Dr Napier, who was told about the incident afterwards. They were just grateful that Shipman had taken the correct action. By then, it was 12 years or so since Shipman had joined the practice. It seems there had been no further discussion about the keeping of controlled drugs. If Dr Bennett and Dr Napier had thought about where Shipman had got the morphine for the injection (which they did not), they would no doubt have assumed that he was now keeping a small quantity of controlled drugs for emergencies. Those members of the practice who kept a stock of controlled drugs maintained their own controlled drugs registers (CDRs). There was no shared CDR and there would have been no reason for one member of the practice to inspect another member's CDR.

8.14 Most of his colleagues were surprised when Shipman announced his impending departure from the Donneybrook practice. Dr Napier believed that Shipman was frustrated at the slow pace of change within the practice. He took Shipman aside and pointed out the disadvantages of moving to single-handed practice.

Conclusions

8.15 It is not in my view surprising that Shipman's colleagues at the Donneybrook practice were unaware of his criminal activities and had no reason to suspect that his practice was in any way unusual. The structure of the practice meant that they knew little of each other's clinical activities. No concerns had been expressed to them about Shipman. There were no unusual features to attract their attention. Indeed, the information which they received about Shipman's practice was generally favourable. It is clear in my view that they had no suspicions at the time and I am satisfied that they cannot be criticised for that.

8.16 Dr Napier told the Inquiry that arrangements within the practice which had been introduced since Shipman's departure would make it more likely that behaviour such as his would be detected. The doctors now have shared lists. The fact that the care of patients is shared leads to discussion between the doctors about diagnosis and treatment. They are more likely to notice if a patient dies unexpectedly. They share one book of MCCDs, which is open to inspection by all. The medical records are computerised and of better quality. Members of the practice have meetings at which they review significant events (including deaths) and perform risk assessments. Similar developments have taken place in many other practices over the same period. Later in this Report, I shall discuss the effect of such changes.

The Concerns of Mrs Christine Simpson

8.17 Mrs Christine Simpson was the resident manager of Ogden Court from about 1987 until 2002. Her husband, Mr Alan (sometimes known as Sam) Simpson worked as a gardener and cleaner at Ogden Court and at other similar properties in the area.

Ogden Court

8.18 Ogden Court was one of a large number of properties owned by the Manchester and District Housing Association (the Housing Association). Ogden Court was a sheltered housing development (or sheltered housing 'scheme'), providing 42 flats for rent, together with various communal facilities for the use of residents. Most of the residents of Ogden Court were elderly. Some were entirely independent, while others received a high level of care provided by Social Services or members of their family. All residents had access to a 24 hour emergency call facility.

Mrs Simpson's Duties

8.19 Mrs Simpson lived in a flat on the ground floor of the main building at Ogden Court. Her role was that of a 'good neighbour' to the residents of Ogden Court. She was required to make a daily check on their welfare and to liaise with the Housing Association in order to ensure that any necessary works of maintenance, repair and adaptation were carried out. She was also responsible for facilitating the residents' access to professional care from agencies such as Social Services, for ensuring that the premises were kept safe and for organising regular social activities for the residents. Her husband told the Inquiry that she formed close relationships with the residents, who were happy to confide their problems and worries to her.

The Management of Ogden Court

8.20 The primary function of the Housing Association in relation to Ogden Court was as landlord with responsibility for the allocation and letting of the flats, the collection of rents, the arranging of necessary works of maintenance, repair and adaptation, the resolution of disputes between tenants and other matters of that kind.

8.21 From 1985 until her retirement in March 2003, Mrs Janet Schofield worked for the Housing Association as a housing officer. Until 1993, she was employed full-time; thereafter she worked part-time only. She had responsibility for Ogden Court for various periods between 1987 and 2001. She could not remember precisely when those periods were, as her duties changed frequently. For part of this time, she had a job share arrangement so that responsibility for Ogden Court was shared between herself and another member of staff. For a period from April 1996, Mrs Schofield alone assumed responsibility for dealing with Ogden Court. Documents in the possession of the Inquiry would suggest that Mrs Schofield's active involvement with Ogden Court may have ceased in late 1998/early 1999.

8.22 Mrs Schofield managed about 800–1000 residential units on behalf of the Housing Association. She held monthly liaison meetings with the resident managers of all the sheltered housing schemes for which she had responsibility. Discussions at her meetings with Mrs Simpson centred on issues relating to the fabric of the premises at Ogden Court and to Mrs Simpson's employment. In addition, there would be discussions about the dependency levels of individual residents and the extent to which they might require additional care from Social Services or transfer to alternative accommodation such as a residential care home. Recent deaths were noted, and forthcoming and existing vacancies ('voids') discussed. Minutes of liaison meetings were kept by Mrs Schofield and forwarded to Mrs Simpson. The Inquiry has seen the minutes of meetings between Mrs Schofield and Mrs Simpson which took place between December 1996 and May 1998. The minutes of earlier meetings are no longer available. In addition to visiting Ogden Court for meetings, Mrs Schofield would visit two or three times a month in order to see residents.

8.23 Between meetings, there was frequent telephone contact between Mrs Simpson, Mrs Schofield and other staff at the Housing Association, in the course of which Mrs Simpson would report day-to-day problems as they arose. She would report the deaths of residents as they occurred, since these would give rise to voids.

Deaths at Ogden Court

8.24 The Inquiry has found that nine residents of Ogden Court were killed by Shipman. They were:

Mrs Alice Prestwich, who died, aged 69, on 20th October 1988
Mr John Charlton, who died, aged 81, on 16th October 1989
Mrs Alice Kennedy, who died, aged 88, on 9th January 1995
Mrs Muriel Ward, who died, aged 87, on 24th October 1995
Mrs Gladys Saunders, who died, aged 82, on 17th June 1996
Mr Samuel Mills, who died, aged 89, on 23rd November 1996
Mrs Betty Royston, who died, aged 70, on 4th February 1997
Mr James King, who died, aged 83, on 24th December 1997
Miss Maureen Ward, who died, aged 57, on 18th February 1998.

8.25 Mrs Simpson co-operated fully with Phase One of the Inquiry, providing a number of statements in connection with the various deaths. She has been unwell for some time and

retired from work in 2002 on health grounds. After she was requested to give evidence in Phase Two, the Inquiry received medical evidence to the effect that attendance at the Inquiry would be detrimental to her health. In those circumstances, she was not required to attend to give evidence. She did provide a detailed witness statement, however, setting out her recollection of the events surrounding the deaths and her developing suspicions of Shipman's involvement in them.

Mrs Alice Prestwich

8.26 The first death, that of Mrs Prestwich, occurred on 20th October 1988. Mrs Prestwich had requested a visit from Shipman because her legs (Mrs Simpson recalled it was her knees) were swollen and painful. Shipman summoned Mrs Simpson and told her that Mrs Prestwich had died a few minutes earlier, while he was examining her. Despite the suddenness of the death, Mrs Simpson said she had no suspicions about it. She did, however, regard Shipman's attitude to the death as flippant, casual and inappropriate to the circumstances.

Mr John Charlton

8.27 Mr Charlton's death occurred a year later on 16th October 1989. Shipman, who had visited Mr Charlton unannounced (probably in response to an informal request for a visit made by his family through the Donneybrook practice nurse), called at Mrs Simpson's flat and said he needed to telephone for an ambulance to take Mr Charlton, who was very ill, to hospital. Shipman asked Mrs Simpson to go to Mr Charlton's flat. There, she found Mr Charlton lying flat on his back on his bed. He was dead. Mrs Simpson said she found it strange that Mr Charlton should have died in that position. He had been experiencing breathing problems and had taken to sleeping in a reclining chair rather than in bed. She was not convinced that Mr Charlton had died a natural death and wondered whether Shipman might have assisted in it in some way, by arrangement with Mr Charlton.

Mrs Alice Kennedy

8.28 More than five years then passed before the death of Mrs Kennedy on 9th January 1995. Shipman called on her, apparently unannounced. He later telephoned Mrs Kennedy's daughter, Mrs Patricia Higgins, to express concern that Mrs Kennedy did not seem well. When Mrs Higgins visited her mother later in the day, she found Mrs Kennedy dead in her chair. Mrs Kennedy had suffered from Parkinson's disease and was quite frail. Mrs Simpson said that she did not find the fact of the death suspicious in itself. It was the knowledge that Shipman had been present shortly before the death was discovered which made her suspect that he might have been responsible for it.

8.29 Mrs Simpson said that, by this time, it had also become clear to her that the deaths of Shipman's patients followed a different pattern from those of other residents at Ogden Court. Usually, deaths were preceded by a period of decline, with a gradual loss of independence and a need for a greater degree of care from Social Services and/or family members. In most cases, death would occur in hospital. On those occasions when a resident died at Ogden Court, it would be known beforehand that death was imminent. By

contrast, Shipman's patients died suddenly and at a time when he was, or had recently been, in physical proximity to them.

Mrs Muriel Ward

8.30 Mrs Ward died on 24th October 1995. She had fallen and fractured her hip two months previously and had suffered a deep vein thrombosis while recovering in hospital. At the time of her death, she was back at home and making good progress. Shipman visited her to take a blood sample just as her daughter, Miss Maureen Ward, was leaving for the shops. When she returned about half an hour later, she found her mother dead in her chair. Mrs Simpson said that it was once again the fact that Shipman had visited Mrs Ward so recently before the discovery of her death that caused her to suspect that the death had not been natural.

Mrs Gladys Saunders

8.31 Mrs Saunders died about eight months later on 17th June 1996. She had been discharged from hospital ten days before she died, following an episode of diverticular disease. She appeared to Mrs Simpson to be in good health and spirits, although she had complained to others about weakness and 'flutters' in her heart. She had asked Shipman to make a home visit. He did so and later called on Mrs Simpson and informed her that Mrs Saunders was dying. Mrs Simpson accompanied Shipman to Mrs Saunders' flat. She believed that Mrs Saunders took her last breath just as they arrived. Mrs Simpson said that she was convinced at the time that Shipman had killed Mrs Saunders.

Mr Samuel Mills

8.32 On 23rd November 1996, Mr Mills died. Mrs Simpson was not at Ogden Court at the time. Mr Mills was suffering from cancer of the prostate and had become very frail. On the morning of his death (a Saturday), he felt unwell and asked Mr Simpson (in Mrs Simpson's absence) to request a visit from Shipman. Shipman duly visited and, while with Mr Mills, he summoned the mobile warden service used by Ogden Court when Mrs Simpson was unavailable, saying that Mr Mills was dying. The warden arrived to find Mr Mills lying on the floor, obviously dying. Shortly afterwards, Shipman appeared and pronounced him dead. Mrs Simpson arrived back a little later and made contact with members of Mr Mills' family. She said that the position in which Mr Mills was lying did not appear natural, causing her to believe that Shipman was once again responsible for the death.

Mrs Betty Royston

8.33 The circumstances in which the death of Mrs Royston was discovered, on 5th February 1997, caused Mrs Simpson's suspicions to be aroused yet again. She discovered Mrs Royston dead that morning. Mrs Royston was lying neatly on the floor. Her spectacles (which she always wore) were on the back of the settee. Shipman had, at the request of Mrs Royston's son, Mr Alan Royston, visited Mrs Royston the day before. On discovering the death, Mrs Simpson telephoned Shipman's surgery. Shipman was not immediately available so Mrs Simpson left a message with a receptionist. She then telephoned the

police to report the death. This was the usual policy when a death was sudden and the deceased person's general practitioner (GP) was not available. Police records show that the call was made at 8.39am. The message received was:

> **'MRS BETTY ROYSTON, HAS BEEN FOUND ON THE LIVING ROOM FLOOR BY WARDEN. APPEARS TO HAVE BEEN THERE ALL NIGHT. PLEASE ATTEND WARDEN'S OFFICE.'**

Mrs Simpson said she thought the police would investigate the death and Shipman would finally be caught out.

8.34 However, before the police arrived, Shipman appeared. He was cross when Mrs Simpson told him that she had summoned the police. He went with her to see Mrs Royston, felt for Mrs Royston's pulse, confirmed that she was dead and told Mrs Simpson that he would be able to issue a death certificate as he had seen Mrs Royston the previous evening. He then left, having been present for only a short time. In her statement to the Inquiry, Mrs Simpson said that the police never came. She believed that Shipman must have telephoned them and told them that their attendance was not necessary. She said that she did not feel able to contact the police again and tell them that she disagreed with Shipman.

8.35 In fact, Mrs Simpson's recollection was at fault there. Police records show that Police Constable (PC) Donna Jones attended Ogden Court with a colleague, arriving at 8.58am. In a statement made in January 1999, PC Jones said that she spoke to Mrs Simpson. At 9am she sent a message to the police Area Operations Room, saying that it would appear that Mrs Royston's GP, Shipman, would issue a death certificate. That information must have come from Mrs Simpson, who had only just received it from Shipman himself. The police then attempted to contact Shipman at his surgery. He was with a patient at the time but subsequently a receptionist confirmed that he would be issuing a death certificate. The police left Ogden Court shortly afterwards.

8.36 It seems that, on this occasion, Mrs Simpson was presented with an opportunity to voice her concerns about Mrs Royston's death to the police in Shipman's absence. It may be that she lacked the confidence to do so in the face of Shipman's assertion that he would sign a death certificate. She may have been taken aback by the police's ready acceptance that a death certificate was to be issued and that no investigation was therefore necessary.

8.37 Another possible explanation for Mrs Simpson's failure to voice her concerns to the police on this occasion would be that those concerns were not as great as she now believes them to have been. However, a conversation which she had with Mrs Royston's son supports her assertion that she was indeed suspicious of Shipman at the time. Mrs Simpson said that when Mr Royston arrived at his mother's flat, he was immediately suspicious and expressed the view that there was **'something not right'** about the death. She described how she did not disagree with his suggestion. She believed that he was going to tackle Shipman. She felt it appropriate that, as Mrs Royston's son, he should be the one to take the matter further.

8.38 Mr Royston has given two statements to the Inquiry. His wife has also provided a statement. Mr Royston confirmed that a number of features about the death – including his

mother's position and that of her spectacles – struck him as odd. He began to wonder if Mrs Royston had died in Shipman's presence and if Shipman had left her because he did not want to deal with the aftermath of the death. Mr Royston recalled having a conversation with Mrs Simpson. He believed that this took place some days after his mother's death rather than on the day itself, as Mrs Simpson suggests. He asked Mrs Simpson (in what he called a **'tongue and cheek way'**) whether Shipman could have **'bumped off'** his mother and whether Mrs Simpson thought Shipman might be a **'serial granny killer'**. He said that Mrs Simpson's face changed and she told him that several people had died after Shipman had been to visit them. She also said that she had discussed the matter with her husband but felt that no one would believe her if she said anything to anyone else. Her remarks caused Mr Royston to wonder whether Shipman had killed Mrs Royston. He talked the matter over with work colleagues and members of his family. They could not believe that Shipman had killed Mrs Royston. Although Mr Royston continued to have lingering concerns about the circumstances of the death, he did not seriously consider telling anyone in authority about those concerns until he heard that Shipman was under investigation. He contacted the police shortly afterwards, on 21st August 1998.

Mr James King

8.39 Mr King died on Christmas Eve 1997. Mrs Simpson said that, despite his age, he was in good general health. On the day of his death, however, he had complained of feeling **'woozy'**, by which she understood that he was experiencing dizzy spells. She did not think anything was seriously wrong. Mr King told her that he had asked Shipman to visit. This was very unusual for him. Shipman visited in response to Mr King's request. Shortly afterwards, Mr King's daughter found him dead in his chair. The suddenness of Mr King's death, and the fact that it occurred so soon after a visit from Shipman, caused Mrs Simpson to believe that Shipman had killed again.

Miss Maureen Ward

8.40 On 18th February 1998, Shipman called at Mrs Simpson's flat and told her that he had found Miss Maureen Ward (the daughter of Mrs Muriel Ward) dead. Miss Ward was only 57 years old and had stayed on at Ogden Court after her mother's death. She had previously undergone treatment for cancer but, immediately before her death, had appeared well. She was planning a holiday and looking forward to moving house in the near future. It was evident to Mrs Simpson, when she accompanied Shipman to Miss Ward's flat, that Miss Ward had been engaged upon her usual daily activities until something had interrupted her. Mrs Simpson was shocked at Miss Ward's death and told Shipman so. He informed her that Miss Ward had been suffering from a brain tumour which had caused her death. Mrs Simpson could not believe that Miss Ward would have been planning so enthusiastically for the future if she had believed that she did not have long to live. Once again, she believed that Shipman was responsible for the death.

Mr Simpson's Evidence

8.41 Mr Simpson gave oral evidence to the Inquiry. He confirmed that his wife had come to believe that Shipman was killing his patients. At first, she had discussed with him the

possibility that Shipman might have an arrangement with his patients to assist them to die when their quality of life became poor. At some time, however, she had ceased to believe that the patients had acquiesced in their deaths. Mr Simpson could not remember when this change of mind occurred. He did recall that, when Mrs Saunders died in June 1996, Mrs Simpson could not believe that she would have wanted to take her own life. Mr Simpson himself recognised the close association between Shipman's visits and the deaths. He believed that they might have occurred with the patients' consent. He told the Inquiry that he just could not accept that Shipman could be killing his patients without their consent, as there appeared to be no reason for him to do so. He was unsuccessful in persuading Mrs Simpson to share his view. Gradually, over a period of time, she became depressed. At the time, she blamed other problems for her depression. In retrospect, however, Mr Simpson believes that her concerns about the deaths of Shipman's patients were a significant factor.

The Communication of Concerns to Third Parties

8.42 Mrs Simpson and her husband described two occasions (in addition to the conversation with Mr Royston which I have already described) when she voiced her concerns to persons outside her immediate family. On one such occasion, she spoke of her suspicions to a respected friend of many years' standing. The friend worked in a medical practice and was a patient of Shipman. She advised Mrs Simpson to say nothing about her suspicions because people would say she **'was mad'**.

8.43 The other person in whom Mrs Simpson claimed to have confided was Mrs Schofield. She says that she raised her concerns at the end of one of her regular liaison meetings with Mrs Schofield. Mr Simpson remembered it being decided that his wife should tell 'management' of her concerns about the deaths. He did not recall when this was. Mrs Simpson herself believed that she spoke to Mrs Schofield after the death of Mrs Ward, i.e. some time after 24th October 1995. That would have been about three years before Shipman's eventual arrest. Mr Simpson thought that the timing sounded about right. He did not know precisely what was said but would have expected Mrs Simpson to give a clear account of her suspicions and of the events that had given rise to them.

8.44 In her witness statement, Mrs Simpson related how she could not bring herself to say that she suspected that Shipman was murdering people. She thought that she mentioned Shipman by name and told Mrs Schofield that:

> **'... there had been a number of deaths where the circumstances of the deaths had been odd and I was suspicious and concerned. I expressed my concern in general rather than specific terms. I said that patients were dying after visits from the doctor and that other people had started to talk about it as well.'**

According to her husband, Mrs Simpson was hoping to obtain some guidance as to what to do or an assurance that Mrs Schofield would assume responsibility for taking her concerns forward. Instead, Mrs Schofield gave no reaction and asked no questions. She made no suggestion as to what Mrs Simpson could or should do. Mrs Simpson had the impression that Mrs Schofield was not taking her seriously. In a sense, she appears to

have found Mrs Schofield's lack of response reassuring, at least in the short term. However, she said that, when Mrs Saunders died the following June, she ceased to feel reassured and felt that she had been right to be suspicious.

8.45 Mrs Simpson recalled that Mrs Schofield made some notes about her concerns but that, when she received the minutes of the relevant meeting, she does not remember seeing any reference to them. As I have already said, minutes of meetings from this period are no longer available. Even if they were, I would not find it surprising that such a sensitive matter was not recorded. I can also understand why Mrs Simpson would not necessarily have pressed for them to be recorded subsequently. She would not have wanted her concerns to be seen by others at the Housing Association, particularly if, by then, she had been to some extent reassured by Mrs Schofield's attitude and believed that her suspicions might be unfounded.

8.46 Mrs Simpson said that she did not think that she mentioned her concerns again to Mrs Schofield. Mrs Schofield never referred to the topic. Mrs Simpson did not know what else to do. She considered consulting a solicitor but did not think she would be taken seriously since she had no direct evidence to support such a serious allegation. So far as she was aware, no one shared her concerns. She was worried about being proved wrong. She was of course aware of the good reputation that Shipman enjoyed among his patients and the wider community.

8.47 On 14th October 1998, Mrs Simpson gave a statement to the police about the death of Mrs Royston. She told the interviewing officer that Shipman had been involved in nine deaths at Ogden Court and supplied details. On 21st October 1998, she was interviewed in connection with those deaths and described to the police her developing suspicions.

Mrs Schofield's Evidence

8.48 Mrs Schofield gave oral evidence. She denied that Mrs Simpson expressed concerns to her at any stage about the deaths of Shipman's patients. She told the Inquiry that, if Mrs Simpson had done so, she would have reported the matter to her superiors. She thought that, if Mrs Simpson had had concerns, she would have expressed them clearly and directly and that, if those concerns had not been acted on, she would have pursued them. Mrs Schofield was adamant that this was never done. She had no recollection of any concern being raised about the death of Mrs Ward. She says she would have remembered this, because she had had previous dealings with the Wards and knew them.

8.49 Mrs Schofield gave three statements to the Inquiry. In the first two, she said that she did recall Mrs Simpson referring to Shipman as 'Dr Death' on a few occasions over the years she had worked with her. She said that, on at least some of those occasions, Mrs Simpson had linked the mention of a visit from 'Dr Death' with the occurrence of a void. The implication was that a void had been or would be caused by a death following a visit from Shipman. Mrs Schofield said that she did not take these comments seriously. She just thought that deaths were inevitable among elderly people.

8.50 When making her third statement, signed only three days before she attended to give evidence, Mrs Schofield changed her evidence somewhat. She said that the phrase

'Dr Death' was not used by Mrs Simpson to describe any specific individual. Mrs Schofield suggested that the term was used generally when speaking of a void caused by a death. She said that she had heard other people speak about Shipman as 'Dr Death', but only after Shipman was known to be under investigation, i.e. after mid-August 1998.

8.51 Mrs Schofield's oral evidence about these references was very confused. At times, she suggested that she did recall Mrs Simpson using the name 'Dr Death' in connection with Shipman. However, she said that she believed this was after Shipman came under investigation in 1998. It is not clear when this would have been, as Mrs Simpson stopped working some time before July 1998 and does not appear to have returned until about October. (Her precise dates of absence cannot be ascertained.) At other times, Mrs Schofield suggested that Mrs Simpson might have used the name 'Dr Death' just to indicate that a death had occurred. She made the point that the words which she was trying to recall were spoken several years ago so her recollection was hazy.

8.52 In the course of her oral evidence, Mrs Schofield said that, after Shipman's arrest, the police had telephoned her to ask whether it was true that people used to call Shipman 'Dr Death'. She said that she had told them, 'That's true, they did.' She explained that she thought she said this because, by that time, the name 'Dr Death' was being used to describe Shipman by people in Hyde and by the newspapers. That explanation was, of course, unsatisfactory since the purpose of the police enquiry would plainly have been to find out what was being said before the investigations into Shipman started, not afterwards.

8.53 In the event, however, the purpose and nature of the police enquiry were quite different from that suggested by Mrs Schofield. After she had given evidence, the Inquiry obtained the police record of a telephone conversation which took place on 15th February 1999. A police officer had been tasked to contact Mrs Schofield in order to investigate Mrs Simpson's assertion, made in a police statement dated 21st October 1998, that she had spoken to Mrs Schofield about her suspicions at about the time of Mrs Ward's death. The record states:

> **'... ON MONDAY 15TH FEBRUARY 1999 AT 3PM I SPOKE TO JANET SCHOFIELD WHO IS A HOUSING OFFICER WITH MANCHESTER AND DISTRICT HOUSING OFFICE ... MRS SCHOFIELD STATED THAT SHE DID NOT FEEL CONFIDENT ENOUGH TO MAKE A STATEMENT IN REGARDS TO ANY CONVERSATION THAT SHE HAD HAD WITH N762 SIMPSON RE THE DEATH OF MURIAL** (*sic*) **WARD AS SHE COULD NOT REMEMBER IF ONE ACTUALLY TOOK PLACE, SHE DOES HOWEVER STATE THAT ON SEVERAL OCCASIONS COMMENTS WERE MADE BY CHRISTINE SIMPSON IN REGARDS TO THE NUMBER OF DEATHS THAT WERE OCCURRING AT OGDEN COURT WHILST DR SHIPMAN WAS PRESENT. MRS SCHOFIELD CANNOT BE ANYMORE SPECIFIC IN REGARDS TO THE CONTENTS OF THESE COMMENTS OR THE TIMES AND DATES THEY WERE MADE, THUS A STATEMENT HAS NOT BEEN TAKEN FROM HER AT THIS TIME.'**

Mrs Schofield was offered an opportunity to comment on the record but chose not to do so. The contents of this record make it clear that Mrs Simpson did make comments linking Shipman's presence at Ogden Court with deaths that had occurred there. It also makes clear that those comments were made, not once, but on several occasions.

Conclusions

8.54 Mrs Schofield was an experienced housing officer and I have no reason to doubt that she fulfilled her duties in a conscientious and professional manner. She acknowledged that she was not a curious or enquiring person. Indeed, she came across as a somewhat detached and distant character. It was perhaps significant that, despite her close connections with Ogden Court over a period of years, she had never sought to find out how many residents there were killed by Shipman, and took no interest in Shipman's trial. One of the counts of which Shipman was convicted related to Miss Ward, who was known to Mrs Schofield. In oral evidence, she observed, 'quite honestly, it wasn't of ... interest to me'.

8.55 Although I have not seen Mrs Simpson, it is plain from the evidence I have heard and read that she was a very different character. Mrs Schofield herself acknowledged that Mrs Simpson made an excellent job of managing Ogden Court. She was competent, capable, professional and committed to the welfare of 'her' residents. Her determination to achieve the best for them led on occasion to tension between herself and her employers.

8.56 Mrs Schofield's perception was that Mrs Simpson was a somewhat difficult personality, with a negative attitude to authority in general and to her employers in particular. This view was plainly shared by another officer of the Housing Association, who referred in his report of an appraisal conducted in December 1994 to Mrs Simpson's **'confrontational approach'**. Other documents record her feelings of isolation and her complaint that she did not receive adequate support from the Housing Association, together with her belief that her employers regarded their sheltered housing schemes **'more or less just as other properties and tenants'**. It is also clear that she became frustrated at the lack of continuity in the housing officers with whom she had to deal. These factors no doubt presented greater challenges to Mrs Schofield when dealing with Mrs Simpson than she encountered in her dealings with other resident managers.

8.57 In addition, it seems that Mrs Simpson exhibited signs of stress and anxiety, certainly in the years leading up to 1998, when she suffered a 'breakdown' and was off work for several months. She had a number of problems, some of which she discussed with Mrs Schofield at their monthly meetings. One was the fact that she lived on site at Ogden Court, with a consequent lack of privacy and constant responsibility for the residents. She and Mrs Schofield discussed the possibility of her acquiring a property elsewhere to which she could escape at weekends. They also discussed practical ways of combating her feelings of isolation.

8.58 In evidence, Mrs Schofield described Mrs Simpson in somewhat unsympathetic terms. She said she was a 'complex personality' with a 'strange way of looking at things'. She was 'obsessed with death' – her own and those of residents. She was said to be 'preoccupied with death ... it almost became a fixation with her'. In short, Mrs Schofield believed

Mrs Simpson to be a difficult and somewhat hysterical personality. I am satisfied that that belief (whether justified or not) would have coloured Mrs Schofield's view of anything Mrs Simpson reported to her. Indeed, in her second statement to the Inquiry, Mrs Schofield herself observed:

> **'... I think it is fair to say that because Christine was so negative and could get a bee in her bonnet about lots of things, I did often take what she told me with a grain of sand. Christine's negativity appeared to be often directed at authority figures and I think I would have regarded her comments about Shipman with that in mind.'**

8.59 I am entirely satisfied that, despite the inaccuracy of her recollection of the circumstances surrounding Mrs Royston's death, the essential features of Mrs Simpson's evidence are both true and accurate. I accept that she did develop suspicions about Shipman and that, on at least one occasion, she voiced them to Mrs Schofield. Whether she did so as early as October 1995 is, in my view, less certain. It may be that it was after the death of Mrs Saunders that Mrs Simpson became really concerned about the possibility of murder. It may have been then that she decided to speak to Mrs Schofield. In any event, I am satisfied that they first spoke about the matter in 1995 or 1996.

8.60 Both Mrs Schofield and Mr Simpson expressed the view in evidence that, if Mrs Simpson had voiced concerns to Mrs Schofield, she would have been likely to do so in a clear and direct manner. That would have been typical of her usual approach. However, Mrs Simpson herself said that she could not bring herself to do so. She said that she expressed her concerns in general, rather than specific, terms. I am satisfied, however, that, when speaking to Mrs Schofield, she linked the deaths with visits by Shipman and that she gave what she believed to be a clear indication of her concern that all was not as it should be.

8.61 In my view, Mrs Simpson's uncharacteristically oblique approach was not recognised by Mrs Schofield as a concern upon which she was expected to act. I say this for two reasons. First, I am satisfied that it would have required a clear and unequivocal statement that Shipman might have harmed a specific resident before Mrs Schofield would have recognised that she had a duty to act. If more general concerns were expressed, I do not think that she would have encouraged Mrs Simpson to elaborate further. She would not have questioned Mrs Simpson as to what might lie behind a more oblique statement and have attempted to draw from her the real cause of her concerns. Such an approach would not have accorded with Mrs Schofield's personality. Second, I am confident that Mrs Schofield would have dismissed Mrs Simpson's concerns, if expressed generally, as part of the latter's morbid fixation with death. It may, of course, be that Mrs Simpson's fears about the deaths of Shipman's patients lay at the root of her expressions of concern about death generally, but Mrs Schofield would not have realised that. She would no doubt have dismissed Mrs Simpson's concerns as another of her 'strange' ideas. Even if Mrs Simpson had stated her fears directly and clearly, it is possible that Mrs Schofield would have dismissed them as a manifestation of Mrs Simpson's personality. However, if they had been voiced obliquely, it would have been far easier for her to do so.

8.62 While Mrs Simpson did not bring up her concerns again in any 'formal' manner, I am satisfied that she referred to them in conversation with Mrs Schofield by means of comments linking Shipman's name with deaths at Ogden Court. She probably used the name 'Dr Death' to describe Shipman on occasion. Again, given her views about Mrs Simpson and the fact that the latter had other concerns and problems of which she also spoke, it is not in my view surprising that Mrs Schofield did not regard these continuing references as being significant. Nevertheless, I am satisfied that they were made and that they indicated a continuing and growing concern on Mrs Simpson's part.

8.63 Mrs Schofield pointed to a number of routes within the Housing Association and the local authority by which Mrs Simpson might have taken her concerns further if she had been dissatisfied that no action had been taken by Mrs Schofield herself. I can well understand why Mrs Simpson would have regarded it as inappropriate to raise such serious concerns in any of these ways. It is in my view natural that she should have preferred to mention the topic to her line manager, whom she had known for some time, in a 'low key' way at the end of an informal meeting. I think she was in effect 'testing the water' to see what reaction she got. She was also no doubt hoping that Mrs Schofield would enquire further into her concerns and pass them on for investigation. When she met with no discernible reaction, she lost confidence and felt unable to mention them again, other than by oblique references. The fact that Mrs Simpson did not pursue her concerns by any of the routes suggested by Mrs Schofield does not, to my mind, in any way suggest that she did not express her concerns to Mrs Schofield in the first place. I am satisfied that she did and also that, in view of Mrs Schofield's reaction, her actions were entirely understandable. Mrs Simpson cannot be blamed for not having taken her concerns any further.

8.64 Should Mrs Schofield be criticised for her failure to recognise that Mrs Simpson was trying to convey to her a real concern that Shipman might be killing his patients? In order to judge this fairly, I must put from my mind the unattractive features of Mrs Schofield's evidence to the Inquiry. It is unfortunate, in my view, that Mrs Schofield sought to deny that Mrs Simpson had ever raised concerns about Shipman and particularly unattractive that, in oral evidence, she should seek to put a different construction on words she had used quite unequivocally in her written statements. However, her lack of frankness to the Inquiry, unattractive though it is, must not affect my judgement as to her failure to respond to Mrs Simpson's concerns at the time.

8.65 In my view, a manager in Mrs Schofield's position should have been alert to the kind of oblique message of concern that Mrs Simpson tried to convey to her and should have taken any such concerns seriously. If, after discussion, it appeared that there was any possibility that the concerns might be well founded, the manager should have taken them forward.

8.66 Mrs Schofield did not realise that Mrs Simpson was trying to raise a concern with her. I have said that Mrs Schofield is not a very curious person. I think also that she did not particularly like Mrs Simpson. She found her difficult to deal with and did not fully recognise her undoubted commitment to the welfare of the elderly people for whom she had some responsibility. I think Mrs Schofield's attitude towards Mrs Simpson inhibited her willingness or ability to listen carefully to what Mrs Simpson was telling her and to think

about its implications. I think Mrs Schofield was dismissive of Mrs Simpson's 'message' and attributed it to an obsession with death. However, the concerns which Mrs Simpson was trying to raise were quite extraordinary and would probably have seemed to many to be preposterous. The friend to whom Mrs Simpson voiced her concerns advised her not to mention them to anyone else because people would say she was 'mad'. The friend was perceptive; Mrs Schofield attributed Mrs Simpson's concerns to an obsession with death. Today, we know that Shipman was a killer and that concerns about him were well founded; before his crimes were uncovered, any suspicion of him was, to many, virtually unthinkable.

8.67 My criticism of Mrs Schofield is muted. She did not listen carefully to Mrs Simpson's attempts to raise her concerns. That was due in part to her own personality and her attitude towards Mrs Simpson. But I think also that her attitude was understandably affected by the belief that any suggestion that a doctor might be harming his patients was unthinkable.

The Concerns of Mr John Shaw

8.68 Mr John Shaw was a self-employed taxi driver in Hyde for about ten years beginning in 1988. Most of his working life had been spent in engineering, although, as a young man, he had served for two short periods in the police force. Mr Shaw gave oral evidence to the Inquiry.

8.69 In August 1998, following press coverage of the fact that Shipman was under investigation by the police for forgery of a patient's will, Mr Shaw contacted the police and expressed concern about the deaths of 21 people (most of them former customers of his) whom he believed to have been patients of Shipman. I have found that Shipman killed 19 of the 21 people identified by Mr Shaw, namely:

Mrs Rene Sparkes, who died, aged 72, on 7th October 1992
Miss Joan Harding, who died, aged 82, on 4th January 1994
Mrs Maria West, who died, aged 81, on 6th March 1995
Mrs Netta Ashcroft, who died, aged 71, on 7th March 1995
Mrs Ada Hilton, who died, aged 88, on 12th July 1995
Mrs Muriel Ward, who died, aged 87, on 24th October 1995
Mr Sidney Smith, who died, aged 76, on 30th August 1996
Mrs Millicent Garside, who died, aged 76, on 23rd October 1996
Mr Thomas Cheetham, who died, aged 78, on 4th December 1996
Mr Kenneth Smith, who died, aged 73, on 17th December 1996
Mrs Irene Brooder, who died, aged 76, on 20th January 1997
Mrs Lizzie Adams, who died, aged 77, on 28th February 1997
Mrs Elsie Cheetham, who died, aged 76, on 25th April 1997
Miss Lena Slater, who died, aged 68, on 2nd May 1997
Mrs Florence Lewis, who died, aged 79, on 10th November 1997
Mrs Norah Nuttall, who died, aged 64, on 26th January 1998
Miss Maureen Ward, who died, aged 57, on 18th February 1998
Mrs Margaret Waldron, who died, aged 65, on 6th March 1998
Miss Ada Warburton, who died, aged 77, on 20th March 1998.

The other two persons identified by Mr Shaw were not, in fact, patients of Shipman and he was not implicated in their deaths.

8.70 Many of Mr Shaw's customers were elderly people who had regular bookings with him. Some travelled with him so frequently that they became personal friends of his. When one of his customers died, Mr Shaw would usually hear about the death from a relative of the customer, who would telephone and tell him why he need not pick up the customer any more. Often, he would be told something about the circumstances of the death. As time went on, he began to notice that a pattern was developing. The common factor in each case was that Shipman had been the dead person's GP. Mr Shaw told the Inquiry:

> **'I couldn't believe what my suspicions were. My suspicions were so fantastic that I just couldn't ... I couldn't grasp what was going on in my own mind.'**

He began to make a point, when he was told about a death, of asking who the deceased's GP had been. He had a card index system of customers and, in it, he began to note down details of the deaths about which he had suspicions.

8.71 Mr Shaw said that the suspicions of which he spoke arose first following the death of Mrs Ashcroft in March 1995. By that time, four of his customers who had been patients of Shipman had died and he had begun to suspect that Shipman might have killed them. In October 1996, another of his customers, Mrs Garside, died. A relative told Mr Shaw that Shipman had given her an injection before her death. By this time, Mr Shaw's concerns were so great that he wanted to inform Mrs Garside's relatives, whom he knew, of his belief that Shipman had murdered her. However, he felt unable to say anything.

8.72 Mr Shaw explained that he did not say anything about his concerns because he was beginning to question his own mental state. He felt that, if he did speak, nobody would believe him and others might also question his mental state. He feared being wrong and that this could lead to him being sued for libel and losing everything he had. His wife too was fearful of the consequences if he spoke out and were proved wrong.

8.73 Another factor was the respect in which Shipman was held in the local community, and his popularity. On one occasion, Mr Shaw warned a customer who was planning to visit Shipman not to go alone. He told the Inquiry that he received a sharp rebuff and was told he was 'paranoid'. The customer concerned dropped him 'like a hot potato' and did not book him again. Such was Shipman's popularity that patients were clamouring to get onto his list. Mr Shaw also pointed out that other people who knew about the deaths did not appear to share his suspicions.

8.74 Mr Shaw felt unable to go to the police with his concerns because he had no direct evidence about the deaths, only hearsay accounts. Moreover, these were often not even firsthand hearsay accounts, but secondhand or even thirdhand. He considered going to the General Medical Council whom he understood to have some responsibility for doctors. However, he had no confidence that his concerns would be taken seriously. He did not know of any other organisation which had responsibility for monitoring or controlling GPs. Even if he had known of the role of the Health Authority, he would not have felt able to approach it as he would have assumed that (like other professions) the medical profession

would have 'closed ranks' in the face of a complaint from outside. Mr Shaw felt he had nowhere to go with his concerns.

8.75 When asked what might have persuaded him to come forward, Mr Shaw said that he would have felt able to report his concerns only to an unbiased and independent organisation that had no connection with the medical profession and dealt with reports from people with concerns and with matters relating to sudden, unexplained deaths. He said that he would have felt able to approach an organisation for advice about how to go about reporting his concerns, provided that the organisation had been well publicised and that it operated on a national – not a local – basis. He would have felt uncomfortable about reporting his concern or requesting advice locally, because Shipman was so well known and highly regarded. He therefore believed it to be of vital importance that any organisation for the use of people like himself should be geographically remote and independent.

8.76 Mr Shaw was a member of the public with no obligation to bring his concerns to the attention of the authorities. Yet he had valuable information to give – information which, if properly considered and investigated, could have led to Shipman's earlier detection. It is important that persons such as Mr Shaw should feel able to bring forward any genuine and serious concerns which they may have, secure in the knowledge that those concerns will be objectively and independently examined and that persons airing the concerns will not be penalised as a result of their action in voicing them.

The Concerns of Mrs Dorothy Foley and Mrs Elizabeth Shawcross

8.77 Mrs Dorothy Foley and Mrs Elizabeth Shawcross were employed as home helps by Tameside Social Services. Mrs Foley worked as a home help from 1985 until she became a resident warden of sheltered accommodation in 1992. Mrs Foley and Mrs Shawcross were home helps for Miss Mona White, Mrs Mary Tomlin and Mr George Vizor. The Inquiry has found that Shipman killed all three of them. Both Mrs Foley and Mrs Shawcross gave written statements to the Inquiry about the deaths. In addition, Mrs Foley gave oral evidence.

The Death of Miss Mona White

8.78 Miss White died on 15th September 1986. Mrs Foley and Mrs Shawcross saw her standing at her front door at about midday on the day of her death. She said that she was waiting for Shipman to visit and was concerned because he had not arrived. They assured her that he would arrive soon and went on their way. They both recalled that Miss White did not look ill. Had she seemed ill, the home helps would not have left her alone to wait. A short time later, Mrs Shawcross saw Shipman near to Miss White's flat. She asked him whether Miss White's problem was with her heart. Shipman replied that it was and that he had given her an injection for her pain. Mrs Shawcross returned to see Miss White about 20 minutes later. She found the door unlocked. She went inside and found Miss White sitting upright in her usual chair. She looked as though she was sleeping. Mrs Shawcross was unable to wake Miss White and realised that she had died. Mrs Shawcross ran to Mrs Foley's house, which was nearby, and together they returned to Miss White's flat. By that time, Shipman had returned. Shipman made no attempt at resuscitation. This was the first death that

Mrs Foley had encountered in the course of her work as a home help. She said that she did not have any particular concerns about the death although she did think that it was very sudden.

The Death of Mrs Mary Tomlin

8.79 Mrs Tomlin died just over three weeks later, on 7th October 1986. Mrs Foley and Mrs Shawcross had visited Mrs Tomlin on the day of her death. They arrived at her flat just before lunchtime and found her unwell. She was sitting up in bed. When asked by the police, in the course of their investigations after Shipman's arrest, neither Mrs Foley nor Mrs Shawcross was able to remember what exactly had been wrong with her. Mrs Tomlin told them that she was expecting a visit from Shipman. Mrs Shawcross and Mrs Foley stayed for a while and chatted. Mrs Tomlin seemed quite cheerful and was looking forward to Shipman's visit. After a short time, the home helps left to continue with their rounds. Shortly afterwards, Mrs Foley saw Shipman go into Mrs Tomlin's flat. About ten minutes later, she made her way to the flat and was met by Shipman. He said to her, 'Go and put the kettle on, we'll ring the family, she's going.' Mrs Foley asked Shipman what he meant, to which he replied, 'She's going, I'll just go and have a look at her.' Shipman then went into the bedroom and Mrs Foley went into the living room. Shortly afterwards, Shipman came through into the living room and told Mrs Foley that Mrs Tomlin was dead. Shipman said that Mrs Tomlin had been a very poorly and lonely lady and that every day had been a 'bonus'. He did not summon an ambulance. Nor did he make any attempt at resuscitation.

8.80 Mrs Foley said that, after Mrs Tomlin's death, she had a strong feeling that 'something was not right' about her death and that of Miss White. Mrs Shawcross shared her views. Mrs Foley believed that Shipman was a good doctor so did not think that medical incompetence was the explanation. It crossed her mind that Shipman was trying to give his patients 'a perfect death'. However, she was aware that neither Miss White nor Mrs Tomlin had been suffering from any terminal illness.

The Death of Mr George Vizor

8.81 Three years then passed before the death of Mr Vizor on 18th October 1989. Mrs Shawcross visited him at home on the day of his death. She thought that he did not look well and requested a visit from Shipman. When Mrs Shawcross had done her jobs for Mr Vizor, she left him alone as usual. She did not think he was so unwell that he needed someone to stay with him. At about midday, Mrs Shawcross and Mrs Foley were visiting another client near to Mr Vizor's home and Mrs Shawcross told Mrs Foley that Shipman was due to visit Mr Vizor. They agreed to call in on Mr Vizor later.

8.82 Some time later, Mrs Shawcross saw Shipman getting into his car, which was parked outside Mr Vizor's flat, and driving away. About 15 to 20 minutes after that, Mrs Shawcross and Mrs Foley went to Mr Vizor's flat. The door was locked but, through the glass panel, Mrs Shawcross could see the lower half of Mr Vizor's body on the floor in the doorway between the living room and the hallway. At the time, she thought that he must have got up to see the doctor out and then collapsed on his way back into the living room.

Mrs Shawcross summoned the warden and the three ladies went into the flat. They examined Mr Vizor's body and concluded that he was dead.

8.83 During the time between Mrs Tomlin's death and that of Mr Vizor, Mrs Foley became aware of the deaths of other patients of Shipman. Other home helps would remark that one of their clients had died and Mrs Foley said that she would 'automatically' ask whether Shipman had been there. Sometimes, a home help would remark that Shipman had given her client an injection before the death. Mrs Foley would speculate with her colleagues about whether Shipman was causing the deaths.

8.84 After Mr Vizor's death, Mrs Foley's suspicions were heightened once again. She and Mrs Shawcross talked about their concerns. However, she does not recall that they had any specific discussion regarding what they might do about those concerns. Mrs Foley explained that, if home helps had concerns about their clients, they were instructed to report them to their line manager. However, she had never felt that she could use this channel to voice her concerns about Shipman. She would not have expected her word to be believed against that of a doctor.

8.85 Mrs Foley said that, if the same thing happened now, she would voice her concerns. This is partly because of her previous experience and partly because she is now more confident. She would raise her concerns with her line manager. If there were an organisation to which she could voice her concerns in private, she would use that. She mentioned an existing organisation which staff can telephone if they believe an elderly person may be the subject of abuse. The organisation ensures that there is someone who will listen and will look into the concerns, whether the caller is right or wrong. She said that employees are now trained to bring forward any concerns that they have. Outside the employment structure, Mrs Foley said she would like to see an independent body which she could telephone and which would investigate her concerns on a confidential basis. She emphasised that such a body should be entirely independent and remote from the locality in which the concerns arose.

The Concerns of Mrs Shirley Harrison

8.86 Mrs Shirley Harrison is the niece of Mrs Erla Copeland. She was also a neighbour of Mrs Mavis Pickup. I found that Shipman killed both Mrs Copeland and Mrs Pickup. Mrs Harrison gave oral evidence to the Inquiry.

The Death of Mrs Erla Copeland

8.87 Mrs Copeland died on 11th January 1996. Mrs Harrison's mother, Mrs Dorothy Proctor, found Mrs Copeland dead, sitting in her usual armchair. Shipman was known to have visited shortly before her death. He came to the house after the death and said that he had not been expecting Mrs Copeland to die. He then proceeded to certify the death as being due to **'natural causes'**.

8.88 Mrs Harrison explained that, in the months leading up to Mrs Copeland's death, Shipman had led the family to believe that she was terminally ill, although they now realise that this was not the case. Following the death, Mrs Harrison and other members of her family

thought that Shipman might have helped Mrs Copeland to die in view of the circumstances in which her body was found. However, they believed that Shipman had saved Mrs Copeland from a lot of suffering and so came to terms with her death and with Shipman's possible involvement in it. Mrs Harrison said that she had spoken to a friend about her belief that Shipman had been involved in the death but the friend warned her to be very careful about what she was suggesting because Shipman was a well-respected GP.

The Death of Mrs Mavis Pickup

8.89 On 22nd September 1997, Mrs Pickup died. A neighbour had discovered the death several hours after a visit from Shipman. The neighbour alerted Mrs Harrison to the death and she went into Mrs Pickup's house. She saw Mrs Pickup lying on her back on the kitchen floor, dead. Following that death, Mrs Harrison became very troubled. She realised that the circumstances surrounding the death of Mrs Pickup were very similar to those of her aunt's death. She believed that Shipman had killed Mrs Pickup. She told the Inquiry that she was 'in turmoil' because, although she had real concerns, she also felt she was reading too much into everything. She spoke to members of her family who continued to believe that the death of Mrs Copeland had been a 'mercy killing'. They pointed out that they were not in a position to know what Mrs Pickup's state of health had been before her death. Mrs Harrison did not mention her concerns to anyone else. Following Shipman's conviction for murder, she said she was 'riddled with guilt' at not having come forward with her concerns sooner.

8.90 Mrs Harrison did not know who was responsible for managing or monitoring GPs. The only people to whom it had occurred to her to talk were her vicar and her doctor. However, she was afraid of being wrong and did not approach either. She said that she would have been reluctant to approach her doctor, as criticising one doctor to another doctor would not have been 'ideal'. She felt that someone outside the profession was necessary.

8.91 Mrs Harrison felt that, if a well-publicised independent advice service had existed, to which she could have expressed her concerns, it would have been easier for her to come forward. She would not, however, have felt able to report Shipman within the Tameside area and it would have been necessary for the service to be outside the immediate locality, e.g. covering the whole of Manchester. She thought it possible that she would have reported her concerns about Mrs Pickup's death if the public were encouraged to take their concerns to the Coroner Service. However, she felt that it would have taken her time to make the decision to do so.

8.92 Like Mr Shaw, Mrs Harrison had been concerned that, if she voiced her suspicions and they proved to be wrong, she would be in serious trouble. In order for her to come forward, she would have needed to be confident that, provided that her concerns were genuine, she would not be penalised for raising them, even if they proved to be unfounded. Like Mr Shaw, she identified the necessary characteristics of an organisation set up to receive concerns, or to give advice about the voicing of concerns, as being independence, distance from the immediate locality and a high profile with the public.

The Concerns of Mr David and Mrs Deborah Bambroffe

8.93 Mr David and Mrs Deborah Bambroffe are funeral directors who work in the family business, Frank Massey & Son, Funeral Directors (Masseys). Mrs Bambroffe's father, Mr Alan Massey, also works in the business although he handed over day-to-day control to his daughter and son-in-law in about 1996.

8.94 In the course of their work, Mr and Mrs Bambroffe dealt with the deaths of many people who had been Shipman's patients. Over time, they developed a growing awareness that there were odd features about some of those deaths. Mr Bambroffe, who joined the business in 1996, soon began to notice that Shipman's patients often died alone while sitting up, dressed in their day clothes and showing no sign of having been ill. This was not the normal pattern. Usually, death occurred in bed with the patient surrounded by his/her family and the paraphernalia of illness. Mr and Mrs Bambroffe discussed these matters and began to notice other strange features. They realised, for example, that Shipman often seemed to be present at or about the time of the death. In a witness statement, Mrs Bambroffe told the Inquiry that she never really formed a firm view about the reason for the different circumstances of the deaths of Shipman's patients. She just knew that something was 'not right'. On the other hand, she was aware that Shipman was widely respected as a good doctor. He was her own GP and she had faith and confidence in him. In late 1997 or early 1998, Mr and Mrs Bambroffe mentioned their concerns to Mrs Bambroffe's parents. Mr Massey, who had known Shipman for years, did not share their anxiety.

8.95 Mr and Mrs Bambroffe were very concerned about making an accusation against Shipman. They were afraid of being wrong. They thought they might not be taken seriously. They thought that people might think they were mad. Mrs Bambroffe was also aware that, if they raised a concern about a death, post-mortem examinations might be carried out. She did not wish to cause unnecessary distress to families, should her concerns turn out to be wrong.

8.96 In February 1998, however, Mrs Bambroffe mentioned her concerns to Dr Susan Booth, a member of the Brooke Practice. Members of the Brooke Practice, including Dr Booth, often signed Form C cremation certificates for Shipman. The full sequence of events thereafter is set out in my Second Report. Suffice it to say here that Mrs Bambroffe's action in speaking to Dr Booth was an important factor in the subsequent decision by Dr Reynolds to report her concerns about Shipman to Mr John Pollard, HM Coroner for the Greater Manchester South District. That in turn led to the first police investigation into Shipman, which failed to detect his criminal activity.

8.97 Mr and Mrs Bambroffe said they would have been more confident in reporting their concerns if there had been an organisation which they could have approached on a confidential basis and which they knew would have taken them seriously.

The Concerns of Dr Linda Reynolds

8.98 Mr Nigel Reynolds, the widower of the late Dr Reynolds, gave oral evidence during the Stage One hearings and afterwards provided further written evidence. He explained that

his wife's greatest fear in reporting her concerns was fear of the consequences of making an unfounded accusation. In particular, she had discussed with him the possibility of a libel action being brought, which would have ruined them financially. He felt that help and advice should be made available to a person in his wife's position. Mr Reynolds also considered that there might be a need for a central body to whom doctors could report any concerns about their colleagues. That central body could then make a judgement about the legitimacy of those fears and decide whether the matter should be taken forward.

The Concerns of Bereaved Families and Friends

8.99 The vast majority of the bereaved relatives and friends of Shipman's victims had no suspicions whatever about the deaths at the time. They were frequently surprised at the suddenness with which the death had occurred but, in general, accepted Shipman's explanation without question. There were, however, those who did have concerns. These misgivings rarely related to the possibility of *criminal* behaviour; more usually, the concerns were that Shipman might have given substandard care – perhaps by failing to attempt resuscitation or to summon an ambulance or by leaving a dying patient alone. Sometimes, the concerns amounted only to a general feeling of unease that there was something 'not quite right' about a death. A few individuals sought an interview with Shipman to discuss their worries. But, until Shipman was under investigation for Mrs Kathleen Grundy's death, none of the bereaved relatives and friends reported their concerns to the authorities. Some were intimidated at the prospect of questioning the actions of a doctor; others were persuaded by members of their families that their worries were unfounded. Several have told the Inquiry that they did not know to whom they should take their concerns.

Conclusions

8.100 As I have said, remarkably few people had any concerns about Shipman and the circumstances in which his patients died. In this Chapter, I have described the difficulties faced by those who did have such concerns and the conditions that they believe might have made it easier for them to report those concerns. There must be not a word of criticism of these people for what, on the face of it, appears to be failure to raise serious concerns in the appropriate quarter. These people did not fail to act because they were irresponsible; they did not act because they felt 'disempowered'. The culture of the time was such that they feared that their concerns would not be taken seriously but would be dismissed as irrational. Some of them feared that they might be wrong to harbour suspicions about Shipman, and that, if they did, the consequences for them would be serious. Some of them had no one to whom they could turn for independent and confidential advice. In Chapter 11, I shall consider what steps might be taken to assist people who have genuine concerns about health professionals to bring those concerns forward for investigation by the appropriate authorities.

CHAPTER NINE

Raising Concerns: the Role of the Practice Staff

Introduction

9.1 General practices are focal points for the provision of primary medical care. That care may be provided by general practitioners (GPs) as well as by a range of other healthcare professionals including midwives, health visitors, counsellors, district nurses and practice nurses. These other healthcare professionals will typically be employed by a primary care trust (PCT) or other healthcare trust or, in the case of a practice nurse, by the practice itself. In addition, there will be practice managers and administrative/clerical staff, in general employed direct by the practice, whose task it is to organise and manage the smooth running of the practice.

9.2 In this Chapter, I shall first examine the staffing arrangements in Shipman's practice at 21 Market Street, together with the extent to which his staff were, or should have been, aware of or alerted to his criminal activities. I shall then go on to consider the channels of communication open to staff for the purpose of reporting any concerns they may have about members of the practice in which they work or about other healthcare professionals employed there.

The Staff of the Market Street Surgery

9.3 When it first became known that Shipman was under investigation for forgery and murder, the staff employed at his surgery – like many of his patients – remained loyal to him. At that time, they believed that Shipman was the victim of a terrible mistake. With the widening of the police investigation and Shipman's subsequent arrest, the surgery became the focus of public attention. A locum was appointed and the practice and its staff continued to function. However, public anger mounted, particularly after Shipman's conviction for murder in January 2000. Strangers visited the surgery and abused the staff. The windows of the surgery were broken and the practice received hundreds of abusive telephone calls after the surgery telephone number appeared in at least one national newspaper. Even when away from work, members of staff were liable to be recognised and subjected to ostracism, harassment and abuse. Underlying all these events appeared to be a general assumption that those who worked at Shipman's surgery must have known that Shipman was killing his patients.

9.4 If the surgery staff had indeed been aware of what Shipman was doing and, for some reason, chose to remain silent and to allow his criminal activities to continue, that would plainly be a very serious matter. If, on the other hand, the staff were completely unaware of what was happening, it is important for their sake that this is stated clearly and unequivocally. Even if the evidence shows that staff did not know of Shipman's criminal activities, the question still arises whether, given the information available to them, they should at least have realised that something was amiss and taken action to bring it to the attention of the appropriate authorities. With these issues in mind, the Inquiry has examined the information available to individual members of staff at the time and their state of knowledge over the relevant period.

The Members of Staff

9.5 At the time of his move to the Market Street Surgery in August 1992, Shipman took with him three members of staff from the Donneybrook practice. They were Mrs Judith Cocker (receptionist), Mrs Alison Massey (receptionist) and Sister Gillian Morgan (practice nurse). He recruited Mrs Carol Chapman, one of his patients, as an additional receptionist. Mrs Margaret Walker (computer operator), who had also worked at the Donneybrook practice for a short time, joined the Market Street Surgery in August 1993 when the new computer was installed. All those members of staff remained in employment at the Market Street Surgery up to the time of Shipman's arrest in September 1998 and beyond.

9.6 Other staff were employed at the surgery for part of the period in question. Mrs Lee Leech worked there between September 1993 and June 1994, mainly entering patient histories onto the new computer. She also worked as a part-time receptionist for approximately six months in 1995 in the absence, first of Mrs Chapman, and then of Mrs Massey. Mrs Jayne Kenyon was employed as a receptionist from the beginning of 1995 until August 1996. After Mrs Kenyon's departure, Shipman's wife, Mrs Primrose Shipman, worked as a part-time receptionist at the practice, covering staff holidays and sickness and some Saturday mornings until the time of Shipman's arrest. Ms Susan Elliot deputised for Sister Morgan while the latter was on maternity leave in 1995.

9.7 There were also a number of other professionals who were attached to the surgery. Mrs Alison Worthington, a health visitor, was based at the premises from 1995 and had an office upstairs. She spent short periods of time there each day. She had little to do with the practice, save that she held a weekly vaccinations clinic for babies there. Mr Colton Reid, a counsellor, held sessions at the surgery for about ten hours a week until some time in 1995. His wife, Mrs Madeleine Reid, a midwife, ran an antenatal clinic at the surgery once a week throughout Shipman's time there.

9.8 Mrs Chapman, Mrs Cocker, Mrs Leech, Mrs Kenyon, Mrs Massey and Sister Morgan gave oral evidence during the Phase Two, Stage Four hearings. Mrs Shipman had given evidence during Phase One. Mrs Walker, Ms Elliot, Mrs Worthington and Mr and Mrs Reid provided statements to the Inquiry.

9.9 It is necessary to consider the evidence relating to the various members or groups of members of staff separately, since the nature and extent of their respective knowledge about deaths of patients differed according to their individual roles.

The Reception Staff

9.10 Between them, Mrs Chapman and Mrs Cocker provided full-time cover for the reception desk. They had an arrangement whereby each would work mornings (8am until 1pm) one week and afternoons (1pm until about 6pm) the next. A third receptionist was on duty from about 10am until approximately 2pm. Until the end of 1994, this was usually Mrs Massey. From the beginning of 1995 until August 1996, Mrs Kenyon worked this shift. Meanwhile, Mrs Massey's duties changed somewhat and her hours were extended. She was then based for part of her time in an upstairs office, although she continued to assist at the reception desk as and when necessary. The receptionists worked Saturday mornings on

a rota system although, towards the end of Shipman's time at the surgery, Mrs Shipman covered most Saturday mornings.

9.11 The reception staff were responsible for answering the telephone, booking appointments for patients with Shipman, Sister Morgan and Mrs Reid, arranging for Shipman to visit patients at home and recording requests for repeat and acute prescriptions. They also liaised with other agencies, such as hospitals, Social Services and the ambulance service. They would type letters and file such items as consultants' letters and test results in patients' medical records. Once the medical records became computerised in 1993, the receptionists were responsible for entering information (which had been previously identified by Shipman) from such items onto the computer record before filing them. From 1997, Mrs Chapman had the title of 'building manager' and was responsible for such matters as arranging any maintenance work which Shipman decided was necessary. Mrs Cocker's special responsibility was to keep records of visits made by the deputising service and of out of hours visits made by Shipman. In 1997, her title changed to that of 'senior receptionist'.

9.12 Members of staff told the Inquiry that, during the working day, the staff were kept very busy, dealing with patients and with various other duties. The main opportunity for social contact occurred at lunchtime when members of staff tended to congregate at the reception desk to eat their meals. Even then, patients sometimes came in and the telephone might ring. The receptionist who was working the afternoon shift would often arrive a little early so as to eat her meal with other members of staff. Messages would be passed and news exchanged. Sometimes, Shipman would join his staff for lunch before leaving for his visits.

9.13 When a patient died and Shipman certified the cause of death, he would complete the Medical Certificate of Cause of Death (MCCD) and place it in an envelope. He would then hand it to the reception staff who would keep it in a designated place at the reception desk until someone – usually a member or members of the patient's family – came to collect it. When members of a deceased patient's family came to collect the MCCD, the reception staff would offer their condolences. If the relatives were upset, the receptionists would attempt to arrange for them to see Shipman. After a death, the reception staff would take out the patient's medical records and enter on the computer record the fact that the death had occurred. They would then place the medical records in a box ready for delivery to the West Pennine Health Authority (WPHA) (formerly Tameside Family Health Services Authority (FHSA)). Also in the box would be the medical records of patients who had left the practice for other reasons. When the box became full, Mrs Chapman would deliver the box to the WPHA's Hyde office, which was on her way home. She estimated that this happened about once every six or eight weeks.

9.14 When a patient died in the community, the practice might be informed of the death in the first instance by a relative of the patient, by the staff of the residential home in which the patient had lived, by the deputising service (if the death occurred out of hours) or by the police or a coroner's officer. News of a death would usually be communicated to the reception staff. Sometimes, Shipman himself would tell them, when he returned from his visits, that a patient had died. On some occasions, he would ring from a patient's home

to say that the patient had died. At times, the first the reception staff would know of a death would be when Shipman handed them the MCCD for collection by the patient's relatives. News of deaths which had occurred would be passed from one receptionist to another as they went on and off duty. Both Mrs Chapman and Mrs Cocker accepted in evidence that they would have come to know about the vast majority (if not all) of the deaths of Shipman's patients which had occurred in the community within a short time of the death. By contrast, they would not necessarily be told of a death which had occurred in hospital until some time after it had occurred. If the relatives did not inform the practice of a death in hospital, the first intimation would be when formal notification was received from the hospital some time later.

9.15 The receptionists would receive requests from patients for Shipman to visit. They would record such requests in the practice visits book and, latterly, also on a visit request form. When a request for a visit was received, the receptionist taking the message would also get out the patient's medical records and put them in a designated place ready for collection by Shipman. When the visit request forms came into use, they would be wrapped around the records. On his return from a visit, Shipman would usually enter a note of the visit in the computer record, then give the medical records back to the reception staff. He would inform them of any patients he intended to visit again and of the period within which the further visit was to be made. A member of staff would then enter the patient's name and the word 'revisit' in the visits book for the appropriate date. The medical records for those patients to be revisited and for any other pre-booked visits for that day were taken out and put ready for collection first thing each morning.

9.16 A receptionist working the morning shift would therefore be aware of most of the visits to be made by Shipman that day. She might not know about visits arranged by the colleague who worked with her for part of the morning shift. Nor would she generally be on duty when Shipman returned to the surgery after making his visits. The receptionist on the afternoon shift would not necessarily know which patients Shipman was due to visit. Mrs Chapman said that she would usually look to see where he was going and at what time he was likely to return to the surgery. Mrs Cocker said that she would do this sometimes, but not always.

Mrs Carol Chapman

9.17 Mrs Chapman left school at 15 and underwent no formal vocational training of any kind. She had various jobs, all of an administrative/clerical type. Before beginning work at the Market Street Surgery in 1992, she had no previous experience of work in a medical setting. It is of significance that Mrs Chapman's husband had died suddenly of a heart attack at the age of 34. He had had no history of heart problems. The experience of that death had made Mrs Chapman only too well aware that death can occur suddenly and without warning.

9.18 A most remarkable and distressing feature of Mrs Chapman's recruitment to the Market Street Surgery is that, by the time Shipman invited her to work for him, he had already killed her aunt, Mrs Mary Winterbottom (in September 1984), and her mother, Mrs Nellie Bardsley (in December 1987). Shipman had claimed to have found Mrs Winterbottom dead and he had told the family that Mrs Bardsley had died in his presence while he was

telephoning for an ambulance. Mrs Chapman told the Inquiry that she had had no suspicions whatever about these deaths. Indeed, if she had harboured any suspicions, it is inconceivable that she would have agreed to work for Shipman.

9.19 Mrs Chapman and other members of the practice staff were questioned in detail by Leading Counsel to the Inquiry about the deaths of Shipman's patients. In particular, they were asked about:

- the number of deaths which occurred, particularly deaths in the community
- the fact that clusters of deaths occurred from time to time. Sometimes, two deaths occurred on one day; on other occasions, several deaths occurred within a short period.
- the fact that five deaths had occurred at the surgery premises over a period of three and a half years
- the fact that it was not unusual for deaths to be discovered shortly after Shipman had visited, or apparently by Shipman himself when he arrived at a patient's house. Nor was it unusual for Shipman to be present when a patient died.
- the fact that many of the deaths occurred suddenly in patients who had previously appeared to be reasonably fit and active.

9.20 Mrs Chapman was adamant that she had not thought there was anything odd or unusual about any of these features. She knew that many of Shipman's patients were elderly and ill and, if a death occurred, she would assume that the patient had been more unwell than she had thought. Even when she heard of the death of a younger, fitter person, the experience of her husband's death caused her to accept it as something that happened from time to time. She said that she accepted events as they occurred. She did not attempt to analyse the circumstances of each death, nor did she detect that any patterns were emerging. Until 1998, she was not aware that the number of deaths in the practice was in any way abnormal. She did not believe that she had seen the practice newsletter of March 1997, which recorded the occurrence of 63 deaths over the previous 12 months. However, she said that it would not have surprised her if she had. Mrs Chapman told the Inquiry that she was aware that Shipman would sometimes visit patients without an appointment if he was not too busy, just to see how they were. She did not think that he did this frequently, nor did she find it in any way unusual.

9.21 Mrs Chapman was on duty at the time of three of the five deaths which occurred on the surgery premises, those of Miss Joan Harding (on 4th January 1994), Mrs Dora Ashton (on 26th September 1995) and Mrs Ivy Lomas (on 29th May 1997). I have found that Shipman killed all three. Mrs Chapman said that Miss Harding looked poorly on the day of her death. She was not suspicious about her sudden death. In the case of the second death, Shipman told her that Mrs Ashton was not well and that he wanted her to go to hospital but she was refusing to do so. He asked Mrs Chapman to telephone Mrs Ashton's son and get him to try to persuade her. Mrs Chapman did this and went into the examination room to tell Mrs Ashton. She found her dead. She then went to tell Shipman the news and got the impression, when she did so, that he already knew. She was distressed at the death as

Mrs Ashton had been a friend of her mother. She did not reflect on Shipman's apparent knowledge of the death until after he had come under suspicion. On the third occasion, Shipman called Mrs Chapman into his consulting room and told her that Mrs Lomas had died. Mrs Chapman then attempted to make contact with Mrs Lomas' son and, having failed to do so, called the police. The police officer who attended raised no concerns about the death. Mrs Chapman told the Inquiry that she saw nothing unusual or suspicious in the fact that these deaths occurred on the surgery premises. She assumed that it was something that happened from time to time.

9.22 Mrs Chapman was asked about a comment which she had written on an internal practice document in late January 1996. Mrs Massey had been preparing a new job description for Mrs Chapman. She had given the draft job description to Mrs Chapman for her comments on the list of duties which should be included in the document. Mrs Chapman wrote on the top of the document:

> **'Can't think of anything else except finding dead bodies in examination rooms.'**

The comment plainly referred to the death of Mrs Ashton whom, as I have said, Mrs Chapman had found dead in the examination room three months previously. In a written statement to the Inquiry, Mrs Chapman said that the comment was an example of the **'black sense of humour within the surgery'**. In oral evidence, she said that it was 'just our (*i.e. the staff's*) way of dealing with things'. She said that the comment might have appeared flippant, but that 'you have to deal with things like deaths in a surgery'. She suggested that she might have felt particularly 'down' at the time she wrote the comment. She did not think that, when writing it, she had in her mind that there was anything 'funny' (in the sense of 'odd') about the death. I accept that evidence and indeed, I do not believe that, if Mrs Chapman had had any real suspicions about Mrs Ashton's death at the time, she would have written the comment in the way she did, especially since Mrs Ashton had been a friend of her mother.

9.23 There were other deaths which had a particular significance for Mrs Chapman. Mrs Elsie Hannible, who was Mrs Chapman's aunt, died in July 1996. I have found that Shipman killed her. Shipman informed Mrs Chapman of the death on his return to the surgery that day, although it was some time later (probably at Mrs Hannible's funeral) that Mrs Chapman learned that he had been present at the death. Far from finding that odd, she says that by that time she was beginning to think that it was the norm. Mrs Irene Chapman, Mrs Carol Chapman's mother-in-law, died on 7th March 1998. I have found that Shipman killed her. Shipman told Mrs Chapman that he had visited her mother-in-law and found her unwell. When he returned later in the day, it was to find her dead. Neither the death of Mrs Hannible nor that of Mrs Irene Chapman excited Mrs Carol Chapman's suspicions.

9.24 The death of Mrs Mavis Pickup, on 22nd September 1997, shocked and upset Mrs Chapman. I have found that Shipman killed Mrs Pickup. Mrs Chapman had spoken to Mrs Pickup a few hours before her death, when Mrs Pickup had been distressed, but not apparently ill. When Shipman told her of Mrs Pickup's death, Mrs Chapman expressed surprise and observed that, when she had spoken to Mrs Pickup, 'she was only crying'.

She told the Inquiry that she was seeking a medical explanation from Shipman for what had happened. She did not consider the possibility that Shipman might have been involved in the death. Mrs Chapman was also very shocked to hear of the death of Miss Maureen Ward (who was only 57) on 18th February 1998. Shipman was convicted of Miss Ward's murder. Mrs Chapman had seen Miss Ward at the surgery the day before her death and exchanged a joke with her. When Shipman told Mrs Chapman of the death, she was annoyed and turned her back on him. She told the Inquiry that she was angry with Shipman, not because she suspected him of being responsible for the death, but because he had been the bearer of the bad news. She was angry that Miss Ward had died at a time when, as I have explained in Chapter 8, she had so much to live for. Mrs Chapman's annoyance with Shipman deepened when he gave one version of the circumstances of his involvement in the aftermath of Miss Ward's death to her and another to other members of staff. When Mrs Chapman pointed this out, Shipman suggested that it was she who was in error. She believed the error was his. Despite her annoyance, however, she put the difference down to confusion or misunderstanding and it did not arouse her suspicions.

Mrs Judith Cocker

9.25 Mrs Cocker left school at the age of 16 or 17. She underwent no formal vocational training. Subsequently, she worked in various capacities, mainly of a clerical and secretarial nature. In about September 1988, she obtained part-time employment as a receptionist with the Donneybrook practice. There, she was one of six or seven receptionists, working for seven doctors. She carried out general reception duties. Mrs Cocker said that, while at the Donneybrook practice, she became aware on occasion that a death had occurred. However, she got no impression of the frequency with which this happened, or of the circumstances in which deaths took place. She had a general impression that most deaths occurred in hospital, rather than at home. She did not specifically remember the deaths of any of Shipman's patients during that period.

9.26 Once at the Market Street Surgery, Mrs Cocker – like Mrs Chapman – says she accepted events as they occurred. The number and pattern of deaths did not strike her as abnormal or in any way suspicious. Over the years, the proportion of deaths occurring in hospital decreased. However, Mrs Cocker says it never occurred to her that an abnormal number of patients were dying at home. She was aware from what she was told by patients, and by Shipman himself, that many elderly people did not wish to be admitted to hospital but preferred to be cared for, and to die, at home. She was aware that Shipman liked to keep his patients living at home for as long as possible and she therefore did not find it surprising that they died at home.

9.27 Mrs Cocker recalled the circumstances of two deaths in particular. The first was that of Mr John Stone on 24th April 1996 and the second was that of Mrs Elsie Cheetham on 25th April 1997. I have found that Shipman was responsible for both deaths. Shipman visited Mr Stone and it seems that he must have telephoned the surgery and asked Mrs Cocker to inform Mr Stone's son, Mr Ronald Stone, that his father had died. Shipman's claim (which Mrs Cocker does not recall) was that, when he arrived, Mr John Stone was already dead. Mrs Cocker did remember telephoning Mr Ronald Stone (whom she knew) and telling him of his father's death. Almost exactly a year later, Mrs Cocker took a call from

Mrs Cheetham, who said that she was having a 'funny do' and requested a visit from Shipman. Mrs Cocker contacted Shipman via his pager. Shortly afterwards, he telephoned the surgery and told Mrs Cocker that Mrs Cheetham was dead. Mrs Cocker informed the family of the death. On the same day, Mrs Cocker took another telephone call from Shipman, informing her that Mrs Jean Lilley had died. When asked by Leading Counsel to the Inquiry whether the fact that she had received two such telephone calls on one day had struck her as an odd coincidence, Mrs Cocker said she had 'never thought anything about it'. She had just accepted what Shipman said at face value because she trusted him.

Mrs Lee Leech

9.28 Mrs Leech was a qualified teacher. She obtained employment at the Market Street Surgery as a result of her friendship with Mrs Shipman. She had no previous experience of working in a medical setting. During her first period of employment, she worked mainly in a small room some distance from the reception desk. If that room was unavailable, she would use a computer anywhere in the building, sometimes in an upstairs room. She helped out occasionally on the reception desk but, apart from that, had little contact with what was going on there. During the second period for which she worked at the surgery, Mrs Leech carried out basic reception duties. She had little recollection of the procedures which followed a death.

9.29 During her two periods of employment at the practice, two deaths occurred on the surgery premises. Mrs Leech was at work on the morning that Miss Harding died. (For a brief account of the circumstances of Miss Harding's death, see paragraph 9.57.) Mrs Leech knew that Sister Morgan had assisted in the attempt to resuscitate Miss Harding. She described how Sister Morgan, in particular, seemed shocked by the death, which suggested to Mrs Leech that it must have been an unusual event. Later, she was told of a second death in the surgery, probably that of Mrs Bertha Moss, whom I have found that Shipman also killed. She remembers a sense of surprise that another person had died on the premises, although she was not at all suspicious. She had not regarded Miss Harding's death as in any way suspicious, so had no reason to be suspicious about the death of Mrs Moss.

9.30 Of the other deaths which occurred during her period of employment, Mrs Leech did not have much recollection. She did not get to know many of the patients personally and knew little of their state of health. She did not recall feeling any surprise at the number of deaths. Nor does she remember being told of occasions when there was a proximity in time between Shipman's visit and the time of the patient's death. She assumed from observation that most of Shipman's patients were elderly and ill. She thought many of them might have been suffering from employment-related conditions. She said that none of the permanent staff appeared concerned at the number or circumstances of the deaths and she took her lead from them.

Mrs Jayne Kenyon

9.31 After leaving school, Mrs Kenyon worked as an assistant in three chemist's shops. The last of these was the Norwest Co-op Pharmacy, next to the Market Street Surgery. While

working there, a vacancy for a receptionist arose at the surgery and Mrs Kenyon successfully applied for the job. She performed duties similar to those of Mrs Chapman and Mrs Cocker. During her time at the surgery, she gained a Diploma in Medical Reception Services, awarded by the Association of Medical Secretaries, Practice Managers, Administrators and Receptionists (AMSPAR).

9.32 Mrs Kenyon agreed that, during her time at the practice, the reception staff would have known about most of the deaths that happened, particularly those in the community. She recalled that there were occasions when a relative would telephone the surgery to report a death and would say that Shipman had visited earlier on the day the death occurred. Sometimes, Shipman would tell the staff that he had been present when a patient died. She said that she would probably have assumed that the patient had wanted a visit because s/he was ill and that the illness had caused the death. However, she had little recollection of her thought processes at the time. She had no idea of the number of patients who were dying and nothing with which to compare that number. She did not remember any discussion among the staff about the fact that the number of deaths was high. She saw no pattern in the deaths.

9.33 Mrs Kenyon was on duty when Mrs Moss died at the surgery premises on 13th June 1995. She remembered little of the events surrounding the death. She was not asked to call an ambulance and did not question this as she assumed that Shipman knew what he was doing. She thought that she would have discussed the death with other members of staff afterwards. However, no one expressed any concerns and she assumed that patients did sometimes die in doctors' surgeries. She did not remember being told that this was the second death which had occurred on the surgery premises.

9.34 Mrs Kenyon was also at work when Mrs Ashton died at the surgery three months later. She saw nothing surprising in the fact that two deaths had occurred on the premises within a short time. A third death, that of Mrs Edith Brady, occurred on the surgery premises during the period of Mrs Kenyon's employment. It took place shortly before her wedding when Mrs Kenyon was having a few days off to make preparations. She did not return to work until three weeks later and could not recall being told of Mrs Brady's death.

9.35 When her employment at the Market Street Surgery was terminated through lack of funding, Mrs Kenyon went to work for two single-handed practices. At one practice, she entered data onto a computer. At the other, she worked as a receptionist. Looking back, she now recognises that fewer deaths occurred at those practices than at the Market Street practice and that more of the deaths occurred in hospital. However, neither the number of deaths among Shipman's patients, nor the fact that so many occurred at home, struck her as unusual at the time.

The Practice Manager

Mrs Alison Massey

9.36 After leaving school, Mrs Massey attended secretarial college and thereafter worked in various capacities, mainly secretarial and administrative. In May 1991, she started part-time work as a receptionist at the Donneybrook practice. Prior to that time, she had

no experience of working in a medical setting. While at Donneybrook, Mrs Massey carried out general reception duties. She had little contact with Shipman.

9.37 After the move to the Market Street Surgery, Mrs Massey continued to work as a receptionist, carrying out similar duties to those of Mrs Chapman and Mrs Cocker. She was not on duty when Shipman returned from his visits, except when she was covering for one of the other members of staff during holiday periods. Mrs Massey was appointed practice manager in early 1994. Initially, her duties remained unchanged but she gradually assumed greater responsibility for administrative work within the practice. She obtained an AMSPAR Diploma in Practice Management in 1996. However, Shipman continued to take all the significant decisions. Indeed, towards the end of his time at the practice, Mrs Massey was becoming somewhat dissatisfied with the level of responsibility that was given to her. As she began to exchange views with other practice managers, she realised that they were playing a more active role in the running of their practices than she was permitted.

9.38 From time to time, Mrs Massey became involved in audit activities. One of the audits she carried out, in 1997, entailed looking at the reasons why patients had left the practice. The intention was to find out from those who had transferred to another practice within the same area why they had chosen to do so. In the course of the audit, it was necessary for Mrs Massey to ascertain how many patients over a period of six months had left the practice by reason of death. A computer printout was obtained; it seems that Mrs Massey must have done this. The printout contained 31 names, 29 of which clearly related to patients who had died. It was not wholly clear from the document whether or not the other two patients were dead. Mrs Massey said that 29 deaths would not have seemed a high number to her as she would have had nothing with which to compare it.

9.39 Another of Mrs Massey's responsibilities was the production of practice newsletters. She said that it was Shipman's idea to record the number of births and deaths in the newsletter. He seemed to think that people would be interested. She was responsible for incorporating the numbers into the newsletters. She said that, although she now realises that the numbers of deaths were high, they had not struck her as such at the time. Nor had she noticed that the numbers appeared to be rising.

9.40 Mrs Massey had a clear recollection of the death of Miss Mary Andrew, on 8th April 1993. I have found that Shipman killed Miss Andrew. She had telephoned the surgery and reported to Mrs Massey that she had a pain at the top of her back. A short time later, Shipman returned to the surgery and told Mrs Massey that Miss Andrew had died. Mrs Massey understood that the cause of death was a heart attack. She was shocked and upset and expressed her surprise to Shipman. On looking back, she remembers him 'smirking' and has the impression that he was laughing at her shock. However, she said that, at the time, the focus of her concern was that she might not have treated Miss Andrew's call with sufficient urgency. She had no suspicion that Shipman might not have acted properly. After that incident, Mrs Massey said that she was very careful when dealing with patients complaining of pains. If she had any doubts, she would consult Shipman about what to do.

9.41 Mrs Massey told the Inquiry that, even after she had ceased to spend all her working time as a receptionist, she would still have known about the majority of deaths which occurred at patients' homes. Like Mrs Chapman and Mrs Cocker, Mrs Massey noticed no striking or unusual association between Shipman's visits and the deaths of patients. Nor was she surprised at the occurrence of deaths on the surgery premises; she knew of four out of the five at the time. She was at work at the time of one of those deaths, that of Mrs Brady. I have found that Shipman killed Mrs Brady. At Shipman's request, Mrs Massey accompanied him into the examination room where Mrs Brady was lying dead. Shipman pressed Mrs Brady's chest with both of his hands for a short time. Mrs Massey understood that he was attempting resuscitation. She was shocked at the sight of Mrs Brady's body but harboured no suspicions. She was unaware at the time that Shipman had told Mrs Brady's family that Mrs Massey had helped him to administer artificial resuscitation. She learned this during evidence given at the inquest into Mrs Brady's death, held in 2001. Until that time, Mrs Massey had always had nagging suspicions that, despite his conviction, Shipman might not be guilty. The evidence she heard at the inquest convinced her of his guilt.

9.42 Mrs Massey could not remember a death, other than that of Mrs Brady, at which she was aware that Shipman had been present. She did not know that he had a habit of visiting patients unannounced and was surprised when she subsequently became aware of this fact.

The Computer Operator

Mrs Margaret Walker

9.43 Mrs Walker had worked at the Donneybrook practice for a period of 12 months between 1989 and 1990. For the first six months, she carried out general clerical duties. Latterly, she worked as a computer operator. Before starting work at the Donneybrook practice, Mrs Walker had been employed by the local council and in a number of part-time positions with other employers. After leaving the Donneybrook practice, she had a period off work due to ill health and then obtained clerical jobs, first with the Tameside FHSA and then in a travel agency.

9.44 After joining the Market Street Surgery in 1993, Mrs Walker's duties included printing repeat prescriptions, typing such documents as medical reports, creating computer records for new patients, entering information from consultants' letters into computer records and collating information for use in audits. Initially, Mrs Walker worked from 10am until 1 or 2pm. Over time, her hours were extended to 9am until 2pm. She worked in an upstairs room at the surgery. She occasionally assisted on the reception desk when the practice was short-staffed.

9.45 The practice computer was linked to the WPHA computer system. When a patient died or transferred to another practice, the WPHA would remove the patient's name from the practice list. On being notified of the removal, Mrs Walker would print off the latest version of the patient's computer record and place it with the patient's other medical records ready for despatch to the WPHA. She estimated that she printed out about 85% of the final computer records. Mrs Massey did the rest. In addition, Mrs Walker and Mrs Massey

shared the task of ascertaining from information held on computer the numbers of patient deaths for inclusion in the practice newsletters.

9.46 By virtue of her involvement with these tasks, Mrs Walker was in a position to gain an overview of the number of deaths which occurred and their approximate frequency. She pointed out, however, that she would often be unaware of the circumstances surrounding a death or of the fact that Shipman had visited a patient shortly before the death was discovered. Occasionally, Shipman would observe to her that he had found a patient dead in a chair or in bed, but Mrs Walker said that these were isolated comments and she noticed no particular pattern to the deaths. Furthermore, she was not in a position to compare the number of deaths occurring at the Market Street Surgery with those at any other practice.

9.47 Nor did Mrs Walker set out to monitor the level of deaths within the practice. She did, however, notice that there were two 'peaks' during her employment at the practice when the number of deaths occurring appeared higher than at other times. I shall refer to these 'peaks' in more detail below.

The Practice Nurse

Sister Gillian Morgan

9.48 Sister Morgan qualified as a registered general nurse in 1983. Before working with Shipman, she had become his patient in 1984. She worked first on an acute medical admissions ward for the elderly and then at a hospital for the elderly. She then had two years' absence from work through sickness, after which she trained as an occupational health nurse. However, she was unable to get a job in that field and, in September 1988, she was appointed as the practice nurse for the Donneybrook practice. At first, she provided nursing services to four of the seven doctors at the practice, including Shipman. Subsequently, two more nurses joined the practice and the work was shared between the three of them.

9.49 Sister Morgan's work included screening for coronary heart disease and asthma, applying dressings, taking blood pressures and blood samples and performing other nursing duties. The practice was a busy one. Sister Morgan saw Shipman on a regular basis, both casually and in order to discuss individual patients as necessary. She found him the most approachable of the doctors at the Donneybrook practice.

9.50 After the move to the Market Street Surgery, Sister Morgan ran chronic disease clinics for the management of hypertension, heart disease, asthma and diabetes. She also ran a 'MOT clinic', carrying out general health checks on patients aged over 30. The rest of her time was spent giving injections, taking blood samples, taking cervical smears, applying dressings and carrying out other nursing tasks. She had her own room, which was down the corridor from the reception desk, near to Shipman's consultation room. She worked a 24 hour week, mainly in the mornings but with one late shift, usually on a Friday.

9.51 Sister Morgan had frequent contact with the reception staff. She would liaise with them about the making of appointments and other administrative matters. She saw Mrs Massey and Mrs Walker daily and sometimes ate lunch with the other staff in the reception area.

On other occasions, she had a sandwich in her room. She saw Shipman every day. On most mornings, she had to see him in relation to a query about a patient or some other topic. She had coffee with him after surgery once or twice a week.

9.52 Between 1996 and 1998, Sister Morgan studied for a Master of Arts (MA) degree in Independent Practice (Nursing). She spent one day a week at Leeds University and one morning a week on study leave. At other times, she worked at the surgery as usual. On completing her degree course, Sister Morgan underwent an assessment of her clinical competence. This was carried out by Dr Alan Banks, then Medical Adviser at the WPHA. Following the assessment, she was appointed a nurse practitioner. In his assessment report, Dr Banks recorded the fact that a significant part of Sister Morgan's work consisted of taking a history from a patient, making an examination and a provisional diagnosis, arranging investigations and treatment and referring the patient as necessary. Sister Morgan told the Inquiry that she would make her own judgements about diagnoses, investigations, treatment and referrals. She would then make suggestions to Shipman as to how the patient should be managed. He would either accept her assessment or see the patient for himself and reach his own conclusion. As a nurse, Sister Morgan did not have the authority to sign a prescription, to order certain types of investigation or to refer a patient, other than to a dietician or chiropodist. Accordingly, it was necessary for Shipman to be involved in any decisions relating to these matters.

9.53 Sister Morgan told the Inquiry that it had never occurred to her that Shipman's medical records were in any way deficient. There appeared to be enough information there for her to see what had happened previously. Since Shipman left the practice, she has had the opportunity of seeing the notes of other doctors and comparing them with his. She now thinks Shipman's notes 'probably were brief'. She emphasised that they were adequate for her purposes. They were not, however, adequate for all those who used them. Mrs Massey recalled that some locums who worked at the practice had difficulty in ascertaining patients' medical histories because Shipman's notes were either illegible or incomplete. Mrs Massey said that she and other staff assumed that Shipman carried a lot of information in his head, since he did not appear to write much down.

9.54 Sister Morgan remembered little about deaths which occurred while she worked at the Donneybrook practice. She did not get to know the individual patients there in the same way as she did at the Market Street Surgery. She could remember no formal system by which she was notified of a death. She told the Inquiry that she did not feel that she had got any clear impression of the number of people who were dying, the frequency with which deaths occurred or the causes of patients' deaths. Nor did she get any impression of how many people died in hospital. While at the Donneybrook practice, an unfortunate incident occurred when the practice sent an invitation to a patient to see one of the nurses. The patient had died some time before. The relatives were upset and angry. From that time on, Sister Morgan resolved to do her best to ensure that this type of mistake did not happen again.

9.55 Once at the Market Street Surgery, Sister Morgan tried to ensure that she was informed of the death of any patient under her care. The receptionists would inform her of the deaths of patients on the chronic disease registers. They would leave messages in her diary.

When she had been away from the surgery for a period, she would ask whether anyone had died in her absence. She would also see envelopes containing MCCDs at the reception desk and would know then that a death had occurred. She felt – but did not know for certain – that she heard about most deaths in the practice by one means or another. She said that she often did not know the circumstances of a death, just the fact that a patient had died. At times, she would hear more details from other members of the practice staff. Sister Morgan said that she did not find it surprising when the patients she was monitoring died of a cause associated with their chronic disease. She said that, if a patient had chronic disease, the likelihood was that s/he had developed a condition which had caused the death. It all seemed very plausible to her. Sister Morgan would not have been surprised to hear that a patient had died on the same day as a visit by Shipman if the reason for his visit was that the patient was ill. Nor did she detect any pattern to the deaths, e.g. that they tended to have sudden causes, rather than to result from chronic conditions such as terminal cancer. The patients who died tended to have high-risk factors for conditions causing sudden death. She did not recall ever being told that Shipman had discovered a patient dead or that a patient had died in his presence. She was aware of only one incident, when Shipman had left the patient for a short time and gone back to find her dead. That was the death of Mrs Irene Turner, which is described at paragraphs 9.63–9.65 below.

9.56 Sister Morgan said that she was able neither to form an impression of the overall number of deaths, nor to say whether the number of deaths in the practice was unusually high. When planning an audit (probably in 1993), Shipman told Sister Morgan that the practice had approximately 40 births and 40 deaths a year. WPHA records show that Shipman had 46 patient deaths in 1993. The number of births is likely to have been significantly less. The numbers of deaths for 1995, 1996 and 1997 were significantly larger. Sister Morgan did not recall seeing the numbers of deaths set out in the practice newsletters and said that, even if she had, they would not have meant much to her. She said that, even now, she has no idea how many deaths per thousand patients could be expected each year in a general practice.

9.57 Sister Morgan was involved in the events surrounding the death of Miss Harding, who died on 4th January 1994. Miss Harding's was the first of the five deaths which occurred at the Market Street Surgery premises. Shipman came into Sister Morgan's office and said that he needed her. He told her that a patient had collapsed. She accompanied him to his examination room. Miss Harding was lying there, pallid and motionless. Shipman instructed Sister Morgan to perform cardiac massage while he attempted mouth-to-mouth resuscitation. They continued for several minutes before Shipman indicated that they should stop. Sister Morgan believed this decision was correct as there were no signs of life. Shipman felt Miss Harding's pulse but Sister Morgan does not recall whether he looked at her pupils. She does not recall him using a stethoscope. Sister Morgan remembered, when asked by the Inquiry, that resuscitation equipment comprising a bag containing a bag and mask and an airway for resuscitation was kept at the surgery, together with a supply of adrenaline. She said that at the time she was on 'automatic pilot' so it did not strike her as surprising that Shipman was not using this equipment. Subsequently, when she was asked to give a statement about the death to the police in

1998, she wondered why it had not occurred to her to go and get the equipment herself. In the event, Shipman had appeared to have no difficulty in establishing an airway. Prior to this time, Sister Morgan had performed about four resuscitations following cardiac arrests. She had had training in resuscitation during her occupational health course and an update after her arrival at the Market Street Surgery.

9.58 Sister Morgan had no suspicions about Miss Harding's death and no doubts that the resuscitation attempt had been genuine. An ambulance had been called for Miss Harding but was later cancelled. Sister Morgan had only a vague recollection of this. She said that she would not have been surprised if Shipman had ceased his efforts to resuscitate Miss Harding before an ambulance (which would have taken between 10 and 20 minutes to reach the surgery) had arrived, as they were making no progress. Dr John Grenville, who gave evidence during Phase One of the Inquiry, disagreed. He said that it would have made no sense to have started resuscitation and then to have ceased before the ambulance arrived. It would, of course, make sense if, as I have found, the resuscitation was a sham, designed to convince Sister Morgan and others that Shipman had made a genuine attempt to save Miss Harding's life.

9.59 In evidence, Sister Morgan told the Inquiry that she and Shipman discussed the death later that same morning. She asked him if she had done the cardiac massage correctly. She did not recall any discussion about the failure to use the resuscitation equipment. In evidence, she seemed at first to suggest that she had not thought about this failure from the time of the incident itself until giving her police statement in 1998. However, afterwards, she suggested that it might have occurred to her later when she 'pondered on it, maybe that night'. She believed that, if she had thought about the failure to use the resuscitation equipment and had not mentioned it to Shipman, it would be because she was busy with other things and had overlooked doing so.

9.60 It seems to me unlikely that Sister Morgan ever considered the failure to use resuscitation equipment until she came to give her police statement, or possibly even later. If she had given the matter any thought at the time, it seems highly likely that she would have discussed it with Shipman and that she would have been concerned to ensure that no such failure occurred again.

9.61 Sister Morgan understood that Miss Harding had appeared ill when she arrived at the surgery and that she had died of a coronary thrombosis. She said that she would have expected such a death to be reported to the coroner and was unaware that it had not been. She knew that a death had occurred on the premises at the Donneybrook practice during her time there so she did not regard such a death as particularly unusual. She was not aware that the patient who had died at the Donneybrook practice, Mrs Mary Hamer, had been a patient of Shipman.

9.62 Sister Morgan was also at work when Mrs Ashton died at the surgery. Sister Morgan played no part in the events surrounding the death and believes that she heard about it later that same day from Mrs Chapman. She did not wonder why no resuscitation had been attempted and she said that she was unaware that no ambulance had been called. She was absent from the surgery on maternity leave or holiday at the time when the other three deaths occurred there. Sister Morgan said that she did not count up the deaths which had

occurred on the surgery premises, nor did she consider them in their totality. The deaths were spread over three and a half years. She did not give any thought as to whether adequate resuscitation techniques had been used on each occasion. She assumed that Shipman would have done what was appropriate at the time.

9.63 In a statement made to the Inquiry, Sister Morgan mentioned three deaths in particular which had caused her some initial surprise. However, she said that in each case she was able to marry up the fact of the death with some other information that made it seem part of a natural process. The first of the deaths was that of Mrs Turner on Thursday, 11th July 1996. Shipman was convicted of her murder. Mrs Turner, who was a diabetic, telephoned the surgery on the morning of her death. Sister Morgan spoke to her. She says that Mrs Turner told her that she had been vomiting for several days and had stopped taking the medication she had been prescribed for her diabetes. Mrs Turner's family told the police that the problem was that Mrs Turner had a cold and was bringing up phlegm and occasionally being sick. They said she was concerned that she was bringing up her medication and telephoned the surgery to ask for advice. Sister Morgan was adamant that Mrs Turner had told her that she had stopped taking her medication several days before. This would have been contrary to the instructions which Sister Morgan gave to diabetics, namely that if they were unwell (particularly if suffering from vomiting and diarrhoea) they should telephone the surgery and should not stop their medication until they had received advice. Sister Morgan says that she told Mrs Turner she should have contacted the surgery earlier. She went on to suggest that Shipman should visit Mrs Turner.

9.64 Shipman visited later the same day. Sister Morgan recalled seeing him after that visit. He told her that he suspected that Mrs Turner had a 'water infection' and that he had brought a urine sample back to the surgery for testing. She thinks that Shipman also told her that Mrs Turner was poorly and should have gone into hospital. Sister Morgan believes she learned of Mrs Turner's death on the following Monday, 15th July. She was aware that Shipman had gone back to Mrs Turner's house on 11th July and found her dead. She does not remember being told the cause of the death. She says that she was taken aback by it. She worried that she had 'missed something'. She also wondered whether, if Mrs Turner had followed her instructions, she would still be alive. She was concerned that she might not have communicated the instructions adequately to Mrs Turner and subsequently made sure that she emphasised the importance of following her instructions when talking to diabetics.

9.65 Sister Morgan said that, although she was concerned that she herself might have missed something, she had no such concerns about Shipman. It did not occur to her that, in leaving Mrs Turner, Shipman might have underestimated the seriousness of her condition. She said that all the care that she had ever seen him provide had been appropriate, so there was no reason for her to doubt him on that occasion.

9.66 The second death mentioned by Sister Morgan was that of Miss Ward, which, as I have said, occurred on 18th February 1998. Sister Morgan saw Miss Ward on 5th February. She gave her inoculations needed for a foreign cruise which she was about to take. She was told of Miss Ward's death later, possibly at a staff meeting which took place the day after the death. Sister Morgan thought what a shame it was that Miss Ward had not been able

to go on her holiday. She learned that Miss Ward had died of 'cancer with secondaries'. It did not occur to her that it would be unusual for someone to be fit and looking forward to a holiday one day and dead as a result of cancer with secondaries within a fortnight. Other members of the practice staff were, of course, aware that Miss Ward had been into the surgery only the day before her death and had appeared in good health then. It is clear that Miss Ward's death was a topic of discussion among the staff and, although Sister Morgan does not remember being told about her recent visit to the surgery, it is likely that she was. In that event, the suddenness of her death would have been even more striking and unusual.

9.67 Thirdly, Sister Morgan referred to the death of Mrs Margaret Waldron on 6th March 1998. I have found that Shipman killed Mrs Waldron. On 4th March, Mrs Waldron, who was 65 and, according to Sister Morgan, 'a very glamorous lady', went to see Sister Morgan in connection with her cholesterol level. Sister Morgan remembered that Mrs Waldron mentioned also that she had backache. Sister Morgan therefore prepared a prescription for a pain-relieving drug and took it for Shipman to sign. Sister Morgan was later told that Mrs Waldron had died of a heart attack. She told the Inquiry that she knew that backache could be an atypical sign of a heart attack and that a high cholesterol level was a risk factor. She said she went on to consider her own actions and whether she could have altered the outcome in any way. She said that she did not follow that consideration through and ask herself whether, in not investigating Mrs Waldron's complaint of back symptoms, Shipman himself might have been at fault.

9.68 In fact, at the time that she saw Sister Morgan, Mrs Waldron had been suffering from low back pain and sciatica for three days. That is evident from a letter which Mrs Waldron wrote at the time and from a conversation she had with a friend just before visiting the surgery. Sister Morgan did not think that the site of the pain or the presence of sciatica was mentioned to her, even though she would have posed specific questions about both these matters. However, Mrs Waldron was a state registered nurse and an articulate woman. It is inconceivable that she would not have given an accurate history in response to Sister Morgan's questions. It is clear that she would have said that the pain was in her lower back and/or leg. That being the case, Mrs Waldron's symptoms could not sensibly have been linked with her subsequent heart attack.

The Other Healthcare Professionals

9.69 The other healthcare professionals attached to the Market Street Surgery (including Ms Elliot who deputised briefly for Sister Morgan in 1995) had no detailed knowledge of events within the practice, or of the number of patient deaths occurring. Insofar as they had any dealings with Shipman, they were impressed with what they saw. They also referred in their witness statements to the fact that they were aware of the high regard in which Shipman was held.

9.70 For the sake of completeness, I should mention Mrs Marion Gilchrist, the district nurse assigned to Shipman's practice from April 1995 until after his arrest in 1998. She was not employed directly by Shipman but by the Tameside and Glossop Community and Priority Services NHS Trust. However, she worked very closely with Shipman. She met him at least

once a week and may have communicated with him more frequently. She formed a very favourable view of Shipman. She found that he knew his patients and their extended families and circumstances very well. He visited patients frequently and went to a lot of trouble and appeared to care genuinely for them. She was particularly impressed by the terminal care that he provided. She would not be aware of the deaths of many patients unless they were those for whom she was providing nursing care. Usually, they would be quite poorly. She was never surprised by the death of any of Shipman's patients; nor did she ever suspect that he might have harmed a patient. She said that had she had any suspicions, she would have raised them with her team leaders. I should briefly mention that Mrs Gilchrist suggested that financial considerations could operate to discourage the raising of concerns. She made this suggestion in the context of fundholding, saying that she and her colleagues were warned that if a consortium of GPs became unhappy with the district nursing service that she and her colleagues provided, it would be entitled to seek those services from an alternative local provider. I can see how this could operate on the mind of a district nurse who was undecided about whether to raise a concern that s/he had about a GP. It would operate far more strongly, of course, if the nurse were directly employed by the GP.

The Practice Staff's Awareness of the Number of Deaths

9.71 In a statement made to the Inquiry, Mrs Walker said that she thought that she noticed the first 'peak' in the level of deaths perhaps a year or two after she started work at the practice. That would have been in 1994 or 1995. Records held by the WPHA show that Shipman had 58 patient deaths in 1995 – up from 37 deaths the previous year. I have found that he killed at least 30 patients in 1995. It seems likely, therefore, that Mrs Walker may have noted the first 'peak' some time during 1995. The WPHA records show that Shipman had 48 patient deaths in 1996 and 57 (possibly 59) in 1997. I have found that he killed at least 37 patients in 1997. It may well be that the second 'peak' referred to by Mrs Walker occurred some time during 1997.

9.72 Mrs Walker described one or two incidents – probably at the times of the 'peaks' of which she spoke – when she recalled wondering why so many deaths were occurring. She said that she wondered whether Shipman could be 'missing something in his diagnoses'. She said that her husband recalled her posing this question to him on one occasion. One incident she remembered had happened at her birthday celebration at the surgery on 15th July 1997. Shipman returned, having visited a patient who had died. This would have been Mrs Muriel Grimshaw, who was found dead on 15th July, having died the previous day. Shipman was convicted of her murder. Mrs Walker recalled a feeling of embarrassment when the news of the death was announced. She cannot now remember whether the embarrassment was on Shipman's part or her own. No one else present appeared to recall this incident.

9.73 Mrs Walker remembered observing to her husband once that another patient had died that day. He replied, 'You do work in a doctor's surgery', suggesting that deaths were only to be expected given the nature of her work. She accepted this explanation and her concern receded for the time being. On each occasion when Mrs Walker contemplated the possibility that deaths might be due to some omission on Shipman's part, she

dismissed the notion. He was held in high esteem by patients, the consultants to whom he referred patients appeared to confirm the diagnoses he had made and others praised his knowledge and abilities.

9.74 In her statement, Mrs Walker referred to light-hearted comments among members of the surgery staff about the apparent association between the large earrings which Mrs Chapman liked to wear (and which Shipman disliked) and the occurrence of a death. According to Mrs Chapman, the association had first been made by Shipman and was subsequently referred to whenever a death occurred. Mrs Heather De-Rome, the daughter of Mrs Eileen Robinson and herself one of Shipman's patients, recalled an occasion when Mrs Chapman came in during a consultation with Shipman to tell him that a patient had died. Shipman referred to Mrs Chapman's earrings and linked them with the death; this was clearly a running joke between the two. Eventually, Mrs Chapman said that the comments began to 'get to' her. After Mrs Elizabeth Battersby died, in December 1997, Mrs Chapman did not wear any earrings for a week.

9.75 Mrs Walker emphasised that the fact that comments were made did not indicate that the staff had any real concerns about the deaths. I accept this and, indeed, the fact that such remarks were made – and to Shipman – demonstrates, in my judgement, the absence of any real concerns. Rather, the comments were, on the part of the staff at least, an example of the sort of black humour often resorted to by those who have to deal with the fact of death on a regular basis. For Shipman, of course, it was quite another matter.

9.76 Mrs Walker also described an occasion when, having read a book entitled *Mort*, she joked with Shipman that it would be a good name for him. He appeared to take her suggestion in good part. Other members of staff have also suggested that Shipman may occasionally have been referred to as 'Dr Death' and 'The Grim Reaper'. Mrs Leech recalled Mrs Chapman using the latter term when she visited the surgery some time after she left. This could have been at any time up to Shipman's arrest. She said there had been a lot of deaths in the practice and she remembers Mrs Chapman making a jocular remark. Mrs Chapman does not remember using the term and no one else has any recollection of this incident. The evidence about the use of such names by surgery staff is not entirely clear but, even if they were used, I am confident that they were not intended seriously to imply that Shipman was criminally responsible for the deaths of his patients.

9.77 In the early part of 1998, things began to change. Mrs Chapman said that, by 1998, the staff had begun to notice the number of deaths which were occurring and that 'eyebrows would be raised' when somebody died. It is clear that there was discussion among some members of staff at least about the number of deaths. Mrs Chapman said that she thought that Shipman might be getting a little bit tired. She considered the possibility that this might be causing him to 'miss something' in his diagnoses. She says she did not voice that thought to others. Whether she did or not, it is clear that the same idea had occurred to both Mrs Walker and Mrs Massey. The belief that Shipman was getting tired might have been supported by the fact that he was known to be seeking a partner in the practice in the early part of 1998. It might therefore have been thought that he felt in need of assistance in managing his workload.

9.78 Mrs Chapman, Mrs Massey and Mrs Walker spoke of an occasion, probably in February 1998, when the subject of the number of deaths was brought up in the presence of Mrs Shipman. Mrs Walker and Mrs Massey were present at the time. Mrs Massey said that Mrs Chapman was also present although Mrs Chapman believed that she was not. She did, however, recall that the conversation was reported to her later. Mrs Massey said that the staff were puzzled and were questioning why so many patients were dying. Mrs Shipman shrugged her shoulders and remarked that Shipman was having (or had had) what she termed 'a run of bad luck'. The surgery appointments sheets show that Mrs Shipman covered for Mrs Cocker on the mornings of 19th, 20th and 23rd February 1998. In the ten days before 19th February, there had been five deaths. Miss Ward had died on 18th February. It seems likely that the conversation referred to took place at around this time. Mrs Chapman was working in the afternoons that week. That would explain why she does not recall being present. The fact that Mrs Cocker was absent during this period would also explain why she recalled nothing of this discussion.

9.79 Sister Morgan told the Inquiry that, at various times when there had been a run of deaths, members of the practice staff would pass comment on this, usually associating it with the fact that it was winter or with a 'flu outbreak. However, she recalled no other discussions about the number of deaths occurring at the practice, even in 1998. She was not present at the time of the conversation involving Mrs Shipman. She said it had never occurred to her that Shipman might be failing his patients in any way, whether as a result of tiredness or otherwise. Sister Morgan expressed doubt that any such discussions had taken place at all before the police investigation began in August 1998. If there had been such discussions, she felt that Mrs Walker and Mrs Cocker (and, she would have hoped, Mrs Massey and Mrs Chapman) would have told her about them. However, it is clear from Mrs Chapman's evidence that this would not have been the case. She told the Inquiry that the other staff would not include Sister Morgan in any such discussions because of her loyalty to Shipman ('she would never hear anything said against him') and because she was 'very, very sensitive'. The fact that Sister Morgan was unaware that the deaths were under discussion, therefore, does not mean that no such discussions took place.

9.80 Indeed, it is clear that Mrs Walker, Mrs Chapman and Mrs Massey were experiencing some concerns about the number of deaths by February 1998. I accept, however, that their concerns were unformulated and amounted to no more than a consideration of the possibility that Shipman might, through tiredness or some other cause, have been omitting to diagnose potentially fatal conditions. They had no suspicion that anything was seriously amiss. If they had, Mrs Walker and Mrs Massey would not have broached the subject with Mrs Shipman. In the event, the high level of deaths continued for less than five weeks after the time when their conversation with Mrs Shipman is likely to have occurred. During that time ten more patients died. I have found that eight of them were killed by Shipman. After 24th March, the rate of deaths dropped. I have found that the reason for that was that Shipman became aware of the first police investigation which had resulted from the report of Dr Linda Reynolds to the Coroner. In the three months that followed, there were only three deaths which occurred at a patient's home. Insofar

as the staff had been concerned, they must have derived considerable reassurance from the slowing of the death rate.

How Shipman Was Viewed

Before Shipman's Arrest

9.81 Mrs Chapman and Mrs Cocker had been patients of Shipman before their employment with him started. They had a high regard for his skills and believed him to be a good and caring doctor. Mrs Cocker, Mrs Massey and Sister Morgan were happy to move with him from the Donneybrook practice to the Market Street Surgery and to stay with him throughout his time there. It is clear that he must have been a good employer and that the surgery was a pleasant place in which to work. Of the three lay members of staff, it seems that Mrs Cocker got on with Shipman best. She shared jokes with him and she was sympathetic when he became 'nowty' (i.e. short-tempered or irritable). Mrs Chapman was less forbearing. It is plain that she got the impression that Shipman regarded what she termed 'the hired help' as intellectually inferior to himself and that he would seek to demonstrate their inferiority from time to time by using complex medical terminology. Mrs Massey regarded Shipman with respect and had a good working relationship with him. However, she had begun to feel some resentment that he would not allow her to manage the practice in any true sense. Mrs Walker also seemed to have a good relationship with Shipman and was able to tease him. However, she was careful not to overstep the mark.

9.82 Of all the staff, Sister Morgan had the closest relationship with Shipman. She had a very high regard for his abilities, as both a patient and a fellow professional. She had the opportunity of seeing him with patients and of observing his rapport with them. She found him approachable when she took queries to him about individual patients and receptive to her ideas about treatment and other matters. He encouraged her to develop her skills and supported her in her attempts to obtain further professional qualifications.

9.83 All the staff trusted Shipman as an individual and as a professional. All were aware of the high regard in which he was held by his patients and by the community at large. He appeared well respected also by his medical colleagues and by the local medical community generally.

After Shipman's Arrest and Conviction

9.84 Mrs Chapman described how, after Shipman had been arrested and the practice had been taken over by a locum, she soon noticed that the death rate dropped markedly. Patients died in hospital or nursing homes. Mrs Chapman could not remember a death which had occurred at a patient's home after Shipman's departure. Patients tended to be bedbound in the period immediately before death. She began to realise the significance of the fall in the death rate. Also, as the practice staff began to make statements to the police and to discuss the circumstances of various deaths among themselves, she noticed a pattern of association between deaths and visits from Shipman. Sister Morgan said that she did not notice any difference in the number or pattern of deaths after Shipman

left the practice. She said that she was struggling to remain at work at the time and could not take in the significance of any changes which occurred.

9.85 On 12th October 1998, Mrs Chapman made a statement to the police about the death of Mrs Ashton. The following day, she telephoned the police to express her concerns about Mrs Pickup's death. In the same telephone call, or a second telephone call made within minutes of the first, Mrs Chapman also told the police that she was worried about the death of her mother, Mrs Bardsley. She told the Inquiry that she reported her mother's death to the police following a conversation with Mr Peter Wagstaff. He had told her some details about the death of his mother, Mrs Kathleen Wagstaff, which had occurred during a visit from Shipman. Mrs Chapman was struck by the similarity between the circumstances of Mrs Wagstaff's death and that of her own mother. She realised for the first time that what was being suggested about Shipman might actually be true. Although she could not remember the date of that conversation, it seems likely that it took place shortly before 13th October 1998.

9.86 As I have mentioned, the same realisation did not come to Mrs Massey until much later, at the inquest of Mrs Brady in 2001. Like Mrs Chapman, she has now come to terms with the fact of Shipman's guilt. Mrs Walker, Mrs Cocker and Sister Morgan are unable to do so, even now. Their difficulty is in reconciling the caring doctor whom they liked and trusted with the calculating killer the evidence shows him to have been.

Conclusions

The Lay Members of Staff

9.87 I am quite satisfied that none of the administrative staff had any knowledge or suspicion of Shipman's criminal activities. Up to and beyond the time of his arrest, the staff admired him and trusted him implicitly. If Mrs Chapman or Mrs Cocker had had any suspicions about him, I think it unlikely that they would have remained as his patients. If Mrs Massey and Mrs Walker had had any concerns that Shipman might be responsible for the high number of patient deaths they had noticed, it seems to me that the last person they would have mentioned it to (apart from Shipman himself) would have been Mrs Shipman. That the staff should have had such difficulty in coming to terms with the reality of Shipman's guilt is also consistent with their claims that their trust and confidence in him had been complete. Mrs Chapman was the first to accept that the allegations were true; she was the one whose relatives he had killed.

9.88 The practice staff are not to be criticised for their failure to realise that there was anything seriously amiss. They had no knowledge or experience of how many deaths might be expected in a general practice the size of Shipman's. Even those who had worked at the Donneybrook practice had no awareness of what was usual and unusual. When the deaths were occurring, the staff had no contact with others working in similar circumstances with whom they might have discussed an apparent increase in patient deaths. They knew that Shipman had quite a lot of elderly, ill patients. They knew that it was his declared policy to allow them to stay at home and die at home, rather than to be admitted to hospital. If reassurance had been required, they would have gained it from

their realisation that Shipman appeared to be uniformly admired and respected. They personally had every reason to trust Shipman and they did not have the knowledge or experience to evaluate him professionally. There must be an end, once and for all, to any suggestion that the practice staff 'must have known'. They did not. Nor could they reasonably have been expected to.

The Practice Nurse and District Nurse

9.89 I must consider the positions of Sister Morgan and Mrs Gilchrist separately. This is not because I am of the opinion that they were suspicious of Shipman; indeed I am quite satisfied that they were not. I consider them separately because, by reason of their professional training, knowledge and experience, they were in a better position to evaluate Shipman's conduct than were the lay members of staff.

9.90 I can deal very briefly with Mrs Gilchrist. Although she worked quite closely with Shipman, she was not part of the surgery team and would not have been aware of the frequency with which his patients were dying. Many of the patients Shipman killed were in reasonably good health; certainly they were not sufficiently unwell to require Mrs Gilchrist's services. Mrs Gilchrist was not present when a death occurred in the surgery. She did not take her lunch break in the surgery and share the news of the day with the practice staff. I find it wholly unsurprising that she had no suspicions about Shipman's conduct.

9.91 Sister Morgan was in a different position. Not only was she a very highly qualified nurse, she worked in extremely close contact with Shipman throughout the period in which he killed most frequently. I accept without hesitation that she did not suspect him of wrongdoing. The question is whether she ought to have done, or at any rate whether she ought to have realised that all was not as it should have been.

9.92 From the evidence I have heard in Stage Four of the Inquiry, I have formed the view that an experienced nurse is often well placed to observe professional misconduct or poor performance by a doctor with whom s/he works. This is particularly so where the nurse is present during consultations, or works, for example, in an operating theatre. I accept that Sister Morgan did not often work alongside Shipman in that way. I have no doubt at all also that, whenever Sister Morgan was present at a consultation, Shipman's conduct would have been impeccable.

9.93 There were a few occasions on which I would have expected a nurse in Sister Morgan's position to feel a sense of unease about events within the practice. One was the occasion of Miss Harding's death, in January 1994, when Shipman required her to help with resuscitation and yet did not ask her or anyone else to fetch the resuscitation equipment. She said that, being utterly absorbed in what she was doing, she did not think of calling for it herself. I accept that she did not, and do not criticise her for that, although I would have expected a nurse in her position at least to realise immediately afterwards that full use had not been made of the available resources. I would certainly have expected her to feel some concern about this and to discuss it with Shipman. I do not think she ever did.

9.94 I accept that, after Miss Harding's death, Sister Morgan asked Shipman whether she had carried out her part of the resuscitation procedure correctly. Indeed, that she should do

so seems to be illustrative of her relationship with Shipman. I think the relationship was one of master and pupil; he would lead and she would follow; he was to teach and she to learn. She might suggest a course of action but he would decide. To some extent, this is inevitable in a professional relationship between a doctor and a nurse, where the doctor must take overall responsibility for decisions. However, I have the clear impression that this professional relationship was more 'unequal' than many such. I think that the inequality stemmed partly from the fact that it was a 'one-to-one' arrangement. Most doctors work with several nurses and most nurses with several different doctors. However, I think the main cause of this inequality was the personalities of Shipman and Sister Morgan. Shipman had a strongly dominant personality. Sister Morgan admired and respected him very deeply. He inculcated admiration quite deliberately; I think that admiration was expected of employees. Indeed, I think it unlikely that anyone who did not admire Shipman would have stayed long in his employment. Sister Morgan, on the other hand, is not, in my view, a strongly independent personality. I think she was content to follow Shipman's guidance at all times. I do not suggest that she was not a competent, conscientious and hardworking nurse; I think she was. However, I do not think there would have been any circumstances where she would have thought that her own opinion was correct and that Shipman's might be wrong. That being so, I find it unsurprising that Sister Morgan should have questioned her own contribution to the resuscitation of Miss Harding but not Shipman's organisation of it.

9.95 The death of Mrs Turner in July 1996 was another occasion when Sister Morgan might have felt a sense of unease. On this occasion, too, Sister Morgan questioned whether she had given sufficiently clear instructions to Mrs Turner about seeking advice before stopping her medication. She did not question whether Shipman had failed to appreciate how ill Mrs Turner apparently was when he left her to return to the surgery.

9.96 I think also that Sister Morgan must lack the degree of curiosity that most people have. In about 1993, Shipman told her that, in the practice, they could expect approximately 40 births and 40 deaths each year. Sister Morgan had no idea what the usual death rate was. She did not notice that, in each ensuing year, there were far more than 40 deaths in the practice. I do not find that wholly surprising; the number of deaths might not be a matter of particular interest. But I do find it surprising that, after Shipman had been arrested, charged and eventually convicted of multiple murder – murder committed almost under her nose – Sister Morgan has still not found out what the usual death rate is.

9.97 In my view, Sister Morgan's lack of curiosity explains her failure to notice the strange features of two deaths that occurred in early 1998. I find it remarkable that Sister Morgan did not realise that it was strange that Miss Ward could apparently die of cancer with secondaries when, to Sister Morgan's personal knowledge, she had been in the surgery two weeks earlier for pre-holiday inoculations. In fact, it is likely, in my view, that Sister Morgan was aware that Miss Ward had been in the surgery only the day before her death. I am not saying that so sudden a death from secondary cancer is impossible, but it must be an unusual occurrence. I would have expected Sister Morgan to wish to discuss that death with Shipman. Nowadays, in most practices, such a death would be the subject of a 'significant event audit', where the clinical team would discuss the adequacy of the treatment provided. In a single-handed practice, I would expect it to be the norm for the

doctor to discuss such an event with his/her nurse. What is more, after her experience at Leeds University while studying for her MA, I would have expected Sister Morgan to know that such was the usual practice. Yet it appears that, if there was any discussion, it can have taken place at only a superficial level.

9.98 The second death that should, in my view, have puzzled Sister Morgan was that of Mrs Waldron. I am afraid that I am unable to accept Sister Morgan's evidence that, after Mrs Waldron's death, she came to the conclusion that the back pain of which Mrs Waldron had complained a day or two before her death must have been a sign of developing heart trouble. I am quite satisfied that, if Sister Morgan had asked about the site of Mrs Waldron's back pain, as I think she probably did, Mrs Waldron would have told her that it was in her lumbar spine. Sister Morgan cannot have thought that this was a sign of heart trouble. I am driven to the conclusion that Sister Morgan has persuaded herself of that explanation while preparing for her appearance at the Inquiry. I do not suggest that she has done so dishonestly, merely that she has sought for and found an acceptable explanation for her own thought processes. However, the explanation does not bear examination. I have come to the conclusion that Sister Morgan did not think carefully or independently about Mrs Waldron's death. I think that she did what she always did about anything that Shipman said; she accepted what he said without question or independent thought.

9.99 I repeat that I accept that Sister Morgan did not suspect Shipman of wrongdoing. I criticise her only to the extent that I do not think that she applied independent or objective thought to events within the practice that ought to have puzzled her but did not. I do not suggest that, had she thought more carefully, she would have realised that Shipman was killing his patients. I think that that would have been too great a step to contemplate. However, had she shown greater curiosity and independence of mind, she might have acted as a deterrent to Shipman. He might have been wary of her. As it was, I think it likely that he recognised that she always deferred to him professionally and knew that she would not question what he told her.

9.100 I do not think that such an unequal relationship would be likely to arise between a doctor and a nurse in a group practice. There, as a rule, there are several doctors sharing the assistance of several nurses. It is unlikely that a one-to-one professional relationship, such as existed between Shipman and Sister Morgan, would ever arise. I regard such relationships as unsatisfactory. They tend to deprive both parties of the professional objectivity that is fostered by working with a number of colleagues. There is another factor present in the relationship between a GP and his/her practice nurse: they are employer and employee. This is in contrast with the position in a hospital setting, where doctors and nurses are all employed by the NHS trust or hospital authorities and the doctors do not have the power of dismissal. In general practice, the nurse's dependence on the doctor for her employment is likely to make it even more difficult for her challenge the doctor.

The Lasting Effects

9.101 The effects on members of Shipman's practice staff have been profound and lasting. Several have suffered from recurrent ill health in the period since his crimes became known. Neither Mrs Chapman nor Mrs Cocker is working at present. Mrs Walker has

moved to another country. Mrs Massey has moved to a different type of work. Both she and Mrs Chapman feel that they have been used and their trust utterly betrayed by Shipman. As a result of the hostility she has encountered, Mrs Cocker feels unable to go alone into the town centre of Hyde. Sister Morgan told the Inquiry that the events of the past few years have had a serious impact on her personal and professional life.

9.102 The lives of all the staff who worked for Shipman have indeed been changed irrevocably as a result of his crimes. Further damage has been done by the distressing accusations made against them to the effect that they 'must have known' of Shipman's criminal actions at the time. I hope that the fact that I have found those accusations to be wholly unfounded may assist in dispelling any doubts which remain in the minds of some people.

The Raising of Concerns by Practice Staff

9.103 I have found that Shipman's practice staff had no significant concerns about him or his clinical practice. Yet, in other circumstances, practice staff may be uniquely well placed to notice signs of poor clinical practice by a doctor or other healthcare professionals with whom they work. They may become aware of complaints from patients, locums and others with whom they have dealings. They may observe instances of poor practice or aberrant behaviour for themselves. They may become aware of failures of organisation within the practice (e.g. poor record keeping) which might put patients at risk. The Inquiry was anxious to discover how easy it would be for a member of staff of a GP practice who possessed this sort of information to report it.

The Problems Faced by Practice Staff

9.104 The Inquiry was told that staff employed in GP practices can experience particular difficulty in raising concerns about the performance of healthcare professionals within the practice. GP practices are small organisations and there may be conflicts of loyalties and a reluctance to bring criticism about one member of the practice to the attention of his/her colleagues. This reluctance is likely to be increased where a lay member of staff has concerns about clinical care. He or she may well feel unable to challenge the actions of a healthcare professional, believing that his/her concerns may prove to be unfounded and fearing the consequences. There may also be a perception (whether justified or not) that, if a concern is raised, the doctors will 'close ranks', with the result that the concerns will go unheeded. Members of staff may be worried that, if they voice their concerns, their relationships with their employers and colleagues will be irretrievably damaged. The smaller the practice, the greater these problems are likely to be. In a single-handed GP practice, for example, there is likely to be no one within the practice to whom a member of staff could voice a concern about his/her employer. In a serious case, where the doctor's fitness to practise may be in doubt, the raising of concerns could have a direct impact on the livelihoods of those employed in the practice.

9.105 These problems are exacerbated by the fact that the staff of GP practices often function in isolation, both from staff in other practices and from the local primary care organisation (PCO). They may have no experience of working in another practice. They may have no idea what procedures are usual and what are entirely outside the norm. They may be uncertain whom to turn to for advice.

9.106 The problems that I have identified were discussed at one of the Inquiry's seminars. Mrs Pauline Webdale represented AMSPAR at the seminar. She is a practice manager herself and, in addition, has experience in advising AMSPAR members how to raise concerns. She confirmed that doctors can often be reluctant to deal with complaints or concerns about a colleague. In those circumstances, it can be necessary for staff to go outside the practice in order to get their concerns dealt with. Staff who are contemplating such action are often concerned that they may be branded as 'troublemakers' as a result of their actions.

9.107 There are signs of a greater awareness on the part of practice staff of their role in protecting patients. Ms Anna Myers, Deputy Director, Public Concern at Work (PCaW), told the Inquiry that it was her impression, from enquiries she had received at PCaW, that the knowledge of Shipman's activities, and of the criminal activities of other GPs, had made practice staff 'very alive' to the fact that it was important to raise with their local PCT any concerns that they might have.

The Need for a Change of Culture

9.108 Mrs Webdale hoped that, in the future, the culture within general practice would change so that more concerns could be dealt with internally, without the necessity to approach an outside organisation. In the practice Mrs Webdale manages, staff are encouraged to report anything that they feel is 'untoward'. Forms are provided for staff to complete. These forms are used to record the occurrence of all sorts of incidents, including matters affecting health and safety or encounters between members of staff and disgruntled patients. Forms are also completed following more serious incidents, such as a mistake made by a locum or an assistant GP. Mrs Webdale thought that the practice of routinely recording and reporting minor matters encouraged and facilitated the reporting of more significant concerns when the need arose.

9.109 Ms Myers endorsed this approach, observing that, if there was a culture whereby concerns were raised on a daily basis as they occurred, this would remove any sense that the raising of concerns was 'deviant behaviour'. Mrs Debbie Mellor, representing the Department of Health (DoH), emphasised that what the DoH was aiming to do was to achieve an open culture, in which it was accepted practice for people to raise their concerns.

9.110 Mrs Webdale also spoke of the importance of ensuring that all members of the staff within a GP practice – including the most junior – feel that their views are of value. She described efforts to introduce a less hierarchical structure within practices, whereby junior members of staff did not regard the doctors as 'untouchable' but, instead, felt able to exchange opinions with them.

Raising Concerns Outside the Practice

9.111 At the seminar, there was a general view that the ideal situation was one where members of staff, whatever their status, felt able to raise concerns openly within the practice. However, even if the culture changes in the way suggested, there will still be times when it is not feasible for members of staff to raise their concerns within the practice, particularly a single-handed practice. For example, had Shipman's staff had concerns about the deaths of his patients, it would hardly have been possible for them to raise those concerns with Shipman himself. They would have had to have gone outside the practice.

9.112 When Shipman's staff were asked what they would have done if they had felt concerns about Shipman, the receptionists said that they would have spoken to Mrs Massey as practice manager. Had that not been possible for any reason, they would have thought it appropriate to approach the WPHA direct. Mrs Massey said that she would have gone to the WPHA although, at the time, she would not have known which member of staff at the WPHA to contact. She would have appreciated a closer relationship with a member of staff whom she got to know and felt confident in approaching. She said that she could also see an advantage in having an independent body from which a member of staff could get initial advice as to whether and how to proceed and where to direct a concern.

9.113 Sister Morgan would have been in a rather better position. Had she had any concerns, she could have spoken to her clinical adviser, or a nursing adviser at the WPHA. Her professional body, the Royal College of Nursing (RCN), was also available to give advice and support. The PCT in whose area Sister Morgan was working at the time she gave evidence to the Inquiry did not employ a nursing adviser, so Sister Morgan had no identifiable contact there. However, the RCN would have advised her on whom to approach and would have accompanied her to any interview if necessary.

9.114 The other healthcare professionals had their own channels of communication and support. Mrs Gilchrist, for example, could have approached both the RCN and her own employers (through her line manager) if she had had any concerns.

9.115 Mrs Webdale said that if she, as a practice manager, had a concern about a doctor in the practice, or if such concerns were reported to her, she would involve the local medical committee (LMC) or PCT. If the concern was of a sensitive nature – such as an allegation of drug abuse by a doctor – she would go to the LMC. She felt that PCTs were, as yet, ill-equipped to deal with concerns of this kind. When facing potentially sensitive issues, it was important to have a relationship with the person in whom one was confiding. She had not yet been able to form the necessary relationships with staff at her PCT. She had considerable confidence in the Clinical Governance Lead there, but said that he had a 'huge' remit and could not do everything. It was for that reason that she would have approached the LMC.

9.116 Other participants at the seminars considered that PCTs were not perceived by staff as being sufficiently approachable. This may be because they are relatively new organisations, have experienced a high turnover of staff and because practice staff have not yet had the time to form relationships with staff at the PCTs. In addition, however, it was

said that PCT staff have a wide range of responsibilities and sometimes cannot manage them all.

Addressing the Problems Faced by Practice Staff

A Practice 'Whistleblowing' Policy

9.117 Ms Myers said that, in her view, the correct approach was for PCTs to help GPs to understand the value of encouraging staff to raise concerns within the practice whenever possible. However, practice staff should be told that, if they felt unable to raise their concerns internally, they should approach a named individual at the PCT. That individual might be the Clinical Governance Lead, or someone else. She believed that practices should regard the PCT as a 'safety net', not as the first port of call for a member of staff who had concerns. She agreed that it would be helpful if the named individual at the PCT was known to practice staff before the need to approach the individual arose. She said that she was not suggesting that a member of staff should be prevented from approaching a different individual at the PCT whom s/he felt more confident about talking to but, for those who did not know whom to approach, a name should be provided.

9.118 Mrs Webdale emphasised that each GP practice should have a written 'whistleblowing' policy, setting out the steps that should be taken by staff who wished to raise a concern. She said that it should be a 'living document', which developed over time and of which everyone in the practice was aware. It seems that many practices have no such policy. In September 2003, Dr Linda Patterson, then Medical Director of the Commission for Health Improvement (CHI), told the Inquiry that CHI had found that there were 'significant gaps' in the application of PCT whistleblowing procedures to GP practices and staff. Among the practices CHI had reviewed at that time, only 24% had reported having a whistleblowing policy. CHI believed that more should be done by PCTs to ensure that GPs and their staff were aware of the procedures to be followed. The RCN also expressed the view that PCTs had a responsibility for ensuring that GPs were aware of the mechanisms available to them to raise concerns about professional practice.

9.119 At the time of the Inquiry's seminars, the DoH was working with PCaW on the preparation of guidance for GPs on how to develop and implement a whistleblowing policy for healthcare professionals and other staff in their practice. The Inquiry has now seen a draft of that guidance and of the whistleblowing policy contained in it.

9.120 The draft policy assures staff that the practice welcomes genuine concerns and is committed to dealing with them responsibly, openly and professionally. It emphasises that staff should raise concerns while they are **'just concerns'**, rather than wait until the level of concern escalates. It assures staff who may wish to raise genuine concerns that they will not lose their jobs or suffer retribution as a result of doing so. Nor will they be asked to provide proof that their concerns are well founded. The draft policy encourages the bringing forward of concerns openly. It sets out in general terms what will happen after a concern is raised and stresses that a person raising a concern will, insofar as is possible, be kept informed of what is being done in response to the concern.

9.121 The draft policy suggests that a member of staff should raise a concern with his/her line manager. If that is inappropriate for some reason, or has not proved effective, the draft

policy advises an approach to the practice manager or to a named GP within the practice. Staff are advised that, if they are unable to raise the concern internally, or if it has not been dealt with properly, they should approach a named contact at the PCT. Contact details are given. The draft policy is clear and reassuring in tone. It contains contact details for PCaW and also mentions that free independent advice may be available from the trade union or professional organisation to which the member of staff belongs.

9.122 The guidance to GPs suggests that a draft policy should be prepared and discussed at a staff meeting after which a practice policy should be agreed. There should be liaison with the PCT. Staff should be briefed on the content of the policy and a poster, reinforcing the message, should be displayed. Employment contracts should be amended as necessary to harmonise with the whistleblowing policy.

Training

9.123 Mrs Webdale emphasised the need for general practice staff to be trained, not only so that they were familiar with the procedure to be followed if they wished to raise a concern, but also so that they were aware of wider clinical governance issues. AMSPAR produces an induction pack for new staff which, if implemented properly at practice level, provides a comprehensive grounding for new staff. It includes the topic of raising concerns. Mrs Webdale said that the training for new staff now covers a much broader range of issues than was the case in the past. This includes clinical governance issues, which she regarded as very important. Mrs Webdale also contributes to educational events for GP practice staff, at the invitation of PCTs. She sometimes goes into practices to provide on-site training. She felt that more GP practices were recognising the value of good training for their administrative staff.

Closer Links with the Primary Care Trusts and with Staff from Other Practices

9.124 I have mentioned the problem of isolation of staff, both from other practices and from staff at the PCTs. Staff may feel that they have no one whom they can consult about their concerns. At the seminar, Mrs Webdale described the directory covering the area of the Norfolk, Suffolk and Cambridgeshire Strategic Health Authority. This contains the names of practice managers and staff who possess particular expertise on different topics upon which staff might need advice. With the assistance of the directory, practice staff are in a position to consult someone with experience in the relevant field. The fields of expertise listed in the directory include the raising of concerns. Mrs Webdale also spoke of arrangements for the sharing of staff between practices.

9.125 Mrs Sue Antrobus, representing the RCN, emphasised the importance of PCTs establishing networks of practice nurses. Dr Grenville felt that it was also important to promote links between practice nurses and district nurses. Dr Patterson described to the Inquiry various steps that she believed could be taken by PCTs in order to strengthen their links with GP practice staff. These included the provision of occupational health facilities and of arrangements for mentoring and peer support.

9.126 Some respondents to the Inquiry's Consultation Paper felt that a major problem lay in the fact that practice staff were employed by GPs, rather than by the PCTs. GPs were

sometimes reluctant to release staff to attend training and clinical governance meetings. As a consequence, it could be difficult for PCTs to form relationships with practice staff. Mrs Stephanie Farr, Head of Service (Children), Castle Point and Rochford PCT, said that her PCT was trying to encourage contact with practice staff but that practices were not always co-operative. Dr Grenville said that, in his area, there was a practice managers' group in each PCT, which met on a regular basis. His impression was that the role of the PCOs in training administrative staff had diminished with the advent of the PCTs, largely because the PCTs had so many functions to fulfil. He hoped that this role would be revived in time. Mr Robin Macleod, representing the General Medical Council, said that, in some areas, PCTs did not have the money to fund staff training.

The Role of the Primary Care Trust in Supporting Practice Staff

9.127 The position of a member of staff who voices a concern may become untenable, especially within a small or single-handed practice. The making of a complaint or the raising of a concern about either a doctor or a colleague may well destroy the working relationship within the practice. Mrs Webdale observed that the 'ideal' would be for practice staff to be employed by PCTs direct, but this was not a realistic prospect. However, if a member of staff were forced to leave a practice as a result of having raised concerns, she said that she thought that the PCT should support him/her in finding another job. She said that she was aware of some staff who had preferred to leave their posts, rather than to raise a concern about the practice in which they worked. She felt that PCTs should take steps to find out why a member of staff had left a practice. One possibility would be to design questionnaires to be completed and submitted to the PCT by staff leaving GP practices. These questionnaires could be collated and, if any trend emerged in relation to a particular practice, this could be followed up. Mrs Webdale felt that the exercise might contribute to the PCT's understanding of staff training needs and, also, to its ability to recognise when staff at a practice required help and support. By contrast, Dr Grenville, for the British Medical Association, believed that such a process would be unwieldy. He suggested that it would be better for PCTs to concentrate on encouraging practices to take steps themselves to find out why members of staff were leaving. It would then be for the practice to take action to eliminate any problems that were revealed.

The Way Forward

9.128 I agree with those who say that every GP practice should have a written policy setting out the procedure to be followed by a member of the practice staff who wishes to raise concerns about any matter, in particular about the clinical practice or conduct of a healthcare professional within the practice. The draft policy that has been developed by the DoH and PCaW seems an excellent starting point. However, a written policy is effective only if staff are aware of it and have the confidence to follow its guidance.

9.129 The first stage of any such procedure should be for staff to raise any concerns they may have within the practice. However, it is not enough just to include an exhortation to do so in a written policy. Staff will be discouraged from bringing forward their concerns within the practice if they find that, when they do so, they are met with lack of interest, irritation

or even outright hostility, and that no steps are taken to act upon the concerns. Much will depend upon the attitude of the doctors in the practice. If they show that they positively value the observations and criticisms of staff, there will be a much more open culture within the practice and it will be much easier for staff to raise a serious concern if one arises. It seems to me that the kind of practical arrangements described by Mrs Webdale would be a useful model. It should become the norm for every untoward incident or concern, whether minor or serious, to be brought to the attention of those responsible for managing the practice.

9.130 The practice policy should give staff the name and contact details of an individual at the PCT to whom the staff can take any concerns that they feel unable to raise within the practice. It seems to me clear that the 'second port of call' for concerns should be the PCT, rather than another organisation such as the LMC. It is the PCT which has responsibility for clinical governance within primary care; if there are problems with doctors or other healthcare professionals within a practice, it is important that the PCT is aware of them. This is particularly important if issues of patient safety arise. The recent Report of the independent investigation into how the NHS handled allegations about the conduct of Clifford Ayling (the Ayling Report) highlighted the 'ambiguous role' played by the local LMC in that case. The Ayling Report emphasised that it was not the role of LMCs to act on information which suggested that patient safety was being compromised. That was the role of the PCT or the relevant professional regulatory body. I would suggest that the guidance within a written policy should make clear, not only that the appropriate 'second port of call' should be the PCT, but also why it is important that the PCT should be made aware of concerns.

9.131 Occasionally, a healthcare professional or other member of staff may have a concern that is so sensitive that it would be difficult to raise it locally. Concerns of the kind that staff might have had about Shipman would be an example. It would have taken a great deal of courage for a member of staff to have raised concerns with the WPHA about Shipman's death rates. Access to advice from an organisation well away from the area would make the prospect of making a report much less daunting. To provide for this situation, the policy should contain details of organisations, such as PCaW, from which staff can obtain free independent advice. If the 'single portal' or 'clearing house' for the signposting of complaints and concerns, which I have referred to elsewhere in this Report, is created, the policy should set out the contact details for that also.

9.132 Practices should be encouraged to train their staff in the procedures set out in their policy and to reinforce that training regularly. It should form part of the induction process for new staff. The policy itself should be reviewed and updated (e.g. by ensuring that the named contacts and contact details are still current) at regular intervals; as Mrs Webdale said, it should be a 'living document'.

9.133 In addition to any training given by GP practices, PCTs should provide information and training about whistleblowing policies direct to practice staff. The training should be placed in the context of general clinical governance issues. Staff should be made aware of the important role they can play in promoting clinical governance within their practices and in protecting patients. PCTs should designate at least one individual to act as a

contact for practice staff who have concerns to communicate. Every effort should be made to ensure that the designated individuals are personally known to practice staff. It would help if there could be an element of continuity so that staff did not continually have to deal with different individuals. The designated individuals should not merely act as recipients for concerns, but should also offer general support and advice to practice staff.

9.134 Special arrangements should be made for staff in single-handed and small practices. The written policies for such practices should refer to the particular difficulties which staff in such practices might face in voicing concerns and should recognise that they might prefer to raise their concerns with the PCT, rather than internally, in the first instance. Extra efforts should be made to promote links between the PCT and the staff of single-handed and small practices and to involve the latter in training and other events. I note that the Ayling Report referred to the need for PCTs to pay particular attention to developing and supporting the independence of practice managers in single-handed practices. I would endorse this recommendation, but would also like to see it extended to other staff within GP practices – in particular, practice nurses.

9.135 In order to reduce the problems caused by isolation, initiatives that promote the 'cross-fertilisation' of staff between one GP practice and another should be encouraged wherever possible. I have in mind here the arrangements mentioned by Mrs Webdale for the sharing of staff and the mentoring and peer support schemes that exist in some areas. The dissemination of ideas and information between staff in different GP practices should, it seems to me, increase the capacity of staff to recognise behaviour and clinical practice that fall completely outside the norm.

9.136 At the Inquiry, the issue arose as to whether practice staff who raise genuine concerns about their GP employer are adequately protected from reprisals by the provisions of the Public Interest Disclosure Act 1998 (PIDA). I describe the provisions of the PIDA in Chapter 11. Although practice staff technically enjoy the protection of the Act, there are two potential problems. The first is that the PIDA requires a whistleblower to raise his/her concerns within the employer's organisation before raising them outside. If the whistleblower goes straight to an outside body, much of the protection of the PIDA will be lost. This provision is really designed to discourage whistleblowers from 'going public' before they have raised their concerns internally. However, the protection of the PIDA is not lost if the whistleblower raises his/her concerns with a person or body that the employer has suggested as a suitable recipient for those concerns. Thus, if a GP practice's whistleblowing policy suggested the PCT as a suitable recipient, the protection of the PIDA would not be lost if the staff member raised his/her concerns with a PCT employee. The same should apply in the event that a 'single portal' or 'clearing house' were to be set up. If it is thought that there is any doubt about the application of the principle I have mentioned, then I suggest that the PIDA should be amended to clarify this.

9.137 The second problem is a more general one. Any protection provided by the PIDA will be ineffective if the staff member raises a concern about someone within the practice (for example a doctor or practice nurse) and if, as a result, the working relationships within the practice break down. The right to retain the employment is then an empty one. I think that the provisions of the PIDA were drafted with large organisations, rather than small ones, in

mind. I do not think that it would be practicable to amend the PIDA to remedy this problem. However, in the event that a staff member 'blows the whistle' on a practice and cannot continue to work there, the PCT should, in my view, assist the employee to find a post in another practice wherever possible.

9.138 Whether or not it would be sensible or practical for PCTs to collect 'exit questionnaires' from staff leaving GP practices I am not sure. The only way to find out would be to run a number of pilot schemes and assess the results. It does not seem to me that this would be difficult to organise. However, I would have thought that, if PCTs ensured that there was a member of their own staff whose responsibility it was to maintain relationships with practice staff, staff with problems would naturally turn to the PCT for help and there would be no need for questionnaires.

9.139 I agree with Dr William Reith who, speaking on behalf of the Royal College of General Practitioners, emphasised the need for concerns to be properly followed up by PCTs. His comments reflected the concerns of many, namely that, if practice staff see a consistent pattern whereby no action is taken in respect of concerns that are raised, that will inevitably discourage them from reporting concerns in future. There are other reasons why concerns expressed by practice staff should be properly investigated and acted upon. A member of the staff of a GP practice is likely to think long and hard before bringing a concern to the PCT; it is not a step that s/he is likely to take lightly. He or she is likely to be one of the few people who work closely with the doctor or other healthcare professional concerned and who would be in a position to become aware of poor clinical practice or aberrant behaviour. While it is of course possible that his/her concerns may be unfounded, they may well be justified and, in the interests of good clinical governance, it is vital that they are taken seriously and subjected to proper investigation. I shall say more about how I believe PCTs should respond to such concerns later in this Report.

CHAPTER TEN

Raising Concerns: the Death of Mrs Renate Overton Revisited

Introduction

10.1 In October 2003, the Inquiry heard further evidence concerning the case of Mrs Renate Overton, about which oral evidence had previously been heard in December 2002. The case is described in detail in the First and Third Reports.

10.2 Mrs Overton was admitted unconscious to Tameside General Hospital on the evening of Friday, 18th February 1994. Shipman had given her a lethal overdose of diamorphine, having attended her home following a report that she was suffering an asthma attack. She never regained consciousness after his intervention and she died in hospital on 21st April 1995. Many doctors and staff at the hospital believed that there had been something wrong with her treatment. They thought that Mrs Overton's collapse had been provoked by an overdose of 20mg morphine, which was inappropriate for an asthmatic. They understood that Shipman had injected the drug intravenously as a 'stat' or bolus dose, that is, a dose given quickly and 'in one go'. Notwithstanding their belief that the collapse was due to inappropriate treatment by Shipman, their concerns were not reported and no investigation was therefore initiated.

10.3 In the Third Report, I concluded that, if there was any duty to report, that duty fell upon Dr Murtaza Husaini, the consultant cardiologist, and Dr Ceri Brown, the consultant anaesthetist, who, in the early stages following Mrs Overton's admission, were jointly responsible for her care. I concluded that no such duty lay on the nursing staff or the junior doctors. They knew that the consultants were aware of the circumstances and they were entitled to expect them to take appropriate action.

10.4 At the time of writing the Third Report, I deferred the question of whether Dr Husaini and Dr Brown were under a duty to report their concerns about Mrs Overton's case and whether they should be criticised for their failure to do so. It was clearly appropriate that I should consider those questions after gaining further understanding of the nature of the duty as promulgated by the General Medical Council (GMC), of the options for reporting available to the two consultants and of the culture within the medical profession at the time, matters which the Inquiry was to consider in the Stage Four hearings. During those hearings, both doctors were given, but declined, the opportunity to give further evidence. They were, of course, by that time aware of my findings in the Third Report. They were represented at the relevant hearings and put forward witnesses whose evidence the Inquiry agreed to consider.

10.5 Questions also remain as to what would have happened if Dr Husaini and Dr Brown had reported their concerns. Would the facts have been investigated fully either locally or by the GMC? Would the seriousness of Shipman's conduct towards Mrs Overton have been recognised and would there have been any further investigation that might have uncovered his other criminal conduct? Would Shipman have been deterred from killing merely by the fact of any investigation that was undertaken? These questions are linked with the question as to what would have happened if Dr David Bee, consultant pathologist,

had reported more carefully following his conduct of an autopsy on Mrs Overton's body in 1995 and had Mr Peter Revington, HM Coroner for Greater Manchester South, decided to hold an inquest. Their conduct was fully considered in Chapter 13 of the Third Report.

Was There a Duty to Report?

Dr Husaini's Position

10.6 When he gave evidence in December 2002, Dr Husaini acknowledged that, as a consultant in charge of Mrs Overton's care, he was under a duty to report to a relevant authority his concerns about Shipman's treatment of Mrs Overton. He said that he realised that this treatment had been quite unorthodox and showed that Shipman might be a danger to patients. In fact, he claimed that he had been so concerned that, in 1994, he had reported the facts to Mr Revington, to Mr Roger Butterworth (Chief Executive designate of the NHS Trust responsible for Tameside General Hospital), to Mrs Lynn Nuttall (the Trust's Business Manager) and to Mr Charles Howorth (then legal adviser to the North West Regional Health Authority). For reasons that are fully set out in the Third Report, I rejected his evidence and found that he had not reported his concerns to anyone. His claim having been rejected, it follows that he must be criticised for having failed to do that which he acknowledged to be his duty. However, this criticism must be viewed in the light of the culture and practice of the time.

Dr Brown's Position

10.7 Dr Brown agreed that he had not reported Shipman's treatment of Mrs Overton to anyone in authority. He gave several reasons why he had not done so. First, he asserted that, at the time when Mrs Overton was under his care, he believed that the circumstances of her collapse were so uncertain that he could not reasonably act. I rejected that contention. I found that his state of mind was encapsulated in the words of a witness statement that he made to the police at the beginning of 1999, in which he said of his opinion in 1994:

> **'It was my opinion at the time that the patient's initial management by the general practitioner was highly unusual, even dangerous. If the initial diagnosis of an asthmatic attack was correct, it was treated appropriately with the nebulisers. Intravenous Morphine plays no part in the management of patients with asthma outside the hospital. There is a statement in the notes by the admitting physician that she** (*Mrs Overton*) **may have had chest pain, although this contradicts the clear statement of the casualty officer that she had no chest pain prior to her collapse. While intravenous Morphine has a place in the management of acute myocardial infarction (heart attack) I have always understood that it should be given intravenously, in small amounts, with time between doses to assess the affect** (*sic*) **of the drug. In addition, it would be essential to monitor the heart rate and blood pressure of the patient in order to detect any signs of a cardiovascular collapse. In my experience of managing patients who have developed wheeze following a heart**

attack, I have never seen a dose of 20mg of Morphine used. I should add that I am familiar with the administration and effects of Morphine because in my work as an anaesthetist I regularly administer Morphine intravenously to patients undergoing surgery. I am also familiar with the use of Morphine post-operatively in patient-controlled analgesia pumps and it is common for these pumps only to allow 1mg of Morphine to be given at a time with five minutes elapsing between doses of Morphine.'

10.8 Second, Dr Brown also said that he believed the only possible route open to him was to make a complaint to the GMC. He was unaware of any local NHS procedure or mechanism for pursuing a complaint against a general practitioner (GP). He did not think he could report the matter to the GMC because he did not think he had sufficient information on which to base a complaint to that body. He did not think that the hospital notes were enough.

10.9 Third, Dr Brown also said that considerations of professional etiquette played a part in his decision not to make a report. He said that, as part of their training, doctors are taught to be very slow to criticise other doctors or to pass opinions on them. He felt that there was a tension between a duty to report a colleague's misconduct and the need to avoid an accusation against a colleague that might turn out to be false. He said that he was worried that, if he made a report, the GMC might criticise him for disparaging Shipman. In the Third Report, I accepted that Dr Brown genuinely held these reservations about medical etiquette. His decision to telephone the Medical Defence Union (MDU) for advice before giving the police a statement about Shipman's treatment of Mrs Overton confirms that. As recently as 1999, he was hesitant about criticising a fellow practitioner, even one who had been arrested for murder.

10.10 Fourth, Dr Brown said that he felt that he ought to honour the wishes of Mrs Overton's family that no complaint should be made against Shipman. As I explained in the Third Report, Dr Brown had told Dr Michael Overton, Mrs Overton's brother, that Shipman had given morphine to his sister. Dr Overton, who is a GP, knew that it was wrong to give an opiate drug to an asthmatic. However, Dr Brown agreed that he had not told Dr Overton how much morphine he understood had been given or that what was given had apparently been injected as a 'stat' or bolus dose. He contended that he had said enough to enable the family to decide whether they wanted to proceed with a complaint. He said that, if they had been anxious to proceed, he could have provided more information. They had decided not to make a complaint and Dr Brown considered that it was therefore reasonable for him to do nothing further. In the Third Report, I expressed concern that Dr Brown had not given the Overton family enough information to allow them to make an informed decision as to whether to proceed with a complaint.

10.11 Each of Dr Brown's explanations must be considered in the light of both the culture and the framework for reporting concerns at the time of Mrs Overton's death.

Guidance from the General Medical Council: the Nature of the Duty to Report

10.12 I shall consider first what the GMC had to say in its publications about the duty of a doctor to report the conduct of a colleague. It appears that this duty has evolved in two relevant

respects over the past 30 years. First, 30 years ago, it was unusual for the GMC to take disciplinary action in respect of poor clinical practice. In general, the GMC would take disciplinary action only against doctors who appeared to have been guilty of misconduct. Mr Alan Howes, an officer of the GMC between 1977 and 2002, said that the most common forms of misconduct were known as 'the three As', denoting 'advertising, abortion and adultery'. Nowadays, many doctors appearing before the Professional Conduct Committee (PCC) of the GMC face charges relating to their clinical practice. Second, there is now a clear obligation on doctors to report a colleague who presents or might present a risk to patients whereas, in the past, that duty was less clear and the emphasis was on avoiding the unjustified denigration of colleagues.

10.13 For many years until about 1995, the GMC provided to all doctors on the register a guide to GMC functions, procedures and disciplinary jurisdiction. This guide was known as the 'Blue Book'. Theoretically, all doctors should have read the Blue Book in order to keep abreast of any changes in the advice given or the requirements imposed upon them by their regulatory body. However, evidence to the Inquiry suggests that most doctors did not do so. Some did not read it at all; others would give it a cursory glance and take in only the main messages.

10.14 As I shall explain in Chapter 15, historically the GMC regarded itself as being under a duty to protect the public by taking disciplinary proceedings against doctors guilty of serious professional misconduct (SPM). The Blue Book of 1971, entitled 'GMC Professional Discipline', provided guidance as to the kinds of offences and professional misconduct that might lead to disciplinary proceedings. The emphasis was on misconduct and breaches of medical ethics, rather than on bad clinical practice. It stressed that the question of whether a particular course of conduct amounted to SPM was a matter to be decided by the Disciplinary Committee of the GMC (the predecessor of the PCC) on the evidence in that particular case. The categories of misconduct described were not to be regarded as exhaustive. It concluded, in words that remained largely unchanged in December 1993:

> **'Any abuse by a doctor of any of the privileges and opportunities afforded to him, or any grave dereliction of professional duty or serious breach of medical ethics, may give rise to a charge of serious professional misconduct.'**

10.15 During the 1970s, there was very little change in the guidance contained in the Blue Book. Advice against deprecating the skill, knowledge, qualifications or service of a colleague appeared in the section dealing with advertising and canvassing. Such advice was aimed at preventing doctors seeking to enlarge their own practices by denigrating the practices of others.

10.16 In August 1977, the new edition of the Blue Book, entitled 'Professional Conduct and Discipline', was published. In a section headed **'Neglect or disregard of personal responsibilities'** it was stated that the GMC might institute disciplinary proceedings:

> **'... when a doctor appears seriously to have disregarded his professional duties to his patients, for example, by failing to visit or to**

provide treatment for a patient when necessary. ... The Council is not concerned with errors in treatment or diagnosis.'

The message seemed to be that the GMC would take action on clinical matters, but only those entailing a conscious decision by the doctor to act as s/he did, in the knowledge of the likely consequences. Negligence, even if gross, would not give rise to disciplinary action. The concluding words in that section might well have been interpreted to exclude the administration of a dangerous overdose of medication, administered in good faith but with gross negligence.

10.17 In 1983, the corresponding passage in the Blue Book was altered so as to enlarge the areas of clinical treatment where action might be taken. It read:

'The Council is not ordinarily concerned with errors in diagnosis or treatment, or with the kind of matters which give rise to action in the civil courts for negligence, unless the doctor's conduct in the case has involved such a disregard of his professional responsibility to his patients or such a neglect of his professional duties as to raise a question of serious professional misconduct.'

The message had not substantially changed, however. Moreover, there was a difficulty for practitioners in that the advice was circular. The GMC was saying that it would act on cases of SPM but that errors in diagnosis and treatment would be subject to disciplinary action only if they were serious enough to raise a question of SPM. Practitioners must have wondered how serious cases had to be before the GMC would become involved.

10.18 The 1985 Blue Book contained a new feature, which was a statement of the standards of medical care that the public was entitled to expect. This was no doubt of assistance to practitioners. However, it was clearly not intended that a failure properly to meet these standards would give rise to SPM proceedings before the GMC. It would not surprise me if doctors still remained in doubt as to what types of clinical mishap were capable of amounting to SPM.

10.19 In 1983, the BBC Television programme 'That's Life' had broadcast an item highly critical of members of the medical profession for having failed to report concerns relating to incompetent laser treatment given by a doctor to patients. Many GMC members were angry with the BBC for having broadcast the programme. The GMC nevertheless accepted the recommendation of its Executive Committee that the GMC should inform doctors in the next GMC Annual Report that **'there may be circumstances in which it would be the responsibility of doctors to report to the Council evidence which may be regarded as raising a question of serious professional misconduct by a professional colleague'**. Thereafter, the April 1987 edition of the Blue Book set out for the first time the ethical obligation of a doctor to report a professional colleague who it was thought might have committed SPM or might have been suffering from serious impairment of health. The Blue Book pointed out that:

'... a doctor has a duty, where the circumstances so warrant, to inform an appropriate body about a professional colleague whose behaviour may have raised a question of serious professional misconduct, or whose

fitness to practise may be seriously impaired by reason of a physical or mental condition. Similarly, a doctor may also comment on the professional performance of a colleague in respect of whom he acts as a referee.'

10.20 I should observe that, more than ten years earlier, the Report of the Committee of Inquiry into the Regulation of the Medical Profession (the Merrison Committee) had suggested that doctors who had information giving them good reason to believe that the conduct of another doctor was putting patients at risk were under an ethical duty to act on that information.

10.21 In December 1990, in the GMC Annual Report, Dr (later Sir) Donald Irvine, then Chairman of the GMC Standards Committee, announced a further shift in the GMC's approach to the reporting of concerns about colleagues. He acknowledged that passages in past editions of the Blue Book, about the disparagement of colleagues, might have discouraged a doctor from making well-founded criticisms of colleagues or from reporting possible misdemeanours. Sir Donald went on to explain that the Standards Committee proposed that the focus of the GMC's guidance should be altered in order to emphasise the duty of doctors to take appropriate action when a colleague's performance might be deficient. The warning against disparagement was to be given a secondary place. The GMC approved the new guidance, which was then incorporated in the February 1991 Blue Book. It said:

'Doctors are frequently called upon to express a view about a colleague's professional practice. This may, for example, happen in the course of a medical audit or peer review procedure, or when a doctor is asked to give a reference about a colleague. It may also occur in a less direct and explicit way when a patient seeks a second opinion, specialist advice or an alternative form of treatment. Honest comment is entirely acceptable in such circumstances, provided that it is carefully considered and can be justified, that it is offered in good faith and that it is intended to promote the best interests of patients.

Further, it is any doctor's duty, where the circumstances so warrant, to inform an appropriate person or body about a colleague whose professional conduct or fitness to practise may be called in question or whose professional performance appears to be in some way deficient. Arrangements exist to deal with such problems, and they must be used in order to ensure that high standards of medical practice are maintained.

However, gratuitous and unsustainable comment which, whether directly or by implication, sets out to undermine trust in a professional colleague's knowledge or skills is unethical.'

10.22 The change widened the duty to report. Whereas previously the duty had arisen only in the case of concern about behaviour that might amount to SPM or serious impairment of fitness to practise, it now included a duty to report a doctor **'whose professional**

performance appears to be in some way deficient'. This seemed to involve a far lower threshold for reporting. It was suggested to the Inquiry that, if doctors had followed this advice to the letter, they would be reporting their colleagues very frequently. It may be that the words were wider than was intended. It seems to me that the passage intended to convey that deficient performance should be reported only **'where the circumstances so warrant'**. Although the passage might have left doctors in doubt about where the threshold for reporting lay, it was at least clear that the duty was an important one and, if a doctor was in doubt about whether the duty arose, it was always open to him or her to take advice. The passage made clear that it was gratuitous, unsustainable comment made with the intention of undermining trust in a colleague that would be regarded as unethical.

10.23 The passage did not give explicit guidance as to who was **'an appropriate person or body'** to whom a report should be made. Nor did it describe the arrangements that existed for dealing with any concerns reported. No doubt that was because the **'appropriate person or body'** would vary according to the circumstances. So would the **'arrangements'**. It may well be that guidance on those matters was not necessary; doctors could very easily take advice, if in doubt, from their medical defence organisation.

10.24 As I have said, this new guidance was incorporated in the February 1991 Blue Book. Subsequent issues, published in April and May 1992 and in January and December 1993, contained no changes of significance. The December 1993 edition was current at the time of the hospitalisation and death of Mrs Overton.

Attempts to Publicise and Explain the New Guidance

10.25 It appears that the new guidance probably received some publicity in the press. In August 1992, the GMC issued a document entitled 'Form of Response to Press Inquiries' which emphasised the importance of doctors reporting colleagues whose conduct was putting patients at risk and warned that doctors who did not follow the guidance might have to answer to the GMC. It is unclear what provoked the production of this document or how widely it was published, if at all.

10.26 The message was confirmed the following year. On 15th July 1993, the GMC issued a press release arising out of the case of Dr Behrooz Sohrab Irani, a locum consultant anaesthetist whom the PCC had found guilty of SPM in connection with his dangerous management of a patient who had suffered serious brain damage under his care. The evidence showed that Dr Sean Dunn, Chairman of the Anaesthetics Division of the NHS trust which managed the hospital where Dr Irani had worked, had received earlier reports of poor practice by Dr Irani but had not acted upon them. Although aware of these reports, Dr Dunn had written a favourable reference for Dr Irani, enabling him to get a job elsewhere. The press release of July 1993 concluded:

> **'Finally, there are appropriate procedures for response to reports of evident and dangerous incompetence; doctors have a duty to activate those procedures promptly, in the interests of the safety of patients, where such cases arise.'**

10.27 Dr Dunn was charged with SPM and his case was heard by the PCC in March 1994. He was found guilty. The decision was a warning to doctors that, if they had reason to believe that a colleague's conduct or professional performance posed a danger to patients, they were under a duty to act on that belief. Doctors were advised that, before taking action, they should do their best to establish the facts. References should be carefully considered and should be issued in good faith. If the doctor was in doubt about a colleague, it would be unethical to provide a reference. There was another reminder that procedures existed for responding to reports of evident and dangerous incompetence. The decision concluded:

> **'At all times patient safety must take precedence over all other concerns, including understandable reticence to bring a colleague's career into question.'**

10.28 The Dunn case was reported in the news section of the British Medical Journal. The relevant article quoted the concluding words from the GMC decision. According to the article, **'The GMC used Dr Dunn's case to send a message to the profession about its duty to protect patients even if this means reporting a colleague or refusing to give a reference.'** Dr Gerard Panting, Communications and Policy Director at the Medical Protection Society, said that the case served to emphasise the need to ensure that doctors took positive action when they saw that patients were at risk. Other evidence given to the Inquiry suggests that the main message received by the profession from the case of Dr Dunn related to the need for honesty and accuracy in the giving of references.

10.29 While, in my judgement, the position of the GMC had been made clear in 1991, certainly any doctor who kept up to date by reading the Blue Book and the medical press should have been aware, by July 1993 at the latest, that s/he was under a professional obligation to report to an appropriate authority any concerns that s/he might have that a colleague had been guilty of SPM or that the colleague's practice had put patients at risk of harm. I recognise that some doctors might not have read the relevant publications. But, whether or not they in fact knew of it, all doctors should have known they were under that duty from that time. I recognise too that doctors might not have had a very clear idea in their minds about what sort of conduct amounted to SPM. However, I do think that all doctors should be able to recognise what types of conduct are putting patients at risk of harm. It was that kind of conduct which was in issue in Mrs Overton's case. She had, after all, suffered the most serious harm possible short of immediate death and her treatment was regarded by Dr Brown as **'highly unusual, even dangerous'**.

10.30 Although the GMC's position as to the existence of the duty of a doctor to report concerns about colleagues had now been made clear to the profession, no specific guidance had been given as to where a report should be lodged. So far as the GMC was concerned, it would always advise that reports of conduct that could not amount to SPM should be pursued locally; if arising out of treatment within the NHS, this should be done by the local NHS body. Even reports of conduct that might amount to SPM would be sent back by GMC staff or screeners to be dealt with locally, unless the report was of conduct that was perceived as giving rise to a risk to the public. I shall deal with this topic at greater length in Chapter 18.

10.31 The GMC might well have thought it unnecessary to advise doctors about their local NHS procedures. It was reasonable to assume that a doctor working in the NHS would know about the local procedures relevant to his/her work. Perhaps the GMC should not have assumed that all doctors would know about the local procedures relevant to those parts of the NHS in which they did not work. For example, a GP might not know about the procedures governing hospital doctors and *vice versa*. However, the GMC might reasonably have supposed that a doctor who knew that s/he ought to make a report would be able to find out to whom it should be made.

Evidence of How the Duty to Report Actually Operated in the NHS in 1994

10.32 It was submitted on behalf of Dr Brown that, even though a doctor's duty might have been made clear by the GMC, the practice within NHS hospitals in 1994 did not reflect the GMC guidance. It was argued that, at that time, the culture was such that many doctors in Dr Brown's position would not have reported their concerns about Shipman's treatment of Mrs Overton. The Inquiry gathered evidence on these issues from a variety of sources. Already, during Stage Two, there had been evidence from the medical, nursing and administrative staff at Tameside General Hospital. In the Stage Four hearings, the area of enquiry was extended to include the practice within the Trusts responsible for three hospitals comparable in size to Tameside General Hospital. The Medical Directors of these Trusts gave evidence. They were Mr Alan Turner (consultant urologist and Medical Director since 1993 of Peterborough Hospitals NHS Trust), Dr Christopher Bateman (Medical Director from 1994 until 1996 at St Richard's Hospital, Chichester) and Mr Ian Harrison (consultant in general surgery at Southport Hospital, Merseyside, and Medical Director of Southport and Ormskirk NHS Trust since 1991).

10.33 On the same issues, the solicitors representing Dr Brown and Dr Husaini supplied witness statements from Professor Alan Aitkenhead and Dr John Givans. Professor Aitkenhead is Professor of Anaesthesia at Queen's Medical Centre, University of Nottingham; he has experience of advising claimants and defendants in clinical negligence claims and also of sitting on the MDU Cases Committee, which decides whether clinical negligence actions against MDU members should be defended or settled. Dr Givans qualified as a doctor in 1958; after a period in the Army, he was in general practice for 25 years, retiring in 1991. He had served on a medical service committee (MSC) for about ten years from 1973. He had been a full-time secretary of two local medical committees (LMCs). Since retiring from general practice, he has done consultancy work for the MDU, assisting doctors appearing before MSCs or, more recently, independent review panels. He has remained, therefore, in contact with the mainstream of clinical general practice.

10.34 The medical defence organisations and the British Medical Association provided written evidence. Dr Panting also gave oral evidence.

Awareness of the Duty to Report

10.35 It was generally agreed by the witnesses giving evidence in Stage Four that the climate of reporting concerns about the clinical practice of colleagues in 1994 was dramatically different from what it is today. Doctors are now much more aware of their duty to report

concerns than they then were and are much more willing to do so. Mr Turner thought that the change began with the Irani and Dunn cases but that a more far-reaching effect was caused by the publicity surrounding the GMC's action against Dr John Roylance, Chief Executive Officer of the United Bristol Healthcare NHS Trust, for his failure, over a long period, to act upon concerns about the high failure rate of paediatric heart surgery at the Bristol Royal Infirmary. Awareness of events in Bristol began following the death of a young child, Joshua Loveday, in January 1995, but the GMC hearing after which Dr Roylance was erased from the medical register was not concluded until 1998. Dr Givans said that doctors did not understand that they had a duty to report until about 1996. Until then, they tended to presume that their colleagues had acted in good faith and to give them the benefit of any doubt that existed in a particular case.

10.36 Mr Butterworth, who was, as I have said, Chief Executive designate of the NHS Trust responsible for Tameside General Hospital, said that it was unusual for a member of the hospital staff to report a concern about a GP. Nevertheless, in 1994, a serious incident such as that involving Mrs Overton should have been reported. If, however, the overdose had been perceived by those treating Mrs Overton as a 'genuine mistake', it might not have been reported; Mr Butterworth added that, in those circumstances, it might not be reported, even today. Nor would the incident be reported (in 1994 or even today) if the consequences were not serious. As the consequences were serious in Mrs Overton's case, Mr Butterworth said that, in 1994, he 'would have expected to have been told'.

10.37 Mr Timothy Dunningham, who was a consultant orthopaedic surgeon at Tameside General Hospital in 1994 and later became its Medical Director, said that he knew of no instance where a hospital (or hospital doctor) had made an official criticism of the conduct of a GP. It was more usual for the patient or family to pursue any concerns.

10.38 Dr Panting said that doctors with a particular interest in ethical issues had always known that they were under a duty to report a colleague where there was a problem that threatened patient care. But that was not so in the case of the profession at large. Many doctors were not familiar with, or interested in, issues connected with medical ethics. Medical ethics were not taught, as they ought to be, as part of the undergraduate course; nor were they usually taught during the post-registration year. A young doctor would hear his/her seniors discussing ethical issues but s/he might well hear attitudes that were not right. When faced with a question such as whether or not to report a colleague, if a doctor did not ask the advice of his/her medical defence organisation, there was a danger that s/he would rely not on the Blue Book, but on more general 'handed-down' values. Dr Panting himself lectures to groups of doctors on ethical issues and is often surprised at the degree of ignorance displayed. Moreover, the pronouncements about the duty to report made in the late 1980s and early 1990s were not very newsworthy. He did not think that the cases of Dr Irani and Dr Dunn had had a great impact. He also had understood that the real message of Dr Dunn's case was about giving honest references, not about reporting bad practice. Dr Panting said that the number of doctors who read the Blue Book was probably quite small. Mr Turner, Professor Aitkenhead and Dr Givans agreed. Only Dr Bateman said that he thought that every consultant should and would have read it. Mr Harrison said that most doctors would have 'browsed' the Blue Book for a short time but that would be all.

10.39 Professor Aitkenhead said that, both before and after 1987 (when the Blue Book set out the obligation for the first time), most consultants would have been aware that their duty was to report concerns about colleagues whose behaviour raised a question of SPM or whose fitness to practise might be seriously impaired by reason of a physical or mental condition. However, in 1994, unless it was clear that 'gross negligence' had occurred, or that there was a pattern of poor performance, a doctor would not have been expected to make a report about poor clinical treatment given by a colleague. The perceived inadequacies would be discussed informally with the doctor or at audit meetings at which the doctor might or might not be present, in the hope that the failings would be identified and steps taken to avoid recurrence. Of course, such options would not be available to a hospital doctor who was concerned about the performance of a GP. Dr Givans said that, even by 1994, the guidance published by the GMC had not been effective in altering the culture that had previously prevailed so as to ensure that reports were made to an appropriate authority.

The Fear of Being Accused of Disparagement

10.40 It seemed to me, from a reading of the various relevant editions of the Blue Book, that the advice against disparagement of another doctor was mainly (if not exclusively) directed against the evil of enticing patients away from a colleague. If that was the case, then it did not appear to me that the advice could ever have acted as a deterrent to a doctor who was thinking of reporting to an appropriate authority genuine concerns about a colleague, affecting patient safety.

10.41 Dr Bateman and Dr Panting both agreed that the advice against disparagement could not have had a discouraging effect on a doctor who was minded to report a genuine concern in 1994. Dr Panting said that, in earlier years, the advice in the Blue Book had had the effect of discouraging some doctors.

10.42 Professor Aitkenhead said that he did not see the warnings against disparagement as having been a major obstacle to reporting poor treatment, but they had discouraged some doctors. Dr Givans said that, before about 1996, all doctors were imbued with a culture that emphasised the dangers of criticising the professional performance of a colleague in the absence of firsthand evidence to support such criticism.

10.43 My view is that a careful reading of the Blue Book should never have discouraged a doctor from reporting concerns about a colleague to an appropriate authority, certainly not after 1991. However, on the evidence, I accept that in fact it did discourage some doctors. That was why, in December 1990, Dr (later Sir) Donald Irvine had announced the shift in focus of the GMC advice. If it is true that very few doctors read the Blue Book with any diligence, it is perhaps not surprising that old-fashioned ideas about the disparagement of a colleague, learned as a student or young house officer, remained current long after they had been rejected by the GMC. In my judgement, since 1991, the advice in the Blue Book about the duty to report concerns affecting patient safety has been clear. It seems likely, however, that the culture against reporting persisted somewhat longer, possibly because so few doctors read the Blue Book and instead retained in their minds the ideas adopted during their early training.

The 'One-Off' or 'Genuine' Mistake

10.44 On many occasions during the course of the Inquiry, witnesses said that a doctor would be unwilling to report a colleague who had made a mistake if it appeared that what had taken place was a 'one-off' or 'genuine' error. The argument is that all doctors make mistakes sometimes; a 'one-off' mistake connotes the type of mistake that does not represent part of a series or pattern of mistakes. A 'genuine' mistake connotes an error that does not arise from a fundamental problem with the doctor's practice but is of a type that any doctor might occasionally make, despite the exercise of all reasonable care. It is the kind of error that causes doctors to be forgiving and to say, 'There, but for the grace of God, go I.'

10.45 It is understandable that a doctor will be reluctant to report a colleague for an error that the doctor thinks s/he might him/herself have made. However, if a doctor is considering whether or not to report a concern and is going to make a judgement about whether the mistake was a 'one-off' or 'genuine' one, s/he is likely to need more information than is usually available. Yet it appears that doctors often assume that the missing information would confirm that the mistake was 'one-off' or 'genuine', even though the known facts are neutral or might even suggest otherwise. In other words, the benefit of the doubt arising from the missing information is given to the doctor.

10.46 Even the doctors giving evidence to the Inquiry displayed this kind of approach. In his written evidence, Mr Turner observed that Shipman's **'mistake'** when treating Mrs Overton might have been a **'one-off'**. He said that, so far as he was aware, this was a single episode. Accordingly, he himself might have decided not to report it. Similarly, Dr Bateman said that, if the doctor enjoyed a good reputation and if it was thought to be the first time such an incident had occurred, he would not have expected the case to be reported. He explained that 'one's first inclination' was to think that the doctor had made a 'one-off' mistake. The doctor would have been given the benefit of the doubt.

10.47 Professor Aitkenhead said that, around the time of the incident involving Mrs Overton, the perception that the incident might have been a 'one-off mistake' would have had a significant bearing on a doctor's decision whether to report. If there was evidence of an error or an instance of poor practice by a doctor who was thought to have a good track record as a competent and caring doctor, there would have been a tendency not to report, but instead to give the benefit of the doubt to the doctor. That might also have been so even where the doctor who was considering whether or not to report had no knowledge at all about the other doctor's general performance.

10.48 Dr Givans said that, if a doctor believed there had been a 'genuine one-off' accident involving a hitherto well-respected clinician, the culture in 1994 was not to report. In the course of his evidence, Dr Givans – in common with other doctors – drew attention to potential *lacunae* and inconsistencies regarding the collapse and admission of Mrs Overton in order to explain why Dr Brown's decision not to report was reasonable. It was clear from what he said that he was displaying the approach which I have described above. He put on the known facts the construction of events most favourable to the doctor. Dr Givans recognised the danger of a culture in which doctors take it upon themselves to decide that a matter does not require investigation on the grounds that they themselves,

without even asking for the account of the colleague whose conduct is at issue, have concluded that s/he is not blameworthy. However, he told the Inquiry that this was 'a fact of life'.

10.49 Professor Aitkenhead suggested that it would be far too onerous to expect doctors to report all errors. As I understand his evidence, he was suggesting that it was reasonable for a doctor to make his/her own assessment of whether the mistake was serious enough to warrant reporting. He produced a French academic article, illustrating that what he said was well known to all people who work in intensive care units (ICUs), namely, that about 8% of admissions to an ICU result from an error in medical treatment. In the majority of such cases, he said, the receiving staff would be aware of that fact. They could not be expected to report all such cases. I accept that a doctor considering whether to report has to make some judgement as to the seriousness of what has happened, although if the mistake has resulted in an admission to an ICU, it must be serious, almost by definition. Moreover, these days, local reporting of the incident would be mandatory. What the doctor must certainly not do, in my opinion, is to base the decision whether or not to report on assumptions or speculation about issues on which s/he has no evidence.

The Insufficiency of Evidence

10.50 Dr Brown claimed that one of the reasons he did not report Shipman was that he did not have enough information to do so; he did not think that the hospital notes were sufficient for the purpose. I must confess that, before hearing the evidence in Stage Four, I was unimpressed by that argument. I believed that he would have known that it would be sufficient for him to report his concerns to an appropriate authority, which would then decide whether to investigate and pursue them. However, it became clear to me during Stage Four that the Tameside Family Health Services Authority (FHSA), which was at that time responsible for primary care in the area, would have expected to be presented with the evidence in support of such concerns and would have carried out little or no investigation of them. Nor would the GMC have carried out such investigation unless and until a decision was made by the PPC to refer the case to the PCC.

10.51 Dr Panting found it understandable that a doctor in the position of Dr Brown might hesitate to report a concern because of a feeling that he did not have enough of a 'handle on the facts'. However, he said that the true obligation was to decide whether he had reasonable grounds to think that there was a problem, in which case he should report what he knew to the appropriate authority.

10.52 Mr Harrison thought that, in 1994, a doctor would have had to feel very sure of his ground before reporting a colleague to the GMC. Dr Givans said that doctors were 'terrified' of being involved with the GMC and were wary of possible criticism. He also said that a doctor would need 'solid evidence which would stand up in court' before going to the GMC. According to Professor Aitkenhead, 'very, very few' doctors in Dr Brown's position in 1994 would have made a report directly to the GMC. Even if it was thought that there had been gross negligence, it was exceptionally unusual for doctors to report each other to the GMC, unless acting in an official capacity such as that of Medical Director of a NHS trust.

10.53 I have now heard a great deal of evidence about the GMC procedures over the last 30 years and I do accept that there is some foundation for the belief that the GMC would have expected the case to have been investigated before it would have been willing to pursue it. It would not have been sufficient for Dr Brown simply to outline his concerns. However, I do not accept that there would have been any reason for a doctor to fear that s/he would be criticised for reporting a case that had not been fully investigated. If Dr Brown had written a letter containing the kind of detailed and clear opinion that he provided for the police in 1999, it is likely that the GMC would have accepted the case and embarked upon its procedures, the first stage of which would have been to obtain Shipman's response. Having said that, I do accept that the GMC would not have undertaken any further investigation of the facts unless and until its Preliminary Proceedings Committee (PPC) had decided, on the basis of Dr Brown's statement and Shipman's response, that the case ought to be referred to the PCC.

Local Procedures

10.54 Dr Brown told the Inquiry that he thought the only way in which he could report Shipman was to write to the GMC. He was not aware of any local procedures by which a concern could be raised by a hospital consultant about a GP. In 1994, at Tameside General Hospital, there was no formal mechanism for reporting concerns about the actions of a GP. However, Mr Butterworth said that, if any report about a local GP had been brought to him or to the Medical Director designate, he would have made enquiries of the FHSA as to the appropriate way to proceed. I do not think Mr Butterworth would have expected one of his consultants to prepare a fully investigated case before telling him about a concern. Mr Turner said that if Dr Brown had been at the hospital in Peterborough and had reported his concerns about Shipman's treatment of Mrs Overton, he (Mr Turner) would have taken matters forward. I do not think any consultant reporting a concern in this way could reasonably have felt in any danger of being accused of disparagement.

10.55 I accept that Dr Brown did not know by what mechanism such a concern could be investigated. I also accept that many hospital consultants would have been in a similar position of ignorance. However, I cannot accept that it would have been difficult for any doctor to find out this kind of information. A doctor could ask his/her medical defence organisation for advice and would have been advised as to his/her duty (in a way that accurately reflected the GMC's position) and would have been told how s/he could go about making a report either to the GMC or through local mechanisms. Also, it must have been obvious to Dr Brown that he could have sought practical advice in discussion with consultant colleagues. I was amazed by the evidence of Dr Husaini and Dr Brown, who both said that they did not even discuss Mrs Overton's case with each other, let alone the issue of what should be done about reporting concerns which, apparently, they both felt. An obvious source of advice within the Trust would have been the Medical Director designate.

10.56 It seems to me that, however uncertain Dr Brown might have been about having sufficient evidence with which to make a report to the GMC, no such difficulty would have arisen in respect of a report made to the appropriate medical authority in the locality.

10.57 In mitigation of Dr Brown's position, I accept that it was very unusual for a hospital consultant to raise a concern about a GP. It seems that there was a view that a hospital doctor did not have the same sense of responsibility for the actions of a GP as s/he had for a colleague in the hospital. Dr Bateman could remember no case in 20 years of practice in which a hospital doctor had reported concerns about a GP to the relevant primary care organisation. It appears that, in 1994, the chances of a hospital consultant reporting a concern about a GP's treatment of a patient were even lower than the chances of him/her reporting a colleague in the hospital, despite the fact that the duty to do so was clear.

The Views of Other Doctors as to Whether Dr Brown Should Have Reported His Concerns in 1994

10.58 Several doctors expressed a view about whether they thought a doctor in the position of Dr Brown should have reported his concerns about Shipman in 1994. In the main, their view was that he should have done so.

10.59 In his statement to the Inquiry, Mr Turner said that, in 1994, he would not have expected most consultants in the position of Dr Brown and Dr Husaini to report their concerns, although they might have done so informally. In oral evidence, he said that, having reflected upon Dr Brown's description, in his police statement, of his state of mind in 1994, and upon the fact that the injection appeared to have been given as a bolus dose, he would have expected Dr Brown to have reported his concerns.

10.60 Mr Dunningham said that, if he had been on duty at the time of Mrs Overton's collapse in 1994, he would have 'taken matters further'. He would have been sure that Shipman could not have thought that 20mg morphine was an acceptable dose for Mrs Overton in the circumstances. Any doctor would have known that such an amount of morphine should not be given intravenously to a patient with asthma. This was a very serious mistake. He could not have understood or condoned the giving of 20mg as a bolus intravenous injection. Although he found it difficult to discard the benefit of hindsight, he maintained that had he been in Dr Husaini's or Dr Brown's position, he would have reported his concerns about Shipman, initially by discussing it with the Medical Director designate or a senior colleague. However, he also said that, had the outcome of any discussion with colleagues been a general consensus that nothing should be done, he considered that it was reasonable, given the culture of the time, to do no more than inform Dr Overton of the circumstances.

10.61 Despite his evidence about the action he would have taken, Mr Dunningham said that he found that Dr Brown's decision to do nothing was understandable. However, when he gave this opinion, Mr Dunningham was under the impression that Dr Brown had explained his concerns fully to Dr Overton and had felt that he need do nothing more. What his view would have been had he been aware of the limited information that Dr Brown gave to Dr Overton, I do not know. Even on the basis of his understanding of the position, Mr Dunningham recognised that Dr Brown's decision to leave the issue of whether to complain with the family was fraught with danger. First, the family might decide to take the matter no further. Second, there was a risk that Shipman might, through negligence (the most likely explanation for his conduct that would have been considered at the time), do

the same thing again. Mr Dunningham said that the decision was nevertheless understandable, in the light of the relationship that existed at that time between GPs and consultants. He thought that Dr Brown was entitled to respect the family's view by leaving the matter there; this was a course that the majority of doctors at the time would have followed.

10.62 Mr Harrison said that, in 1994, he would not have expected a consultant to report a single error on the part of a colleague. There was, he said, a tolerance of errors as long as they were not persistent. When he had read the brief written account provided to him by the Inquiry of the circumstances surrounding Mrs Overton's admission, he had entertained some doubts as to what had occurred; he had wondered whether Mrs Overton had in fact had an asthma attack or whether she might have suffered chest pain as the result of left ventricular failure. He had wondered exactly what was meant by a bolus injection. In other words, when he first looked at the facts of the case, he thought that Dr Brown might have seen Shipman's actions as not unreasonable. However, in oral evidence, he said that if it was Dr Brown's view that Shipman's management had been **'highly unusual, even dangerous'** (the phrase used in his police statement), he should have discussed the matter with colleagues within the hospital to seek confirmation that his interpretation was correct. If it was, then action would have been appropriate and Dr Brown could have taken advice from his Medical Director designate.

10.63 Dr Givans agreed that most people would have taken the view that Shipman's management of Mrs Overton was **'highly unusual, even dangerous'**. Dr Givans accepted that the guidance from the GMC imposed a duty on a doctor to report his/her concerns in such circumstances, but he maintained that many doctors sharing Dr Brown's view would have failed to comply with that duty in 1994. Dr Givans said that many consultants would have acted as Dr Brown did. The culture on reporting was that 'one just did not do it'. Dr Givans was not saying that this attitude was right, just that it was prevalent.

10.64 Professor Aitkenhead said that he would not have expected the circumstances of Mrs Overton's collapse to be reported. He took a different view about the appropriateness of Shipman's treatment of Mrs Overton from that expressed by all other medical witnesses to the Inquiry. He regarded the administration of 20mg morphine to Mrs Overton as not necessarily wrong. I think he is mistaken in that respect; I am quite satisfied, from all the evidence I have heard, that the administration of such a dose to an asthmatic patient by a GP in the patient's home would be dangerous. Professor Aitkenhead's view on that issue was, however, bound to affect his opinion about Dr Brown's decision not to report Shipman.

Informing the Family

10.65 In the Third Report, I found that Dr Brown's admitted failure to tell Dr Overton of the suggested dose and mode of administration of the morphine amounted to a withholding of important information. This information would have been highly relevant to the family's decision whether or not to make a complaint about Shipman. I was surprised by and critical of this failure.

10.66 This withholding of information was condemned by most of those who gave evidence in Stage Four. Dr Panting said that he would have expected a doctor in Dr Brown's position to have provided the family with all relevant information so that they were fully informed as to what had given rise to his concern. Mr Turner agreed, although he said he had come across cases in other hospitals where that had not taken place. Dr Bateman agreed that the best policy towards families is openness, so that they acquire a full understanding of events. Dr Givans expressed surprise that Dr Brown did not draw the morphine dosage to Dr Overton's attention. Mr Harrison said that a doctor should explain all the important elements of his/her concern about the treatment in order to enable a relative to make a proper judgement as to how to proceed.

10.67 Professor Aitkenhead said that a doctor should not tell a family that a mistake had occurred and then minimise it, or omit components of the treatment which compounded or were an important part of the mistake. However, he also told the Inquiry that, in 1994, the tenor of the advice given by hospital employers and the medical defence organisations was that doctors should not admit to or seek to attribute blame when a mishap occurred. Doctors would be advised to withhold from relatives information as to the mechanism of injury which might point more towards fault than against it. The advice was that it would be appropriate to do no more than to suggest to relatives that they might wish to complain about what had happened. The effect of this attitude was that relevant information suggesting liability or fault on the part of a hospital or doctor was sometimes withheld from the families and never became known to them. That evidence accords with my own experience of clinical negligence work at the Bar in the 1980s and early 1990s. Professor Aitkenhead acknowledged that the situation in 1994 was unsatisfactory. He said that the problem still persists, although to a lesser extent. That evidence accords with my more recent experience of clinical negligence work while on the Bench in the late 1990s. Professor Aitkenhead said that in 1994 doctors were afraid that disciplinary action might be taken against them if they made adverse comments about the treatment provided by their hospitals. He could not identify any case in which this had occurred but believed that there had been such incidents. The perception was that a doctor might be penalised, for example by the withholding of discretionary merit award points, if s/he said something that caused the hospital to suffer financial loss through a clinical negligence claim.

10.68 Professor Aitkenhead told the Inquiry that it was common for a hint to be given to a patient's family by a doctor that a matter should be investigated, without specifically criticising a colleague's actions. In the context of Mrs Overton's case, he suggested that it would have been reasonable to have told a fellow doctor, such as Dr Overton, only that morphine had been given to an asthmatic and then to have left that doctor to decide whether to ask any more questions. This was so even though the fellow doctor might well infer, from the limited information given, that there were no other causes for concern.

10.69 In my view, the dropping of hints, or the giving of incomplete information, is and was completely unacceptable. All patients and relatives are entitled to a full factual account of the treatment given and the events that have occurred. If a doctor believes that a colleague has made a serious mistake, s/he should explain the basis of his/her concern to the patient or relatives. If s/he feels uncertain as to whether the treatment was wrong but believes that it might have been, s/he should give a clear indication to the patient or

relatives that some doctors would take the view that a mistake had been made and that it would be appropriate to take advice. Having said that, I accept that the practice of dropping a hint was common in 1994.

10.70 In the Third Report, I expressed some surprise that Dr Brown did not record the extent of his concern in Mrs Overton's hospital notes. I was particularly concerned because the reason he gave for not doing so seemed to be based on the need to protect the doctor or hospital rather than to assist the patient. Dr Brown's view that he should not do so did not, however, surprise Dr Panting. Had he been asked to advise Dr Brown, he would have advised against recording his concerns in the notes as it would have served no useful purpose. Dr Bateman agreed and said he would have expected only a factual account to be written. I can see that, provided the concern was passed on by the doctor, it might serve no purpose to record the nature of the concern in the hospital notes. What is really to be deprecated is the failure fully to inform the family, as I have set out in the preceding paragraph.

A Final Consideration of the Positions of Dr Brown and Dr Husaini

10.71 At the beginning of this Chapter, I summarised Dr Brown's suggested reasons for not reporting his concerns. I now return to evaluate them in the light of the evidence I have heard. I have already said that Dr Brown's state of mind soon after Mrs Overton's admission was that Shipman's treatment of her had been **'highly unusual, even dangerous'**. It had plainly had a disastrous effect.

10.72 It is clear from the evidence that Dr Brown was, and should have known that he was, under a duty to report to an appropriate authority any concern of a serious nature affecting the safety of patients. In my judgement, Dr Brown's concern about Shipman's treatment of Mrs Overton fell into this category. Dr Brown has never claimed that he was unaware of the existence of this duty, rather he considered that it did not apply to him in the particular circumstances. It was enough, in his view, that he had given information to the family and left it to them to make a complaint if they chose to do so.

10.73 Dr Brown did not, however, provide the family with the full information necessary for them to make an informed decision as to whether they wished to make a complaint. He told Dr Overton only that Shipman had given Mrs Overton some morphine. He enquired whether Dr Overton appreciated the significance of giving morphine to an asthmatic patient. Dr Overton said that he did. Dr Overton was not told that Shipman had apparently given 20mg, a wholly inappropriate dose, or that he appeared to have given it as a 'stat' or bolus dose. In my judgement, if Dr Brown thought it appropriate to pass to Dr Overton the responsibility of deciding whether Shipman's conduct should be looked into, he should have ensured that Dr Overton was fully informed. In criticising Dr Brown in this respect, I recognise that, at the time, there were some doctors, probably many, who would have acted as he did.

10.74 However, in my view, it was not acceptable for Dr Brown to excuse himself from his own duty by passing the decision to Dr Overton, certainly not once he realised that the Overton family had decided to do nothing. By that stage, Dr Brown knew or should have known that

it was up to him and Dr Husaini to take any action that was required. I accept that it was reasonable for Dr Brown to take into account the family's wishes but, even if the family had expressed a strong wish that no action should be taken, Dr Brown could not be absolved from all responsibility. As Dr Husaini has recognised, the circumstances gave rise to a duty to report. Both Dr Husaini and Dr Brown were aware that Shipman's treatment of Mrs Overton was unacceptable and had gravely injured her. They knew nothing about what Shipman thought about the treatment he had given. He might have mistakenly picked up the wrong ampoule. But, for all they knew, he might have been under the impression that 20mg morphine was appropriate treatment for an asthmatic patient apparently suffering from chest pain. If he was under that impression, his patients were at risk of serious harm. In those circumstances, the duty lay jointly on Dr Husaini and Dr Brown to make a report to an appropriate authority. The right course would have been for one of them to speak to Dr Overton and to explain why, notwithstanding the family's decision not to complain, the consultants felt unable to let the matter pass, on patient safety grounds. I think it likely that, had such a conversation taken place, Dr Overton and Mrs Sharon Carrington, Mrs Overton's daughter, would have agreed to co-operate, so long as Mrs Overton's parents were not required to be involved.

10.75 What would have been an appropriate authority to which the doctors could have reported their concerns? It is clear that there were two possibilities. The consultants could have made a report to the GMC or they could have made one locally in Tameside. I can well understand Dr Brown's reluctance to make a report to the GMC. For one thing, he might have been uncertain whether an error of the kind he believed had been made would amount to SPM. Also, I accept that doctors believed (not unreasonably) that, before they could properly approach the GMC, they had to investigate the facts fully and present a case, rather than just report a concern without something more to back it up. I accept that it would have been difficult, and indeed probably inappropriate, for Dr Brown and Dr Husaini personally to undertake any further investigation of Shipman's conduct. I also accept that some doctors hesitated to report a colleague to the GMC because they feared that they might be accused of disparagement. I have said that any doctor who took an interest in ethical matters and kept himself up to date would have known that there was no danger of that, provided the report was made in good faith. However, I accept that Dr Brown held that outdated view. Taking these factors into account, I would not criticise Dr Brown and Dr Husaini for not having taken their concerns direct to the GMC, if they had reported them locally.

10.76 However, there was no local report. None of the explanations advanced by Dr Brown amounts to a real excuse for that. Dr Husaini claimed that he did make a report to Mr Butterworth. In fact, I have found that he did not, but it is clear that Mr Butterworth would have been an appropriate person to whom such a complaint could have been made. If Dr Brown was at a loss regarding to whom he should speak in Tameside, he could have asked the MDU for advice. MDU staff could have explained to him the local arrangements for the disciplining of GPs. They might have told him that, in order to lodge a formal complaint, it was necessary to identify a complainant and that, in the light of the family's attitude, that might have presented a problem. They might well have advised him to speak to the Medical Director of his own Trust or to approach the FHSA or the LMC. They would

certainly not have left him without a lead. They would have assured him that, provided his concerns were genuine, as they plainly were, he was under a duty to act and would not be accused of disparagement; nor would he be expected to have carried out a full investigation. In short, I am critical of both Dr Husaini and Dr Brown for their failure to make any attempt to report their concerns to an appropriate person or body in Tameside. The fact that neither of them telephoned their medical defence organisation for advice convinces me that they did not even give the matter serious consideration.

10.77 My criticism of these doctors is tempered by the evidence that I have heard about the actual practice of reporting concerns in NHS hospitals in 1994. Quite simply, the culture was that it was 'not done'. The leadership of the profession, over a substantial period of time, is responsible for that culture. By 1994, both Dr Brown and Dr Husaini had been qualified as doctors for many years. For the bulk of their professional lives, it had been normal practice to turn a blind eye to the faults of colleagues. In my early career at the Bar, it was extremely difficult to find a medical expert who would give evidence which was critical of a colleague, even though the treatment complained of was grossly negligent and even though the two doctors were not acquainted. The evidence I have heard is, therefore, consistent with my own experience. In the late 1980s and early 1990s, the GMC took active steps to change this culture of mutual protection. It might be said with some force that it could and should have acted sooner. However, starting around 1987, it did begin to act. A minority of doctors responded. Some had already recognised the duty that was by then clearly promulgated. But many did not. Many members of the profession were, and perhaps still are, very conservative. Their deeply rooted *mores* were not to be changed overnight and it required the tragedy at the Bristol Royal Infirmary to bring the message home. So, although I am critical of Dr Brown and Dr Husaini for their failure to comply with their professional duty to report a doctor whose conduct gave rise to a danger to patient safety, I moderate my criticism by accepting that, in 1994, a majority of doctors in this country would probably have acted in a similar way.

10.78 There remains one outstanding issue concerning Dr Brown. For reasons explained above, I am critical of him for failing to give Dr Overton a full account of his concerns. He gave 'a hint' but not a proper explanation. However, I temper that criticism because I accept that, in 1994, it was common practice to withhold relevant information about mishaps from patients and relatives. Such conduct was not acceptable but I recognise that many doctors, possibly a majority, would have acted in the same way. Some might well not have mentioned it at all.

10.79 Finally, I turn to the position of Dr Husaini. In the Third Report, I was severely critical of the evidence that he gave. He sought to persuade me that he had reported his concerns but I am quite satisfied that he did not. I think that by the time he came to provide his witness statement to this Inquiry, Dr Husaini felt embarrassed or ashamed about his failure to report his concerns. I accept that Dr Husaini cared very much about what had happened to Mrs Overton and he did a great deal to help and support her family during her 14 month stay on ward 17. I think that, when Dr Husaini realised how serious Shipman's conduct towards Mrs Overton had been, he persuaded himself that he had reported his concerns appropriately but that others had failed to act upon them. In not reporting his concerns at

the time, as he should have done, he acted in the way that many other doctors would have done at that time.

Causation

The Immediate Consequences of a Report of Concern

10.80 Had Dr Brown or Dr Husaini reported their concerns to Mr Butterworth or to the Medical Director designate or to some other person in a senior position, such as Mrs Linda Lloyd, the Hospital's Director of Operations, then, in all likelihood, the report would have been passed to the Tameside FHSA. Mr Butterworth said that he did not know what the arrangements were for investigating a concern about a GP but he explained how he would have gone about finding out. As it would immediately have appeared that the allegation involved a potential breach of Shipman's terms of service, the report would probably have led to MSC proceedings, provided that a suitable complainant could be identified. I have already said that, if the consultants had explained to the Overton family their decision to report Shipman, a member of the family might well have been prepared to co-operate by acting as complainant. However, if they had not, there might have been a difficulty in finding a suitable complainant. If Dr Brown had been willing to act as complainant, the MSC might have been prepared to accept him. If not, it would have been possible for the Tameside FHSA to act as complainant itself, in which event the case would have been transferred to the MSC of an adjacent FHSA. I acknowledge that such a course of action would have been unusual. If no satisfactory solution had presented itself to the FHSA, the decision might well have been taken to report the case straight to the GMC.

10.81 The case might also have reached the GMC by other routes. The consultants might have reported to that body direct or the case might have been referred there after the MSC hearing via the Family Health Services Appeal Authority (FHSAA). A further possibility is that, if an inquest had been held after Mrs Overton's death in 1995, the Coroner might have reported Shipman's role in the matter to the GMC.

Shipman's Likely Response

10.82 By whatever route the case had been reported, and whether to the FHSA or to the GMC, it is necessary to consider what Shipman's likely response would have been and how convincing it would have appeared. To answer this question, it is helpful to look again at the note Shipman made in Mrs Overton's medical records concerning her admission to hospital:

> **'V** (*visit*) **Called at 8.50.**
> **arrived 9.15 – Acute Asthma**
> **given nebuliser**
> **Pulmicort nebul.** × **1**
> **Ventolin nebul** × **5ml.**
> **BP 150/100. HR 120/m**
> **Resp** > **30.**
> **After nebuliser A/E** = **BS good**

not cyanosed
Approx 9.30 collapsed C/O chest
pain sweating + pulse thready
given IV diamorphine 10mg stat (only
dose in bag)
Settled then ?arrested
Laid down ECM × 5
Daughter called
MTM/established patient
ECM/not cyanosed
pupils dilated fixed
Ambulance called. pupils dilated
ECM/maintained
MTM/
15 mins Ambulance crew IV Adrenaline
IV Lignocaine. Intubated pink
pupils fixed dilated'.

Then, continued on a separate sheet:

'H/R. established output OK
(*illegible*) **No respiration established**
→TGH
CAS S/N informed of arrival
× diagnosis + Rx'.

10.83 I am quite sure that in making this note, which was uncharacteristically detailed for him, Shipman was seeking to paint a picture which was consistent both with the circumstances as Mrs Carrington knew them and with his having provided appropriate care to Mrs Overton in difficult circumstances. I think it most likely that his explanation would have been along the following lines. He would have said that he had attended Mrs Overton and had treated her acute asthma attack appropriately with a nebuliser, achieving good relief from her symptoms. Some time later, but while he was still with her, Mrs Overton had begun to complain of chest pain. Shipman would have said that, knowing (as he would have claimed he did) that Mrs Overton had some coronary heart disease, he believed that her chest pain was due to a cardiac episode and was unrelated to her asthma. As the pain seemed severe and as Mrs Overton appeared very distressed, he had decided to administer some diamorphine. He had with him only one ampoule, containing 10mg. He made it up and administered some of it intravenously. He would probably have said that he did not administer all 10mg but had paused to observe its effect, which was satisfactory, for a few moments until Mrs Overton had suddenly collapsed. He had realised that she had stopped breathing and he could find no pulse. He had run to call Mrs Carrington and the two of them had started resuscitation. If asked why he had given as much as 10mg of diamorphine, he might well have said that he was unsure how much he had in fact given although he knew that he had not given the whole dose. He might well have claimed to be unsure of the amount given owing to the shock of Mrs Overton's sudden collapse. He might well have said that he had recorded that he had given 10mg

in order to account for the use of the ampoule. He had used the word **'stat'** to indicate that he had given the dose 'there and then' as opposed to having prescribed it for future use.

10.84 If the circumstances had been appropriately investigated, Shipman would have found himself in serious difficulty defending his conduct. In particular, although he would have been able to refer to a recent (probably fabricated) entry in Mrs Overton's medical record suggesting that she had had cardiac symptoms on 10th February 1994, a battery of tests following her admission to hospital showed that she had not suffered a recent heart attack. Moreover, the autopsy in 1995 revealed no ischaemic heart disease. Thus, an investigation in 1994 would have cast doubt on Shipman's claim that Mrs Overton had had a heart attack and, if the investigation had continued into 1995, it would have demonstrated that Mrs Overton could not have had any cardiac episode at all. Second, Shipman's claim that he had given less than the recorded 10mg of diamorphine would have come under scrutiny. Why say that the 10mg ampoule was the **'only dose in bag'** if he had administered only a part of the available ampoule? The excuse of **'only dose in bag'** appears to be an explanation for giving 10mg. Why say he gave it as a **'stat'** dose? Third, if Mrs Carrington had made a statement, it would have been known that Shipman had administered something to Mrs Overton after she had collapsed and was unconscious. What could that have been? His record is silent on the subject. If he were to claim that Naloxone or adrenaline had been given (either of which would have been appropriate), he would have to explain why this was not mentioned in the notes. Finally, the terrible outcome suffered by Mrs Overton was absolutely consistent with her having been given a gross overdose of diamorphine.

The Case before the Medical Service Committee

10.85 I have already said that, if one of the consultants had explained the situation fully to Dr Overton and had said that he must make a report even if the family did not, I think the family would probably have co-operated. A case would have been mounted against Shipman and I think it likely that an oral hearing by the MSC would have been ordered. It is possible that Shipman would have 'put his hands up' and suggested that he had inadvertently given more diamorphine than he should have done. He had done this in 1990 when a complaint about an error in the prescribing of anti-convulsant medication had been made on behalf of one of his patients, Mr W. In that case, the MSC dealt with the matter without an oral hearing. However, in Mrs Overton's case, taking into account the discrepancy between the account Shipman would have given (based on the entry he made in the GP records), and what was recorded in the hospital records, it is likely that the Chairman of the MSC would have ordered a hearing. This would probably have taken place in early 1995. It might have occurred before Mrs Overton died, in which case the results of the autopsy would not have been available. Shipman would have been charged with a failure to render Mrs Overton all necessary and appropriate personal medical services of the type usually provided by GPs, a breach of paragraph 12 of the terms of service set out in Schedule 2 to the NHS (General Medical Services) Regulations 1992. There would have been no evidential difficulty if Mrs Carrington had given evidence and if one of the consultants (probably Dr Brown on account of his relevant expertise) had provided expert opinion as to

Shipman's conduct. It might also have been sensible for the family to have asked for one or more of the staff on duty at the time of Mrs Overton's admission to hospital to be called to give evidence as to what Shipman had said and how the hospital records had come to be made.

10.86 It is possible that the MSC might have accepted Shipman's account and acquitted him of any breach of the terms of service. However, given the problems that would have been faced by Shipman, as outlined above, I think it likely that he would have been found to be in breach of paragraph 12. I think it likely that the conclusion of the MSC would have been that Shipman had made a serious error and had given an overdose of diamorphine, owing either to carelessness or to lack of knowledge of its effect. I do not think it at all likely that the MSC would have suspected him of causing deliberate harm. Nor do I think it would have gone into the question of where he had acquired the diamorphine. Many doctors carry diamorphine in their bags as a matter of course. They buy it on requisition from a pharmacy and keep their own controlled drugs registers (CDRs). The concern would have been over his clinical competence rather than his observance of the regulations relating to controlled drugs. That Shipman was carrying a 10mg ampoule of diamorphine in his bag would not have aroused any concern.

10.87 Nor am I convinced that the MSC would have formed the view that Shipman had prepared a false record, either in relation to the entry prior to 18th February 1994 in which he claimed Mrs Overton had reported cardiac symptoms or in relation to the occasion of her collapse. It might have done. If it had, obviously it would have formed a much more serious view than otherwise. On balance, I think it unlikely that it would have made such a finding unless the evidence was crystal clear; it would have been unwilling to make such a finding if there was any plausible explanation for the discrepancies between Shipman's record and the facts as it had found them to be.

10.88 When considering what penalty to recommend, the MSC would have been informed that two other findings had been made against Shipman within the last five years. These cases are described in detail in Chapter 6. The MSC would have been told of the findings in the case of Mr W and Mrs B. The case of Mr W involved the prescribing of the wrong amount of anti-convulsant medication, an error which had caused significant harm. For that breach of his terms of service, Shipman had been warned but there had been no financial penalty. In the case of Mrs B, Shipman had failed to visit the patient when he should have done. He was warned and a withholding of £800 from his remuneration had been ordered. As a result, I am sure that a significant withholding in excess of £1000 would have been made in Mrs Overton's case and would have been upheld by the FHSAA after advice from the Medical Advisory Committee. I think the likelihood also is that the case would then have been referred to the GMC. That would not have come about until late 1995 at the earliest, and more likely well into 1996.

10.89 Without family support for pursuing the case, the position would have been more complex. In Dr Givans' considerable experience, very few cases were brought before the MSC by persons other than the patient him/herself or a member of his/her immediate family. However, occasionally a complaint was made to the FHSA by a third party (for instance, a community nurse). In such cases, the FHSA took over the role of complainant

in accordance with the procedure I have described in Chapter 6. Thus, while it would have been possible to proceed without the participation of the family, particularly that of Mrs Carrington, it is less likely that the complaint would have proceeded before a MSC.

The Inquest

10.90 Had there been an inquest, informed by an appropriate autopsy report which would have recorded the potential role of opiates in Mrs Overton's death, Mr Revington would have heard evidence about the circumstances of the death. This might have included evidence from Dr Brown and Dr Husaini. It is too speculative to say what would have been the verdict of the Coroner or the jury. However, there is a real possibility that the Coroner might have taken the view that the death had been caused by Shipman's action in administering an overdose of diamorphine. If so, it would have been open to him to refer Shipman to the GMC. Whether he would have done so, I find it impossible to say. Examination of some of the cases comparable to Mrs Overton's case, which were considered by the GMC at about the same time, reveals that coroners did not always refer such cases to the GMC, even where there had apparently been gross negligence.

The General Medical Council

10.91 I consider, first, what would have happened if Dr Brown had reported Shipman to the GMC and it had decided to consider the case rather than to advise Dr Brown to report the matter locally. The relevant GMC procedures are dealt with in Chapters 18–21. The first stage would have been for the report to be considered by a member of the office staff. I am satisfied that, since it was being brought by a senior doctor, the case would then have been passed to a medical screener. It is likely that, before the screener considered the case, Dr Brown's report would have been sent to Shipman and his response sought. There would not have been any other investigation by the GMC. Internal Guidance from 1994 reflected the rarity of the cases in which the GMC undertook any investigative role. The Guidance stated:

> **'The onus to produce evidence is almost entirely on the complainant, and not on the GMC, because the GMC does not have much by way of investigative powers at the preliminary stage of the procedures; its powers of subpoena are confined to cases being heard by the PCC or Health Committee.'**

Then, in the next paragraph, it stated that:

> **'In a very small number of cases, however, the medical preliminary screener may consider, on the advice of the office, that the matters alleged are so serious that a thorough informal investigation should be carried out locally by the Council's solicitors, who will then attempt to investigate the case and take statements, insofar as potential witnesses are prepared to co-operate.'**

10.92 It then pointed out that it was not possible, because of limited resources, to investigate many cases of potential SPM in this way. Thus, and this is consistent with what Dr Brown thought, as well as what the MDU and other organisations were advising, if any investigation or evidence gathering was to be done, it had to be done locally and would not be done by the GMC, at least not during the early stages.

10.93 Thus, the documents before the medical screener would probably have been limited to Dr Brown's letter of complaint and Shipman's response to it. The GMC might have asked Dr Brown to send the hospital notes and Shipman would probably have sent the relevant extracts from Mrs Overton's GP records. Dr Krishna Korlipara, who was a GMC medical screener from 1998 until 2004 and gave oral evidence to the Inquiry in November 2003, was of the view that Shipman's case would have been passed by the medical screener to the PPC. I accept that that would probably have occurred. Dr Korlipara also said that the PPC would have referred the case on to the PCC. He may be right, although, in the course of Stage Four, I have seen some cases that have been closed by the PPC which were every bit as serious as this one would appear to have been. For example, in the case of Dr JK 07, which was considered by the GMC in the late 1990s, there was compelling evidence that the doctor had injected an overdose of lignocaine (a local anaesthetic given before an operative procedure) and that this had caused the death of a young patient. The GMC obtained medical evidence from an eminent professor in anaesthesia (who was also a member of the GMC) which expressed the view that the dose given was unacceptably large and suggested that the doctor had been guilty of SPM. However, the PPC decided that it was not necessary to refer the matter to the PCC and issued a warning to the doctor as to his future practice I will describe the case in greater detail in Chapter 20.

10.94 Although I am uncertain about it, I do accept that Mrs Overton's case might well have gone through to the PCC. Had it reached the GMC after an adverse finding by the MSC or after criticism by the Coroner, the case would have been quite likely to go through to the PCC. Would there have been a finding of SPM? Dr Korlipara said that he thought there would have been and that there was a possibility that Shipman might have been erased from the register. Alternatively, he said, there might have been a period of suspension, or conditions might have been imposed, restricting Shipman's freedom to prescribe controlled drugs.

10.95 Assuming that the case had been sent to the PCC for hearing (in which case the GMC solicitors would have undertaken any further investigation they considered necessary, in preparation for the hearing), I cannot predict whether there would have been a finding of SPM. It is possible that there would have been. However, if there had been, I do not think it would have resulted in erasure. I reach that conclusion after scrutinising a number of similar cases dealt with by the GMC at about this time. The following cases are, in my view, relevant.

Dr JC 02

10.96 Over a period of two years in the early 1990s, Dr JC 02, a GP, caused the deaths of two patients by administering excessive doses of diamorphine. Both deaths led to inquests. The first death was apparently caused by the doctor having given 15mg diamorphine. At

the inquest, the Coroner suggested to the doctor that he (the Coroner) had received expert evidence that the appropriate dose was between 5 and 10mg. The doctor said that he remembered a conversation with a GP in Scotland who had advised him never to give less than 15mg as a smaller dose would 'only irritate the patient'. The Coroner returned a verdict of death by misadventure but did not refer the case to the GMC. About 12 months after the first inquest, the same doctor came before the same Coroner. This time, the doctor reported having administered 20mg diamorphine. The Coroner reminded the doctor that he had in the past had occasion to admonish him about his injudicious use of diamorphine and the doctor said that he would never use it again. The Coroner returned a second verdict of death by misadventure and referred the case to the GMC. The case came before the PCC and the doctor was found guilty of SPM. He was made subject to eight months' conditional registration with the requirement that he should not prescribe or possess diamorphine and should undergo retraining in the use of **'therapeutics'**. When his case was considered by the PCC, after the expiry of the eight-month period, the case was referred to the Health Committee, which later found the doctor's fitness to practise to be impaired by reason of ill health and imposed further conditions on his freedom to practise.

Dr JF 02

10.97 In the early 1990s, a consultant orthopaedic surgeon reported to the GMC a GP, Dr JF 02, who had given 100mg diamorphine to a patient who then suffered a respiratory arrest. The patient was successfully resuscitated. The case came before the PCC and, following a finding that he was guilty of SPM, the doctor's registration was made subject to conditions for a period of six months. He was required to pursue a structured programme of retraining in the use of scheduled and controlled drugs. At the hearing, it was accepted by the PCC that this had been an isolated incident. In fact, an unrelated complaint of indecent assault, made at about the same time against the same doctor, had foundered because the complainant had not supported the complaint with a statutory declaration as was necessary at that time.

Dr JG 03

10.98 In the early 1990s, Dr JG 03 gave propranolol to a young female asthmatic patient with the result that she died following respiratory depression. At the inquest, the doctor produced and relied on falsified computerised medical records. The purpose of falsification had plainly been to mislead any subsequent investigation into his conduct. There was a verdict of accidental death and the police became involved. The doctor was charged with manslaughter and perverting the course of justice in respect of the falsified records. He was acquitted of manslaughter but convicted of perverting the course of justice and was sentenced to six months' imprisonment. On reference to the GMC, the PCC found that the doctor's care of the patient had fallen deplorably short of a reasonable standard and found him guilty of SPM but, because of the period of imprisonment served and other factors regarded as mitigating the severity of the offence, he was made subject to one year's conditional registration. The conditions were that he should undergo assessment by and follow guidance (about the keeping of full, accurate and contemporaneous medical

records) from his Regional Adviser in General Practice. The Inquiry did not come across any case similar to that of Mrs Overton, in which the doctor had been erased, although in one case the doctor was erased after failing to comply with conditions imposed on his registration, following a similar episode.

The Overall Effect of Reporting Shipman

10.99 I have already said that I think it unlikely that the true extent of Shipman's criminality would have come to light, or even have been suspected, as the result of any report by Dr Brown or Dr Husaini. Nor do I think that a report or a referral to the GMC would have resulted in Shipman being erased from the medical register. He would have been free to continue in practice with or without a short interlude of suspension or of restricted practice. However, a period of suspension would necessarily have led to some curtailment of his criminal conduct, as would the imposition of a condition not to prescribe or administer controlled drugs. It would have been much more difficult and risky for him to obtain illicit supplies of diamorphine, his preferred drug. Indeed, if notice of any restriction were to have been properly circulated he might have had great difficulty in obtaining a supply.

10.100 In the First Report, I drew attention to the fact that Shipman did not kill for a period of three months after Mrs Overton's admission to hospital. In my view, if any disciplinary processes had begun, this period of abstinence would probably have been lengthened. There would have been a beneficial effect, even if the processes had not resulted in any penalty or restrictions upon his registration. I think it likely that Shipman would have stopped killing for a significant time. However, I cannot say for how long.

10.101 A finding of a breach of his terms of service would, I think, have had some salutary effect on Shipman. I think even this would not have been great, as MSC proceedings are held in private and relatively few people would have been aware of the proceedings and the finding. There might have been some talk in the town and this might have taken the shine off his reputation. It is unlikely that people would have realised the seriousness of what he had done. It appears that the findings against Shipman in the case of Mr W and Mrs B did not significantly harm his reputation. They were, of course, much less serious than the complaint in respect of Mrs Overton. It is possible that the MSC complaint about his prescribing an excessive quantity of anti-convulsant medication for Mr W contributed to the slowing of his criminal activity in 1990 and his complete abstinence in 1991, although in the First Report I have identified at least one other possible reason for these features. It does not seem, however, that the MSC complaint about his treatment of Mrs B had any lasting effect on his behaviour; during 1993, he regularly obtained single diamorphine ampoules to replenish the stocks he needed to kill his patients. A complaint in 1994 about his treatment of Mrs Overton might have had a more salutary effect. First, he had killed her. Second, he had done so using diamorphine. Third, this would have followed quite shortly after the other complaints.

10.102 If Shipman had been criticised by the Coroner at an inquest into Mrs Overton's death in 1995, the effect on his future course of conduct might have been very significant. Inquests are held in public and are usually reported in local newspapers. If the Coroner had made it plain that Shipman had given Mrs Overton a dangerous dose of diamorphine, several

things might have happened. First, Shipman's reputation would have been dented to some extent. Some of his patients, some of his patients' relatives, his staff and some of his colleagues might have been a little less trusting of him than they otherwise would have been. Fellow GPs, when asked to sign cremation Forms C, might have been more careful when endorsing his opinion as to the cause of death. Mrs Ghislaine Brant, the pharmacist at the premises next door to Shipman's surgery from where he obtained most of his supplies, might have reflected upon Shipman's use of 30mg ampoules of diamorphine in 1993 and she might have resolved to scrutinise his prescriptions more carefully in future. His staff might have been less trusting of him if and when, from 1995, the death rate in his practice increased significantly. It is not possible to say whether these suspicions would ever have been enough to lead to his detection. I think it likely that Mr David and Mrs Deborah Bambroffe, the funeral directors who came to suspect Shipman of killing his patients, would have felt more confident about raising their concerns and might have done so rather sooner than they did. If they had mentioned their concerns earlier, the members of the Brooke Practice might have realised sooner than they did that the death rate among Shipman's patients was abnormally high and might have made their report to the Coroner sooner than they did. If, when the West Pennine Health Authority became aware of a police investigation, it had also known of the outcome of the MSC hearing in relation to Mrs Overton, Dr Banks' approach to the examination of medical records might have been more open-minded and the result might have been different. The greatest effect in my view would have come from Shipman's awareness that he was not completely trusted, as he had been before. That, I think, would have made him more careful and would have restricted the number of patients he felt confident to kill. In short, I believe that publicity or any kind of disciplinary action or even the threat of it would have had a restricting effect on Shipman and lives would have been saved. I cannot say how many.

CHAPTER ELEVEN

Raising Concerns: the Way Forward

Introduction

11.1 In Chapters 8 and 9, I have considered how various people did or did not come to suspect that Shipman might be killing his patients and what, if anything, those with concerns felt able to do about raising them. I have also considered in Chapter 10 the position of two doctors who did not suspect that Shipman was deliberately doing anything wrong but who believed that he had given an inappropriate dose of morphine to a patient, with disastrous results. They did not report their concerns to anyone in authority.

11.2 I have concluded that, before March 1998, when the late Dr Linda Reynolds reported her concerns and those of her partners about the death rate among Shipman's patients, very few people had had any concerns about him. Mr David Bambroffe and Mrs Deborah Bambroffe were concerned and Mrs Bambroffe had mentioned their concerns to Dr Susan Booth. That communication contributed to the raising of anxieties within the Brooke Practice which led, some time later, to Dr Reynolds' report to the Coroner. The only other person who had attempted to raise a concern was Mrs Christine Simpson, who tried to alert her manager, Mrs Janet Schofield. However, her concerns were expressed rather obliquely and Mrs Schofield did not realise what Mrs Simpson was trying to tell her. Mrs Simpson had hesitated before speaking to Mrs Schofield because she feared that people would think she was 'mad' for harbouring suspicions about a respected general practitioner (GP). When her first attempt met with no response, she did not broach the subject directly again but did make comments linking Shipman's name with deaths at Ogden Court. The two home helps, Mrs Dorothy Foley and Mrs Elizabeth Shawcross, were concerned about Shipman but did not feel able to say anything. They did not know to whom to turn and were concerned that, if they did speak out, they would not be taken seriously. Mr John Shaw, a taxi driver who had become suspicious about the deaths of several of his customers, did not mention his concerns to anyone because he did not know where to raise them. Also, he was afraid of the possible legal consequences if it should turn out that he was wrong.

11.3 The apprehension and anxiety felt by these individuals typify the reaction of others who have found themselves in the position of wishing to report a concern. In this Chapter, I shall examine the steps that have been taken over the last decade or so to improve the position of people who have a concern and wish to raise it but who hesitate to do so for some reason. I shall also consider what further steps, if any, should be taken.

Terminology

11.4 In this Chapter, I have tried to avoid using the term 'whistleblowing'. Typically, a person is said to have 'blown the whistle' if s/he has brought to the attention of the authorities or of the public some form of illicit behaviour which has been perpetrated by or within the organisation in which s/he is employed or with which s/he is in some other way connected. Frequently, the 'whistleblower' will make his/her disclosure to a journalist and it will be reported in the media. There may be a number of reasons why the 'whistleblower' has

made his/her disclosure outside – rather than within – the organisation. He or she may have reported the behaviour within the organisation previously, but with no result. He or she may fear (perhaps because the illicit behaviour was being perpetrated by senior members of the organisation) that there would be no point in making a report inside the organisation; s/he may even be fearful of the consequences of making such a report. The essential feature of 'whistleblowing', however, is that the person making the report has chosen for some reason to take that report outside the organisation to which one would have expected the report to have been directed. Usually, there is little doubt in the mind of the 'whistleblower' that the information s/he has is true; his/her energies are directed at ensuring that the information is made known to those who are in a position to right the wrong of which s/he complains.

11.5 The term 'whistleblower' is, therefore, a convenient shorthand way of describing the person who brings information about some form of misbehaviour to the attention of those outside his/her organisation. None of the people to whom I have referred at paragraph 11.2 could properly have been termed 'whistleblowers' had they taken their concerns to the police, the primary care organisation or (in the case of Mrs Foley and Mrs Simpson) to their employers. Mrs Bambroffe was not 'blowing the whistle' when she voiced her concerns to Dr Booth; nor was Dr Reynolds when she made her report to the Coroner. Mrs Simpson was not 'whistleblowing' when she spoke to her line manager of her concerns. None of those persons worked within the same organisation as Shipman; they were merely voicing their concerns to those who they felt were the appropriate authorities.

11.6 Another feature which set those people apart from the typical 'whistleblower' was the fact that most of them were far from confident that their concerns were justified. They were not seeking to make a complaint or to air a grievance about something that they knew to be wrong. Indeed, one of the factors that inhibited them from speaking out was their concern that they might be proved to be wrong and their fear of the consequences of such an error.

11.7 The public generally becomes aware of an incident of 'whistleblowing' when things have gone wrong – usually when the 'whistleblower' has been dismissed from his/her employment for breach of his/her duty of confidentiality or has suffered some other detriment. In some cases involving national security, 'whistleblowers' have even been prosecuted. When it appears that the 'whistleblower' has been motivated by genuine and well-founded concerns, public opinion tends to support the 'whistleblower' and the feeling is that s/he has done his/her public duty. Nevertheless, the message that emerges from media reports of 'whistleblowing' cases is in essence a negative one; namely that those who put their heads above the parapet and dare to speak out are liable to be penalised in some way. I do not think it is helpful to confuse that negative message with a discussion of how people with genuine and legitimate concerns affecting the public interest can be helped to bring forward those concerns in a responsible and effective manner.

11.8 I recognise that the meaning of the term 'whistleblower' has recently been extended somewhat. It is now sometimes used to describe a person who reports his/her concerns within the organisation to which those concerns refer, or even to describe a member of the public who raises concerns about a person or organisation with which s/he has no personal connection at all. It is used also to describe the raising of concerns which are

less serious in nature than those that have formed the basis of the most celebrated 'whistleblowing' cases. Many of the witnesses to the Inquiry used the term 'whistleblowing' virtually synonymously with 'the raising of concerns'.

11.9 I propose to avoid using the expression 'whistleblowing' wherever possible. However, the term has come into such general use that many organisations now have what they call 'whistleblowing' policies, which are really policies to assist employees to 'raise concerns' in an appropriate way, giving them an assurance that they will be taken seriously and will not be victimised as a result of their action. Because the term 'whistleblowing' is used in this way by some, I will occasionally have to use it myself in this Chapter, as I did in Chapter 9. Otherwise, I shall not.

Serving the Public Interest

11.10 The raising of genuinely held concerns about issues of public importance is to be encouraged. The public interest may be served in many different ways, such as by the prevention or detection of crime, by the prevention of accidents or by the protection of the public purse. I have already mentioned some natural barriers to the raising of concerns encountered by those who harboured concerns about Shipman. Others include the fear of being seen as a troublemaker or 'maverick', the fear of recriminations and a feeling of impotence grounded in the belief that, even if the report is made, nothing will be done about it. There may be a concern that making a report might lead to proceedings for defamation. There may be anxiety that the report of a concern will be interpreted as an attack on an individual or body whereas no such attack may be intended. There may be a fear that the group or team of which the person to be criticised is a member will rally round him/her and will ostracise the person who has raised the concern.

11.11 Such fears may be well founded. As I will explain later in this Chapter, the experience of Dr Stephen Bolsin, the consultant anaesthetist who tried unsuccessfully to report his concerns about the high mortality rate among paediatric cardiac patients at the Bristol Royal Infirmary (BRI) in the late 1980s and early 1990s, demonstrates how serious the consequences of raising concerns can be. His decision to cease practice in the UK and to set up practice in Australia resulted, at least in part, from the response to his attempts to raise his concerns. In my view, individuals must be encouraged to raise their honest concerns; they need to know how to do it and they need to have the confidence that, if they do, those concerns will be taken seriously and that they will not be victimised in any way.

11.12 It is now generally recognised that the raising of a concern within the organisation in which it arises is usually preferable to more public disclosure. There are several reasons for this. There is a proper public interest in ensuring that genuinely confidential information is kept confidential. There is also a real public interest in promoting the internal accountability of organisations. Of course, some mistakes and misdeeds are so important that it is only right that the general public should be made fully aware of them; there are, however, many occasions when it would be preferable, in the public interest, that the organisation responsible for an error should be able to correct it and learn from it without any outside involvement. Disclosure to the press can attract a disproportionate degree of publicity with adverse consequences for all. The organisation is 'put on the back foot' by the

unexpected disclosure and can become defensive and secretive. There is a tendency for attention to be focussed on the messenger rather than on the message and the 'whistleblower' may suffer reprisals. In brief, no one benefits.

11.13 The task of devising a system is relatively easy. The real challenge is in developing a culture where every member of a group, team, department or profession feels a sense of responsibility for the actions of the others. Where what is in issue is a question of poor clinical performance, that sense of responsibility may lead, first, to an attempt to assist the person who is performing badly to improve, but should extend, if necessary, to making an official report to an appropriate person. There is also a need to develop a culture in which, when a concern is raised about the conduct or practice of one member of a group, the rest of the group does not 'close ranks' and ostracise the person who has spoken out. In the last few years, real attempts have been made to improve the position of people who raise concerns.

The Evidence

11.14 The Inquiry received a large number of statements, articles and other documentary material from many sources on the topic of raising concerns. A questionnaire was sent to a number of local authorities and other organisations requesting details of their policies and practices. Many responses annexed copies of the relevant body's whistleblowing policy. Several witnesses and participants in seminars held by the Inquiry described the procedures for raising concerns within their organisations. Some explained their own experience of raising a concern. An important contribution was made by Mr Guy Dehn, Director of Public Concern at Work (PCaW), an organisation which, as I shall explain below, has done a great deal of work to promote a legal and cultural climate in which people feel confident to raise their concerns. He gave oral evidence to the Inquiry, and the Deputy Director of PCaW, Ms Anna Myers, attended the Inquiry seminars in January 2004.

Public Concern at Work

The Organisation

11.15 PCaW, which was established in 1993, is a small limited company with charitable status. It offers help and encouragement to organisations (in particular the NHS) that wish to create and foster a culture in which staff feel safe to raise concerns. It gives advice on the relevant law. It provides materials (such as draft policies) and consultancy and training services relating to the raising of concerns and to accountability within organisations. It seeks to influence public policy by the conduct of research and by the publication of articles. It has also set up and administers a telephone helpline that provides free, confidential legal advice and practical assistance to individuals who are unsure how to raise concerns about malpractice, particularly malpractice in the workplace. The service is available to all employees, although a number of leading employers, including the NHS, have begun to take out subscriptions to the service. This subscription scheme was introduced by PCaW to help employers to demonstrate their commitment to the active promotion of whistleblowing policies. PCaW does not play any part in investigating or pursuing those concerns, although it will, if requested, pass on concerns to the

appropriate recipient and assist callers in drafting and communicating concerns, if requested to do so.

11.16 Mr Dehn has been personally responsible for much of the progress that has been achieved by PCaW in improving the position of those who wish to raise concerns. He is a barrister and assisted in the drafting of the Public Interest Disclosure Act 1998 (PIDA), which provides a measure of protection from victimisation by employers of those who have raised a concern.

11.17 As its name implies, PCaW focusses its attention on the raising of concerns about activity in the workplace. In fact, much of the evidence heard by the Inquiry about the raising of concerns related to problems that had arisen in the workplace. This is not surprising. First, the great majority of incidents that might give rise to concern about public safety are in some way connected to the workplace. Second, it is employees who are most likely to become aware of such incidents and it is they who have the most to lose if the concern that they raise is not favourably received.

Factors Influencing the Raising of Concerns

11.18 Mr Dehn confirmed to the Inquiry the causes for anxiety that are widespread among people who are thinking of reporting a concern. Among these are included the factors that I have already mentioned, namely, uncertainty as to how to go about making a report, as well as a fear that the report will not be taken seriously and that nothing will be done about it. Also, he spoke of the worry that there will be some sort of reprisal or detriment at work, either from management or from colleagues.

The Genesis of the Public Interest Disclosure Act 1998

11.19 In the late 1980s and early 1990s, when Mr Dehn was working as the Legal Officer to the National Consumer Council, he had to consider the reports of a number of public or judicial Inquiries into major disasters. He saw that, in almost all cases, those Inquiries had found that employees had been aware of the danger that was looming but either had been too frightened to raise their concerns or had raised their concerns in the wrong way or with the wrong person. They had lacked the necessary confidence and/or knowledge to voice their concerns effectively. Examples included the Clapham rail crash (where the Hidden Inquiry heard that an inspector had not raised his concern because he did not want to 'rock the boat'), the Piper Alpha disaster (where the Cullen Inquiry concluded that employees did not want to put their continued employment in jeopardy through raising a safety issue which might embarrass management) and the Zeebrugge ferry sinking (where the Sheen Inquiry found that staff had raised concerns but had done so 'with the wrong people in the wrong way so that nothing was done about it'). Similar conclusions had been drawn from reports on financial scandals. In all these cases, there had been a failure of effective communication between staff and management. Mr Dehn formed the view that communication breakdown was likely to have been a relevant factor in many other accidents which had caused death or serious injury, and in many frauds which had resulted in financial loss but which had not, because of their more modest scale, justified a public or judicial inquiry. It was these thoughts that led to the formation of PCaW in 1993.

11.20 Soon afterwards, as Mr Dehn told the Inquiry, the Nolan Committee on Standards in Public Life (the Nolan Committee) and the Audit Commission also became interested in the issue. The Nolan Committee's Second Report said:

> **'All organisations face the risks of things going wrong or of unknowingly harbouring malpractice. Part of the duty of identifying such a situation and taking remedial action may lie with the regulatory or funding body. But the regulator is usually in the role of detective, determining responsibility after the crime has been discovered. Encouraging a culture of openness within an organisation will help: prevention is better than cure. Yet it is striking that in the few cases where things have gone badly wrong in local public spending bodies, it has frequently been the tip-off to the press or the local Member of Parliament – sometimes anonymous, sometimes not – which has prompted the regulators into action. Placing staff in a position where they feel driven to approach the media to ventilate concerns is unsatisfactory both for the staff member and the organisation.'**

11.21 These views – which I share – summarise the purpose of the legislation that was to follow. That purpose was not to encourage employees with concerns to broadcast them. It was to ensure, through legislation, that employees would feel sufficiently confident to raise their concerns internally. The object was to encourage external disclosure only where internal disclosure was inappropriate.

11.22 The idea of a legislative framework to encourage employees to raise public interest concerns, and to protect those who did so from adverse consequences, was first raised in Parliament in 1995 in a 'ten minute rule' Bill, drafted by PCaW and the Campaign for Freedom of Information (CFOI). The Bill received broad support but got no further. In 1996, a Private Member's Bill with the same object was unsuccessful, although it had been strongly supported inside and outside Parliament. The Rt Hon Tony Blair MP, then Leader of the Opposition and now Prime Minister, pledged that a future Labour Government would introduce legislation with these objectives. Within a few weeks of the election of the Labour Government in 1997, PCaW and the CFOI were asked by Ministers to promote the Bill again, this time through the Private Members' ballot. A Conservative MP, Mr Richard Shepherd, a supporter of the earlier Bills, was successful in the ballot and introduced the Bill which was later to become the PIDA.

The Public Interest Disclosure Act 1998

The Objectives of the Act

11.23 The PIDA came into force on 2nd July 1999. The preamble describes it as:

> **'An Act to protect individuals who make certain disclosures of information in the public interest; to allow such individuals to bring action in respect of victimisation; and for connected purposes'**.

11.24 The PIDA offers protection from dismissal and victimisation to workers who raise genuine concerns about 'malpractice' in the workplace. This protection forms part of employment

legislation but the PIDA had a far broader underlying purpose than the extension of employees' rights to protection from victimisation. It was seen as a valuable tool to promote openness and good governance. It was intended to help to ensure that organisations responded to disclosures by addressing the concern raised (the 'message'), rather than by focussing attention on the person who had raised that concern (the 'messenger'). It was envisaged that the PIDA would make it more likely that organisations would resist the temptation to cover up serious malpractice. According to PCaW, these wider implications for governance and their relevance across all sectors of the workplace meant that the legislation received broad support from the Confederation of British Industry, the Institute of Directors and other key professional groups.

11.25 The PIDA (like the best whistleblowing policies) is designed to reassure employees that it is safe and acceptable for them to raise their concerns within their organisation. If this is achieved and the raising of concerns internally becomes the norm, management will often receive early warning of malpractice and will have the opportunity to investigate and put matters right. Even where early warning is not given, a later report may lead to the detection of those responsible and the knowledge that malpractice is likely to be reported will, in any event, act as a deterrent to wrongdoing. The accountability of those responsible for the organisation will be improved. Furthermore, if management fails to act on receipt of a concern that is later seen to be well founded, management can be held to account. If the raising of concerns becomes the norm, there is less likelihood of a breakdown in the relationship between employer and employee when a report is made, even if the report turns out to be ill-founded. This point was made by Mrs Pauline Webdale, Fellow and previous national Chairman, Association of Medical Secretaries, Practice Managers, Administrators and Receptionists (AMSPAR), as I explained in Chapter 9. Thus, the policy of the PIDA is to encourage internal reporting but, where there is good reason to doubt that internal reporting will suffice and the employee makes his/her report to a regulator or even more publicly, the protection afforded by the PIDA will not necessarily be lost.

The Tiered Regime of the Act

11.26 The provisions of the PIDA are incorporated into the Employment Rights Act 1996 (ERA), by amendment to a number of sections of the ERA, mainly sections 43 and 47. The PIDA creates a three tiered disclosure regime under which employees dismissed for having reported a concern are entitled to have their dismissal automatically treated as unfair if the report meets certain criteria laid down in the PIDA. Those criteria become progressively harder to satisfy according to the remoteness of the person to whom the concern is reported from the organisation about which the concern is raised.

The Classes of Person Protected

11.27 The PIDA affords protection to all **'workers'** within the definition set out in section 230(3) of the ERA. It also extends that definition (in circumstances where their terms or place of work are not under their own control) to agency workers and independent contractors and to GPs contracted under General Medical Services Contracts. It has, therefore, very broad application.

The Nature of the Protection

11.28 The PIDA confers on workers the right not to be subjected by their employers to any **'detriment'** on the ground of their having made a disclosure that is protected by the provisions of the PIDA (a **'protected disclosure'**). Where a worker suffers such detriment, and/or is dismissed for having made a protected disclosure, s/he has certain enhanced rights in bringing a claim before an employment tribunal. A worker is automatically to be regarded as having been unfairly dismissed if the sole or principal reason for dismissal is that s/he made a protected disclosure. Awards of compensation are based on the losses suffered and there is no upper limit. Aggravated damages can also be awarded. The employee may also, within seven days of dismissal, seek interim relief so that his/her employment continues or is deemed to continue until the full hearing of the claim by an employment tribunal. No qualifying periods or age limits restrict the application of the protection. The protection is available whether or not the information disclosed is confidential and whatever the geographical location of the reported malpractice.

Qualifying Disclosures

11.29 Under the PIDA, only what is termed a **'qualifying disclosure'** has the potential to be a protected disclosure. In order for a disclosure to be a qualifying disclosure, it is first necessary for the worker making it to have a **'reasonable belief'** (reasonable suspicion will not suffice) that his/her disclosure **'tends to show'** (and not merely to suggest) that one or more of the following types of malpractice has taken place, is taking place or is likely to take place. The types of malpractice, which may overlap, are:

(a) an actual or apprehended breach of the criminal law or of **'any legal obligation to which a person is subject'**

(b) a miscarriage of justice

(c) a danger to health and safety

(d) damage to the environment

(e) the deliberate concealment of any such malpractice.

Protected Disclosures

Disclosures to Employers and Related Disclosures

11.30 The first 'tier' of disclosure at which the PIDA affords protection covers those disclosures made to the worker's employer, those made to a person authorised by the employer's whistleblowing policy to receive them directly and those made to the person with **'legal responsibility'** for the malpractice in question. The meaning of the phrase **'legal responsibility'** is uncertain, as I shall explain below.

11.31 Because the object of the PIDA is to offer the maximum encouragement to the raising of concerns within the organisation responsible, the evidential burden on the employee seeking to make a first tier disclosure is set at a fairly low level and the disclosure quite readily becomes protected. The same ready protection extends to disclosures made to a

Minister of the Crown, where the worker's employer is either an individual appointed under any enactment by a Minister, or a body, any of whose members are so appointed. This would apply to the case where a worker employed by a public body subject to Ministerial appointment (e.g. the NHS or a primary care trust (PCT)) 'blows the whistle' directly to the Secretary of State (SoS) for Health (or, more likely in practice, to a senior official at the Department of Health (DoH)).

11.32 Such qualifying disclosures become protected disclosures provided that they are made **'in good faith'**. The question whether or not a protected disclosure is made **'in good faith'** is a question of fact for the employment tribunal to decide. There is no statutory definition of the phrase, although the Court of Appeal has recently held (in the case of Street v Derbyshire Unemployed Workers' Centre[1]) that **'in good faith'** requires that the predominant motivation for the making of the report was the public interest. A person whose predominant motive is, for example, personal dislike would not be entitled to the protection of the PIDA, even though the information disclosed was truthful and accurate and was about the commission of a serious crime. If, therefore, a member of the practice staff employed by Shipman had reported concerns about his conduct, she would not have enjoyed the protection of the PIDA if her main reason for making the report had been personal dislike of Shipman. This is despite the overwhelming public interest in the disclosure that he might be murdering patients. I shall discuss this problem further below.

Disclosures to External Regulators

11.33 The second 'tier' of disclosure covers the protection to be afforded to qualifying disclosures made to certain external regulators and similar bodies or, using the words of section 43F of the ERA, to persons **'prescribed by an order made by the Secretary of State** (*for Trade and Industry*) **for the purposes of this section'** (**'prescribed persons'**). The object of the PIDA is to offer only slightly less encouragement to concerns raised in this way than to concerns raised within the organisation responsible. These **'prescribed persons'** – all external regulators – include bodies such as the Financial Services Authority, the Health and Safety Executive, the General Social Care Council and the Environment Agency. They do not include the General Medical Council (GMC) or the Commission for Healthcare Audit and Inspection (known as the Healthcare Commission).

11.34 Before a disclosure made to an external regulator can be protected under the PIDA, the worker making the disclosure is required not only to have acted **'in good faith'**; s/he must also have had a **'reasonable belief'**, first, that the information disclosed or allegations made were **'substantially true'** and, second, that the disclosure fell within the description of the kinds of disclosure that the **'prescribed person'** was authorised to receive. I have already mentioned that, before a disclosure can gain even the status of a qualifying disclosure, it is necessary for the worker to have a **'reasonable belief'** that his/her disclosure **'tends to show'** one or more of the various types of malpractice. Under the second tier, the reasonable belief must be that the information is **'substantially true'**, a higher threshold than for the first tier, where the additional requirement before a qualifying

[1] [2004] EWCA Civ 964.

disclosure becomes a protected disclosure is, as I have said, only that the disclosure should have been made in good faith. I shall return to this issue below.

Wider Disclosures

11.35 The third 'tier' of disclosures covers those qualifying disclosures that do not fall into either of the above categories. I shall refer to them as 'wider disclosures'. They may include disclosures to the media or to regulators that are not **'prescribed persons'**, such as the GMC at the present time. For such disclosures to attract the protection of the PIDA, the worker must satisfy quite onerous requirements, additional to those required in the case of disclosures to **'prescribed persons'**. The first additional requirement (which can be fulfilled in any one or more of three alternative ways) is satisfied where:

(a) the worker reasonably believes that s/he will be subjected to a detriment at the hands of his/her employer if s/he makes the disclosure either to that employer, to a person authorised by that employer to receive it, to the person responsible for the malpractice or to a **'prescribed person'**

(b) where there is no **'prescribed person'** to whom the disclosure could be made (e.g. because no person is prescribed to receive disclosures of that description), or the worker reasonably believes that relevant evidence will be concealed or destroyed if s/he makes the disclosure to his/her employer

(c) where the worker has previously disclosed substantially the same information to any of the persons listed at (a).

11.36 Broadly speaking, therefore, this first additional requirement depends on the worker either having the reasonable belief that his/her employer will 'respond badly' to the disclosure or having already unsuccessfully raised his/her concern (provided it has been made through the proper channels or there are no proper channels through which to take it).

11.37 The second additional requirement for a wider disclosure is that the person making the disclosure does not do so for personal gain. Thus a disclosure made to the press for financial reward would not be protected.

11.38 The third and final additional requirement for a wider disclosure is that it must be reasonable, in all the circumstances, for the worker to have made the disclosure. In determining this question of reasonableness, regard has to be had to:

(a) the identity of the person to whom the disclosure is made

(b) the seriousness of the matter at issue

(c) whether the malpractice is at an end or is likely to recur

(d) whether the disclosure puts the employer in breach of a duty of confidentiality owed to another person and (in a case where the person concerned has previously disclosed substantially the same information to any of the persons listed at (a) in paragraph 11.35 above) whether s/he did so in compliance with a procedure authorised by his/her employer.

11.39 Where wider disclosures are of what are described as **'exceptionally serious failures'**, the requirements at (a) to (c) in paragraph 11.35 do not have to be satisfied. The other requirements do, however, have to be satisfied and, when determining the question of reasonableness, particular regard is to be paid to the identity of the person to whom the disclosure is made. By way of illustration, a report to the GMC of concern about a serious continuing risk to patient safety where the worker has previously raised the concern internally would be more likely to be protected than a first-time disclosure to the press of a minor concern not involving public safety.

Contractual Duties of Confidentiality

11.40 Many contracts of employment contain express confidentiality clauses; in many others a duty is implied. When parties to an employment contract fall into dispute and reach agreement over the terms for the dissolution of their relationship, there is often a clause in the agreement (a 'severance agreement') to keep its terms confidential. Such confidentiality clauses are usually perfectly proper. However, the PIDA provides that a provision in any agreement between a worker and an employer shall be void insofar as it purports to preclude the worker from making a protected disclosure. The PIDA therefore covers all agreements between employers and workers and is not limited to contracts of employment. It also covers severance agreements.

Disclosure to Legal Advisers

11.41 These are fully protected. However, I think it unlikely that many cases will arise out of disclosure to a legal adviser because, in the nature of things, such disclosures are confidential and are therefore unlikely to result in dismissal or other detriment.

The Impact of the Act

11.42 Mr Dehn told the Inquiry that the PIDA is working well and that it has had a significant beneficial effect. Since its enactment, many employers have become more aware of the need to develop and put in place good, robust whistleblowing policies that embody the features I shall shortly describe. Employers are now more aware that it is legitimate for their employees to raise concerns, that they need to be circumspect about how they handle concerns when raised and that 'if it goes wrong they may have to pay'. In this way, the balance of power has been somewhat redressed.

11.43 Mr Dehn was keen to emphasise the deterrent effect of a good, robust written policy setting out the procedure to be followed when raising and dealing with a concern. He spoke of 'early evidence' that such policies are having that effect. He told the Inquiry that a wrongdoer is more likely to commit malpractice if s/he suspects that his/her peers and colleagues will not know what to do, or will be too afraid to act, if and when they become aware that malpractice is being committed.

Employment Tribunals

11.44 According to information collated by PCaW in 2003, the public register of employment tribunal applications suggested that some 1200 claims under the provisions of the PIDA

were registered in the first three years after the PIDA came into force. These claims had led to one Court of Appeal decision, one Scottish Court of Session decision, six decisions of the Employment Appeal Tribunal and about 100 full decisions of employment tribunals. I have mentioned already the later Court of Appeal case of Street v Derbyshire Unemployed Workers' Centre. These are substantial numbers. They confirm the need for employees to be protected in this way. The concerns raised by those who brought claims ranged from quite trivial matters to serious crimes and grave dangers. The reprisals suffered also covered a wide spectrum. While the majority of the cases involved the raising of concerns internally, employment tribunals readily regarded disclosures to regulators as protected. Five public disclosures – including two to the media – were also held to merit protection. Aggravated damages have been awarded in several cases and, in one case, compensation of £50,000 was given for injury to feelings. While the largest tribunal award by 2003 was £805,000, PCaW suggested that several cases had been settled for more than £1m.

11.45 Mr Dehn was at pains to emphasise, however, that neither the number of employment tribunal decisions nor the sums awarded are the correct measures of the success of the PIDA, the primary purpose of which was to create a culture where employees would feel able to raise genuine concerns in a constructive way and where employers would address properly any real danger or risk.

Changing Attitudes and the Development of Whistleblowing Policies

11.46 Mr Dehn told the Inquiry that the PIDA has provided a major stimulus for organisations to introduce their own whistleblowing policies. Such policies can be a very useful and positive tool for 'corporate governance' and 'risk management' and they are viewed favourably by employers' and employees' organisations. The key elements of such policies, as described by PCaW and as endorsed by the Nolan Committee, are:

(a) a clear statement that malpractice is taken seriously in the organisation

(b) an indication of the kinds of matter regarded as malpractice

(c) respect for the confidentiality of staff raising concerns, if they want it

(d) affording the opportunity to raise concerns outside the line management structure

(e) indicating the way in which concerns may, if necessary, properly be raised outside the organisation

(f) affording access to confidential advice from an independent charity

(g) giving staff of contracting firms access to the organisation's whistleblowing policy

(h) imposing penalties for malicious false allegations

(i) effective promotion of the policy.

11.47 According to PCaW, there have been some good recent local government initiatives and larger private organisations are becoming more interested and involved. There is, however, still a lack of awareness of the legislation in small and medium-sized institutions.

Of the large Governmental organisations, the NHS apparently has the greatest awareness; at paragraphs 11.66–11.73, I will deal specifically with the raising of concerns in the NHS. The position is probably very much the same in large commercial and industrial organisations. Awareness is variable in Government Departments other than the DoH but is quite high in local government.

11.48 Although progress is being made, Mr Dehn told the Inquiry that he believes that it will take a generation or more to achieve a real change in attitude. Clearly, PCaW has an important long-term role to play.

11.49 Several contributors to the Inquiry seminars confirmed that, although attitudes towards people who raise concerns are improving, there is still a long way to go. Mrs Webdale said that one of the main comments from her membership was that there was a lot of work still to be done to make people brave enough to 'put their head above the parapet'.

Raising Concerns in the Health Sector

The History

11.50 To modern eyes, it seems obvious that a culture in all healthcare organisations that encourages the reporting of concerns would carry with it great benefits. The readiness of staff to draw attention to errors or 'near misses' by doctors and nurses, and the facility for them to do so, could have a major impact upon patient safety and upon the quality of care provided. However, those benefits have not always been generally appreciated. In Chapter 10, I described how, in 1994, the culture within the medical profession was not conducive to the raising of concerns by one doctor about another. The Inquiry also heard evidence about the way in which nurses or more junior staff might be ignored or even victimised if they reported malpractice or poor performance by a colleague or doctor. In the early 1990s, the GMC had made plain to doctors where their duty lay; it was to make a report in any case where poor practice or performance might affect patient safety. Yet, as I was to hear from numerous witnesses, the GMC message was not really heeded. Thus, although things may have improved in the aftermath of Shipman's convictions and of the Public Inquiry into children's heart surgery at the BRI (the Bristol Inquiry), there is still room for improvement. As I explained in Chapter 10, Dr Gerard Panting, Communications and Policy Director at the Medical Protection Society, lectures to groups of doctors on ethical issues and is often surprised by the degree of ignorance displayed in relation to such issues.

11.51 Within the NHS also, there has been a move in the direction of greater openness, although it seems originally to have come about, not as the result of concerns about patient safety, but because doctors felt that they were being inhibited from speaking publicly about their concerns over the running of the NHS. In 1993, the NHS Management Executive published guidance entitled 'Guidance for Staff on Relations with the Public and the Media'. This guidance was intended to address the concerns of hospital doctors who felt that their complaints about political interference in health matters were being stifled by confidentiality clauses in their employment contracts. The guidance represented the first formal attempt by the DoH to give guidance to NHS employers and staff about how staff

should go about raising matters of concern, but it was less than ideal. Mr Dehn explained that the procedures to be adopted under the guidance were long and exhausting. The guidance did not make clear what employees should do when they wanted to make a disclosure; nor did it offer them any degree of comfort about what might happen to them if they did so. It did not make clear that the options were to say nothing, to make an internal disclosure or to make an external disclosure.

11.52 Moreover, the procedure for raising concerns described in the guidance was akin to a grievance procedure. The procedure had an adversarial feel to it, which was the opposite of what was wanted. The person raising the concern was the 'owner' of it and was identified with it. In other words, the issue for the employer was 'Is this grievance made out?' rather than, as it should have been, 'What do we need to know about this concern? How do we remedy it? What can we learn from it?' The PCaW view is that employers have to encourage their employees to communicate their concerns to someone within the organisation who is able to assess those concerns and act if appropriate. The employee should not normally have to do any more than raise the concern. It must be emphasised that it is 'concerns' and not 'complaints' or 'grievances' that are being raised.

11.53 Mr Dehn said that this period (by which I understood him to mean the early 1990s) was a time of great activity in the NHS. There were probably several reasons for it but, in brief, the initiative taken by the DoH in 1993 was not followed up. The then Chief Executive of the NHS said in a letter introducing the 1993 guidance that **'a sustained effort is required to ensure that these guidelines** (*i.e. those that made up the guidance*) **are carried through, both in spirit and in detail at local level'**. In May 1995, the Nolan Committee's First Report recorded that the Audit Commission had found that none of the 17 NHS bodies they had visited was promoting a whistleblowing scheme, as the 1993 guidance had recommended. The Audit Commission had also found that one third of NHS staff interviewed said that they would not raise a serious concern if they had one, for fear of losing their jobs.

11.54 The Nolan Committee's First Report recommended that every NHS body that had not already done so should allocate to an official or to a board member the duty of investigating staff concerns about propriety which had been raised in confidence. It recommended that staff should be able, where necessary, to make complaints outside the normal line management chain and, when doing so, should be guaranteed confidentiality. If they were dissatisfied with the response they received, they should also have a clear route for raising concerns about propriety with the sponsor department, i.e. the DoH.

11.55 According to PCaW, the Nolan Committee's Second Report, published in May 1996, reminded NHS bodies of this advice and provided a checklist for use by NHS trust boards to assess how far they were complying with their obligations.

11.56 Fresh DoH guidance was issued on 27th August 1999, following the coming into force of the PIDA. Health Service Circular 1999/198 recommended revision of existing whistleblowing policies in accordance with the PIDA and stated in terms what was expected by Ministers. The Circular read:

> **'Ministers expect a climate of openness and dialogue in the NHS, a culture and environment everywhere in the NHS which encourages staff**

to feel able to raise concerns about healthcare matters sensibly and responsibly without fear of victimisation. The Public Interest Disclosure Act provides fresh impetus for further action.'

11.57 The Circular required positive action by NHS trusts and health authorities. In line with what had been said in the Nolan Committee's First Report, senior managers or non-executive directors were to be given specific responsibility for addressing concerns that were raised in confidence and had – because of their sensitive nature – to be dealt with outside the usual line management chain. Guidance had to be made available to staff to enable them to raise any concerns they might have had about health care, reasonably and responsibly and with the right people. A clear commitment had to be given that concerns would be taken seriously and would be properly investigated. There should also be an unequivocal guarantee that staff raising concerns reasonably and responsibly would be protected from victimisation. Enclosed with the Circular was a resource pack produced by PCaW. This included a copy of the PIDA and a toolkit, comprising an introductory explanatory booklet and a number of case studies, an implementation guide, a computer disk containing educational and promotional materials and other material including checklists. The initiative was in the spirit of the legislation and was welcomed by PCaW.

The Bristol Inquiry Report

11.58 Further impetus towards a culture of open reporting within the NHS came from the Report of the Bristol Inquiry. The Bristol Inquiry began in October 1998 and its Report was published in July 2001. It was set up to inquire into the management of the care of children receiving complex cardiac surgical services at the BRI between 1984 and 1995 and relevant related issues. It was to establish what action had been taken to deal with concerns that had been raised about the services and to identify any failure to take appropriate action.

11.59 The Bristol Inquiry Report concluded that standards in the relevant areas of clinical practice at the BRI had fallen below what was acceptable. Over a period of about four years, from 1991 to 1995, about one third of all the children who underwent open-heart surgery had received less than adequate care. The shortcomings had been recognised by some, in particular Dr Bolsin, a consultant anaesthetist at the Hospital. His attempts to raise his concerns about the standards in the Hospital's paediatric cardiac unit and the poor outcomes had fallen on deaf ears. He first wrote to the Chief Executive of the Hospital Trust, Dr John Roylance, in 1990. This initial, **'rather oblique'** (as the Bristol Inquiry Report described it) approach to Dr Roylance was rebuffed. Thereafter, Dr Bolsin spoke to others including Mr James Wisheart, the relevant consultant in charge, and colleagues within Dr Bolsin's specialty. Later, Dr Bolsin spoke or wrote to anaesthetic colleagues outside the Hospital, to his Hospital peer group among the newly appointed consultants in a number of specialties including surgery, and finally to the management of the Hospital Trust and of the DoH. According to the Bristol Inquiry Report, the difficulties he encountered revealed **'both the territorial loyalties and boundaries within the culture of medicine and of the NHS, and also the realities of power and influence'**. The manner of Dr Bolsin's approach was criticised by his colleagues, and, according to the Bristol Inquiry Report, he seems to have antagonised both senior management and senior medical

figures at an early stage. Thereafter, he felt that he had to take a more circuitous route to make his concerns known. He was not alone in having difficulty in getting a response from Dr Roylance and Mr Wisheart. The Bristol Inquiry Report concluded that **'while Dr Bolsin's actions may not always have been the wisest, and sometimes he gave mixed signals he persisted and he was right to do so'**.

11.60 The Bristol Inquiry Report noted that the systems and hierarchical **'club culture'** in place at the time (and still said to be **'too prevalent'** at the time of publication of the Bristol Inquiry Report) were such as to make open discussion and review of outcome data difficult. Staff were not encouraged to share their concerns or to speak openly. Nursing staff were let down by this culture, which excluded them. Those who tried to raise concerns found it hard to have their voices heard. I note that, in a different context, similar findings were made by the Inquiry into the case of the gynaecologist Rodney Ledward.

11.61 The Bristol Inquiry Report concluded that there was a need in any organisation to have in place systems that allow it to learn and develop; a key feature of such systems should be that all involved must feel able to be open about their work and about the work of colleagues. The Bristol Inquiry Report and the related proceedings before the GMC have, I believe, had an important effect upon attitudes within the NHS. The culture is changing but it is a slow process.

The UNISON and Public Concern at Work Survey

11.62 In May 2003, the public services trade union UNISON published the results of a survey of its members, reporting their experience and levels of awareness of whistleblowing procedures in the NHS. PCaW helped to design the survey, the responses to which were analysed by an academic statistician.

11.63 About 50% of UNISON members did not even know whether their hospital or NHS trust had a whistleblowing policy and about 30% said that their trust would not want to be told if there was a major problem. Unfortunately, of those who had raised concerns, one third had suffered some personal **'comeback'** (not elaborated upon), although one half felt their concerns had been dealt with reasonably. At first sight, these results can only be described as disappointing.

11.64 Mr Dehn's attitude was, however, optimistic, and he was encouraged by the significant improvement in awareness and positive experiences of whistleblowing, as compared with the position when he had first become involved. Most encouraging was the fact that 90% of UNISON members who had had a concern over the previous three years had felt able to raise that concern. This was particularly encouraging because the membership of UNISON is populated by a large number of junior staff. One quarter said that the culture had improved over the previous three years.

11.65 I suspect that these results are significantly better than would generally be expected of results in the workplace outside the NHS. This strongly suggests to me that, when such policies are vigorously and enthusiastically promoted, the benefits can swiftly become apparent. As Mr Dehn said, the message is that, where time is invested in the setting up and administration of a well-designed whistleblowing procedure, that investment is repaid

by an improvement in the culture of the organisation. According to PCaW, the media emphasised the negative but not the positive elements of the survey results.

Public Concern at Work and the NHS: the Current Position

11.66 Mr Dehn told the Inquiry that, since PCaW had been established, 515 of the 3846 expressions of concern received had been from the healthcare and care sectors. In the years 2000, 2001 and 2002, PCaW had received, respectively, 78, 87 and 73 concerns from persons employed in those sectors. There had been a marked increase after 1999, which Mr Dehn ascribed to the Bristol Inquiry and Shipman's arrest in 1998 and conviction in 2000.

11.67 According to Mr Dehn, many NHS organisations now encourage their staff to raise concerns and offer them access to independent advice. Staff are also told that, if, for any reason, they are unwilling to report a concern within the organisation where it has arisen, they may raise it externally.

11.68 In July 2003, the DoH sent a circular letter to the directors of human resources of all NHS trusts, PCTs, strategic health authorities (SHAs) and special health authorities, reminding them of the guidance in Health Service Circular 1999/198. The letter drew attention to the UNISON and PCaW survey and reminded the organisations of the need to introduce and promote a whistleblowing policy for staff. It enclosed a policy pack (in electronic form), produced in partnership with PCaW, which was designed to help NHS bodies to draft a suitable policy. It said that the Government expected organisations to foster a climate of openness.

11.69 Clearly, the DoH and PCaW have been working closely together on the introduction of whistleblowing policies within the NHS. At present, the development of whistleblowing policies is still primarily regarded as a human resources function. I can understand how that comes about; the human resources department will be responsible for drafting the policy and incorporating it into employment contracts. Also, the policy will be intended to cover many different types of concern besides those relating to clinical treatment. However, the purposes of the policy include ensuring that staff feel able to report concerns about clinical treatment, that any such concerns are properly investigated and that lessons are learned. Preparing the policy is a human resources function but making it work should be, as Mr Dehn suggested, an aspect of clinical governance. PCaW welcomed the fact that the reporting of concerns about clinical matters was increasingly being used as a clinical governance tool. PCaW would also like the DoH to give directions rather than exhortations to NHS bodies about the introduction of whistleblowing policies. It would, I think, be sensible if circulars or directions about raising concerns were sent to clinical governance leads and medical directors, as well as to the human resources directors of NHS bodies. These suggestions would help foster the culture of openness about clinical errors and shortcomings that the DoH is seeking to promote.

Primary Care

11.70 Primary medical care is provided by GPs and also by a range of other healthcare professionals such as midwives, health visitors, counsellors and district nurses. These

other healthcare professionals are usually employed by the local PCT or community health trust. Practice nurses are usually employed by the GP practice itself. In addition, there will be practice managers and administrative/clerical staff, whose task it is to organise and manage the smooth running of the practice. In general, they are employed directly by the practice. In Chapter 9, I described some of the difficulties that such staff face if they wish to raise a concern about something that is happening within the practice.

11.71 Historically, PCaW was involved only rarely with the primary care sector. Mrs Webdale had, until recently, not heard of the organisation despite her involvement in AMSPAR and the fact that she is very much in the vanguard of GP practice management. In 2003, the PCaW advice line received about 15 calls in relation to primary care, of which at least three concerned single-handed practice.

11.72 However, at the time of the Inquiry's seminars, the DoH and PCaW were working together on the preparation of guidance for GPs on how to develop and implement a whistleblowing policy for healthcare professionals and other staff in their practice. The Inquiry has now seen a draft of that guidance and of the whistleblowing policy contained in it. The draft policy embodies most of the key elements identified in paragraph 11.46 above. I have described it in more detail in Chapter 9. Staff are advised that, if they are unable to raise the concern internally, or if it has not been dealt with properly, they should approach a named contact at the PCT. The draft policy is clear and reassuring in tone. It contains contact details for PCaW and also mentions that free independent advice may be available from the trade union or professional organisation to which the member of staff belongs.

11.73 It will in my view undoubtedly be beneficial for the raising of concerns to be publicised and promoted in primary care, as it has been in secondary care. It seems to me that the same broad principles should apply in primary care as apply in secondary care. Practice staff at all levels should feel confident that their employment structure allows them to raise concerns without fear of detriment. However, the complex and differing employment/partnership relationships that exist in primary care are not conducive to clarity or certainty about lines of disclosure. As I have already suggested, the option of disclosure to the PCT (or to the GMC) could be written into the whistleblowing policy of a GP practice (the effect of which would be to afford maximum protection to disclosures to those bodies).

Private Healthcare Organisations

11.74 Ms Beverley Cole, transitional project manager of the National Care Standards Commission (NCSC), said that staff working in private care homes, hospitals and clinics often experience even greater difficulty in voicing concerns because they have no PCT to go to. It was a big leap for them to go directly to the NCSC, whose responsibilities included the regulation and inspection of private healthcare organisations, a role now undertaken by the Healthcare Commission.

11.75 Fewer than 5% of referrals to PCaW emanate from private healthcare organisations. When someone from the private sector contacts PCaW with a concern, it is sometimes difficult for PCaW to advise. Very few private hospitals have a whistleblowing policy and this means that it can be difficult for PCaW to give clear advice.

11.76 In my view, staff working in the private sector should have the same opportunity to raise concerns without fear of retribution as staff within the NHS. Also, the same culture of openness should be fostered in non-NHS healthcare organisations as within the NHS. The Healthcare Commission could require all private healthcare organisations to have a clear written policy for the raising of concerns as a condition of registration. The position of staff working in the private sector could be improved if the Healthcare Commission were to be included as a **'prescribed person'** for the purpose of receiving expressions of concern about the private healthcare sector, as well as under the NHS.

The Professional Obligation of Doctors

11.77 The case of Mrs Renate Overton brought to light important questions concerning the duty of a doctor who has concerns about the professional conduct or performance of a colleague, where patient safety may be at risk. My First Report contains my decision about Shipman's involvement in Mrs Overton's death. My Third Report contains an examination of the roles played by the various agencies and individuals who became involved in the case from the time Shipman administered the lethal dose of diamorphine in February 1994. Chapter 10 of this Report deals with the question of whether two consultants at Tameside General Hospital should have reported their concerns about Shipman's treatment of Mrs Overton.

11.78 As I explained in paragraph 11.50, in the early 1990s, the GMC made plain the duty of a doctor to report to an appropriate person or body any concern about the conduct or performance of a colleague that might have an impact on patient safety. The current guidance to doctors appears in the latest (May 2001) edition of 'Good Medical Practice', which is provided to all doctors by the GMC. It says:

> **'Conduct or performance of colleagues**
>
> **26. You must protect patients from risk of harm posed by another doctor's, or other healthcare professional's, conduct, performance or health, including problems arising from alcohol or other substance abuse. The safety of patients must come first at all times. Where there are serious concerns about a colleague's performance, health or conduct, it is essential that steps are taken without delay to investigate the concerns, to establish whether they are well-founded, and to protect patients.**
>
> **27. If you have grounds to believe that a doctor or other healthcare professional may be putting patients at risk, you must give an honest explanation of your concerns to an appropriate person from the employing authority, such as the medical director, nursing director or chief executive, or the director of public health, or an officer of your local medical committee, following any procedures set by the employer. If there are no appropriate local systems, or local systems cannot resolve the problem, and you remain concerned about the safety of patients, you should inform the relevant regulatory body. If you are not sure what to do, discuss your concerns with an impartial colleague or contact your defence body, a professional organisation or the GMC for advice.**

28. If you have management responsibilities you should ensure that mechanisms are in place through which colleagues can raise concerns about risks to patients.'

11.79 The guidance is clear in that it leaves doctors in no doubt about their obligation to report concerns about another health professional. It could usefully be updated to mention that other recipients for the expressions of concerns could include the clinical governance lead and/or other officers of a PCT. It seems to me that the important thing now is to ensure that doctors accept where their duty lies and act accordingly. In Chapter 10, I explored in some detail the reasons why doctors have been reluctant to report concerns about colleagues, even in the face of clear advice that they should. Historically, the culture has been that it is 'not done'. The Inquiry was told that there has been a significant change of culture and attitude since 1994 and that doctors are now far more likely to comply with their duty to report. I have not received evidence directly on that issue but such evidence as has touched upon it suggests that the old culture lingers on. As I have mentioned, the change of attitude was ascribed to, among other things, learning from the events revealed to the Bristol Inquiry. However, the Bristol Inquiry Report itself suggested that the **'club culture'** still prevailed to some extent in 2001. There is other evidence that confirms that this is so. Reports prepared for the GMC by a firm of management consultants (described further in Chapter 26) suggest that, within the GMC, there is still scepticism about the level of reporting of concerns about doctors. Evidence submitted to the Inquiry by the British Medical Association Junior Doctors Committee suggested that junior doctors are unwilling to raise concerns about a consultant because of the fear that consultants might block their juniors' career progression. It is inevitable that deeply engrained attitudes take a long time to change. In my view, it is important that young doctors are imbued with the new culture from the start. But it is also vital that the leaders of the profession consistently put the message across to the present generation of doctors.

The Position of Nurses

11.80 Evidence given to the Inquiry suggests that nurses have faced particular difficulty in reporting concerns about doctors, although they have found it rather easier to report concerns about members of their own profession. Both the Bristol Inquiry Report and the Ledward Inquiry Report said that the culture in medicine inhibited the proper reporting of concerns by nurses about doctors. Most of the nurses who gave evidence about Mrs Overton's case said that, in the past, they would have found it very difficult to raise a concern about the conduct or performance of a doctor. The position was now easier, they said, and either they would report a concern to their line manager, or they would seek guidance from the Nursing and Midwifery Council as to what they should do.

11.81 Mr Ian Hargreaves, retired Regional Director of the Royal College of Nursing (RCN), giving evidence in October 2003, said that he still remained concerned about the continuing existence of a culture in hospitals that discouraged the raising of concerns, although he had noticed improvement over the year or so prior to his retirement in the spring of 2003. He had noticed that NHS trusts and the managers within them showed a greater acceptance of the raising of concerns openly. Although his impression was that change

was happening at the top of organisations, he was unsure 'how embedded it is ... at the front line ... and that is where some of the problems arise'. There are at least two reasons that might explain why the message is not getting through despite the efforts to bring about change. First, it may well be that the perception 'at the front line' is that policies and procedures are regarded as 'fine words', which do not reflect the approach that will be taken in practice. The fear of retribution may still be real. Second, it may be that some people remain to be convinced of the benefits of the new openness in terms of improving patient care.

11.82 The RCN has set up a 24 hour helpline in order to advise nurses who wish to know how to raise concerns. This is regarded as an important element of the support it provides for its members. The College also publishes guidance on raising concerns and offers professional counselling, where needed. From that perspective, therefore, nurses are well supported.

11.83 Mr Hargreaves said that the experience of the RCN is that the raising of concerns can be followed by disadvantage in at least two forms. Usually, such disadvantage comes from the doctor who has been complained about, who may refuse to work with the nurse and/or demand the nurse's transfer. Sometimes, nurses who have raised concerns become the subject of investigation themselves because they may have delayed before reporting and/or because they may be said to have participated in the conduct which was the subject of concern. In such situations, it has been suggested, there is the possibility that, if healthcare professionals witness dangerous practice once and do nothing about it, 'they too have an interest in any subsequent cover-up'. Thus, it may not be surprising if there is a reluctance to raise concerns.

11.84 Mr Hargreaves said that, despite the assistance that the RCN is able to give, the anecdotal evidence received is that it is still very difficult for a nurse to challenge poor practice by a doctor. He said that he still knew of consultants who could put 'fear and trepidation' into nurses and who sometimes used that power to impose their will on the rest of the team, though not necessarily to hide poor clinical practice. He told the Inquiry that nurses who complain about hospital doctors are often moved on to another position, away from the doctors about whom they have raised a concern. This, he said, is counter-productive. It does not resolve the concern about the doctor and it also acts as a disincentive to other nurses who might find themselves in a similar position. First, the nurse's concern is not addressed and, second s/he loses her position. Plainly this kind of situation ought not to arise, although I can see that, sometimes, working relationships within a clinical team may become very difficult following the raising of a concern about poor practice. It seems to me that, where a concern has been raised honestly, every effort should be made to encourage the parties to 'mend their fences'. If that cannot be done, someone will have to move but there should not be a presumption that it is always the nurse. Even less should there be a presumption that it should be the one who raised the concern rather than the one whose conduct gave rise to it. In any event, there must be seen to be a proper, fair and thorough investigation of the concerns.

11.85 Although much of Mr Hargreaves' experience was with nurses employed in a hospital setting, he also knew of instances where practice nurses had raised concerns about their

GP employer. In a single-handed practice, that might mean that they could no longer work with their employer. He said that there was evidence, even in a group practice, that if a nurse raises concerns about one partner, the reaction of the other partners is to 'wrap themselves round that partner' with the aim of preserving the partnership.

A Study of Community Nurses

11.86 A paper published in the Medical Law Review in the summer of 2001[2] revealed the results of a study undertaken in March 2000 of the level of awareness among 70 community nurses in Sheffield of the legal protection afforded to whistleblowers. The community nurses in Sheffield are not in a direct line-management relationship with GPs and it was thought that this might have encouraged openness in the reporting of concerns.

11.87 Nearly one third of the nurses questioned said that at some stage during their career they had had concerns about a GP's performance to the extent they felt patients were at risk, yet over half of them had not reported those concerns. Of the 41% who had reported the concern, no action was taken in more than half of the cases. Only 61% of nurses said that they would report a concern about 'risky' GP performance. Even among those who said that they would report a concern, there was little clarity about the correct reporting procedures. I share the author's concern that this has worrying implications for patient safety.

The Position of Local Authorities

11.88 In the last few years, according to PCaW, local authorities have shown considerable interest in the development of whistleblowing policies. The Inquiry sought and obtained a large number of such policies; two, in particular, from local bodies which provide home support services (Tameside Metropolitan Borough Council Home and Support Service) and warden-controlled accommodation (the New Charter Housing Trust). Each policy meets the criteria I have outlined. Each also offers reassurance that the employer is genuinely interested in receiving reports of concern and states that the worker will be kept informed of progress of any inquiry into the concern and action taken. The Tameside policy states:

> **'As a Home & Community Support Worker you have a duty to report any concerns you may have in the provision of the service to our service users. These could be provided by colleagues, private/voluntary workers, others.**
>
> **We cannot ignore any form of abuse that would affect the well-being of our service users.**
>
> **If you have any concerns:-**
>
> **Procedure**
>
> **1) Ring the office and inform a Manager.**

[2] Julia Burrows. 'Telling Tales and Saving Lives: Whistleblowing – The Role of Professional Colleagues in Protecting Patients from Dangerous Doctors', Medical Law Review, 9, Summer 2001, pp. 110-129.

2) Write a short summary of events in your diary – day, date and the incident. Write the name of the Manager you have spoken to.

(This information will assist you at a later date if you need to make a statement).

This will then be actioned, you will be kept informed of the situation and the outcome.'

11.89 Without hearing extensive and detailed evidence from employees of these and other organisations, it is impossible to assess how well understood and how well implemented these policies are. However, some evidence received from witnesses with responsibility for the operation of these policies indicates that there has been a significant change in attitudes towards the raising of concerns within the last few years.

Improving the Position for the Future

11.90 It appears to me that the position of any person seeking to raise a concern is now very much better than it was even six years ago, when the PIDA was passed. I think that the PIDA has been of great value, both in the relief it has provided for individuals and also in changing general attitudes. However, I am sure that more remains to be done. Mr Dehn told the Inquiry that the operation of the PIDA had been found to be less than perfect in some respects and it was intended that its operation should be reviewed with a view to introducing amendments. That being so, I propose to make some suggestions as to how the PIDA should be amended.

Possible Changes to the Public Interest Disclosure Act 1998

11.91 It is perhaps worth saying again that the object of any legislation of this kind must be to encourage persons to bring forward genuinely held concerns where the bringing forward of those concerns, whether subsequently found to be right or wrong, is in the public interest.

Use of the Word 'Disclosure'

11.92 As I have said, the PIDA refers generally to the making of **'disclosures'**. To my mind, the use of that word conveys the presumption that the 'disclosed' facts are true. What is in fact happening is that concerns or information (that may be true or false) are being 'reported'. I would suggest that thought be given to the possible substitution of the word 'report' for the words **'disclose'** and **'disclosure'**.

Extension of the Categories of Persons Prescribed under Section 43F

11.93 In the context of raising a concern about a doctor or nurse or other healthcare worker, it is not satisfactory that a **'disclosure'** or report made to the GMC or to the Healthcare Commission does not attract second tier protection. If and when the legislation is amended, I suggest that the Healthcare Commission, all the healthcare regulators and possibly even the Council for the Regulation of Healthcare Professionals (now known as

the Council for Healthcare Regulatory Excellence) should be included in the list under section 43F of the Act. I note that the Ledward Inquiry Report recommended that second tier protection should be given to workers reporting a doctor to the GMC.

Good Faith

11.94 As I have explained above, no disclosure (except a disclosure made to a legal adviser in the course of obtaining legal advice) can be a qualifying disclosure unless it is made **'in good faith'**. When Mr Dehn gave evidence, in September 2003, he was asked about his understanding of that phrase. His response suggested that PCaW generally advised that **'good faith'** equated to honesty. He said:

> **'I think two things – and this was an issue that came up slightly with the discussion after the Bristol Inquiry reported – is that the good faith test or the reference to good faith was very much certainly in my understanding – subject to what you and the Chairman would say – is in the narrow legal meaning of ''good faith'', as in honesty or an absence of predominant or improper motive rather than in this sort of slightly more common meaning of ''good faith'' meaning sort of ''virtuous''. So we generally say that the phrase ''good faith'' if we are speaking to a public audience is we equate that with honesty. In other words, it is a disclosure that is made honestly.'**

11.95 The first point to make is that the proper question for the employment tribunal to ask will always have to be framed in the words of the statute. At present, the question will be 'Was the complainant acting in good faith?' and not 'Did the complainant act honestly?' or 'Did the complainant have mixed motives?'

11.96 The question of the meaning of **'in good faith'** in the context of the PIDA arose in the recent case of Street v Derbyshire Unemployed Workers' Centre to which I referred earlier. The facts were as follows. In January 2001, the Derbyshire Unemployed Workers' Centre dismissed the appellant, Mrs Frances Muriel Street, from her employment as an administrator. She had made an allegation that the manager of the Centre had committed a fraud on the Centre by spending time on other projects when he should have been working in the interests of the Centre and that he had spent money on other projects which should have been applied for the benefit of the Centre. Following a disciplinary interview, Mrs Street was dismissed for **'gross misconduct'** and **'breach of trust'** on the basis of her **'unfounded and libellous'** allegations against the manager and because she had refused to co-operate with an investigation into her allegations. Mrs Street's internal appeal against dismissal was unsuccessful. She applied to an employment tribunal (ET) alleging that she had been unfairly dismissed. She claimed that, because they fell within the protection of the PIDA, the circumstances of her dismissal entitled her to claim that it had been 'automatically' unfair. One of the disclosures had been made internally and for that Mrs Street claimed first tier protection. Another was made to the treasurer of the local Borough Council; that person was not a **'prescribed person'** and so, in order to gain the protection of the PIDA, Mrs Street had to satisfy the third tier requirements.

11.97 The ET dismissed Mrs Street's claim for interim relief and 'automatic protection', although her 'ordinary' unfair dismissal claim (i.e. that not attracting automatic protection) was allowed to continue. None of her disclosures was, it was found, protected by the PIDA. The ET held, in relation to the external disclosures, that Mrs Street had reasonably believed that:

(a) her disclosures tended to show that the manager had failed to comply with his legal obligations

(b) they were substantially true

(c) they were not made for personal gain

(d) she would be subject to a detriment if she reported the matter to her employer.

11.98 The ET also held that it had been reasonable in all the circumstances for her to make the disclosures. Nonetheless, her claim failed because the ET found that Mrs Street had not made her disclosures in **'good faith'**. It found that Mrs Street had been motivated by her personal antagonism towards the manager of the Centre. There was evidence that, in one of her disclosures, Mrs Street had made a passing reference to something about the manager which she knew to be untrue. So she had successfully overcome all the hurdles, save for the one relating to **'good faith'**, which applied to both the first tier and third tier disclosures. Mrs Street's appeals to the Employment Appeal Tribunal (EAT) and to the Court of Appeal were dismissed.

11.99 Mrs Street's argument before the Court of Appeal was that the phrase **'in good faith'** meant no more than 'honestly'. As she had proved that she had had a reasonable belief in the substantial truth of her allegations, the requirement of **'good faith'** was satisfied. It would, it was argued, subvert the purpose of the PIDA to hold otherwise. The employers, seeking to uphold the decision of the ET and the EAT, argued that the requirement for **'good faith'** was an additional requirement over and above the need to show a reasonable belief that the allegations were substantially true. The phrase **'in good faith'** must be taken to impose an additional requirement, otherwise it would not have been included in the statute.

11.100 PCaW was allowed, as an interested party, to make written submissions. The main thrust of those submissions, which supported Mrs Street's argument, was that it would seriously damage the working of the PIDA if ulterior motivation – in particular the promotion of a grudge – were to prevent a finding of **'good faith'** and result in the loss of statutory protection. PCaW argued that motives other than the 'pure' desire to promote the public interest are often present when disclosures or allegations are made. The Court should not concern itself with the motive of the messenger but should concentrate on the message and whether there was a reasonable belief in its truth. The purpose of the legislation was to encourage people to bring forward their allegations in the public interest; the fact that they might have mixed or ulterior motives should not matter. PCaW submitted, in the alternative, that an ulterior motive should operate to vitiate **'good faith'** only where it was the predominant motive and/or was 'wicked' or 'malicious'.

11.101 Counsel for Mrs Street adopted these submissions as an alternative to his main submission, arguing that the presence of an ulterior motive should indicate lack of **'good faith'** only if it were the predominant motive.

11.102 The Court of Appeal accepted the employer's submission and held that the words **'good faith'** must require something more than a reasonable belief in the substantial truth of the allegation and something more than 'honesty'. The purpose of the PIDA, it emphasised, was the protection of those who make certain disclosures and were motivated by 'the public interest'. The preamble to the PIDA was cited. That says that the PIDA exists to protect those who make certain disclosures of information in the public interest. The phrasing suggests that the PIDA exists to protect 'individuals' who act in the public interest. I observe that it does not say that the PIDA is to protect individuals who disclose information, the disclosure of which is in the public interest. If it had done so, Mrs Street might have been on stronger ground before the Court of Appeal.

11.103 In the Court of Appeal, Lord Justice Auld observed that the draftsman had plainly contemplated that, although a disclosure might have been made with a reasonable belief that it was true, it would not qualify for protection if it had not been made **'in good faith'**. He said that, **'shorn of context'**, the words **'in good faith'** do have a **'core meaning of honesty'**. However, **'in good faith'** had to be construed in the context of the PIDA. Having considered and drawn comparison with the law of defamation, where the defence of qualified privilege can be defeated by the presence of malice, Auld LJ concluded that the words **'in good faith'** required that the dominant or predominant purpose of the worker had to be that for which the statute was passed, namely, the disclosure of information in the public interest. If another purpose was dominant, good faith would be absent.

11.104 In a concurring judgement, Lord Justice Wall stated that **'good faith'** is a question of motivation and observed that, **'as a matter of general human experience, a person may well honestly believe something to be true, but, as in the instant case, be motivated by personal antagonism when disclosing it to someone else'**. He went on to define the extent to which mixed motivation should undermine the protection afforded by the PIDA, at the same time acknowledging that the question for the ET will always be 'Was the complainant acting in good faith?' and not 'Did the complainant have mixed motives?' He said that the primary purpose for the disclosure of the relevant information should be to remedy the wrong that is occurring or has occurred (or, presumably, to prevent that which may be about to occur). Alternatively, the primary purpose must, at the very least, be to bring the information to the attention of a third party in an attempt to ensure that steps are taken to remedy the wrong. In answering the question whether **'good faith'** was present, Wall LJ said that ETs must be free to conclude that a worker had mixed motives and was not, therefore, acting **'in good faith'**. It would be open to them to conclude – though they would not be bound to do so – that a worker was not acting **'in good faith'** if his/her predominant motivation was not the remedial or preventive purpose described above.

11.105 The Court of Appeal quoted with approval the following words from the EAT decision:

> **'It is not, in our view, the purpose of the Public Interest Disclosure Act to allow grudges to be promoted and disclosures to be made in order to advance personal antagonism. It is ... to be used in order to promote the**

public interest. The advancement of a grudge is inimical to that purpose.'

The Court of Appeal dismissed the appeal. It seems to me the decision was plainly right as a matter of law. As I have explained, the preamble to the PIDA shows that it was intended to protect those who act (by disclosing information) in the public interest; it is not designed to protect those who disclose information, the disclosure of which is in the public interest. The Act plainly intends that protection will be provided only if the person making the disclosure is motivated by a desire to promote the public interest or, as the Court of Appeal has now held, if the person has that as a predominant motive. The position of PCaW, based on its extensive experience of advising people who are considering whether to make a disclosure, is that such people often have mixed motives but should be encouraged to make their disclosure, if it is in the public interest that it be made. In other words, if disclosure is in the public interest, it should not matter whether the person making the disclosure has mixed (or, possibly, even malicious) motives.

11.106 I can see the force of PCaW's argument. If employers are able to explore and impugn the motives of the 'messenger', when trying to justify having taken action against him/her, many 'messages' will not come to light because organisations like PCaW will have to advise those who come to them for advice that, if their motives can be impugned, they may not be protected by the PIDA. The Court of Appeal emphasised that someone in Mrs Street's situation was not totally without remedy; she lost the 'automatic protection' of the PIDA but retained the right to argue that, in all the circumstances, her dismissal had been unfair. That is undoubtedly so, but anyone advising her before she made her disclosure would have had to give very cautious advice. The effect of receiving that cautious advice might well have meant that she would have kept quiet. This would be unfortunate if the information affected, for example, patient safety in a healthcare setting. It is clear that, prior to the decision in Street at least, PCaW did not advise those who sought its advice that the presence of mixed motives would defeat a claim to automatic protection under the legislation.

11.107 It also appears that some organisations operate a policy which guarantees their employees greater protection than is, in fact, provided by the PIDA. Mr Alan Turner, consultant urologist and, since 1993, Medical Director of Peterborough Hospitals NHS Trust, provided the Inquiry with a copy of the whistleblowing policy operated by his Trust. Its language does not have the clarity that would be desirable in an Act of Parliament but its message is tolerably clear. It says:

'No disciplinary action will be taken against someone who makes a disclosure in good faith regardless of whether or not it is substantiated. (Of course, we do not extend this assurance to someone who maliciously raises a matter they know to be untrue).'

The phrase **'in good faith'** in that context, juxtaposed with the state of mind of a person who **'maliciously raises a matter'** s/he knows to be untrue, would not appear to require the absence of mixed motives that the PIDA has been held to require. The policy of the New Charter Housing Trust contains the following paragraph, which again goes further than the PIDA:

> **'If it is discovered you have abused this confidential reporting process and have maliciously or in bad faith or without reasonable belief raised unfounded allegations, we will treat this as a very serious disciplinary matter. No-one who comes forward in good faith and/or with a reasonable belief has anything to fear even if it turns out that their concerns were unfounded.'**

Although the words **'in good faith'** appear in that policy, it would seem that a person with 'mixed motives' would not have **'anything to fear'** so long as s/he had **'a reasonable belief'**, even if his/her concerns were unfounded.

11.108 It seems to me that the assurances given in these two policies are pitched to give the level of protection that the PIDA ought to give – and that PCaW would like it to give – but does not. I think that there should be public discussion about whether the words **'in good faith'** ought to appear in the PIDA. In my view, they could properly be omitted. The three tiered regime of the PIDA, with its incrementally exacting requirements, should afford sufficient discouragement to those minded maliciously to raise baseless concerns. I think that it would be appropriate also if the preamble to the PIDA made it plain that the purpose of the PIDA is to protect persons disclosing information, the disclosure of which is in the public interest. That would serve to focus attention on the message rather than the messenger. The public interest would be served, even in cases where the motives of the messenger might not have been entirely altruistic.

Reasonable Suspicion and Reasonable Belief

11.109 I have already explained that, before any disclosure can become a qualifying disclosure, it is necessary for the worker making disclosure to have a **'reasonable belief'** that the information tends to show that an act falling into one or more of the listed categories of malpractice has been, is being or is likely to be committed. Reasonable suspicion of that is not enough.

11.110 It seems to me that this requirement also may operate against the public interest, especially in cases where the worker has access to incomplete or secondhand information. I am concerned that, in order to make a disclosure even to his/her employer, a worker has to be in the position where s/he could say, for example, 'I believe that this disclosure tends to show that a crime has been committed and my belief is reasonable.' As can be seen in Chapters 8 and 9, if this threshold were applied to workers having the state of mind of Mr Shaw, Mr and Mrs Bambroffe, Mrs Foley, Mrs Shawcross and Mrs Simpson, I doubt that they would confidently have been able to cross that threshold. Moreover, I do not think that anyone answering a call on the PCaW helpline could confidently have assured any of those persons (had they been **'workers'**) that their state of mind was such that they were guaranteed protection.

11.111 The onus should not, in my view, be on an individual to establish **'reasonable belief'** in the case of internal disclosures and disclosures to external regulators. The public interest would, in my view, be best served by substituting 'suspicion' for 'belief'. The Tameside Families Support Group suggested this and I agree with its suggestion.

11.112 I am also of the view that to apply the **'reasonable belief'** test to reports of concern to **'prescribed persons'** sets the threshold for protection too high. In determining whether disclosures to **'prescribed persons'** attract protection, this test requires a **'reasonable belief'** that the information disclosed and any allegation contained in it is **'substantially true'**. This may be desirable and appropriate when the information is a matter of firsthand observation but the position is different when the information is secondhand, perhaps a strong rumour or suspicion. The individual concerned might well not be in a position to say that s/he reasonably believes **'that the information disclosed, and any allegation contained in it'** is **'substantially true'**, although s/he might strongly suspect that to be the case and that suspicion might well warrant investigation. In an area where the natural tendency will be for people to 'sit tight' or 'keep quiet' I take the view that to apply as a threshold 'reasonable belief in substantial truth' will result in the regulators remaining unaware of cases of which they should be aware.

11.113 The third **'reasonable belief'** test, applicable, for example, to disclosures to the media, depends on the worker having the **'reasonable belief'** that his employer will 'respond badly' to the allegation, before an external disclosure (other than to a regulator) becomes protected. I do not regard this as being so onerous. It is far less exacting to expect a worker to be able to explain the basis for a belief about the likely response of his/her employer than it is to require justification of a belief about a state of affairs of which s/he may have only partial knowledge or understanding.

Internal Disclosures

11.114 As I have explained, the PIDA affords protection most readily to disclosures made to the worker's employer, to a person authorised by the employer's whistleblowing policy to receive them directly or to the person with **'legal responsibility'** for the malpractice in question. In my view, these provisions leave some employees in a difficult position. In particular, I have in mind employees in very small organisations. There may be no whistleblowing policy or it may be impossible in practice for an employee to raise a concern directly with the employer. There may be no person or organisation that appears to have any legal responsibility for the malpractice in question. Take, for example, the position of a nurse who is directly employed by a GP practice and who becomes suspicious that one of the GPs in the practice is guilty of irresponsible prescribing of controlled drugs to patients. The practice nurse may well not want to raise his/her concerns directly with the practice but deserves, it seems to me, a high level of protection if s/he wishes to report those concerns to the PCT. It is arguable – but far from certain – that such protection exists under the PIDA. It could be said that the PCT has **'legal responsibility'** for the GP's acts because it has a duty of quality imposed by the Health Act 1999 in respect of the services provided by the GP. However, the argument might well fail. Protection under the PIDA would be very unlikely to be available where the concern was that the GP was prescribing controlled drugs irresponsibly for him/herself.

11.115 The problem could be resolved in the particular example I have given by imposing a requirement that each GP practice have a policy authorising disclosures to be made directly to the PCT. That is desirable and, indeed, it is contemplated by the draft policy to which I refer in paragraph 11.72. However, there may be other situations in which the

problem cannot be resolved so easily. I have in mind, for example, the position of an employee in a small firm or business who begins to suspect that his/her employer may be defrauding clients. He or she is likely to feel unable to raise the matter within the firm, yet may not feel sufficiently certain to make a report to the police. A report made to a trade or professional organisation would attract protection under the PIDA only at the third tier, with all the additional hurdles that must be overcome before protection is secured. A possible but unwieldy option would be for the range of **'protected persons'** to be extended. The preferable solution – and I suggest this for consideration only – may be to consider requiring all employers to specify a third party recipient for expressions of concern. Provision could be made to allow third tier disclosures by employees of employers who did not take this step to be treated as second tier disclosures. I recognise that this suggestion is outside my Terms of Reference but, if the PIDA is to be reviewed, it occurs to me that it might help for such a provision to be included.

Reporting Concerns in Relation to Linked Organisations

11.116 It will sometimes happen that an employee in one healthcare organisation develops concerns about the conduct or performance of a healthcare professional in another organisation. The most common situation will probably be where a concern arises in a hospital about the care provided by a GP or *vice versa*. The case of Mrs Overton is an example. A hospital employee who is concerned about the treatment provided to a patient by a GP will or should know of the policy for raising concerns operating within the hospital but may not know of the policy operating within the PCT or GP practice by which the patient has been treated. In cases such as this, there will not usually be any anxiety about loss of employment or fear of any other kind of retribution; the only problem may be one of ignorance or confusion as to what to do.

11.117 I suggest that policies for raising concerns, certainly in the healthcare sector, should in future be capable of being used for the raising of concerns by and about persons who do not share common employment. One example has been the recent development in Hyde, whereby, following the publication of the Inquiry's Third Report, which dealt with Shipman's unlawful killing of Mrs Overton, the local PCT and the local Hospital Trust have joined forces to devise a very useful policy. In essence, the policy provides that a concern should be raised initially within the organisation of the employee who has the concern. The concern is then assessed by a member of senior management within that organisation. If the concern is considered well founded, it will be passed on to the organisation employing the person about whom concern has been expressed. That organisation will investigate the concerns but the directors of both organisations should agree the action to be taken, including disciplinary action. I suggest that other NHS trusts and PCTs should develop such policies. On a wider footing, it would be sensible for employees in general to be told that, if they have concerns about persons employed by another organisation and do not know what to do, they should seek advice from their own employers. Not everyone can have reciprocal arrangements.

Self-Reporting and the No-Blame Culture

11.118 There has in recent years been a move within the NHS to encourage doctors and nurses to report any incident in which they have made an error resulting in harm or giving rise to

a **'near miss'**. The idea is to promote an atmosphere of openness in which, instead of seeking to blame someone who has made a mistake, the organisation will seek to learn from its mistakes. In many ways, this is the ideal situation and, if it were to come to pass, there would be very little need for the reporting of concerns. However, the evidence I have heard suggests that we are a long way from that ideal at present. In this context, I should say that I have already explained the proposed **'duty of candour'** in Chapter 7. I have not analysed the topic in detail but I share the concerns of the GMC and of the RCN.

Concerns Felt by Others

11.119 So far I have dealt mainly with the position of employees. Nevertheless, as I explained at the beginning of this Chapter, some of the constraints on disclosure by employees apply also to others whose concerns do not arise in the employment context. For example, although the concerns of Mr Shaw and Mr and Mrs Bambroffe arose in the course of their work, they had no employer to whom they could take them. Mr and Mrs Bambroffe had a professional association but they cannot have thought it appropriate to discuss their anxieties with its officers.

11.120 The fear of litigation operated on the minds of at least two of the people who had concerns about Shipman. Mr Shaw and Dr Reynolds both feared the prospect of potentially ruinous defamation proceedings if they were to 'speak out'. At the time when they became concerned, of course, the very idea that Shipman might have been killing his patients would have been considered unthinkable by most members of the public. Also, much of the evidence that has since been uncovered was not available to either of them. They had no way, therefore, of taking further steps to refute or confirm their suspicions. Nor was it their responsibility to do so. All they wished to do – and all they could reasonably be expected to do – was to bring their suspicions to the attention of the proper authorities and to leave it to them to investigate.

11.121 In fact, neither Mr Shaw nor Dr Reynolds need have feared an action for defamation. However, they would not have known that without legal advice. They need have had no fear for two reasons. First, if they had confined themselves to saying that which was in fact true, they would have had no need to worry, because statements that are true cannot be defamatory. If Dr Reynolds had provided the statistics of the number of cremation certificates that she and her partners had been asked to sign for Shipman, who had a patient list of 3000 patients, and those that she and her partners asked other doctors to sign, in respect of their list of 8000 patients, she would not have needed to make any allegation of wrongdoing against Shipman, even though the implication behind her report would have been clear. The facts alleged would have been plainly true. Mr Shaw's information was less demonstrably true because what he was concerned about was not the number of patients who were dying but the fact that they did not appear to have been ill beforehand. The truth of those facts would have been more difficult to demonstrate although, in the event, we now know that he was right.

11.122 Second, even if Dr Reynolds and Mr Shaw had not been at all sure of the truth of the facts, they could have successfully defended an action for defamation, provided that they had raised their concerns in an appropriate quarter and had not been actuated by malice.

They could have relied upon the defence of qualified privilege. The defence of qualified privilege applies when the person making the communication does so because s/he has some legal, social or moral interest or duty to make it and where the person to whom it is made has some corresponding interest or duty to receive it. The defence classically avails those who report concerns to the police or to other investigatory or regulatory bodies. The defence is available even where it turns out that the information communicated is untrue. In order to strike a balance between encouraging the fulfilment of the duty and discouraging the malicious making of unfounded complaints, the defence is not available where the making of the communication is actuated by malice or improper motive.

11.123 Had Mr Shaw reported his concerns to an appropriate body, he would have done so out of a sense of moral obligation. Dr Reynolds considered herself to be under a professional duty to make the report that she did and, in view of the nature of the information to be communicated in each case, no one would seriously doubt the existence of the duty. Mr Shaw might have needed advice about the suitable recipients of the information, i.e. those organisations with a duty to receive it. The GMC, the West Pennine Health Authority, the Coroner and the police all come to mind. In Dr Reynolds' case, another appropriate recipient might have been the medical referee of the crematorium at which the bodies of many of Shipman's former patients had been cremated. Dr Reynolds consulted her defence organisation. Neither Mr Shaw nor Dr Reynolds need have feared the suggestion that they were actuated by malice or improper motive and nor would others in this situation. Moreover, the House of Lords has stated that judges and juries should **'be very slow to draw the inference that a defendant was so far actuated by improper motives as to deprive him of the protection of the privilege unless they are satisfied that he did not believe that what he said or wrote was true or that he was indifferent to its truth or falsity'** (in the case of Horrocks v Lowe[3]). In short, a person who feels under a duty to raise a concern and does so as a result of honestly held suspicions need not fear an action in defamation, provided that care is taken in making the report to the right quarter. For that, some people, such as Mr Shaw, may need advice. Such advice should be made readily available.

11.124 I mention in passing that the protection that the common law gives against proceedings in defamation is rather wider than that given under the PIDA to workers who have suffered a detriment on account of making a disclosure. The effect of the decision in Horrocks to which I have referred, is that, at common law, if it appears that the person making the allegation had mixed motives, judges and juries should not closely scrutinise those motives to ascertain which was predominant. Instead, they should concentrate on whether the person believed in the truth of what s/he said. If the words **'in good faith'** were removed from the PIDA, the test under the PIDA would be brought more closely into line with the test for 'malice' in defamation proceedings. It would seem to me to be desirable that the tests should be as close as possible so that a person thinking of making a report can be safely advised about his/her position in respect of both types of proceedings. It would also bring the test to be applied under the PIDA closer to the terms of many whistleblowing policies currently in force.

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[3] [1975] AC 135, 150.

The Availability of Advice

11.125 I have said that people who are contemplating making a report or disclosure need advice on how to go about it for reassurance and so as to avoid, so far as possible, any adverse consequences. If there is a policy governing the raising of concerns in operation at the place of work, that should provide all that is needed. If there is not, there may be other sources of help and advice connected with the workplace, such as a trade union or professional association. However, there is a *residuum* of cases in which there is no or no appropriate source of advice. The problem is exemplified by Mr Shaw, who had no employer and no professional association to advise him. Another type of case arises where the information to be divulged is so sensitive in the locality in which it arises that the person concerned is unwilling to speak to anyone in that area. A number of witnesses told the Inquiry that, if they had had concerns about Shipman, they would not have felt able to talk to anyone in Tameside because Shipman was so well known and respected. These witnesses told the Inquiry that what they needed was an organisation upon whose confidentiality they could rely utterly, which was in a position to give them sound advice and which was completely unconnected with the subject of their concerns or the area in which they arose. Those requirements seem to me to be entirely reasonable.

11.126 How and by whom should such advice be given? PCaW provides this kind of advice and is prepared to give advice to callers about all manner of problems related to the raising of concerns. A caller will not be turned away because s/he is not an employee raising concerns about events occurring in the workplace. However, at present, PCaW is not very well known and money would have to be spent on publicising its services if it were to be able to fulfil the need I have identified. I confess that I had not heard of the organisation before this Inquiry began. Another factor is that it is a charity and I am not sure that it would be fair to impose upon it a duty to advise any member of the public about the raising of any concern outside the field of interest that it has taken upon itself. It could certainly not be expected to fund the necessary publicity. However, I do not doubt its ability to give sound advice, in confidence and in a helpful and supportive way.

11.127 If financial support can be provided and if PCaW is willing, then it could undertake this function. If not, the need will have to be met in some other way by some other organisation. In a different context, the Inquiry has considered the idea that there should be a 'single portal' for the signposting of all complaints about the healthcare system. In the event that a 'single portal' is set up for that purpose, I envisage that it would direct persons seeking advice to PCaW or whichever organisation is to undertake the function I have described.

Conclusions

11.128 The value of the honest raising of concerns within the healthcare services should not, in my view, be underestimated. Together with patient complaints, of which I shall say more later in this Report, it provides an important source of information about clinical performance and has a vital role to play in clinical governance. The culture that for many years effectively prevented the raising of such concerns is changing but the old attitudes have not yet by any means died out. It is important, in my view, that those in positions of leadership, whether in managerial positions or at the head of the professions, should be

committed to openness of reporting, not only by endorsing policies and the like but by practising what they preach.

11.129 I have already suggested a number of ways in which the momentum for change can be kept up. I have suggested amendments to the PIDA which would, if implemented, strengthen the position of those who raise concerns. I shall not repeat those suggestions here. I have also suggested that policies for the raising of concerns across different sections of the healthcare services should be promulgated. I have called for the provision of an advice service available to any person, whether or not a healthcare professional, so as to provide the advice, encouragement and reassurance necessary for them to bring forward concerns which it is in the public interest to report.

CHAPTER TWELVE

Clinical Governance

Introduction

12.1 I have already said in Chapter 5 that clinical governance is the means by which it is intended that NHS organisations should discharge the duty of quality imposed by the Health Act 1999. The theory of clinical governance developed from the initiative of corporate governance which originated in the early 1990s as a means of addressing unacceptably low standards in the world of business. It was heralded in the White Paper 'The New NHS', published in December 1997. At that time, there was a recognition on the part of Government that standards of care in the NHS were very variable and that this was leading not only to harm to patients, but also to loss of confidence on the part of the public. Clinical governance was to address that problem.

12.2 Clinical governance is defined by the Department of Health (DoH) as:

> **'... a framework through which National Health Service organisations are accountable for continuously improving the quality of their services and safeguarding high standards of care by creating an environment in which excellence in clinical care will flourish'**.

12.3 I personally did not find that definition easy to understand and it does not seem surprising that, in the early days at least, there was a great deal of confusion and uncertainty in the medical profession about the concept of clinical governance and about what it would mean in practice. Some general practitioners (GPs) were suspicious about its purpose (believing it to be an attack on their independent contractor status) and hostile to its introduction. These feelings were heightened by the speed with which it was implemented and by the changes to the organisation of primary care which were occurring at the same time.

12.4 I hope that my own understanding of the concept of clinical governance has improved in the last few months. For those who are still unfamiliar with it, I shall attempt, not to define it, which seems to me well nigh impossible, but to describe it. Clinical governance is a system for improving the standard of clinical practice in the NHS and for protecting the public from unacceptable standards of care. The system comprises several different types of activity which should all fit together into a framework. This integrated system has replaced the previously disparate and fragmented approaches to the improvement of quality of care. The different types of activity include continuing education, the introduction and maintenance of good management systems, the promotion of clinical effectiveness, clinical audit, risk management, research and development and the fostering of an ethos of openness and accountability. Some of these activities are developmental in nature, such as continuing education and the dissemination of good practice. Risk management, by which organisations seek to analyse untoward events and learn from them, is another example of a developmental activity. Other activities are of a monitoring or supervisory nature; for example, organisations are required to collect data and information about the care being provided by their clinicians. This should enable the

organisation to detect poor performance so that it may be corrected, but data collection should also draw attention to good performance and therefore have a developmental effect. Yet other activities are designed to encourage clinicians to monitor themselves, with the intention that this should provide the opportunity and incentive to improve clinical performance. For example, clinicians are provided with data about their own performance and that of their team or group; they are also encouraged to audit their own activities and those of their colleagues.

12.5 DoH guidance published in 1999 required NHS trusts and primary care organisations (PCOs) to identify clinical governance leads (who were to be clinicians) and to set up appropriate structures for overseeing clinical governance within their organisations. Once the primary care trusts (PCTs) came into existence, they appointed their own clinical governance leads and sub-committees. Many of these clinical governance leads were local GP volunteers, who were uncertain of their precise role and lines of accountability. Some found their dual role as members of the local medical community and part of the PCT 'establishment' difficult to reconcile. Others were uncertain about how they could seek to promote good clinical governance without any 'teeth'. There were, however, many within the medical profession who welcomed the emphasis on quality that clinical governance brought and who viewed positively the opportunity of working with PCT managers to raise local standards.

Structures and Systems

12.6 At the Inquiry's seminars, Professor Aidan Halligan, Deputy Chief Medical Officer for England and Director of Clinical Governance for the NHS, emphasised that the essence of clinical governance was 'a system of accountability for care'. Delivery of clinical governance was, he said, dependent on 'architectural artifices': structures, processes, mechanisms and clear accountability arrangements.

12.7 It is, of course, evident that good governance – of whatever organisation – requires sound structures and well-designed systems. If there are no effective lines of management accountability, for example, no one will take responsibility when things go wrong. If no proper complaints system is in place, complaints will go unrecorded and potentially valuable information about poor practice or outcomes will be lost. If an organisation has no whistleblowing policy, staff may be deterred from reporting colleagues who may be guilty of dishonesty or incompetence. An absence of a system of financial checks may result in widespread fraud.

12.8 However, sound structures and systems are not, on their own, enough to secure good governance. A complaints system is of no value unless those who are intended to use it (customers, clients, patients, etc.) know of its existence and unless staff within the organisation are trained to operate it effectively. A whistleblowing policy will not be used unless staff are made aware of it and are confident that, if they voice their concerns, those concerns will be taken seriously and the organisation will deal with them fairly. It is essential to ensure that clinical governance extends to every layer of a NHS organisation so that all members of the organisation are putting into practice the systems intended to promote quality.

12.9 In the context of primary care, this means extending the systems, not only to the level of PCT staff, individual GPs and other healthcare professionals, but also to members of staff of all general practices in the area. Under the new General Medical Services (GMS) Contract, contracting practices are required to have in place an effective system of clinical governance.

The Implementation of Clinical Governance by Primary Care Trusts

12.10 At first, the term 'clinical governance' may have sounded alien; however, its translation into practical action often proved rather less daunting than had been expected. Some of the methods used were not new – for example, the monitoring of complaints against GPs, the production of data comparing the performance of one GP practice with others in the area, the encouragement of clinical audit and the monitoring of prescribing. The effect of clinical governance was to bring together these initiatives (and many others) into one coherent policy. There were, however, novel areas to be tackled, notably the implementation of the guidance contained in the new National Service Frameworks (NSFs) and issued by the National Institute for Clinical Excellence (NICE). In the early days of clinical governance, the development of strategies to monitor and improve adherence to this guidance was a major priority for the PCTs.

12.11 Recent evidence suggests that PCTs are using a wide variety of strategies to monitor and improve the quality of care locally. In this Chapter, I shall discuss a number of those in most common use. In doing so, I shall consider how (if at all) those strategies might have a beneficial effect on quality of care. I shall also consider the extent (if any) to which each of the various strategies described gives rise to meaningful information that might be of assistance to a PCT in assessing whether an individual GP is giving an acceptable standard of care to patients.

12.12 The strategies which I shall examine are:

(a) monitoring of GPs' prescribing

(b) monitoring of GPs' referrals

(c) monitoring of performance indicators and/or comparative data about the performance of general practices

(d) monitoring of data collected in connection with the new GMS Contract

(e) practice visits

(f) practice accreditation

(g) monitoring and analysis of patient complaints

(h) operation of systems for identifying and dealing with poorly performing GPs

(i) clinical audit

(j) risk management

(k) significant event review

(l) appraisal.

(a) Monitoring of General Practitioners' Prescribing

12.13 In Chapter 4, I described briefly the ePACT.net system, which is used by PCTs to monitor GPs' prescribing. This monitoring is carried out primarily in order to enable the medical and pharmaceutical advisers employed by PCTs to offer advice to GPs about the efficacy and cost-effectiveness of the drugs they prescribe. However, prescribing data might reveal defects in the quality of a doctor's prescribing. For example, it might show that s/he frequently prescribes drugs that have been replaced by better alternatives or that are inferior to newer drugs which are available. It might show that the doctor is prescribing drugs that are known to be of limited clinical value, such as nasal decongestants. The data might show that a doctor is prescribing significantly less than the average quantities of drugs used in cardiovascular disease. All these circumstances might be indicative of defects in a doctor's prescribing practice. They might also indicate a poor standard of care going beyond the issue of prescribing. For example, a doctor who persistently prescribes drugs which have been replaced by more effective alternatives may be out of date in other areas of his/her practice.

12.14 The data might even suggest the possibility of criminal activity (e.g. if a very high level of benzodiazepines were being prescribed on a regular basis). PCTs are now advised to run quarterly analyses for prescribing of opiates, benzodiazepines and amphetamines by every GP in their area. The analyses can be carried out by means of simple techniques, using the ePACT.net system. The range of drugs for which these techniques are available is expanding as new problems, involving different drugs, come to light. Of course, prescribing data can only highlight a pattern of prescribing which appears unusual. It cannot afford an explanation for the unusual pattern. The data requires interpretation in the light of local factors and of the circumstances of the individual patient(s) for whom the drugs were prescribed, before a judgement can be reached.

12.15 The monitoring of prescribing practice began primarily as a tool of financial management. However, it has now developed into a part of clinical governance. As I have said, it can raise questions about the quality of a doctor's prescribing. Those questions can lead in turn to consideration of the doctor's performance more generally. If a problem is identified, it may be capable of being remedied by the provision of advice and information. It may be more complex and require, for example, referral to the PCT's performance procedures. In either case, it can provide a valuable source of information about quality of care.

Problems with Prescribing Data

12.16 In the past, the value of prescribing data was reduced by the fact that it was available only at practice level. It was not possible to obtain data for an individual doctor, unless that doctor was a single-handed practitioner. If a doctor was a member of a large group practice, his/her prescribing pattern would have had to be very unusual indeed in order to be evident from the data relating to the practice as a whole. More often, any problems

with the quality of the prescribing of an individual member of the practice would have been obscured by the data relating to others.

12.17 Analysis of prescribing at the level of an individual prescriber is now possible. Each prescriber within a GP practice has an individual prescriber code printed on his/her prescription forms. The Prescription Pricing Authority (PPA) now produces data referable to individual prescribers. The accuracy of the data is, however, reduced if (as has been common in the past) members of a GP practice use prescription pads belonging to other members of the practice. A further problem which became evident during the course of the Stage Three seminars was that a computer generated prescription issued by one doctor might, if the computer were programmed in a certain way, carry the name of the doctor with whom the patient was registered (or, under the new GMS Contract, the patient's preferred doctor), rather than that of the doctor who had prescribed the medication. This can be prevented by adjustment of the computer but, in order for this to be done, the practice must first be aware of the problem and the need to avoid it. I have recommended in the Fourth Report that all prescribers should use only their own prescription pads, marked with their own professional registration numbers, so that all prescribing can be correctly attributed to the clinician responsible for it.

12.18 Problems also arise with repeat prescriptions. It is common for members of a GP practice to check and sign repeat prescriptions for the whole practice on a rota basis. The doctor who signs the prescription may not, therefore, be the doctor who originally prescribed the drug in question. He or she will have had no real clinical input into the choice of medication. This has the inevitable effect of rendering the prescribing data for the whole practice inaccurate. It could have the effect of obscuring an unusual pattern of prescribing by one member of a practice. Some practices, alert to this problem, have taken steps to avoid it in the past but many have not.

12.19 At the Stage Three seminars, Dr Jim Smith, Chief Pharmaceutical Officer for England, DoH, explained that a new system of dealing with repeat prescriptions had been successfully piloted in several areas and would soon be put into general operation. Under this system, a doctor who wishes to prescribe medication on a long-term basis will write a prescription to provide for periodic dispensing over a period of up to a year. The patient will leave the prescription at the pharmacy of his/her choice, will collect the drugs every few weeks and need not return to the surgery until the expiry of the prescription. The pharmacist will be responsible for reviewing the appropriateness of the continuing supplies dispensed under the prescription during its currency. Not only will this system save a great deal of time for GPs, it will also allow greater accuracy of the prescribing data because the whole quantity supplied under the prescription will be attributed to the doctor who made the original decision.

12.20 Another problem is the use by non-principals, such as locums and GP registrars (i.e. trainees), of prescription pads belonging to GP principals. These non-principals do not at present have their own individual prescriber codes. Instead, they are required to endorse their prescriptions with a red 'T' (locums) or 'D' (registrars) to differentiate themselves from the principal whose prescription pad they are using. There is no means of identifying which non-principal is the prescriber. Consequently, no individual prescribing data is

available for an individual locum and there is, therefore, no way of ascertaining whether his/her prescribing practices are in any way unusual. Furthermore, the use of their prescribing pads by others has the effect of 'blurring' the data relating to GP principals.

12.21 Steps are being taken to change these arrangements. It is hoped that, in the future, locums, deputies and other non-principals will be allocated their own unique prescriber codes. This should greatly enhance the opportunity to detect aberrant prescribing by a GP non-principal. However, it will be up to the PCT on whose list the locum is included to take responsibility for monitoring his/her prescribing and for any follow-up action which may be necessary.

12.22 Another difficulty is that the data currently available may not reveal a complete picture of an individual doctor's prescribing. If s/he issues any private prescriptions those will not be included within the data. This is a serious *lacuna* that can result in excessive or aberrant prescribing by a doctor remaining undiscovered. In my Fourth Report, I recommended that all prescriptions, whether NHS or private, should go to the PPA for processing and should be included within the prescribing data available to PCTs. This seems to me vital if PCTs are to have the information about prescribing which they need for the purposes of discharging their clinical governance responsibilities.

12.23 Current prescribing data does not necessarily reflect the prescribing practice of individual doctors and cannot, therefore, provide reliable information about the quality of practice of an individual doctor. Only if the various changes that I have described are implemented will it be possible to use it as a reliable source of information for clinical governance purposes.

(b) Monitoring of General Practitioners' Referrals

12.24 There seemed to be general agreement among witnesses and participants in the Inquiry's seminars that data about GPs' referrals to other services (in particular, hospital services) was both unreliable and difficult to interpret. It is not clear what, if any, correlation there is between referral patterns and quality of care. That being the case, the usefulness of referral data is plainly limited. Also, it is available only at practice level, so gives rise to problems similar to those already mentioned in connection with past prescribing data.

(c) Monitoring of Performance Indicators and/or Comparative Data about the Performance of General Practices

12.25 Since the mid-1990s, some PCOs have developed a range of performance indicators, compiled from the data available to them. They have compared the indicators as between practices within their own areas and practices elsewhere. They have used the results in different ways. I have previously mentioned in Chapter 5 that such indicators have sometimes been used as a trigger for investigations into the performance of certain doctors.

12.26 Many experts have doubts about the use of performance indicators as a means of assessing quality. At the Inquiry's seminars, Professor Martin Roland, Director, National Primary Care Research and Development Centre and Professor of General Practice,

University of Manchester, referred to his experiences on the Manchester Performance Panel. The Panel responded to concerns expressed about doctors, rather than (as was done elsewhere) using performance indicators to identify potential cases of poor performance. Professor Roland felt that experience had shown that the approach of the Manchester Panel was probably the right one. He pointed out that the types of problem the Panel identified (e.g. poor communication within a practice, poor teamwork, inability to work with others, poor communication with patients and poor management) were the most difficult issues to identify by means of routine data.

12.27 Dr Sarah Wilson, Director of Public Health and Medical Director, Trent Strategic Health Authority (SHA), said that, before attending the Inquiry's seminars, she had contacted the PCTs in her area to find out what clinical governance arrangements they had in place. Some had developed very sophisticated performance indicator sets, using such indicators as prescribing data, mortality rates, immunisation rates, screening uptake rates and complaints. They operate a 'traffic light' system whereby a GP who has a 'red light' (indicating that s/he is an outlier) on more than a certain number of indicators is targeted for enquiries to be made. Dr Wilson asked the clinical governance leads of the PCTs that operate this system whether there was any correlation between the incidence of a lot of 'red traffic lights' and a perception within the local health community that the performance of the doctor in question was poor. They told her that the only indicator which gave rise to such a correlation was an excess of complaints against a doctor. Dr Wilson said that there was a real concern that clinical governance leads were doing a great deal of work in developing indicator sets using data which was never intended for the purpose of determining the quality of care given by an individual doctor. Ms Fiona Freedland, Legal Director, Action against Medical Accidents (AvMA), and a non-executive director of Hackney PCT, expressed doubt, based on her own experience of the use of performance indicators, about the extent to which there was any correlation between such indicators and the competence of a GP.

12.28 Professor Dame Lesley Southgate, Professor of Primary Care and Medical Education, University College London, and Professor Richard Baker, Director, Clinical Governance Research Development Unit, University of Leicester, also referred to the limitations of the data currently available to PCTs. Such limitations exist even when the data is used to examine quality of care at practice – rather than individual doctor – level. For example, Dame Lesley mentioned problems with handling the data and with using data collected for one purpose to fulfil a different purpose. The problem becomes much more acute when an attempt is made to use the data to assess the quality of care given by an individual doctor.

12.29 Both Dame Lesley and Professor Baker pointed out that indicators and other similar data provide no information about such matters as a GP's communication skills, relationships with patients and clinical care. All these matters are vital to an assessment of quality of care.

(d) Monitoring of Data Collected in Connection with the New General Medical Services Contract

12.30 In order to discharge their responsibility for administering payments under the new GMS Contract, PCTs are obliged to collect a large quantity of data from individual GP practices.

Some of this data is similar to that collected previously in connection with targets for certain types of preventive treatment and qualification for financial incentives. According to Professor Roland, however, the new GMS Contract will 'alter radically' (by which I understand him to mean materially increase) the information available to PCTs about the quality of care being provided in practices operating under GMS Contracts. There will be the same framework of assessment for practices providing personal medical services (PMS). It is not yet clear whether individual PCTs will have the expertise or resources necessary to analyse the huge amount of data that will be available to them, and to use it to improve quality of care.

12.31 The data collected is practice-based and is not, except in the case of a single-handed practice, referable to an individual GP. At the Inquiry's seminars, Professor Roland pointed out that the GMS Contract is deliberately aimed at practice level which is, in many instances, an appropriate level at which to consider patient care. He gave the example of an individual doctor who may be poor at managing diabetes, but has a first class nurse who takes responsibility for managing diabetic patients. Those patients will get good care from the practice, notwithstanding the weakness of the individual doctor, and that is what matters. Provision of data at practice level is therefore entirely appropriate for the purposes of the GMS Contract. However, that same data cannot be used to evaluate the quality of care given by an individual doctor within the practice.

12.32 Participation in the GMS Contract's quality and outcomes framework (QOF) is voluntary, although failure to participate will mean that a practice will not qualify for additional payments under the GMS Contract. It remains to be seen whether many practices will choose not to participate in the QOF or will do so only to a limited extent. For those practices which choose this course, little or no data will be available. I suppose, however, that the very fact that a GP practice declines to participate in the QOF – or participates only to a limited extent – may in itself raise questions about the standard of care offered by that practice and may cause a PCT to subject it to closer scrutiny.

(e) Practice Visits

12.33 The clinical governance leads of many PCTs have developed a system of regular, routine practice visits. Ms Freedland spoke about the importance of these visits. First, they enable the clinical governance lead to form a relationship with GPs and to encourage a greater sense of 'ownership' of clinical governance by the profession. They have the additional benefit of enabling the clinical governance lead to observe such features as arrangements for storage of medicine and vaccinations and for infection control and the cleanliness of the surgery. They offer an opportunity to ask questions of practice staff about the procedures and policies in operation. Dr Wilson said that visiting GP practices in a systematic way is what clinical governance leads would like to do. By visiting, they can get 'a real sense of the practice'.

12.34 The form that clinical governance visits take – and, indeed, whether they take place at all – depends on the co-operation of the practice in question. Ms Freedland said that there were 'a couple of GPs' in her PCT who had denied access to the clinical governance lead. On the whole, however, the system of visiting had worked well. Dr Wilson said that, in her

area, there had been problems in the past about gaining access, but these had largely been resolved. On occasions, practice staff and practice managers had taken the initiative and arranged a visit from the PCT. Clinical governance leads (usually members of the local professional community) were conveying the message that the PCT was not there to 'beat up' GPs, but to give support and assistance. This approach appeared to have had the desired effect.

12.35 While the fact that such visits are taking place is clearly to be welcomed, it seems to me that the approach which Dr Wilson described must limit the extent to which a visiting clinical governance lead can 'challenge' members of the practice about data relating to the practice which the PCT holds or, indeed, about any other aspect of its activities. To do so would hardly be consistent with the PCT's stated role of a giver of support and assistance. This was well illustrated in the evidence of Dr Michael Taylor, Chairman of the Small Practices Association and Clinical Governance Lead, Heywood and Middleton PCT. He said that, if he visits a practice in his PCT, members of the practice know that he is never there in anything other than a supportive capacity. If he has concerns about a colleague, he has in place arrangements with neighbouring PCTs and they will carry out any necessary investigation. Nevertheless, it seems to me that there must be an intermediate stage – where no positive concerns have yet arisen but probing questions need to be asked – at which it is difficult for a PCT to maintain its wholly supportive stance. In such circumstances, the position of a clinical governance lead, usually a local GP, must be particularly difficult. At the seminars, Professor Halligan observed that clinical governance visits could have 'perverse consequences'. They could, he said, 'reinforce subversive behaviour by amplifying a culture of fear'. He said that the value of such visits had consequently been 'patchy'. He emphasised the need for a change of culture.

12.36 I am surprised and disappointed that an annual visit by officials of a PCT to a GP practice should be viewed with such suspicion – even fear – by some. It is plainly unsatisfactory that a practice should decline to permit a clinical governance visit at all. There must be a concern that those practices which are unwilling for visits to take place are the very ones where standards of care may be unacceptably low. Their failure to permit a visit has the effect of thwarting the PCT's attempts to discharge its clinical governance responsibilities.

12.37 I have already mentioned in Chapter 5 that PCTs will undertake annual reviews of the performance of all contracting practices under the arrangements for the new GMS Contract. These reviews will include a visit to the practice premises and discussions with the contractor. They will be obligatory. Practices providing PMS are already reviewed annually. Quite how these reviews will dovetail with the clinical governance visits – and whether they will, in time, replace them altogether – is not yet clear. Nor, as I have previously observed, is it clear how closely practices will be scrutinised in the course of a review.

(f) Practice Accreditation

12.38 As I have already explained in Chapter 5, practice accreditation also offers an opportunity for a practice visit and for assessment of the practice against set criteria. Under the model in use in South Yorkshire, Leicestershire and Lincolnshire, there is full involvement of the

PCT, which can use the information gained during the process of preparation for the assessment, and in the course of the assessment itself, for the purposes of clinical governance. Although the assessment is practice-based, there are, as I have explained, aspects of it which would shed light on the practice of an individual doctor.

(g) Monitoring and Analysis of Patient Complaints

12.39 At present, there are, as I have already mentioned, constraints upon the ability of PCTs to monitor and analyse complaints made about GPs and to use them effectively for clinical governance purposes. A PCT does not have a full picture of the nature and subject matter of the complaints made by patients about a doctor. A practice might 'fob off' a complaining patient or the patient might abandon his/her complaint and the PCT might never hear of it. In addition, there may be many incidents which are indicative of a poor standard of care but which are not the subject of complaints. This is particularly so under the present system, where patients may be deterred from complaining by the requirement that they should first direct their complaint to the doctor or practice concerned. (In the future, they will be able to choose whether to lodge their complaint with the practice or the PCT.) Nevertheless, it is clear that, despite the limitations upon the information available to them, PCTs find complaints a valuable indicator of the performance of a doctor and use them as a monitoring tool. Complaints by patients can, of course, provide an insight into such matters as a GP's communication skills (or lack of them), his/her relationships with patients and the quality of his/her care. These are all aspects of a doctor's practice on which performance indicators can shed no light. Moreover, many complaints can be linked clearly with an individual doctor.

12.40 I identified in Chapter 5 some of the gaps which remain in the information available to PCTs about the GPs on their list. The gaps relate to previous complaints and expressions of concern about a GP and to his/her involvement in proceedings for clinical negligence. Some of this information may be highly relevant to the quality of care being given by a doctor.

12.41 If a PCT is to have an effective system of clinical governance, it is essential that any complaint which has a bearing on quality of care is thoroughly and effectively investigated. If there has been a lapse in the quality of care, action should be taken as soon as possible to minimise or eliminate the risk that such a lapse might occur again. The present patient complaints system makes it difficult, if not impossible, for PCTs to do this.

(h) Operation of Systems for Identifying and Dealing with Poorly Performing General Practitioners

12.42 As I have explained in Chapter 5, some PCTs use data routinely collected by them in order to identify doctors who may be performing poorly. Others activate their performance procedures only in response to expressions of concern from healthcare professionals and others. Some PCTs have taken active steps (e.g. by means of distributing leaflets) to increase awareness, on the part of healthcare professionals and other staff working in primary care, of the importance of making known any concerns which they may have about the performance of GPs. PCTs should have in place effective systems for

investigating concerns when raised and for assessing performance. Remedying poor performance when identified (if necessary, by removing from practice a doctor who is providing an inadequate standard of care) is a vital part of clinical governance.

12.43 I have described in Chapter 5 the progress being made in establishing local procedures for dealing with poorly performing doctors. It is plain that the quality of local procedures (in particular, local assessments of doctors' performance) is variable at present and that further development is required in order to make them fully effective.

(i) Clinical Audit

12.44 I described in Chapter 5 the development of clinical audit in primary care. Audit is now organised by PCT sub-committees. They co-ordinate exercises, covering the whole PCT, to audit certain topics in which the PCT or local profession has a special interest. Individual practices will also carry out their own audits on subjects of particular interest to them.

12.45 Clinical audit has the potential to enable doctors to review their practices and outcomes and compare them with those of their peers. As a result, improvements can be planned and implemented and then reviewed in the same way. Audit can be a valuable tool for learning and for improving quality. The new GMS Contract makes no specific provision for audit. The thinking appears to be that the collection of data required to demonstrate quality achievement under the QOF will, in effect, amount to audit and will be rewarded by payments under the Contract.

12.46 As I have said previously, however, participation in the QOF is not obligatory. In the NHS Plan, published in 2000, the Government announced its intention of making participation in clinical audit compulsory for all doctors employed in or under contract to the NHS. This has not yet been implemented.The Inquiry understands that there are GP practices (albeit, in all probability, only a small number) which still do not undertake clinical audit.

12.47 While audit can be a means of improving quality in individual practices and can provide general information to the PCT, it is of limited, if any, use as a monitoring tool. There is no obligation on practices to share their audit results with the PCT. If they do so, it is likely that the results will be seen only by clinicians on the audit sub-committee. Any wider circulation will be on an anonymised basis, often with the results aggregated across the PCT, rather than by reference to individual practices. The audit results will usually reflect the performance of the practice as a whole and not (unless it is a single-handed practice) that of an individual doctor.

12.48 At the Inquiry's seminars, Sir Donald Irvine, former President of the General Medical Council (GMC), lamented the failure to make full use of clinical audit by employing the results to assess and improve doctors' performance. Professor Halligan agreed, saying:

> **'Sir Donald said very eloquently that 500 million** (*pounds*) **had been invested in audit, to what benefit? ... the closure did not happen. The event was carried out, the audit was carried out, the tabulation and qualification was performed but did it change anything? So people lost confidence in that process.'**

12.49 Despite these concerns, there appear to be no plans to change significantly the arrangements for clinical audit in the future. As I shall explain later in this Chapter, practice audits may form part of the evidence produced by a doctor at appraisal. However, there is no obligation on him/her to produce them. Under the present arrangements for appraisal, if an appraisee refers to an audit which his/her practice has conducted, but does not produce the audit itself, the appraiser has no power to call for it.

(j) Risk Management

12.50 The introduction of clinical governance has provided an impetus for developing systems for risk assessment and risk management within NHS organisations. In the context of secondary care, systems were initially focussed on reducing the risks of litigation resulting from adverse clinical events. There was also a move to reduce financial risk in both primary and secondary care settings. More recently, there has been greater emphasis on local risk assessment and risk management as part of the clinical governance framework.

12.51 Risk can take many forms, clinical and non-clinical, and risk can be managed in a large number of different ways. It is arguable that all initiatives which a PCT takes to improve the quality of clinical care should also have the effect of reducing risk to patients. However, a primary focus of attention within the area of risk management has been the development of mechanisms designed to ensure that adverse incidents are reported and analysed, that lessons are learned from them and that appropriate changes to practice are made in order to minimise the risk of recurrence.

12.52 The importance of such mechanisms was discussed in 'An organisation with a memory', the report of an expert group chaired by the Chief Medical Officer, which was published in 2000. The report suggested that over 850,000 adverse healthcare events (i.e. events or omissions arising during clinical care and causing physical or psychological injury) occurred annually to patients in NHS hospitals in the UK. These events were costing billions of pounds in compensation payments and additional hospital stays, quite apart from the human misery and wider economic costs associated with them. The report recognised also that some types of adverse event (sometimes the most serious) recurred over and over again, without lessons being learned from past experience. Most of the data in the report was drawn from secondary care. The authors acknowledged that little was known about the situation in primary care where incident-reporting systems appeared to be poorly developed. This was despite the fact that primary care accounted for the great majority of NHS patient contacts and that adverse events could and did occur in the primary care setting, with serious consequences for individual patients. In addition, the report noted that, in all NHS organisations, there was no systematic reporting of 'near misses'.

12.53 In 2001, the DoH publication 'Building a safer NHS for patients' set out the Government's plans for promoting patient safety. Central to those plans was the creation of a new special health authority, the National Patient Safety Agency (NPSA). It was to provide a central point for the collection of information about adverse events and near misses (known today by the collective term 'patient safety incidents') and for the analysis of the cause of the most serious incidents and of any patterns and trends which emerged. The NPSA was also

to disseminate the lessons learned from past incidents throughout NHS organisations and to have an advisory and educational role. Local systems for reporting patient safety incidents were also to be instituted. Emphasis was placed on promoting a culture of reporting and patient safety within NHS organisations. This culture was termed elsewhere in the document **'an open, no-blame reporting culture'**.

12.54 The NPSA was established in 2001 and has now started to put in place the National Reporting and Learning System (NRLS) to receive reports of patient safety incidents from NHS organisations (including PCTs) and staff, patients and carers. The NRLS is not yet fully operational and, as yet, has had little impact on primary care. It is planned that, in due course, the NRLS will also receive relevant information from other organisations (e.g. the Health and Safety Executive) which collect safety data. Reporting will be voluntary and confidential. All reports received by the NPSA will have the names of patients and staff, and other identifying data not required for the purposes of learning, removed. There will be no investigation of the individual cases reported. No data from the NPSA systems will be available for use in disciplinary actions. The sole purpose of the collection of the data is to learn from past incidents and to develop strategies for improving patient safety.

12.55 In parallel with the national system, local NHS organisations are expected to have systems in place for collecting data on patient safety incidents. The aim is to have fully integrated local and national systems to enable NHS staff and others to report incidents directly to the NPSA. SHAs already have mechanisms in place for the reporting of serious untoward incidents. Hospitals have developed systems for the reporting of patient safety incidents. Within a hospital setting, there is relatively little opportunity for incidents to go unreported. Several members of staff may be aware of them, complaints may be made to the hospital authorities, and litigation (to which the NHS trust responsible for the hospital is likely to be a party) may follow. The position is very different with primary care. GPs work in settings that are physically separate from PCTs. In general, they employ their own staff. The current system is that patient complaints are directed in the first instance to the practice and may never come to the attention of the PCT. If civil proceedings are brought against a GP, they will be dealt with by his/her medical defence organisation. Claimants will be represented by a variety of firms of solicitors. The PCT will not be a party to the litigation. There is no requirement for a GP to inform PCTs of any claim which has been intimated or brought against him/her. Thus, there is much greater potential for a PCT to remain unaware of a patient safety incident involving a GP on its list. In 1994, the PCO for Tameside did not become aware of the fact that Mrs Renate Overton had been admitted to Tameside General Hospital in an unconscious state and that the doctors at the hospital believed that her condition was attributable to a serious error made by Shipman in administering an overdose of an opiate drug. If such an incident were to occur today, it is likely that it would be reported (on an anonymous basis) to the NPSA. However, there is no system which would guarantee that the incident and the identity of the doctor would be drawn to the attention of the PCT.

12.56 The Inquiry was told that PCTs are in the process of developing systems for the reporting and analysis of patient safety incidents. At present, there is no requirement on a GP to report incidents (even serious untoward incidents) to his/her PCT or to the relevant SHA. At the Inquiry's seminars, Dr Wilson referred to her own experience of operating her SHA's

serious untoward incident reporting system. She said that the circumstances giving rise to a civil claim against a hospital doctor had almost always been reported previously to the SHA. By contrast, she could remember only one serious untoward incident being reported from the primary care sector. She said that it made her 'nervous' that she knew exactly where there was likely to be litigation in secondary care and the mental health trusts, but had no such knowledge about primary care. Ms Freedland said that she had found, when sitting on the clinical governance sub-committee of her PCT, a general ignorance of the fact that GPs were involved in adverse incidents at all. She also reported a conversation with a GP who had said:

> **' ''I sat trying to work out this week how many adverse incidents I had had in my particular practice. I sat down with a black notebook this week and I recorded 48 potential adverse incidents. I was so depressed I decided no longer to log them. When I thought about it, I am not sure what an adverse incident is or a serious untoward incident.'' '**

12.57 Ms Freedland said that a knowledge of such matters had been instilled into doctors working in the acute sector but not in general practice. She was concerned as to who was responsible for getting the message across to GPs, particularly given the PCTs' clinical governance role. Dame Lesley Southgate pointed out that many adverse incidents which occur in the context of primary care (e.g. failure to diagnose meningitis or cancer) are very serious. Yet, even when litigation has taken place, PCTs may remain unaware that these incidents have occurred.

12.58 The gathering of information about patient safety incidents (including near misses) and their cause is critical to risk management and to clinical governance. It is clear that, in the primary care setting, there is a great deal of work to do to encourage GPs, other healthcare professionals and practice staff to report relevant incidents. Even so, there may be a reluctance on the part of some to report an incident which reflects badly on their own professional performance or that of a member of their team. It is important, therefore, that PCTs are given access to information about such incidents which is available from other sources, such as patient complaints. Only if they have a full picture of incidents occurring in their areas will they be able to take appropriate steps to prevent such incidents from recurring. It will also then be possible for them to fulfil the obligation which will no doubt be placed upon them in the future to report all relevant incidents to the NPSA.

(k) Significant Event Review

12.59 Significant event review (also known as significant event audit or analysis or critical incident review, audit or analysis) is a process whereby a group of doctors (usually, but not always, from the same practice) or (less commonly) a multidisciplinary team or group discusses significant events which have occurred in the course of its practice(s) and the lessons which can be learned from those events. The event need not have been negative or had a poor outcome. It may have demonstrated good practice from which participants in the review can learn. If the event was a negative one, the participants may want to discuss whether things could have been done differently and, if so, whether a better outcome could have been achieved. In general, significant event reviews are confidential

in order to encourage participants to speak frankly. Usually, some record is made of the content of the discussion taking place at the review.

12.60 The new GMS Contract offers a financial reward to practices which have undertaken a minimum of six significant event reviews in the previous three years. A further reward is available if the practice has undertaken a minimum of 12 significant event reviews in the previous three years, which include (if these have occurred) any death occurring on the practice premises, two new cancer diagnoses, two deaths where terminal care has taken place at home, one patient complaint, one suicide and one sectioning under the Mental Health Act. Previously, there had been no financial incentive for significant event review and only about 10% of GP practices were thought to carry out significant event review. That proportion may well rise following the inclusion of incentives in the Contract.

12.61 A number of witnesses to the Inquiry spoke of the value of significant event review as a learning exercise. Dr William Reith (former chair of the Scottish Council of the Royal College of General Practitioners (RCGP)) said that the RCGP considered it such an important and helpful technique that, under the criteria for the Quality Practice Award, practices were encouraged to undertake reviews involving all members and employees. Professor Baker told the Inquiry that little formal research into the utility of significant event audit had been undertaken but those who had used the technique were positive about its impact.

12.62 At the Inquiry's seminars, Dame Lesley Southgate observed that, if Shipman had sat down with her and talked about some of the deaths of his patients, it would rapidly have become evident to her that there was something odd about them. The circumstances of many of the deaths were so very different from her own experience that this would have been immediately apparent to her. Sir Donald Irvine agreed that analysis of the deaths in discussion with a peer would have been the process most likely to have led to Shipman's discovery.

12.63 However, the value of significant event review must depend upon the amount of relevant information available to the review participants. An analysis of a death without the relevant medical records is likely to be of far less value than one where the records are available for inspection. The value of significant event review is also dependent upon the personalities of the respective participants and the extent to which they are able and willing to approach whatever information is available in an analytical manner and, if necessary, to question what they are told. As I pointed out during the evidence, the discussions between Shipman and the Form C doctors (i.e. the doctors who acted as second certifiers for the purposes of cremation) could have been viewed as 'significant event reviews' of the relevant patient's death. Yet those discussions resulted in the Form C doctors accepting unquestioningly what Shipman told them, even when there were unusual features about the deaths which should have been clearly apparent from the cremation Forms B completed by Shipman. Those discussions took place between Shipman and GP peers. Within a single-handed GP practice team, the inequality of status between the doctor and other participants in a significant event review would make it difficult for the latter to raise questions about the doctor's conduct. Certainly, it is difficult to imagine that Sister Gillian Morgan, Shipman's practice nurse, would have questioned

Shipman's conduct in the course of a review of the circumstances surrounding the death of one of his patients, or that a lay member of his staff would have felt able to do so. Some single-handed practitioners join together in groups for the purpose of significant event review. In those circumstances, other participants are dependent on the information brought to the review by the doctor whose event is being discussed. If the participants are open and honest, the review can be a valuable learning experience for all. If, however, a participant is determined to conceal his/her poor performance or criminality, it is unlikely that this would be detected.

12.64 The fact that significant event review is confidential means that, while a PCT may become aware that it is occurring, it has no access to information about the content of reviews under the new GMS Contract. PCTs will be entitled to check practices' review reports for the purpose of confirming that the relevant QOF indicators have been met. However, it seems highly unlikely that the reports will contain anything more than the bare information necessary for the purposes of confirmation.

12.65 Like clinical audit, significant event review cannot be regarded as a monitoring tool. It can be a valuable means by which individuals and teams can learn from past experience. Thus, it can assist in improving quality. However, it provides no information to the PCT about the quality of practice of an individual doctor.

(l) Appraisal

The Introduction of Compulsory Appraisal for General Practitioners

12.66 Until recently, neither GPs nor hospital consultants had been routinely required to undergo appraisal. This was in contrast to other NHS healthcare professionals, who were subject to annual appraisal. The only GPs who had had experience of appraisal were those who held posts outside general practice, e.g. in universities, where appraisal was the norm. In addition, some general practices operated their own in-house appraisal procedures.

12.67 In Chapter 5, I have described how, in the late 1990s, successive high profile cases of poor clinical performance had given rise to public concern about the arrangements then in place for identifying and eliminating incompetent and aberrant clinical practice. In addition, there was concern about the extent to which doctors were keeping their medical knowledge up to date. At that time, financial incentives were available for GPs who undertook continuing professional development. Most GPs attempted to keep abreast of new developments by attending lectures and other events. However, an individual GP's decision to attend certain educational events and not others would often be governed by such factors as geographical convenience, rather than by any coherent and structured plan to develop his/her knowledge or expertise in a particular area of practice. Choice of event would also be governed by personal preference for a topic, as opposed to remedying areas of weakness. Furthermore, those responsible for providing continuing education were not necessarily aware of the precise needs to which that education should be directed. Some groups of doctors, such as locums, found it particularly difficult to get access to continuing professional education.

12.68 In 1999, the DoH published 'Supporting doctors, protecting patients', a Consultation Paper on preventing, recognising and dealing with poor clinical performance of doctors

in the NHS in England. The paper proposed that appraisal should be made compulsory for all doctors working in the NHS, including GPs. The primary aim of appraisal was to assist in planning the individual's developmental and educational needs. However, it was also intended to assist in the recognition of poor performance. The Consultation Paper stated:

> **'It is not the primary aim of appraisal to scrutinise doctors to see if they are performing poorly but rather to help them consolidate and improve on good performance aiming towards excellence. However, it can help to recognise at an early stage developing poor performance or ill health which may be affecting practice.'**

The Consultation Paper also observed that:

> **'A comprehensive appraisal by the NHS employer** (*the Paper made it clear that this term was intended to include PCOs*) **is essential in enabling the NHS to fulfil its statutory duty of quality through clinical governance.'**

12.69 In addition, the Consultation Paper linked appraisal with the revalidation process to be introduced by the GMC. Appraisal was to provide 'a core of information' for revalidation. I shall discuss the relationship between appraisal and revalidation in Chapter 26. For the present, I shall consider appraisal solely in the context of clinical governance.

12.70 Appraisal for NHS consultants was introduced in 2001. From April 2002, participation in the appraisal scheme set up by their PCO was mandatory for all GP principals providing GMS and PMS. The vast majority of, if not all, GP principals have now been appraised at least once. A programme of appraising GP non-principals has started.

The Nature and Purpose of Appraisal

12.71 Appraisal can have a number of different aims and can be conducted in a variety of ways, depending on the purpose it is to serve. The way in which the appraisal of GPs is conducted will determine, to some extent at least, the value of the process for clinical governance purposes. It is, therefore, necessary to examine the stated purposes of GP appraisal and the way that appraisal is currently being carried out.

12.72 Appraisal usually takes place in a hierarchical employment setting. The appraiser is frequently the appraisee's line manager. The appraiser will have knowledge (often firsthand knowledge) about the appraisee's past performance. The appraisal may consist of a formal evaluation or assessment of a person's past performance, together with the setting of targets for performance in the future. Such a process could involve questioning the appraisee about aspects of his/her past performance and seeking an explanation for performance which appears to fall below the standard expected. The appraisal might identify ways in which the appraisee's performance could be improved and his/her career developed in the future. This type of appraisal has a clear performance management function.

12.73 Professor Baker described to the Inquiry his own experience of appraisal in a university setting. He said that, as an appraiser of junior members of his team, he would be familiar with their work. The purpose of the appraisal would be to look at the appraisee's plans for

the previous year and to discuss with him/her what elements had been achieved and where difficulties had arisen. If the team member had been performing inadequately or was presenting problems of any kind, Professor Baker would have been aware of this before the appraisal. He would have dealt with those issues as they arose. He would not wait for the appraisal to raise them. However, at the appraisal, he would seek to explore the appraisee's understanding of what had happened and of his/her situation because, if there was a gap between the reality of what had occurred and the appraisee's perception of it, there would be a serious management problem which he would have to address. If, on the other hand, the appraisee showed insight into his/her problems, and was working hard to improve, the focus of the appraisal would be on assisting him/her in that. Although the process described by Professor Baker was rather different from the appraisal process previously described, it was also directed at performance management.

12.74 The appraisal process described in 'Supporting doctors, protecting patients' appeared to have elements of performance management. It was described thus:

> **'The employer will wish to appraise an individual's performance in their post as well as their participation in local clinical governance activities and these two strands will tie in specifically to a health organisation's accountability to achieve high standards of quality. An employer will wish to ensure that the doctor adheres to the standards laid out in the *Duties of a doctor: good medical practice* document. However, the process will need to be strongly supported by information from external peer review so that judgements can be made about how the doctor's local practice compares to his or her peers nationally as well as to best and excellent practice.'**

12.75 The Consultation Paper made clear that the appraisal mechanisms described in it were intended to apply to independent contractor GPs, as well as to employed doctors.

12.76 When appraisal for GPs was proposed, there was considerable concern within the profession. There was a fear that appraisals would be used to 'police' doctors and that they would in reality be performance assessments which would result in judgements being made about GPs' competence. There was resistance to the use of appraisal as a management tool by the PCOs. The nature of GP appraisal, as finally agreed between the DoH and the profession, was very different from that which had been feared and, indeed, from the description set out in 'Supporting doctors, protecting patients'. It is described in DoH literature as:

> **'... a professional process of constructive dialogue, in which the doctor being appraised has a formal structured opportunity to reflect on his or her work and to consider how his or her effectiveness might be improved'**

and

> **'... a formative** (*i.e. educational*) **and a developmental process. It is about identifying development needs, not performance management.'**

12.77 As will become apparent when I come to describe the way in which GP appraisal is being conducted, it involves no objective scrutiny of past performance. It is not possible to 'fail' an appraisal. It is possible that something may occur during appraisal which causes an appraiser to have concerns about an appraisee's performance. An obvious example would be if, at the appraisal, the appraisee appeared to be under the influence of alcohol or drugs. Appraisers are instructed that, if they have serious concerns, they should suspend the appraisal. DoH guidance advises:

> **'It would be exceptional for serious concerns about performance to be first raised in an appraisal. The appraisal itself should be formative. However, both the appraiser and appraisee need to recognise that as registered medical practitioners they must protect patients when they believe that a colleague's health, conduct or performance poses a threat to patients ...'**.

12.78 In such cases, appraisers are advised to refer the matter immediately to the senior clinician/clinical governance lead and the PCT chief executive to take appropriate action. The matter should then be dealt with under the PCT's procedures for dealing with concerns about performance. The Inquiry is not aware of any appraisal which has so far resulted in serious concerns about performance being raised by an appraiser in this way.

12.79 Dr John Chisholm, Chairman of the General Practitioners Committee (GPC), British Medical Association (BMA), told the Inquiry that the character of appraisal in general practice was slightly different from that in hospital where there is 'more of an element of performance review as well as pure appraisal about the process'. He said that both the GPC and the RCGP had felt that the 'confusion' of performance review with 'pure appraisal' was 'unhelpful' and had wanted to 'maintain the purity of appraisal as a developmental tool'.

The Appraisal Process in England

12.80 Appraisal has followed a different course in England from that in other parts of the UK. In England, unlike Wales and Scotland, there has been no central system for implementing appraisal. Instead, each PCT has been left to make its own arrangements, subject to guidance issued by the DoH after negotiation with the profession. Each PCT is responsible for organising annual appraisals of all GPs, principals and non-principals, on its list.

12.81 In England, the appraisal of a GP is usually carried out by another GP from the same PCT. However, in some PCTs, appraisals have been carried out by nurses, midwives, even practice managers. The appointment of appraisers has been conducted differently from area to area. Some PCTs have selected appraisers from among the GP trainers in the area. Such appraisers will have experience of training and issues relating to professional education. They will also have attained the high standards of practice necessary for approval as GP trainers. In other areas, volunteers willing to act as appraisers have been sought and all those putting their names forward have been accepted. Some PCTs have had to 'trawl' local GPs in order to find candidates willing to act as appraisers. Others have selected appraisers from those who expressed interest in the job.

12.82 Appraisers undergo a day's (sometimes two days') initial training, during which they view a video, familiarise themselves with the relevant documentation and perform role-playing exercises. Initially, training was organised by the National Clinical Governance Support Team (NCGST) and provided by a private company. Subsequently, some PCTs have organised further training events, workshops, meetings and support groups to enable appraisers to discuss progress and any problems they may have encountered. In other areas, appraisers have received little support and only the initial training. Some PCTs have also given training to potential appraisees. Responsibility for the provision of appraiser training has now devolved to the postgraduate deaneries.

12.83 The Inquiry was told that some PCTs have allowed appraisees to choose their own appraiser from the list of appraisers in the area. Others have appointed a member of each group practice in their area as an appraiser. That appraiser has then appraised all the other members of his/her own practice. In most areas, however, appraisers have been allocated so that they are not paired with members of the same practice, or with relatives or close friends. Nevertheless, within a small professional community such as that covered by a PCT, it is inevitable that most appraisers and appraisees will at least know each other. It appears that most PCTs have operated a system whereby appraisers have been allocated to appraisees by the person appointed by the PCT to organise the appraisal process. If an appraisee objects to the appraiser allocated, the usual arrangement is that s/he can request a change. In most – but, it appears, not all – PCTs, both appraisers and appraisees are paid to participate. The rates of payment vary. In Tameside, each is paid £300, to cover preparation time as well as time spent on the appraisal itself.

12.84 Second and subsequent appraisals may or may not be carried out by the same appraiser. The Inquiry heard of several PCTs which planned to maintain, where possible, the same appraisers for a second – or even a third – year although, in the future, there was to be some rotation of appraisers to preserve the distance between appraiser and appraisee.

12.85 The appraisal process uses five standard forms which appear at Appendix D to this Report. The first two, to be completed by the appraisee, seek basic details about the appraisee (name, registered address, current posts, etc.) and information about his/her current medical activities. Form 3, entitled 'Material for Appraisal', constitutes the basis of the appraisal. It is organised under nine broad headings, namely Good Clinical Care, Maintaining Good Medical Practice, Relationships with Patients, Working with Colleagues, Teaching and Training, Probity, Management Activity, Research, Health. Seven of these headings are taken from those in the RCGP's publication 'Good Medical Practice for General Practitioners', a document which is based on the GMC publication 'Good Medical Practice'. The wording under each heading differs but, typically, Form 3 invites the appraisee to give a commentary on his/her work:

- identifying the main strengths and weaknesses in each area
- stating how his/her performance in each area has improved since the last appraisal (or over the previous year)
- giving his/her view of his/her continuing development needs

- giving a summary of factors which constrain him/her in achieving what s/he aims for.

12.86 Suggestions are made as to the documentation which an appraisee might refer to and supply in connection with his/her answers. For example, under the question relating to what the appraisee thinks are the main strengths and weaknesses of his/her clinical practice, the suggestions are:

> **'... up-to-date audit data (as appropriate); prescribing analyses (if applicable); PCT clinical governance reviews (as appropriate); relevant clinical guidelines you use; records of any significant event audits or critical incident reports; any complaints and records of their investigation; any reflective diary you keep about these events; any plaudits you have received; any ''in-house'' or personal monitoring materials you use; references or feedback from colleagues'**.

12.87 The DoH guidance which accompanies Form 3 states that the appraisee is **'invited'** to submit documents in support of what is said on the form. The appraisee is not, it is said, expected to **'prove'** his/her assertions about his/her work, but the appraiser will probably want to **'test'** some of those assertions through discussion and the documents will help both appraiser and appraisee. There is, however, no obligation to produce any particular document or class of documents. Moreover, the relevance of a document to the discussion at appraisal seems likely to be determined by the information which the appraisee chooses to include on Form 3.

12.88 The DoH guidance also advises appraisees to prepare a folder containing a set of all the documents, information, evidence and data collected for the purpose of the appraisal process. The appraisee should also prepare an outline personal development plan, setting out key development objectives and ways in which these objectives are to be addressed. This folder should be sent to the appraiser at least two weeks before the appraisal, to allow sufficient time for preparation. This can be done confidentially on-line, using the NHS Appraisal Toolkit.

12.89 The Inquiry heard that the amount of documentation provided by appraisees varies widely. According to Dr Robert Ashworth, a GP appraiser from Bradford South and West PCT (who, at the time when he gave evidence in September 2003, had conducted 21 appraisals), some GPs offer 'virtually nothing – maybe a few certificates of attendance at courses'. Others produce large amounts of information about courses attended, prescribing, referrals, significant incidents, complaints and other matters relating to their practices. Dr Ashworth had sought to encourage those who had produced little material to collect more in the future and was hoping that this would bear fruit in the second round of appraisals. However, he said that he could do no more than encourage appraisees to collect more evidence. Appraisers have no power to insist on the production of evidence.

12.90 When making the appointment for an appraisal, Dr Ashworth tells the doctors he is to appraise what they should do in preparation, i.e. complete Forms 1, 2 and 3 and gather the necessary evidence. He encourages them to deliver the forms and evidence to him well in advance of the appraisal date, so that he can read them and note any points

he wishes to raise at the appraisal. He has received the completed forms in advance in every case, but only in about half of cases did he receive any supporting evidence in advance. Again, he felt that he could not insist on this. Mrs Chris Page, Head of Service Redesign, Bebington and West Wirral PCT, who is in charge of the appraisal process for her PCT, agreed that, if a GP declined to produce documents, there was nothing that the appraiser (or, indeed, the PCT, if it became aware of the situation) could do.

12.91 Dr Chisholm explained that the wording in the DoH guidance, which 'invites' (rather than 'requires') the appraisee to provide documentation, was consciously chosen. The DoH and the GPC of the BMA had been aware during their negotiations that the profession did not view the introduction of appraisal with any enthusiasm and that, in order to get GPs to 'buy in' to the process, it was necessary to adopt a 'softly softly' approach. He hoped that a trusting relationship would develop between appraisers and appraisees which would enable appraisers to seek documentary evidence which was not at first proffered voluntarily.

12.92 The appraisal itself should be centred on the information contained within the appraisee's folder, on the contents of Form 3 and (for all but the first appraisal) on the progress which has been made on achieving the objectives set out in the appraisee's personal development plan (PDP). The appraisee should also be invited to raise any specific issues which s/he wishes to discuss. At the conclusion of the appraisal, the appraiser and appraisee should agree a summary of the appraisal discussion and of any action which it has been agreed should be taken. This should be recorded on Form 4. The appraisee then updates his/her PDP, using a standard template. It is open to an appraiser, if s/he so wishes, to complete Form 5, giving a confidential account of the appraisal interview. This is intended to inform the next appraisal. It is confidential and should be kept by the appraiser. Its completion is entirely optional.

12.93 In the vast majority of, if not all, cases, the result of appraisal will be the completion of Form 4 and the production of a PDP. The exception would be if serious concerns were identified, in which case the appraisal should be suspended and the concerns reported, as previously described. If an appraisee failed entirely to co-operate with the appraisal process, such that it was impossible to have a meaningful discussion, then, presumably, the appraiser would suspend the appraisal process and report this fact to the PCT, although the Inquiry has seen no specific guidance to deal with this situation. The more difficult problem would arise where minimal co-operation is given. It is not at all clear how limited an appraisee's co-operation must be, or how little information must be provided, before it can be said that no meaningful appraisal has taken place.

12.94 Following appraisal, it is up to individual GPs to ensure that they address the needs set out in their PDPs. DoH guidance advises that an appraiser and appraisee should make arrangements to speak or meet at least once during the course of the year following appraisal. They should spend about half an hour reviewing progress on the appraisee's agreed actions and his/her PDP. However, research has suggested that this rarely happens in practice.

Information Resulting from the Appraisal Process

12.95 The appraisal itself is confidential. Only the appraiser and appraisee are privy to what passes between them. Only the two of them see the folder prepared by the appraisee and the forms (1, 2 and 3) completed by him/her.

12.96 DoH guidance states that a copy of the completed **'appraisal summary statement'** (by which is meant Form 4) should be sent, together with the appraisee's PDP, to the senior clinician or clinical governance lead of the relevant PCT and to the PCT chief executive. In practice, this does not always happen. The Inquiry heard that, in some PCTs at least, the chief executive does not see Forms 4. Dr Ashworth's PCT does not receive copies of Form 4, just PDPs. Mrs Page reported that her PCT had agreed with local GPs that the PCT would receive only the PDP and the 'sign-off sheet' of Form 4 (i.e. the sheet containing the signed declaration that Form 4 is an accurate summary of the appraisal discussion), but not the summary itself. Sometimes, appraisers send the whole set of appraisal forms to the PCT.

12.97 If completed fully, Form 4 should give some insight at least into what passed during the appraisal. It should identify those areas where improvement or development is perceived to be needed and the action plan to address that need. The Inquiry obtained a small number of anonymised Forms 4 from the first appraisal round organised by Tameside and Glossop PCT. These contained varying amounts of detail. In one example, typical entries were (under the heading Good Clinical Care):

> **'Commentary: Good clinical care**
>
> **Action agreed: Maintain standards'**

and (under the heading Maintaining Good Medical Practice):

> **'Commentary: Good medical practice**
>
> **Action agreed: Maintain standards'**.

12.98 It may be, as one witness suggested, that those entries were made after a searching appraisal at which the appraiser had taken all necessary steps to satisfy him/herself that the appraisee was practising to a high standard. On the other hand, the appraisal may have been perfunctory and the appraiser may merely have accepted, without more, the appraisee's own assertion that s/he was performing well in the relevant areas. The completed Form 4 gives no information about what was discussed at the appraisal. At the Inquiry's seminars, Professor Halligan said that the contents of this Form 4 did not enable the PCT to make any judgement about the adequacy of the appraisal or the robustness of the process, or indeed the standard of the practitioner being appraised. He suggested that the DoH guidance may be 'too soft' and said that this would be addressed. Some of the Forms 4 supplied to the Inquiry were more detailed than the one referred to above. Even so, little indication could be gleaned from them about the quality of the appraisal which had been carried out.

12.99 Senior clinicians or clinical governance leads of PCTs are required to submit annually to the PCT chief executive an aggregated and anonymised report based on the limited

information which they receive about appraisals. This report should be discussed at board level. It should deal with emerging training and development needs and organisational service issues requiring action or investment. It should also review the operation of the appraisal process.

Information Contributing to the Appraisal Process

12.100 In an employment setting, an appraiser, who is likely to have some managerial responsibility for the appraisee, will have a background of knowledge about the appraisee and his/her performance. He or she will also have access to information from the appraisee's colleagues. The appraiser will, therefore, have hard information on which to base the discussion at appraisal. This is not the case with an appraisal conducted by a GP peer (unless, as happens in some areas, the appraiser is a member of the same practice). A GP appraiser from another practice may or may not have some general knowledge about the appraisee's practice and reputation. He or she will certainly have some knowledge about local conditions and problems affecting general practice. However, unless provided with it by a third party, s/he will have no data about the appraisee's performance, other than that which the appraisee chooses to produce. This gives an appraiser limited material on which to base the appraisal, particularly if the appraisee discloses little or no data beforehand. In those circumstances, the agenda for the appraisal will inevitably be set by the appraisee, rather than the appraiser.

12.101 The DoH guidance stated that it was **'intended that most of the documentary evidence will be supplied by the PCT as part of the regular monitoring of organisational performance undertaken by the Trust'**. The documentary evidence referred to would presumably include such information as prescribing data, data on hospital referrals, performance indicators and data about complaints and disciplinary proceedings, all of which would be within the PCT's possession. What the guidance did not make clear was whether the evidence referred to was that which would have been already supplied to the appraisee as part of the PCT's ongoing clinical governance arrangements and would (or should) be included in his/her appraisal folder, or whether it was envisaged that the PCT would supply the relevant material direct to appraisers. Sir Nigel Crisp, Permanent Secretary of the DoH and Chief Executive of the NHS in England, told the Inquiry that he would expect PCTs to provide appraisers with any information which the PCTs thought was relevant. Current guidance to GPs which accompanies the appraisal forms states, in relation to documentation: **'Your PCT may be able to help with some material'**.

12.102 It is clear that, whatever the original intention of the DoH may have been, there has been no general provision of information by PCTs to appraisers. Dr Ashworth said that, in his area, the PCT gave no information to appraisers. He said that any move to provide such information 'would ... be frowned upon by the GPs'. He pointed out that GPs are not used to being appraised and, for appraisal to develop successfully, they need to feel that it is a confidential, developmental process. If 'outside agencies' were to provide or receive information relating to the appraisal, the development of the appraisal process could, he suggested, be jeopardised. Mrs Page said that there was no routine provision of information by her PCT. However, in three cases, where there had been concerns or difficulties of which the PCT was aware and which could have impacted on the

appraisee's performance, the appraiser had been given a limited amount of information. The primary purpose of this had been to enable the appraiser to ask relevant questions and see whether any further support from the PCT was needed. Mr Julian Hartley, Chief Executive, Tameside and Glossop PCT, was also aware of one example in his PCT where the GP to be appraised had previously expressed concerns about workload and about managing the practice; the appraiser had been made aware of those concerns before the appraisal took place. Dr Robert Queenborough, Medical Director, Trafford North and Trafford South PCTs, said that no information was routinely provided by his PCTs. Indeed, there would be resistance from some appraisers to the idea of using PCT data as a basis for appraisal. He said that their attitude would be that GPs were independent contractors and that it was entirely a matter for the appraiser and the appraisee what went into appraisal.

12.103 Dr Taylor, who was in charge of appraisal for Heywood and Middleton PCT, said that he could see no difficulty in his PCT informing appraisers about such matters as the fact that an appraisee was an outlier in the prescribing of controlled drugs. However, he did not appear to believe that appraisers should be made aware of such matters as complaints or adverse disciplinary findings affecting an appraisee. Dr Linda Patterson, former Medical Director, Commission for Health Improvement (CHI), said that there was a need to discuss information about such matters as complaints at appraisal. The purpose of appraisal was to help the doctor become a better doctor so that s/he could give better care to patients. Once appraisal was viewed in that light, she thought that it became clear that such matters should be discussed. However, guidance issued by the BMA specifically prohibits discussion of complaints under investigation during the appraisal process.

12.104 Dr Chisholm told the Inquiry that he felt that the availability of information was an essential underpinning of good quality appraisal. He believed that, in accordance with the DoH guidance, to which I have already referred, PCTs should provide to both the appraiser and the appraisee information about such matters as prescribing, referrals and complaints, for use at the appraisal. Indeed, he said that he was disappointed to learn that this was not happening, since it had been intended by those involved in negotiations about the arrangements for appraisal that it should. The provision of this type of information might, he said, lead to an appraiser asking 'probing questions' during the appraisal. Sir Donald Irvine observed that the quality of the appraisal process was very largely dependent upon the quality of evidence on which it was based.

12.105 Some of the information which might usefully be discussed at appraisal (e.g. practice audits and significant event reviews, complaints logs, practice protocols) will be within the possession of the practice, and the PCT will not have access to it. An appraisee might or might not choose to produce these documents. Similarly, s/he might or might not include in his/her folder documents, such as prescribing data, which the PCT will also have. As I have already explained, there is no requirement that s/he should produce any of this documentation at the appraisal. At the conclusion of the appraisal, the PCT will have no means of knowing on what information the appraisal was based. The PCT receives no list of documents produced. Nor, even if it were aware of what documents had been available at the appraisal, would the PCT have any means of knowing which of those documents had been the subject of discussion at the appraisal meeting.

Quality Assurance of Appraisal

12.106 The Inquiry was told that quality assurance of the appraisal process was to be carried out by the Commission for Healthcare Audit and Inspection (known as the Healthcare Commission). According to Dr Patterson, it was likely to cover such issues as whether appraisers had been trained and whether clinical outcomes data had been available and used in the course of appraisal. It was not envisaged that there would be any inspection of appraisal folders. It was difficult therefore to know how those carrying out the process would know what evidence had been available and used at appraisal. More recently, the Inquiry has been informed by the Healthcare Commission that the Commission expects to carry out periodic reviews of various aspects of the appraisal process. This will be done as part of its overall programme of themed reviews. The Commission has made clear, however, that its reviews **'could not be regarded as a comprehensive quality assurance system for the appraisal process for doctors'**.

12.107 More recently, it has been reported that the Healthcare Commission intends to consider how to assess appraisal systems as part of a general evaluation of its general review of PCTs. A consultation document is due to be produced shortly before publication of this Report.

12.108 A report by the National Association of Primary Care Educators (NAPCE), commissioned by the RCGP and published in October 2003, refers to the difficulty faced by those seeking to monitor the appraisal process:

> **'The processes involved in GP appraisal are complicated, and the status of GPs as independent practitioners in an appraisal system administered by PCTs makes observation and monitoring the system even more challenging. GP appraisal is never going to be easy to monitor.'**

12.109 The report suggests that one means of quality assurance would be to evaluate appraisals by seeking the views of appraisers and appraisees on how the appraisal went and monitoring the outcomes. Dr Malcolm Lewis, Director of Postgraduate Education, University of Wales College of Medicine, is in charge of appraisal in Wales. He told the Inquiry that the Welsh appraisal process has internal quality assurance mechanisms, including the sampling and matching of Forms 3 and 4. The opportunity of seeing and assessing the content of Form 3 (which should contain a list of the documentation brought to the appraisal by the appraisee) would give helpful information about the extent to which the appraiser had prepared for the appraisal and about the information available to the appraiser. It would not, however, provide any information about the content of any discussion which took place during the appraisal. It is difficult to see how a confidential meeting of this kind can be effectively quality assured.

Views of Appraisal

12.110 It is clear that there is an initial perception that appraisal has had some positive effects. Some GPs have pointed out that it is the first opportunity they have had to talk about themselves, their practices and their personal development needs since the end of their

training. This is particularly valuable at a time when there is concern about the isolation of and pressure upon GPs. The preparation for appraisal, if done conscientiously, compels GPs to consider their strengths and weaknesses and how they wish to develop their practices. The appraisal itself offers an opportunity to sit down in 'protected time' and have a professional dialogue about issues affecting the appraisee's practice. Many found this an enjoyable experience. The experience may well have real benefits for non-principals, especially locums, who can suffer from particular problems of isolation.

12.111 For PCTs, one benefit of appraisal is that it gives them valuable information about the training and development needs of GPs and enables them to plan for the future. It also informs the deaneries and others involved in local GP postgraduate education of the areas where educational input is required. Dr Ashworth stressed the value of this and the potential for developing training targeted at meeting the needs of local GPs, as well as at the priorities of PCTs. Mrs Page hoped that appraisal would offer an opportunity for PCTs to build up supportive relationships with GPs. Of course, much will depend upon whether the educational needs of GPs, as identified by the appraisal process, can successfully be met.

12.112 The lack of any central system for implementing appraisal has meant that there has been a corresponding lack of consistency in the arrangements made by different PCTs. There have been wide variations in the financial resources provided for appraisal and in the approaches adopted, for example, to the selection and support of GP appraisers. It seems inevitable that there will have also been wide variations in the quality of appraisals, as a result both of the differing abilities and approaches of appraisers and of the level of co-operation of appraisees. Some GPs have been very reluctant to participate.

12.113 So far, the information which has been available to appraisers has come solely from appraisees. Sometimes, very little information has been provided. The agenda for the appraisal is more or less entirely set by the appraisee. 'In a sense', as one witness put it, appraisers are 'at the mercy of the appraisee.' The School of Health and Related Research, University of Sheffield (ScHARR), which advised the DoH on the implementation of appraisal, originally suggested that PCTs might wish to nominate topics for discussion at appraisal, either with individual GPs or across the board. This appears to have happened to only a very limited extent, e.g. where specific concerns already existed about a GP to be appraised. A further difficulty is that much of the information produced by an appraisee (in common with data which is held by the PCT) is practice-based, rather than referable to the individual doctor being appraised.

12.114 I have already mentioned the failure of PCTs to provide data to appraisers for use at the appraisal meeting. Even if such data were provided, it is not clear precisely how appraisers would be expected to use it. In what detail would they be expected to read it? Would they, as Dr Chisholm suggested, be expected to study it and ask 'probing questions' about its content? Would GP appraisers be prepared to take on such a role? Would they be accountable if it subsequently became clear that they had failed to spot vital clues which should have suggested that the appraisee was harming his/her patients? Would appraisers be happy to accept such accountability? How would appraisees react to being asked 'probing questions' by their colleagues? These are questions which will

require resolution in the future if it is intended that appraisal should be based on objective data provided by the PCT.

12.115 The PCTs' position in the appraisal process highlights some of the ambiguities which they face in relation to clinical governance issues generally. The PCT organises the process and funds it. It is the PCT which has the duty of quality to discharge yet it receives a limited amount of information from the appraisal process, has little or no control over appraisers and has no means of assessing the quality of the appraisal which has taken place. There are no standards or criteria against which an appraisee's past performance is judged. A PCT can, therefore, have no confidence that an appraisee who has been 'successfully' appraised has attained a certain standard of practice. Indeed, the Inquiry heard evidence from the Medical Director of one PCT that at least one doctor who was currently being investigated by the PCT for poor performance had been appraised without any concerns being raised by the appraiser.

12.116 Professor Roland raised a different problem. He pointed out that the involvement of PCTs in the appraisal process might have the effect of preventing appraisees from being frank about any weaknesses they might have. While I can appreciate that this may be so, the same can presumably be said of any appraisal which takes place in an employment context. However, as Professor Roland and others have said, the position would be exacerbated if there were to be a direct link between appraisal and revalidation and thus between appraisal and a GP's continuing licence to practise. Witnesses have pointed out that a link between appraisal and revalidation might also be a source of concern to potential appraisers, who might be unwilling to become involved in a process that might, in theory at least, lead to a colleague losing his/her right to practise.

Future Changes to the Appraisal Process

12.117 Appraisal is in its infancy and it is too early to predict precisely how it will develop. As I have already mentioned, the RCGP has commissioned a report from the NAPCE, which contained some exploratory research on quality standards for GP appraisal. The NAPCE report makes a number of suggestions for action, including:

- the establishment of more rigorous processes for appraiser selection and training
- the provision of continuing support and development for appraisers, including a system of regional appraisal support units for appraisers
- ways to address the problem of inadequate appraisers
- the introduction of a system whereby appraisers are appraised by GPs from outside their own PCTs
- the agreement of a standard national written contract between appraisers and PCTs
- the provision of training for appraisees.

12.118 In addition, in July 2003, ScHARR reported on the arrangements for extending appraisal to non-principals, who may well experience some difficulty in accumulating evidence

for the purposes of appraisal. Recently, the NCGST and the RCGP have carried out work on drawing up a list of evidence to be produced by GPs. The results of the NCGST's work have recently been published in a document, 'Defining the evidence for Revalidation – supporting the Royal College of General Practitioners', written by the NCGST Expert Group. As its name suggests, the document is primarily concerned with revalidation and seeks to identify the minimum number of items of evidence that its authors regard as essential to allow local clinical governance certification for revalidation purposes. It seems to be envisaged that these same items of evidence (together with any others that the appraisee may wish to volunteer) may also, if the appraisee so wishes, form the basis of appraisal.

12.119 In August 2004, the RCGP published a consultation document, 'Portfolio of Evidence of Professional Standards for General Practitioners: A Tool for Continuing Professional Development, Appraisal and Revalidation'. The purpose of the document is to set out proposals for the evidence that GPs may wish to gather to demonstrate their professional standards, to use for the purpose of appraisal and to submit for assessment for the purposes of revalidation. I shall discuss the evidence identified in each of these documents in Chapter 26. Suffice it to say for the present that type of evidence set out by the NCGST Expert Group appears somewhat 'softer' than that proposed by the RCGP. An example of this is that the RCGP proposes the submission of a standardised audit conducted by an independent colleague that demonstrates the appropriate quality of the doctor's clinical records; by contrast, the NCGST Expert Group suggests that a self-reported audit of records would be acceptable. Similarly, the RCGP proposes that GPs should produce copies of all complaints involving the doctor, together with evidence that any learning needs identified have been met, whereas the NCGST document suggests that the doctor should produce only a list of complaints received and of subsequent action taken.

12.120 Recently, the DoH has commissioned further work on the progress of GP appraisal; this is shortly to be published and further guidance on the appraisal process is also expected to be published imminently. The DoH has informed the Inquiry that it will be taking steps in the future to ensure that all PCTs have sight of appraisal Form 4 in its entirety, as well as the appraisee's PDP.

12.121 As to the approach to be adopted in the future, Mr Michael Warner, former Project Director, Avon, Gloucestershire and Wiltshire SHA, stressed the need to appraise past performance and to highlight strengths and weaknesses in past performance in order to form an appropriate development plan for the future. He felt that PCTs had to work towards a more systematic and robust system of appraisal. Under such a system, the PCT would collate all the information about the GP, sit down with him/her and go through a formal appraisal process of that information. He observed that the chief executive of the PCT was ultimately accountable if poor performance led to poor service and felt that this accountability should be reflected in the appraisal process. He said that PCTs were beginning to realise that they must link past performance and future development but they were 'struggling' to make that link. He suspected that such a move would not be welcomed by the profession, although he felt that some GPs would be sympathetic. He advocated a sensitive approach, with the profession and PCTs working in partnership.

Dr Queenborough also felt that the appraisal process was likely to become more like performance management in time. Dr Patterson said that there must be some accountability for performance within the appraisal process. She spoke of her own experience of appraisal in a hospital setting which she found a very positive experience. She said that there must be an element of performance management.

12.122 I have previously referred to the fact that DoH guidance had described GP appraisal as **'formative'**. In its response to the Inquiry's Consultation Paper, however, the DoH stated that appraisal **'has both summative** (*i.e. pass/fail*) **and formative elements'**. At the Inquiry's seminars, Professor Halligan said that it should be possible to 'fail' appraisal by falling below the standards which had been accepted and received. He observed that there was no point in having a process that everyone passes. However, it was not clear whether, by 'failing', he was referring to the situation already referred to (where an appraiser has concerns serious enough to warrant suspending the appraisal) or whether he had in mind something less serious (e.g. inadequacy of documentary material, failure to comply with a PDP, or other concerns falling short of 'serious' but nevertheless requiring investigation).

12.123 Although it seems likely that many PCTs would welcome an approach which more closely resembles performance management, such a shift of emphasis would plainly be resisted by many within the profession. And, since the vast majority of appraisals will continue to be conducted by GP appraisers, it is difficult to see how such an approach could be enforced. The reality may well be that any performance management function exercised by PCTs will have to take place in a context other than appraisal, while appraisal remains aimed wholly at encouraging continuing professional development and seeking to ensure that it is occurring. The latter approach plainly has a part to play in the maintenance of standards. However, it produces little, if any, useful information about the performance and competence of individual doctors.

Monitoring of Clinical Governance Arrangements

The Commission for Health Improvement

12.124 I have already explained that, over the past few years, considerable attempts have been made within NHS organisations to establish appropriate structures and systems designed to promote good clinical governance. Those attempts have been monitored by CHI. Between 2000 and April 2004, CHI carried out a programme of local reviews of clinical governance arrangements in NHS trusts and PCTs. Each review resulted in a report which was published on CHI's website. Every review involved a visit, lasting a week, to the PCT by a team of reviewers. The team comprised about ten people, including a CHI employee (who managed the review), a doctor, a nurse, a manager, an allied healthcare professional, a representative of Social Services and a lay person. The review covered all the services provided by the PCT, including medical services. Before the visit, the PCT would be requested to submit a large amount of information (written policies, protocols, strategies, minutes of meetings and other data) to CHI. That information would be analysed in preparation for the visit.

12.125 Also before the visit took place, CHI would hold a meeting in the locality of the PCT and invite members of the public in order to get some background information about the way in which the PCT was viewed by patients, carers and other interested parties. CHI would also have access to patient surveys conducted in some areas. CHI would seek views on the PCT from such bodies as the relevant SHA, local NHS trusts and Social Services.

12.126 Reviews of PCTs were based on what Dr Patterson described as 'the seven components of clinical governance'. These were:

- patient involvement
- risk management
- clinical audit
- staffing and staff management
- education and training
- clinical effectiveness
- use of information.

12.127 Visiting teams would also look at the 'patient experience' and at the PCT's strategic capacity for developing and improving clinical governance. Dr Patterson explained that this latter element depended largely on the quality of leadership and the culture within the PCT being reviewed.

12.128 The visiting team would examine the strategies and policies which the PCT had in place under each of the seven components and would assess how they operated on the ground. Dr Patterson gave the example of risk management. A review team would want to know if the PCT had a strategy for risk management. It would then want to see how that strategy was translated into policies and procedures and, more importantly, whether it was understood by frontline staff. Where possible, staff of the PCT would be asked how they would deal with specific incidents and how they had dealt with actual incidents in the past. Thus, the CHI team would hope to discover whether the structures and systems which the PCT claimed to have in place were working effectively in practice.

12.129 In the course of the visit, the review team would spend time at the PCT offices, interviewing managers and staff and discussing the systems in operation. The team would also conduct approximately six visits to GP practices. It would attempt to choose practices of different types (e.g. urban and rural, single-handed and large group). It would look out for such obvious matters as cleanliness within the practice surgery and whether appropriate information leaflets were displayed. However, the purpose of the visit was not to look at the quality of care given by the individual practice. It was primarily to ascertain whether the PCT had an appropriate quality framework in place that was operational at practice level. The extent to which CHI was able to gather information about the way in which PCT systems and policies were working on the ground was necessarily limited by time and other factors. Its inspection would not detect poor clinical practice by individual doctors.

12.130 After the visit, a written report would be prepared, setting out CHI's assessment of the PCT's systems under each of the seven components of clinical governance. A PCT's

performance in relation to each of the seven components would be scored by the reviewing team on a four-point scale. The report would set out CHI's recommendations for future action. These recommendations were in the main directed at the setting up of new systems or the improvement of existing systems. Some recommendations related to the provision of education and training. Recommendations were not (and, indeed, were not intended to be) directed at the actual quality of clinical care being provided by GP practices. However, compliance with the recommendations might well have had the effect of improving the quality of care. An example would be a recommendation under the 'clinical effectiveness' component. This requires that PCTs should have systems in place for ensuring that treatment given is based on the best available evidence, e.g. from research, literature or local or national guidelines (including NSFs and NICE guidelines). A recommendation that a PCT should develop a system for disseminating to all GP practices new evidence about best practice might result in changes in treatment on the part of some GPs and a consequent improvement in patient care. It would not, of course, have this effect on all. The CHI report would also set out areas of notable practice by PCTs and practice from which CHI believed that the rest of the NHS could learn. Following receipt of the report, PCTs were expected to produce action plans identifying the steps they proposed to take to comply with CHI's recommendations. SHAs were then responsible for overseeing compliance with these action plans by PCTs.

12.131 The conduct of CHI reviews was extremely resource-intensive. Initially, it was intended that CHI would operate a rolling programme of inspections, returning to each organisation every few years or so. This proved impractical. Over the four years of its operation, CHI carried out 377 reviews, including 86 reviews of English and Welsh PCOs.

The Healthcare Commission

12.132 CHI's functions have now been transferred to the Healthcare Commission which is, in the short term, continuing with reviews of PCTs. In the longer term, however, it is intended that no routine clinical governance reviews should be conducted. Instead, the Healthcare Commission will carry out themed reviews of the provision of health care which will be conducted by reference to standards laid down by Government and more detailed criteria which the Healthcare Commission will itself develop. The reviews will be conducted by collecting, analysing and screening data (so-called 'intelligent information') generated by NHS bodies. The relative levels of performance of different bodies will be assessed. For those which appear to be performing less well, there will be further reviews to diagnose problems and identify any necessary remedial action. For those which appear to be performing well, there will be further reviews with a view to identifying the factors which enable them to perform well and to communicating those factors to others. There will be no comprehensive visiting programme.

12.133 So far as clinical governance is concerned, the proposed reviews will give only limited information about whether systems and policies are being implemented on the ground. Inevitably, the Healthcare Commission will be looking primarily at institutional arrangements and systems, not the practice of individual doctors.

Conclusions

12.134 Dr Patterson told the Inquiry that the reviews of PCTs by CHI completed at the time she gave evidence in September 2003 had revealed that they were 'struggling' to implement arrangements for clinical governance. As I have said, PCTs are small organisations, with a wide range of functions and a competing set of priorities. They have had little time to set up comprehensive structures and systems. Their problems have been compounded by the fact that they are not, as Dr Patterson pointed out, operating within 'a managed environment' so far as GP practices are concerned. They are not dealing with a cohesive group of employees whose behaviour they can direct. Instead, they are dealing with a number of small, geographically separate and independent organisations. Dr Patterson said that CHI had found a 'nervousness' on the part of the PCTs and a lack of clarity about what their management role was in relation to GPs. There is less of a problem with doctors working under PMS contracts. But for doctors working under the GMS Contract, there were, in Dr Patterson's view, 'some structural and cultural barriers' to implementing clinical governance arrangements across a PCT. She anticipated that this might change under the new GMS Contract.

12.135 In September 2003, the National Audit Office (NAO) published a progress report, 'Achieving Improvements through Clinical Governance', on the implementation of clinical governance by NHS trusts. The report did not deal with primary care. Given that the PCTs had been created only relatively recently, it was thought premature to report on them. Within NHS acute, mental health and ambulance trusts, the NAO found that the introduction of clinical governance had had **'many beneficial impacts'**. However, progress in its implementation was **'patchy'**, varying between trusts, within trusts and between the components of clinical governance. It seems highly likely that the implementation of clinical governance in PCTs is similarly – if not even more – patchy. This was acknowledged by Professor Halligan at the Inquiry's seminars when he said that clinical governance was not yet 'embedded' in primary care. Dame Lesley Southgate pointed out that PCTs are young organisations which are constantly changing and developing. She said that it is impossible to reach a conclusion about consistency or lack of consistency between PCTs since not enough is known about their activities. Professor Baker felt, on the basis of his own observations, that there were differences in the ways in which different PCTs had embraced clinical governance. He felt that this was largely a question of leadership and that it depended on the attitude of the clinical governance lead and chief executive of the PCT. Professor Isobel Allen, Emeritus Professor of Health and Social Policy, University of Westminster Policy Studies Institute, said that some PCT medical advisers interpreted governance in terms of discipline while others regarded their role as 'much more educative'. Professor Halligan also stressed the importance of leadership in the effective implementation of clinical governance arrangements. More recently, in a letter to the Inquiry dated 10th November 2004, Sir Liam Donaldson, Chief Medical Officer, has stated his belief that the culture and process of clinical governance are now **'strongly embedded in local NHS organisations'**. I do not know on what evidence that statement is based. It seems unlikely that there has been a significant advance since January 2004, when Sir Liam's colleague and other witnesses commented on the position of clinical governance in primary care.

12.136 It seems to me clear that there is indeed some way to go before clinical governance is fully implemented in primary care. I have explained also that some of the tools being used at present by PCTs in the implementation process have limitations with regard to the extent to which they can be used for clinical governance purposes. However, I do not wish to appear negative about the efforts that PCTs are currently making. Any steps taken with a view to improving the quality of patient care are to be welcomed. With time, the focussing of effort on a coherent strategy for improving quality of care must be of benefit to patients. I am merely attempting to draw attention to the difficulties currently faced by PCTs in implementing clinical governance.

12.137 In my view, the real obstacle to implementing clinical governance is that identified by Dr Patterson, namely the position of GPs as independent contractors and the consequent inability of PCTs to 'manage' them for clinical governance purposes. The tension is well illustrated by the debate over appraisal and the form which it should take. The PCTs are accountable for quality and feel the need to find ways of monitoring and assessing the quality of care being given by GPs. The profession fears 'policing' by the PCTs and consequent loss of clinical freedom. There is some confusion over accountability, particularly the accountability of clinical governance leads who, as local GPs, often have 'a foot in both camps'. Many of them have tried to adopt a 'softly softly' approach, attempting to promote a supportive climate and to encourage 'ownership' of clinical governance by the profession. The difficulty comes with those general practices which are unwilling to embrace the principles of clinical governance and where problems of poor standards of care might exist. A PCT may be virtually powerless to act if, for example, a practice will not allow a clinical governance visit to take place. It seems to me that PCTs may need to be given greater powers if they are to discharge their clinical governance responsibilities effectively and are to be accountable for discharging the duty of quality placed upon them. They will also need leadership and determination to make quality their first priority and to root out substandard practice.

12.138 Clinical governance is primarily about systems. At present, it yields little information about individual doctors. It produces even less information about such matters as a doctor's medical knowledge or consultation skills (i.e. whether s/he is skilled at eliciting the information necessary to take a history, at making a diagnosis and deciding with the patient what should be done). These are the aspects of care which matter most to patients and are absolutely fundamental to the quality and safety of medical care. It seems to me that, in primary care at least, the focus of clinical governance should move away from organisational systems and instead be directed towards the gathering and use of information about the performance of individual practices and practitioners.

12.139 In my view, if properly developed and well resourced, clinical governance could provide the most effective means of achieving two important aims. First, it could enable PCTs to detect poorly performing or dysfunctional GPs on their lists. It could also help practices to discover any problems or weaknesses among their own number. Second, it could have the beneficial effect of helping doctors who are performing satisfactorily to do even better. At the moment, I do not think it is achieving these ends, for two main reasons.

12.140 First, as I have said, the amount of information available that relates to individual doctors is very small. Most data relates to practices and not individuals. Even prescribing data

is not as sharply defined as it should be. Clinical governance will not reach its full potential until it entails the collection of data relating to individual doctors. Data relating to say six or seven practitioners may well conceal real deficiencies about an individual. Much more effort must go into the collection of data relating to individuals. This could include prescribing data, referral data and complaints. Patient satisfaction surveys should seek reactions to individual doctors and not just to the service provided by the practice. If and when mortality statistics can be analysed, they should be included. I am sure that there are other possibilities which I have not thought of.

12.141 Second, clinical governance should be given a much higher profile in the PCT. My understanding is that, at present, the clinical governance lead is usually a GP who has an interest in the subject and undertakes it on a part-time basis. I can see the value of a clinical governance lead remaining in clinical practice. However, it does not seem to me to be satisfactory that s/he should just 'pick up' what there is to be learned about clinical governance as the result of experience. There should be opportunities for clinical governance leads to share experience and to learn what more can be done and how. Also, if the experience of clinical governance leads shows that they need greater powers, they should be given them. To use a colloquial term, the process needs 'beefing up'.

12.142 I said that I would consider whether, if clinical governance had been in operation in the mid-1990s, it would have been capable of detecting Shipman's criminal activities. The short answer is that clinical governance as operated at present would not have done. If an analysis of mortality statistics could have been included, it obviously would have done; the death rates among his patients were noticeably high. I cannot think of any other clinical governance tool that would definitely have detected his crimes. Clinical audit might have done so, if the right topic had been chosen. Significant event review, focussed on a sudden death, particularly a death in the surgery, might well have done. I cannot be certain. If clinical governance were to operate in conjunction with improved death investigation and certification (as recommended in my Third Report) and improved regulation of the use of controlled drugs (as recommended in my Fourth Report) then I think the prospects of detection would be quite high. Even more important, perhaps, would be the deterrent effect of these measures.

12.143 Having said that, I do not think that clinical governance will ever be the method of choice for detecting deliberate malpractice. Those who deliberately do wrong usually take steps to cover their tracks. The usefulness of clinical governance is to be found, in my view, in what it discovers about doctors who are not performing badly on purpose and who may be quite unaware that their clinical performance is poor. Just because clinical governance would not necessarily 'catch another Shipman' does not mean that it is not thoroughly worthwhile.

CHAPTER THIRTEEN

Single-Handed Practitioners

Introduction

13.1 For the last six years of his career as a general practitioner (GP), Shipman worked 'single-handed' from premises at 21 Market Street, Hyde. After his conviction for the murder of 15 of his patients in January 2000, there were many calls for a move away from single-handed practice. These murders had been committed over a period of three years and it was suggested that Shipman would not have escaped detection over such a long period had he been working in a group practice; his partners or working colleagues would have recognised that something was amiss. Alternatively, the very fact of having to work in close proximity to colleagues as part of a team would have served as a deterrent to him.

13.2 This feeling that there was 'safety in numbers' was reflected in the result of research conducted by Market & Opinion Research International (MORI) for the General Medical Council (GMC) in April 2000[1]. It reported a feeling that **'doctors in group practices to some extent regulate each other'**, a view that was later echoed in the responses to a questionnaire sent by the Inquiry to 15 randomly chosen primary care trusts (PCTs). That same year, the Royal College of General Practitioners (RCGP) spoke of continuing concern about the lack of accountability to close colleagues of single-handed GPs and of GPs who worked within a group but who nevertheless operated separate patient lists. It was said that there was safety in the informal mutual supervision of the members of a group practice, with teams of professionals working together to ensure each other's continuing development[2]. By contrast, there were real dangers of professional isolation for single-handed GPs.

13.3 Although it seems to be generally recognised that many single-handed practitioners practise alone for perfectly proper reasons, I also detect a suspicion, in some quarters, that those who engage in single-handed practice do so from less satisfactory motives. I think that there is a view that some seek to avoid group practice, fearing that scrutiny of their work by colleagues would result in the exposure of their clinical or other inadequacies. Another suspicion is that they may have character traits which make them difficult professional partners and possibly also poor doctors. Doctors with something to hide – be it criminal behaviour or clinical incompetence – will, so the feeling goes, naturally seek to hide themselves away in single-handed practice. The suggestion is that Shipman might have been an example of this.

13.4 The Inquiry heard oral evidence from Dr Michael Taylor, Chairman of the Small Practices Association (SPA). SPA is a national body for single-handed and small practices. It has a wide range of functions. These include a representative and political remit. It carries out surveys, research and data collection. It also issues written guidance to its members on continuing professional development and on subjects, such as complaints procedures,

[1] 'Views on Erasure and Restoration of Doctors – General Public Consultation conducted for the General Medical Council', April 2000.
[2] 'The Future of Professionally Led Regulation for General Practice – a Discussion Document issued in conjunction with and on behalf of The Royal College of General Practitioners, The General Practitioners Committee of the British Medical Association and the Joint Committee on Postgraduate Training for General Practice'.

which may give rise to particular difficulties for small practices. Its mission statement is that it exists **'to improve the quality of care for patients in small practices'**. Professor Dame Lesley Southgate, Professor of Primary Care and Medical Education, University College London, told the Inquiry seminars that some of the best work on developing clinical governance for single-handed and small practices has been done by SPA. I found Dr Taylor's evidence helpful.

13.5 I also heard evidence from Dr Hugh Whyte, senior medical officer, Directorate of Health Policy and Planning, Scottish Executive Health Department, about the position of small and single-handed practices in Scotland. Several witnesses, called to give evidence mainly on other subjects, provided their views on certain aspects of single-handed practice. As mentioned above, the Inquiry sent a questionnaire to 15 randomly chosen PCTs, seeking information about their attitudes towards single-handed practice and about any special arrangements they made for such practices. The problems of clinical governance in single-handed practice were discussed at the Inquiry seminars. I also considered a large volume of written material, mainly comprising articles from the medical journals and statements from interested bodies, such as the RCGP.

13.6 In this Chapter I shall summarise the evidence the Inquiry received relating to these issues and I shall consider the ways in which the perceived drawbacks of single-handed practice may be mitigated.

Definitions, Statistics and Trends

Definition of Single-Handed Practice

13.7 The term 'single-handed practice' is not a term of art. It can be applied to describe practitioners working under many differing arrangements. The Department of Health (DoH) defines a single-handed GP as one who has no partners, although s/he may have an assistant or a GP registrar. Another definition of a single-handed practice, referred to in the RCGP paper, is:

> **'a practice in which all the patients are registered with one general practitioner, contracted by the relevant health authority and who is responsible for those patients 24 hours a day and 365 days per year, although the practitioner is able to access other health professionals, including general practitioners, in order to discharge the contractual responsibilities'**[3].

13.8 Dr Taylor's evidence was consistent with this definition. According to him, 'A single-handed practice is a group of patients registered with a GP principal who receives funding for those patients.' Essentially, what distinguishes the single-handed practitioner is the fact that s/he has his/her own patient list. Although some of his/her patients may be treated by an assistant at the practice, the single-handed GP does not share with other doctors the care of patients in a shared list.

[3] Wylie AM et al (1999) 'Single-handed practices – their contribution to an undergraduate teaching network in the first year of the new curriculum', Medical Education, Vol 33: pp 531–536.

13.9 In some single-handed practices, there may be only one doctor regularly working at the practice, with locums standing in during sickness or holidays. This is the model that most members of the public would identify as a single-handed practice. In others, the doctor may have a part-time or full-time salaried GP registrar or assistant to help. Elsewhere, although these are now apparently few, there are practices in which GPs have their own patient lists but share staff, premises and other facilities. Although they would regard themselves (and would be regarded by the profession and the DoH) as single-handed, they would probably not be regarded as such by most members of the general public. Dr Taylor described several other variations on the theme.

13.10 A small practice is defined by SPA as a practice that has either fewer than 7000 patients or fewer than four GP principals. Again, this is not a term of art. Shipman was never in a small practice (rather than a single-handed practice) but some of the evidence I have considered suggests that certain problems are common to both single-handed and small practices.

The Typical Profile of a Single-Handed General Practitioner

13.11 Dr Taylor identified four groups of single-handed GPs. Not all single-handed GPs would fall into one of these groups but the four groups account for a large proportion of the total. The first group comprises doctors who came to the UK from the Indian sub-continent in the 1960s and 1970s and who never went into group practice. The majority of these doctors serve deprived inner-city areas; many are soon to retire. Second is a group of younger doctors from Western Europe, in particular the Benelux countries, who are accustomed to and enjoy single-handed practice, which is the norm in their home countries. A third group comprises doctors who find themselves in single-handed practice after a partnership split. The fourth group is what was described by Dr Taylor as the 'small is beautiful' group, among whose number Dr Taylor would probably count himself. Those in this group prefer single-handed practice, believing that it gives them the opportunity to treat their patients in the 'holistic' way most appropriate to their needs. Of course, doctors in any one or more of the first three groups may also be in the fourth. The practices tend to be located in deprived inner-city areas. Some are in rural localities that could not support more than one doctor.

Numbers

13.12 The number of single-handed practitioners in England is gradually declining. In 1952, about 43% of GPs were single-handed. By 1993, there were only 2888 single-handed GPs out of a GP population of 25,968. In 1998, there were more than 200 fewer (2683) out of a substantially increased GP population of 27,392. By 2003, the respective figures were 2504 out of a total of 28,568. Thus, over that 11 year period, the percentage of single-handed GPs in the GP population fell from about 11% to less than 9%. These figures do not distinguish between 'pure' single-handed GPs and those GPs who are in a group practice with their own patient lists. The GP population referred to is the population of 'unrestricted principals and equivalents' (UPEs), a DoH term that excludes groups such as restricted principals, assistant GPs and salaried doctors.

13.13 Women doctors and young doctors are under-represented among single-handed GPs. Over 50% of single-handed GPs are over 50, compared with 25% of GPs as a whole. Only 11% are under 40, compared with 40% of GPs as a whole. Only 15% of single-handed GPs are women, compared with 27% of GPs as a whole[4].

The Decline in Numbers

13.14 According to Dr Taylor, the decline in numbers began in the 1960s and seems likely to continue. It is largely attributable to fiscal, practical and administrative considerations that give group practice a broader appeal to most aspiring GPs.

13.15 In the early 1960s, the view was prevalent that single-handed general practice was inhibiting the development of good clinical practice. Consequently, in 1966, a financial incentive in the form of the Group Practice Allowance (GPA) was introduced, in order to encourage the formation of group practices. The GPA achieved its goal and the number of single-handed GPs consequently declined. The GPA was abolished in around 1990 when fundholding was introduced. In its early stages, fundholding was not in effect available to single-handed GPs and small practices, and the additional allowances paid for such services as chronic disease management were not easily achievable by single-handed GPs, who would not usually have possessed the necessary infrastructure or staffing levels.

13.16 Mr William Greenwood told the Inquiry that, in 1980, when he was working as the Assistant Administrator at the Tameside Family Practitioner Committee (FPC), there would be between 20 and 40 applications for a vacancy in a single-handed practice whereas now there are only three or four. Dr Taylor suggested that applications are 'astonishingly few'. There are several reasons why the shift away from single-handed practice appears to be continuing. First, aspiring young GPs are most likely to train in a group practice (only 2% of GP training is delivered in small or single-handed practices) and are therefore likely to seek a position in the kind of practice with which they are familiar. It has also been suggested that young doctors find the practical arrangements in group practice more satisfying. They may also find them more flexible and less personally demanding. Finally, many single-handed GPs began practising in the 1960s and 1970s and have reached or are approaching retirement.

13.17 It also appears to me, from the responses to the Inquiry's questionnaire, that PCTs generally discourage the continuance of single-handed practice. When a single-handed GP retires or gives up his/her practice, the PCT will encourage a merger with another practice. The justification for this attitude towards single-handed practice is said to be that group practice provides better patient care. However, it may be that pragmatic considerations play a part. First, it must be easier for PCTs to manage a smaller number of practices, even though the number of doctors overall may be the same. In written evidence to the Inquiry, Professor Richard Baker, Director, Clinical Governance Research and Development Unit, University of Leicester, suggested that single-handed practices may be unpopular with PCTs because they present greater management challenges and

[4] Lunt N et al (1997) 'Staying single in the 1990s: single-handed practitioners in the new National Health Service', Social Science & Medicine, Vol 45(3): pp 341–349.

cost. Dr Taylor also spoke of the significant expense of putting a new single-handed GP into an established single-handed practice. The departing practitioner may well not have kept the premises and equipment up to date and significant sums may be incurred in 'refreshing' them. These sums are avoided when the patient list is absorbed into an existing group practice, as are the costs of advertising and appointing a new single-handed GP, which would otherwise fall onto the PCT. Expenditure on premises and equipment will be greater still where a new single-handed practice is formed (as with Shipman in 1992).

13.18 There is now an additional reason why the decline in the number of single-handed practitioners is likely to continue. Under the old General Medical Services (GMS) Contract, every GP in a group practice had his/her own list of patients, even though s/he might share the care of those patients with his/her partners. If the practice broke up, a GP could take his/her list of patients to form a single-handed practice. Under the new GMS Contract, which came into force in April 2004, patients are registered with the GP practice and not with an individual GP. In future, if a GP leaves a partnership, s/he will not be able to take his/her patients to form a new practice.

13.19 For all these reasons, it appears that the number of single-handed GPs will continue to decline. However, it seems to me likely that there will always be a need for some.

Shipman

Todmorden

13.20 As I have described in my First Report, Shipman joined the Abraham Ormerod Medical Centre in Todmorden in early 1974. There were between 9000 and 12,000 patients registered with the practice, which comprised five partners, including Shipman. Each partner had his/her own list of patients. It is not now clear to what extent Shipman inherited the list of his predecessor, who had just retired from practice. It seems that Shipman was expected to build up his own list. The partners were, therefore, single-handed within the definition mentioned above although their patients probably regarded the practice as a single unit.

13.21 In my First Report, I found that, while in Todmorden, Shipman unlawfully killed one patient, Mrs Eva Lyons. She was probably a patient on his list. She was terminally ill and Shipman visited her frequently in the period leading up to her death. She died late one evening after Shipman had called to attend to her. She was in quite severe pain and Shipman gave her an injection of a drug, which resulted in her death within a few minutes. Her death was expected and, even had she been registered with another doctor, it is unlikely that that doctor would have seen any cause for concern. I found that there were reasonable grounds for suspecting that he had killed six others, all of whom were probably his patients. I also found in my First Report that there was an occasion in August 1974 when Shipman probably did inject Mrs (now Professor) Elaine Oswald, a 25 year old female patient, with an opiate, causing her to suffer respiratory arrest. I did not feel able to reach any positive conclusion as to his motive. However, I thought it highly unlikely that he had any intention to kill her or to cause her serious harm. She too was his patient.

13.22 When in Todmorden, Shipman also flouted the legal requirements governing the keeping of the practice's controlled drugs register, for which he had responsibility. He amassed large quantities of pethidine for his own use. Thus, in Todmorden, Shipman was neither deterred nor detected by such 'mutual supervision' as existed where the doctors worked together in the same premises, sharing the services of staff. It is perhaps revealing that it was a member of staff at the local pharmacy who eventually 'blew the whistle' to Shipman's partners about his acquisition of excessive quantities of pethidine. The courses of action open to her might have been less clear cut had Shipman been the only doctor working in the practice.

The Donneybrook Practice

13.23 In October 1977, Shipman joined the Donneybrook practice, Hyde, where there were seven doctors. Five of the seven had their own patient list and two shared a list. Shipman inherited the list of Dr John Bennett. The five doctors organised themselves into two groups for the purpose of providing cover for their half days off. For the first three years or so, Shipman and Dr Geoffrey Roberts provided half day cover for each other. After Dr Roberts left the practice, Shipman made the same reciprocal arrangements, first with Dr Wojciech Kucharczyk and then with Dr Jeffery Moysey. In addition, a doctor would be responsible for all the patients registered with the practice when he was on duty in the evenings, at weekends and over bank holidays. The system was that each of the members of the practice provided out of hours cover on a rota. When on evening duty, a doctor was responsible for providing cover from 5.30pm or 6pm until about 11pm, after which telephone calls were diverted to the deputising service used by the practice. The deputising service would then respond to all calls made until 8 or 8.30 the following morning. The charges made by the deputising service for dealing with calls received by them from 11pm onwards were shared between all the partners in the practice. Before 11pm, telephone calls made to the surgery were transferred to the home of the doctor on duty. That doctor could choose to have calls diverted to the deputising service earlier than 11pm but, if he chose to do so, he would be financially responsible for the charges of the deputising service for responding to those calls.

13.24 The general financial and administrative arrangements remained essentially those of a partnership until 1st January 1992, from which time, having announced his intention to move, Shipman ran a completely separate single-handed practice from within the shared premises. When he announced his intention to move in 1991, one of his partners thought that he was moving to single-handed practice because of his 'individualistic' approach to his work. He also thought that Shipman wanted to be free to practise without any interference from others; it was suggested that he used to show signs of irritation when colleagues or staff disagreed with him. Dr Graham Bennett worked in a neighbouring practice and signed cremation Forms C on several occasions when Shipman had certified the cause of death and completed a cremation Form B. He said that he considered it inevitable, given his character, that Shipman would go into single-handed practice where he would have his 'own little empire' and would not be overlooked.

13.25 During his years at the Donneybrook practice, Shipman killed 71 patients and I found that there were reasonable grounds for suspecting that he killed 30 more. It is likely that all were on his patient list. At no stage did any of his partners suspect what he was doing.

The Market Street Surgery

13.26 In August 1992, Shipman moved with some of the staff from the Donneybrook practice to new surgery premises at 21 Market Street, Hyde. To the annoyance and financial detriment of his former partners, he took with him his patient list. That list was to grow so large that, at the end of 1997, Shipman was setting in train the process for recruiting a partner. Between 1992 and 1998, Shipman enjoyed an excellent reputation as an attentive, caring doctor. In the six years before his arrest, he killed 143 patients and there are reasonable grounds for suspecting that he killed eight more.

13.27 It is clear, therefore, that Shipman was, to all intents and purposes, a single-handed practitioner throughout his professional life as a GP. Although there may have been some degree of mutual awareness, at the Donneybrook practice, of what other doctors within the practice were doing, this would only rarely extend to knowledge of the medical history or circumstances of the patients of another doctor. Thus it is not surprising that the other doctors in the Donneybrook practice noticed nothing unusual about the deaths of Shipman's patients. Concern that Shipman might have evaded detection because he practised alone may have some foundation. Later in this Chapter, I shall consider whether the mutual supervision that may be expected in a group practice with shared patient lists would have had a significant effect upon Shipman's course of conduct.

Government Policy

13.28 Concerns about single-handed GPs are not recent. In the mid-1990s, there were statements in the medical press quoting representatives of the National Association of Health Authorities and Trusts, who said that the days of the single-handed GP were numbered. Single-handed GPs, it was said, could not be expected to provide the kind of services required of them, given the burden on primary care and the need to develop practice teams offering a range of professional expertise and facilities.

13.29 At times, Government policy has seemed to favour a move away from single-handed practice, on the assumption that this would lead to improved standards of patient care by reducing the 'clinical isolation' said to be experienced by doctors practising alone. One of the proposals contained in 'The NHS Plan, A plan for investment, A plan for reform' (the NHS Plan), which was presented to Parliament in July 2000, was that special contractual arrangements were needed for single-handed GPs. According to paragraphs 8.10 and 8.11:

> **'It is particularly important to be able to confirm that single-handed practices are offering high standards, because although most single-handed GPs work hard and are committed to their patients, they tend to operate in relative clinical isolation. They do not have the ready support from colleagues enjoyed by GPs in larger practices. The current ''red book'' contract is a particularly poor mechanism for protecting quality standards in these practices.**
>
> **For this reason, new contractual quality standards will be introduced for single-handed practices. This will either be done through a negotiated**

> **change to the ''red book'', or if this proves not to be possible, a new national Personal Medical Services contract will be introduced into which all single-handed practices will be transferred by 2004. The role of primary care groups and primary care trusts in promoting and auditing clinical governance will also help reduce isolation and encourage co-operation between GPs.'**

Then, on 3rd July 2002, the Prime Minister, the Rt Hon Tony Blair MP, said in the House of Commons:

> **'There has been a move over time away from single-handed practices so as to improve the quality of care that people receive. That has been based on a great deal of evidence over a long time.'**

13.30 This announcement caused disquiet in the medical profession, which did not accept that such evidence existed. Within a short time, there was a 'softening' of the policy line. On 17th October 2002, the then Secretary of State for Health, the Rt Hon Alan Milburn MP, told the publication 'Doctor' that the future for smaller practices was 'positive' and that this would be recognised in the new GMS Contract. The new GMS Contract does not impose any special restrictions or requirements on single-handed GPs. It leaves it up to individual practices, including single-handed practices, to decide how best to design their arrangements so as to meet local needs. It sets out to reward high quality of care by remunerating GPs in accordance with their performance, which is to be measured against a number of quality markers. Although SPA welcomes the focus on quality of care, there is disappointment that there is to be no specific reward for continuity of care.

13.31 At the Inquiry seminars, held in January 2004, it was said that there was still a perception in some quarters that single-handed practice is discouraged. Indeed, I got this impression myself from the evidence of some PCT officers. In response, the Deputy Chief Medical Officer for England, Professor Aidan Halligan, made it clear that the DoH was not actively encouraging PCTs to persuade single-handed GPs to move into multi-handed practice. In written evidence to the Inquiry, the DoH stated that the policy now is that the future for single-handed practice is **'safe'**. Small practices will be encouraged to co-operate with each other so as to ensure the provision of a full range of services to patients. Improved PCT support, for example by the provision of practice nurses and experienced practice staff, will help to improve the quality of service offered by those practices. I should add that PCTs now also have list management powers which give them a greater ability to deal with all problem GPs, including single-handed GPs. In short, single-handed practice is here to stay and will not be allowed to be the poor relation of primary care.

The Advantages and Disadvantages of Single-Handed Practice

13.32 The general perception of the public and of the medical profession appears to be that single-handed practice is popular with patients because it provides continuity of personal medical care. The general perception among the medical profession is that single-handed practice does not provide as high a quality of care as is delivered by group practice.

Objective Measurements of Clinical Performance

13.33 A review of the literature over the past decade suggests that there is no good evidence that the clinical performance of single-handed GPs is inferior to that of their colleagues in group practice. It appears that no single type of practice can claim a monopoly over high quality care[5] and that there is no association between practice size and quality of care[6]. Differing sizes of practice are recognised to have differing strengths and weaknesses. In those instances where the data would appear to suggest that group practice provides better care, the disparities disappear when adjustments are made for patients' age, sex and social deprivation. In any event, it might be expected that research would suggest that group practices provide a better standard of care than do single-handed practices, because the performance and other indicators used to assess practices are based largely on the numbers of patients who receive particular forms of treatment (such as immunisation, cervical cytology or regular chronic disease management) and do not reflect the less quantifiable advantages of single-handed practice, such as those associated with continuity of care.

Practice Size

13.34 The witness evidence generally supports the view that there is no association between practice size and quality of care. At the Inquiry seminars, Professor Martin Roland, Director, National Primary Care Research and Development Centre, Professor of General Practice (University of Manchester) and Principal in General Practice, Rusholme Health Centre, Manchester, said that single-handed GPs are represented among those who provide very high standards of care as well as among those at the other end of the spectrum. Sir Donald Irvine, President of the GMC between 1995 and 2002, told the Inquiry:

> **'... some SHPs** (*single-handed practices*) **have quite the best arrangements for clinical governance that one could wish to see. The assumption that smallness or single-handedness cannot be equated with quality is just not true.'**

Dr John Grenville, representing the British Medical Association, told an Inquiry seminar that there are some 'incredibly good' single-handed practices, with very high standards of clinical governance.

Chronic Disease Management

13.35 Chronic disease management is often cited as an area of general practice in which the group practice model is inherently preferable to the single-handed model. Nowadays, it is expected that chronic diseases, such as diabetes, heart disease and hypertension, will be managed as part of primary care, with only occasional hospital referral. The expectation is that a group practice will have a GP with a special interest in the relevant

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[5] Roland M et al (2001) 'Identifying predictors of high quality care in English general practice: observational study', BMJ, Vol 323: p 784.
[6] Majeed A et al (2003) 'Association between practice size and quality of care of patients with ischaemic heart disease: cross sectional study', BMJ, Vol 326: p 371.

field and that s/he will run clinics, often in conjunction with a (specialist) practice nurse. According to Mr Mike Newton, Head of Performance Management, South Yorkshire Strategic Health Authority (SHA), setting up such a clinic puts significant demands on a single-handed GP, who may not have any special interest in the management of the relevant disease and whose practice nurse may be part-time. The problem could be remedied, if thought desirable, by the single-handed doctor referring patients with a chronic disease to a clinic run by an adjacent practice.

13.36 Dr Taylor said that treating patients at clinics held for the monitoring of specific conditions does not fit comfortably with the 'holistic' ethos of the small practice. He described this as 'providing care for patients who have diseases, rather than care for the diseases that people have'. He also gave an illustration of the type of case in which chronic disease management might be better in a single-handed practice. He said that, when treating a patient with rheumatoid arthritis, it is very useful for the doctor to be familiar with the family dynamics. If s/he is, it becomes easier to treat the patient in a way that enables him/her to cope with the situation, rather than just treating the symptoms of his/her disease. A single-handed GP is more likely to have the relevant knowledge, according to Dr Taylor, and is also less likely to make an unnecessary hospital referral, because s/he will be confident in his/her knowledge that the family dynamics will allow the patient to be treated at home. I envisage that the proponents of the clinic system would say that the doctor running the clinic would gain the relevant knowledge within a short time of starting to see the patient.

13.37 Other witnesses supported Dr Taylor's views about holistic care. Dr Whyte said that the type of practice advocated by Dr Taylor is widely regarded as very desirable, if not optimal. The point is also made that specialisation for GPs should not be taken too far. In primary care, where the GP has to be able to deal with a wide range of conditions and presentations and where s/he is effectively the gatekeeper for the secondary care system, the skills of the generalist must be maintained. It is clear that both sides in this debate are able to make valid points in support of their respective contentions.

Patient Preference and Continuity of Care

13.38 There is a considerable body of evidence to suggest that patients like single-handed or small practices. In a 1995 study[7], patients were reported to prefer smaller practices, practices with personal list systems and non-training practices. Another more recent study confirmed this preference; smaller practices were regarded as being more accessible and achieved higher levels of patient satisfaction[8]. There is other evidence suggesting that continuity of care leads to high levels of patient satisfaction. The Audit Commission Report of 2000, entitled 'A focus on general practice in England', confirms that continuity of care tends to be better in small practices and is valued by patients. The PCT responses to the Inquiry's questionnaire also suggest that patients like single-handed GPs. According to Mr Newton, they are especially popular with the elderly.

[7] Baker R and Streatfield J (1995) 'What type of general practice do patients prefer? Exploration of practice characteristics influencing patient satisfaction', British Journal of General Practice, Vol 45: p 654.
[8] Roland et al. 'Identifying predictors of high quality care in English general practice: observational study', BMJ 2001; 323:784.

13.39 There was anecdotal evidence from Mr Newton that single-handed GPs tend to attract a greater number of complaints than do their colleagues. Neither SPA, the GMC nor any of the medical defence organisations was able to provide statistical evidence on the point. In 1996, the Medical Defence Union (MDU) published a pamphlet on complaints that suggested that single-handed GPs attracted a smaller relative proportion of complaints than their colleagues in group practice. However, the MDU has explained that the work on which that suggestion was based was not valid statistically because it took into account only complaints against those GPs whom the MDU knew to be single-handed (which was not all).

13.40 It is almost axiomatic that it is easier to achieve continuity of care in a practice where each patient is assigned to a particular doctor. The smaller the practice, the fewer the number of doctors who are likely to see the patient. Dr Taylor describes continuity of care as 'an important measurable component of holism'. He suggested that, according to evidence from US studies, continuity of care is associated with a reduced number of hospital referrals. That may or may not be a good sign.

13.41 According to Dr Taylor, continuity of care leads to increased levels of trust and reduced levels of patient anxiety. These factors enable the patient, who regularly sees a familiar face that s/he can trust, to take an active and informed interest in his/her own treatment. I can see how this can lead to improved patient care, provided that the trust in the doctor is not misplaced. I accept that continuity of care can, and often does, offer real benefits in terms of quality of care and also gives rise to high levels of patient satisfaction.

13.42 However, it seems to me that there are some real disadvantages stemming from a continuous one-to-one doctor/patient relationship. First, the patient may come to place unwarranted trust and confidence in the doctor. Shipman illustrates the point. He had a one-to-one relationship with his patients. He offered them a high level of continuity of care. There was never any difficulty in getting an appointment to see him or in arranging a home visit. Only on rare occasions was there a locum in his place. He was greatly admired and respected – even loved – by his patients. As a result, he enjoyed the absolute trust of many of his patients (and of their families) and so the threshold at which patients or families might have questioned his actions or advice (already high in the doctor/patient relationship) was even higher than usual. He was able to perpetrate a colossal abuse of trust without arousing any suspicion. Of course, I accept that Shipman was a most unusual case, but over-confidence in a doctor may easily result in an inability to question his/her actions and opinions when they ought in fact to be questioned.

13.43 Second, there is a quite different type of problem that may be associated with continuity of care. This is the danger of overlooking a disease of insidious onset, where the doctor sees the patient regularly and fails to notice and take heed of gradually developing signs. Third, patients who repeatedly see the same doctor and no other have no experience against which to compare their consultations. This problem is illustrated by the experiences of the patients of Clifford Ayling, who in many cases did not know whether the intimate examinations that they underwent were 'normal'. Ayling was a single-handed GP who was convicted in December 2000 of 12 counts of indecent assault, relating to ten female patients, and was sentenced to four years' imprisonment. Fourth, patients do not

have any 'yardstick' by which to measure the competence of their GP, if they do not see how their health and illnesses are managed by other doctors.

Isolation

13.44 When discussing the advantages and disadvantages of single-handed practice, many witnesses and contributors to the Inquiry seminars suggested that single-handed practitioners tended to be 'isolated'. This term connotes a lack of involvement with one's peers and a failure to keep up to date with current practice. According to Dr Taylor, there is no evidence to suggest that single-handed practitioners are any more isolated than their colleagues. Dr William Reith, a GP principal in Aberdeen and former Chairman of the Scottish Council of the RCGP, told the Inquiry that there are many doctors who work in larger practices who are professionally isolated and feel unable to discuss matters with colleagues. I accept what both say but I would have thought that common sense would indicate that the dangers of isolation were greater in single-handed than in group practice. Moreover, if a doctor in a group practice becomes 'isolated' in this way, the problem is more likely to be observed by colleagues.

13.45 Dr Roger Freedman, medical adviser to the Tameside Family Health Services Authority from November 1991 until August 1993, was later involved in the work of the Manchester Performance Panel, which was established in the late 1990s to assess and, if appropriate, remedy the performance of doctors about whom concern was expressed. In the first two years of its operation, the Panel considered the performance of 14 GP principals and one locum. Three of the principals were single-handed GPs and none was in a partnership of more than three. Dr Freedman confirmed that there are some excellent single-handed GPs but felt that problems arise where the less good are in single-handed practice; the lack of peer contact can mean that they are unaware that their clinical and managerial standards are slipping. The problem, he suggested, is lack of insight.

13.46 I observe that Shipman did not show any sign of professional isolation. He became involved in organisations outside the practice. While at the Donneybrook practice, he was an area surgeon for the local St John Ambulance, secretary of the Tameside and Glossop Local Medical Committee and a member of the Tameside FPC. When working at Market Street, he regularly attended professional development events, was active in local medical politics and was an enthusiastic member, latterly treasurer, of the West Pennine SPA. Shipman was also known to be keen on introducing new ideas to the Donneybrook practice. The Market Street practice was regarded by the WPHA as being innovative and advanced. At Market Street, Shipman and his staff performed regular medical audits, which impressed the WPHA Primary Care Clinical Audit Group (WPPCCAG). The following comment was made in January 1998 after a practice audit visit by a member of the WPPCCAG:

> **'Great to see a single-handed enthusiastic GP with a rolling programme of audit. Practice nurse also very enthusiastic and takes part in audit. We think it would be very useful for you to have an audit assistant and hope you follow this up. Keep up the good work.'**

This comment is indicative of the way in which his participation was regarded.

Clinical Governance

13.47 In Chapter 12, I described the ways in which PCTs seek to carry out their duty of clinical governance of GPs. Some of these methods involve the collection and/or scrutiny of data relating to the doctor's practice. With a group practice, much of the data collected relates to the practice as a whole and cannot be attributed to the performance of any single doctor. Examples are data relating to immunisation and cervical cytology. Some kinds of data, for example prescribing data, are supposed to relate to an individual doctor but, because doctors use each others' prescription pads, the data becomes 'blurred' and does not provide a clear picture of an individual doctor's practice or performance. When data is supplied by a single-handed GP, it relates only to that doctor and the picture provided to the PCT is clearer than that available for a group practice.

13.48 Some clinical governance activities are undertaken within group practices. For example, it is common practice for the partners in a group practice to discuss prescribing data. Discussion between the doctors may reveal anomalous practice by one member of the group that might well not be picked up by PCT monitoring. A single practitioner may choose to scrutinise his/her own prescribing data; many GPs now regard 'self-audit' as good practice. However, if a single-handed practitioner chooses not to examine his/her personal data, there is no one to ensure that it is done. If a single-handed GP chooses to ignore any problems that the data might reveal, there is no one to insist that the problems be dealt with.

13.49 Other forms of clinical governance can operate effectively only in a group. An example is significant event review or audit, a process whereby a group of doctors and other healthcare professionals discuss the care that was provided shortly before a patient's death or some other event – usually (although not always) an adverse event. The objective is to analyse the care provided with a view to learning lessons either from the mistakes made or from the success achieved. In a single-handed practice, there is often no one with whom the doctor can have a challenging discussion. The practice nurse might well feel unable to criticise the doctor's treatment of a patient; a peer view is necessary. Significant event review was not commonly undertaken when Shipman was in practice. If it had been, and if he had worked in a group practice, this form of review might have been effective in detecting Shipman's unlawful killing. If Shipman had had professional colleagues who were entitled to scrutinise his account of a patient's death and the management decisions he had taken, I think it would have provided a real deterrent to him and a greatly improved prospect of detection of his misconduct if it had continued.

13.50 Other forms of audit are more effective in a group setting than within single-handed practice. Although, for over ten years, it has been official Government policy to encourage audit within general practice and funding has been provided to reward it, audit activity is essentially private to the practice to which it relates. Thus, the results of an audit of patient deaths in a particular period would remain confidential to the practice, even if those results were to reveal serious deficiencies of care. In 1998, Shipman claimed to have carried out an audit of deaths occurring in his practice in the first three months of the year. In fact he had done no such thing. In the context of a group practice, the fact that an audit is carried out will be known to all partners and the results will be available to all. If they give rise to

concern, there is a far greater prospect that action will be taken to remedy the problem than if the problem is known only to the single-handed doctor. Although such audits may not be widely practised, there is published evidence that they are or can be of value.

Individual Responsibility and Accountability

13.51 Dr Taylor suggested that, in single-handed practice, there is a much greater degree of accountability and responsibility for patient care. The doctor is individually responsible for the care of every patient and cannot pass on responsibility to anyone else. Thus, in his view, a doctor is more likely to address and resolve a problem of patient care than to sit back, in the hope or expectation that more positive action will be taken by a colleague at some later date. I can see the force of that argument. I can also see how a doctor who shares the responsibility for a patient's care with other doctors might be reluctant to recommend treatment that has not been initiated by any of his/her colleagues when the patient has presented in the past with the same symptoms. There may be a natural tendency to 'go along with' the majority view, even though that course may not be correct.

13.52 The exclusive responsibility described by Dr Taylor also carries with it the disadvantage that the doctor's treatment will never come under the type of informal discussion and peer review that takes place every day in practices where patient care is shared.

Management and Administration

13.53 I have already mentioned that one of the reasons given for the declining numbers of applicants for single-handed posts is the preference of young doctors for the environment of a group practice. Professor Baker suggested that economies of scale and the sharing of the clinical workload make group practice attractive to doctors. PCT respondents to the Inquiry questionnaire raised concerns about poor working infrastructure, premises and recruitment arrangements in single-handed practices.

13.54 Studies have also shown that single-handed practices tend to be less well developed than group practices and may be slower to install modern facilities. This would not necessarily mean that they provided a lower standard of care. However, one study showed that single-handed practices had greater difficulties than group practices in, for example, the recruitment and retention of a practice nurse. Other areas of concern were computerisation and general management[9]. Mr Newton's personal experience confirmed the existence of this type of problem in single-handed practices. Responses to the survey of PCTs suggested that single-handed practitioners encountered greater difficulties in providing out of hours cover although this should cease to be a problem after January 2005 when PCTs assume responsibility for the provision of out of hours care. Mr Newton said that managing a practice single-handed and trying to keep abreast of developments in clinical treatment imposed a heavy burden on GPs, especially as they approached retirement age.

[9] Leese B and Bosanquet N (1995) 'Change in general practice and its effects on service provision in areas with different socio-economic characteristics', BMJ, Vol 311: pp 546–550.

Complaints

13.55 In Chapter 7, I described the system of handling complaints against GPs that has been in operation since 1996. I mentioned the particular difficulties experienced by patients who, at present, are obliged to lodge their complaint directly with the GP practice concerned. The patient feels embarrassed and will often decide not to complain rather than confront the doctor or the practice staff. The problem is exacerbated if the complaint is about a single-handed practitioner. The September 1999 report by the Public Law Project, entitled 'Cause for Complaint? An evaluation of the effectiveness of the NHS complaints procedure', to which I referred in Chapter 7, mentioned the desirability of having a 'buffer' between the person complaining and the person complained about. This buffer is absent in the single-handed practice, where the staff are likely to feel a strong sense of loyalty to their employer. The need for a patient to be able to take a complaint to a person or body unconnected with the practice is clear, in my view, throughout general practice but is that much greater when the complaint is about a single-handed GP.

Reporting Concerns and Staff Complaints

13.56 I have also explained, in Chapter 9, that it is difficult in any general practice for a member of staff to raise a concern about the conduct, health or performance of a GP in the practice. Raising a serious concern may well in effect signal the end of the relationship. Those problems are accentuated in small and single-handed practices.

Mitigating the Problems of Single-Handed Practice

13.57 It will be clear from the above that the main problems associated with single-handed practice are the absence of peer review, the risk of clinical isolation and the danger of abuse by the doctor of the trust implicit in the continuity of care. I shall now examine the mechanisms that may be used to alleviate these problems.

Clinical Governance and Clinical Audit

13.58 According to the RCGP, with the advent of PCTs, the problems of isolation in general practice are being reduced. PCTs are smaller, more local organisations than their predecessor health authorities (HAs). They are closer to the practices for which they have a responsibility. Greater involvement with the PCT has resulted in more frequent meetings with colleagues and more collaboration at PCT level. The extent to which this occurs no doubt varies from place to place. Mechanisms are in place to require single-handed GPs to participate in clinical governance and appraisal. I am of the view that appraisal and revalidation could have substantial value if they really assured continuing competence and fitness to practise. Single-handed GPs may also participate in peer support schemes. Dr Reith explained to the Inquiry how significant event review can be undertaken in the context of single-handed practice.

13.59 According to Mr Michael Warner, former Project Director, Avon, Gloucestershire and Wiltshire SHA, it became standard practice during the late 1990s in his SHA for

single-handed GPs to share their results and to discuss their audits with each other. This was overseen by the Medical Audit Advisory Group.

13.60 Dr Taylor's practice seeks to reduce any danger of isolation by an association with two other small practices in the district. The three practices have separate patient lists but they share some members of staff. The doctors operate a rota for emergency and out of hours work and have a joint database of patient records to facilitate the working of the rota. They also use these shared computerised records for the purpose of collective clinical audit and prescribing analyses. Dr Taylor said that more small practices were co-operating in this way since clinical governance and clinical audit were introduced. Many small or single-handed practices close for half a day each week to carry out significant event review.

13.61 The Inquiry was told of one 'Small Doctors Group' whose members met to discuss their practices. I got the impression that, although their initiative was regarded by the SHA as a positive step, their practices were very disparate and the meetings did not provide any rigorous contribution to clinical governance.

13.62 Professor Baker recognised the potential for such local initiatives to enhance clinical governance in single-handed practice. I think he was right, however, when he said that the success of such initiatives depended upon someone recognising where action was needed and being determined to lead a group of practitioners down the right path. Those who are most likely to recognise where action is needed are single-handed GPs themselves but they may have the least time available to initiate it.

13.63 At the moment, involvement in group activities such as I have described is not only voluntary, it is not even universally available. Even where it is available, the products of collaboration – such as the results of joint audit – are not verifiable. According to the RCGP, all doctors should be accountable, primarily to their patients, and, more widely, to the NHS and to the public. I agree that they should, but the fact is that at the moment they are not. At present, it is quite possible for any GP, perhaps especially the single-handed GP, to avoid participation in joint activity and/or to mislead his/her colleagues or peers. I can well imagine how Shipman would have selected a number of 'significant events' for review in a way that would have shown him only in the most favourable light. Under most of the collaborative arrangements I have heard about, there would be no possibility that he would be required to offer a particular death for significant event review.

13.64 In the Report of the independent investigation into how the NHS handled allegations about the conduct of Clifford Ayling concern was expressed that GPs still practise in isolated situations where there is no immediate mentoring, either formal or informal. Acknowledging that there will always be single-handed GPs, it specifically recommended that PCTs should develop support programmes for single-handed GPs, to be agreed with each single-handed practitioner and with the SHA. Such programmes should pay special attention to managing the risks of isolation associated with single-handed practice. Implementation should be monitored by the SHA and should form part of the regular Commission for Healthcare Audit and Inspection (now known as the Healthcare Commission) review of the PCT. I would agree with this proposal and would only add that the programmes should provide a real element of mutual supervision as well as support.

Management and Administration

13.65 Mr Greenwood told the Inquiry that PCTs in several areas promote improved management in single-handed practices by encouraging the sharing of practice staff, practice managers and nursing staff. In this way, small practices can benefit from a range of expertise and services, which they would otherwise not be able to afford. Some PCTs will also pay a 'locum allowance' to enable single-handed GPs to engage a replacement doctor while attending continuing professional development events. Recognising the management difficulties often experienced by single-handed or small practices, Manchester HA established a Small Practice Adviser Scheme. This involves two very experienced practice managers working with a number of small practices to provide advice and support in practice organisation. Mr Newton told the Inquiry that, in areas of social deprivation, where significant PCT input may be required, a PCT might fund the appointment of a salaried doctor and nurse to assist a single-handed GP.

13.66 The Inquiry heard evidence about steps that have been taken to accommodate the needs of single-handed GPs working in very isolated areas in Scotland (e.g. the Highlands and Islands). Historically, they were unable to obtain regular time off and encountered problems of social and professional isolation. Under the 1991 GMS Contract, an 'associates' allowance' was successfully introduced in such areas to fund the employment of an 'associate' GP. Dr Whyte told the Inquiry that more than two thirds of rural practices have made use of such schemes, which allow the employment of associates, shared between two or three practices, so as to allow the single-handed GP time off for holidays, sickness and continuing professional development. In fact, I take the view that any arrangement whereby doctors, nurses or members of staff from outside the practice are brought in on a regular basis has the advantage of bringing a 'fresh pair of eyes' and of enabling comparisons with practice elsewhere to be made. It could also enable a PCT to be informed of any problems or shortcomings with the practice.

The Netherlands

13.67 Single-handed practice has been the traditional model for delivery of primary care in the Netherlands, although this is now changing. Over time, and in an *ad hoc* way, single-handed GPs have grouped together in ways intended to improve quality of care. The historical basis for this co-operation in so-called **'quality circles'** or peer review groups began about 20 years ago when there was an obligation for every single-handed GP to organise his/her practice into a larger group for the provision of out of hours care. Grouping of practices developed to meet this objective and gradually the same group took on a role in continuing medical education. According to Professor Baker, clinical audit meetings are held at which attendance is compulsory. Groups of practitioners, led by trained facilitators, review their clinical performance by reference to data submitted by individual practices.

Conclusions

13.68 It seems to me that single-handed practices vary in much the same way as do group practices. Some of each are good, bad or indifferent. Certainly, group practices do not

have a monopoly on high quality patient care. Small and single-handed practices have their devotees, particularly among those who seek a personal relationship with their GP and who value the continuity of care which this provides. The number of small practices may be diminishing for a variety of reasons. However, there are still a significant number of them and this is likely to be the position for the foreseeable future.

13.69 That being so, it seems to me that the policy of the DoH and of PCTs should be to focus on the resolution of the problems inherent in single-handed or small practices rather than to try to reduce the numbers of them in existence. I know that the DoH says that it has no such policy but I have the clear impression that such a policy exists in the regions, if not in Whitehall. It is typified by the attitude that single-handed practices are a problem and that the NHS would be better off without them. As I have said, the numbers are likely to decline with time in any event.

13.70 I have already described a number of the problems that are inherent in single-handed and small practices. I have also described a number of initiatives that are already being undertaken in an attempt to resolve or mitigate those problems. To my mind, the important thing now is that, for the sake of the patients registered with them, single-handed practitioners should be given more support and encouragement. In return, more should be asked of them in terms of group activity and mutual supervision. It is not for me to suggest how this should best be achieved. The current initiatives are patchy and uncoordinated. I do not suggest that there is a 'one-size-fits-all' solution to these problems. The needs of small practices in Cornwall may be very different from those in Central Manchester. What is needed, in my view, is a pooling of ideas, a willingness to examine the ways in which things are done in other places, such as the Netherlands, and a determination to solve the problems.

13.71 I turn to consider what significance, if any, attaches to the fact that Shipman was always technically a single-handed practitioner and never worked in a group practice with a shared patient list. Did this make it easier for him to escape detection? Did he feel more confident that his crimes would go undetected? First, I observe that Shipman killed at least 71 patients when he was at the Donneybrook practice and that his colleagues at the practice were, through no fault of theirs, unaware of what was going on. This confirms my belief that a devious and aberrant doctor is not significantly more likely to be deterred or detected just because s/he is in partnership and/or working under the same roof with other doctors. I suspect that it was Shipman's general character rather a feeling of likely detection if he were to remain that caused him to move from the Donneybrook practice. Second, I believe that if the Donneybrook practice had been a true group practice with shared lists, Shipman probably would have felt less confident that he would escape detection. If his fellow doctors had had some involvement in the treatment of those who were to become his victims, he would have felt less confident in making up false medical histories and they might have become suspicious if unusual patterns had developed. Much depends on what would have been the actual arrangements and the extent to which there would have been true mutual supervision or monitoring. Of course, that leaves open the question whether, if that had been the situation, Shipman would ever have applied for the position or remained there for so long – he might well not have done.

13.72 In my view, the fact that Shipman had his own patient list, and was free from the informal supervision and monitoring that accompanies the sharing of patient lists, did mean that he was less likely to be deterred or detected. However, the availability of other more formal methods of monitoring, through clinical governance, could have had a similar effect. If resources and ingenuity were to be applied to the problem, clinical governance methods of monitoring could be applied to single-handed and small practices, as well as to larger group practices. I do not think that the fact that Shipman was a single-handed practitioner should be used as a reason for preventing GPs from practising alone.

CHAPTER FOURTEEN

The Monitoring of Mortality Rates among the Patients of General Practitioners

Introduction

14.1 At the time when Shipman was in practice, there was no system in place for monitoring mortality rates among the patients of general practitioners (GPs). There is not – and never has been – any requirement that primary care organisations (PCOs) should monitor mortality rates at GP or GP practice level. Nor is any such monitoring carried out by any national body, such as the Department of Health (DoH).

14.2 When the scale of Shipman's crimes became evident, many people were surprised that no system of monitoring GP patient mortality rates was in operation. It was suggested that, had such a system existed, it might have alerted the authorities, years before Shipman's eventual detection, to the fact that there was an unexplained excess of deaths among his patients.

14.3 In this Chapter, I shall consider the feasibility of setting up a system for the routine monitoring of mortality rates among the patients of GPs. I shall discuss the potential benefits of introducing a system for monitoring mortality rates, and shall consider also the problems that might be encountered by anyone seeking to set up such a system.

The Analysis of Mortality Data before Shipman's Arrest

In England and Wales Generally

14.4 The Inquiry team wanted to know what steps, if any, had been taken by PCOs in the past to monitor mortality rates among the patients of GPs in their areas. Accordingly, in August 2002, the Inquiry distributed a questionnaire to all strategic health authorities (SHAs) in England and health authorities (HAs) in Wales, requesting information about any monitoring of mortality rates which had been undertaken by the PCOs in their areas in the past, or was being undertaken currently. The responses to this questionnaire revealed that, before Shipman's arrest in 1998, there had been very few attempts by PCOs to collect and analyse GP patient mortality data of any kind. Those few attempts that had been made had been directed, not to detecting abnormal mortality rates, but to examining deaths from specific diseases or conditions or, in one case, to providing data to GPs about the deaths of their patients in order to enable them to carry out significant event reviews of those deaths. The Inquiry was told that, in some PCO areas, attempts to analyse mortality data had met with little success, largely because of problems with data linkage.

In the West Pennine Area

14.5 Neither the West Pennine Health Authority (WPHA) nor its predecessors, the Tameside Family Practitioner Committee and the Tameside Family Health Services Authority (FHSA), had undertaken any monitoring of the mortality rates among the patients of GPs on their list prior to Shipman's arrest. As I have explained, that was entirely typical of the vast

majority of PCOs in England and Wales at that time. There can be no criticism of the WPHA for the fact that it did not undertake any monitoring of this kind.

The Reasons Why Monitoring Was Not Undertaken

14.6 There are a number of reasons why PCOs did not monitor GP patient mortality rates. First, as I have said, there was no requirement for them to do so. Nor were they advised that monitoring of this kind might be of value. It seems likely that most PCOs never even considered the possibility of doing so. It is doubtful that it would have occurred to anyone before Shipman's activities came to light that a GP might be guilty of criminality or neglect on such a scale that it would result in an observable excess mortality rate for patients of his/her practice. As I have said, those PCOs which attempted to collect and analyse mortality data did so for purposes other than monitoring the numbers of deaths.

14.7 The Office for National Statistics (ONS) holds mortality data collected from death certificates. That data includes details such as cause and place of death, together (except in the case of deaths certified by a coroner) with the name of the doctor who certified the cause of death. The ONS mortality data does not include the name of the GP or GP practice with whom the deceased person was registered.

14.8 Individual PCOs hold lists of patients registered with GPs and GP practices in their areas. In order to collect data about the deaths of patients registered with an individual GP or GP practice, it is necessary, under the present system, to link the data held by the ONS with data stored in the PCO systems.

14.9 I have mentioned that there were problems with data linkage. These problems arose from the absence of any national system linking the fact or details of a person's death to the GP practice with which that person had been registered. It was possible for a PCO to make the link in an individual case if it wished to do so, by matching ONS mortality data with its own patient list data. However, the task of matching the data from these different sources was laborious and time-consuming. Also, its success depended on the accuracy of the information contained in the PCO system. The Inquiry was told by Dr Peter Goldblatt, Chief Medical Statistician, ONS, that, even now, the accuracy of the data on PCO systems varies widely from area to area. There is a problem in some areas with inflation of lists, i.e. the inclusion on GP patient lists of the names of people who are no longer patients of the GP practice on whose list their name appears. The Inquiry was told that, in some urban areas with a mobile population, there is list inflation by as much as 15% to 20%. Also, the data on a PCO system includes only information relating to patients living within that area. It does not include information about patients who live outside the area but are registered with a GP in the area. Thus, the information on a PCO's system about the patient lists of GPs practising near to the area boundaries of the PCO tends to be incomplete.

14.10 As I have said, the problems with data linkage caused difficulties in the past for some PCOs which attempted to collect or analyse mortality data for GPs in their areas. It no doubt had the effect of deterring others from making the attempt at all. Until 1998, PCOs confined themselves in general to conducting analyses which examined deaths from specific causes among resident populations at electoral ward level. The data for such analyses was readily available and no complex linkage was required. The WPHA carried

out this type of analysis with the aim of identifying any socio-economic, environmental or other factors that might be affecting death rates.

The Analysis of Mortality Data after Shipman's Arrest

By the West Pennine Health Authority

14.11 After Shipman's arrest and after it became clear that he might have killed a large number of his patients, the WPHA conducted various analyses of the mortality rates among his patients. The object of these analyses was, first, to discover the likely extent of his criminality and, second, to ascertain whether it would have been evident that Shipman's mortality rates were excessive if those rates had been monitored during the period of his criminality. The task of linking the data used in these analyses was difficult and time-consuming.

14.12 The analyses showed that, in several years, Shipman had a statistically significant excess number of deaths. However, when the analyses were focussed on the deaths of patients which had occurred at the patient's home or on the deaths among his elderly female patients, there was a statistically significant excess of deaths among these groups of patients in most years from 1992 to 1998.

14.13 In April 1999, the WPHA submitted to the DoH a report on the policy implications for the NHS arising from what was then known about Shipman's activities. In that report, the WPHA recommended that routine monitoring of GP patient mortality rates should be introduced and that the value of such monitoring should be tested. The report acknowledged that there might be difficulties in interpreting apparent excesses in the mortality rates of the patients of individual GPs. However, it suggested that such excesses might give an indication that more in-depth investigation was warranted in the case of a particular GP. The monitoring of mortality rates might, it was suggested, form part of **'the overall performance assessment framework'**.

By Other Primary Care Organisations

14.14 Shipman's arrest and conviction caused a number of other PCOs to consider conducting some form of analysis of mortality rates among patients of the GPs in their areas. Some PCOs carried out a 'one-off' exercise. Others were more ambitious and attempted to develop systems of monitoring mortality rates on an ongoing basis. A few developed systems for gathering and analysing mortality data which was then fed back to GPs, as part of a collection of performance indicators. Following receipt of the responses to its original questionnaire, the Inquiry sought and obtained further information from some PCOs which had undertaken analysis of mortality statistics over the last few years. Their accounts of their experiences were very illuminating and I shall refer to some of them later in this Chapter.

By Professor Richard Baker

14.15 Following Shipman's convictions for murder in January 2000, the Chief Medical Officer, Professor (now Sir) Liam Donaldson, commissioned a clinical audit of Shipman's practice.

The audit was carried out by Professor Richard Baker, Director, Clinical Governance Research and Development Unit, University of Leicester. Professor Baker first analysed the pattern of deaths in respect of which Shipman had issued a Medical Certificate of Cause of Death (MCCD). As I explained in my First Report, a GP will generally be in a position to issue a MCCD only when a patient has died in the community (i.e. at home or in a care home) and where the death does not have to be reported to a coroner. If a patient dies in hospital, the MCCD will usually be issued by a hospital doctor. The process of issuing a MCCD is often termed 'certifying the death'.

14.16 Professor Baker carried out two analyses. His first analysis involved comparing the number and various features of the MCCDs issued annually by Shipman with those of the MCCDs issued annually by two control groups of other GPs who had been in practice at the same time and in the same localities (i.e. Todmorden and Hyde) as Shipman, and whose patients had similar socio-economic characteristics.

14.17 Professor Baker's second analysis compared the annual number of deaths which had occurred among persons who had been patients of Shipman from 1987 onwards (not just those patients whose deaths Shipman had certified) with the annual number of deaths that could have been expected to have occurred among that patient population. Shipman's patients were identified by means of the patient list data held by the WPHA. The ONS performed the necessary linkage of that data with information about deaths. The number of expected deaths was calculated by reference to figures which were provided by the ONS and which related to deaths among the population of the local (Tameside) district and of a group of districts sharing population and socio-economic characteristics similar to those of Tameside, and also by reference to deaths among the general population of England and Wales.

14.18 Professor Baker's analyses indicated that, while practising in Todmorden and Hyde, Shipman had issued an 'excess' total number of 236 MCCDs relating to deaths occurring at the patient's home or on his practice premises. This figure was very similar to the number of deaths that I found had been caused by Shipman during his time in Todmorden and Hyde.

14.19 At the conclusion of the report on the results of his clinical audit, Professor Baker made a number of recommendations. Among these was a recommendation that systems for the monitoring of GPs should be reviewed and extended to include routine monitoring of mortality rates among their patients. He pointed out that Shipman's case had demonstrated that, in the absence of the monitoring of mortality rates, it was possible for a GP with a sustained excess rate of mortality among his/her patients to go undetected for many years. However, Professor Baker acknowledged that there were a number of difficulties with the monitoring of mortality rates. The first was their inherent variability. The second was the fact that, under normal circumstances, many of a GP's patients will die at a time when they are not under his/her management. The most common example of this is when a patient dies in hospital. Professor Baker suggested that his clinical audit had highlighted some factors that might improve the ability of monitoring systems to detect abnormal mortality rates or criminal activity. He also suggested that the monitoring of the number of deaths certified by GPs – rather than the mortality rates among their registered

patients – would be more indicative of the GP's clinical activities. He also referred to the potential value of analysing the excess cumulative mortality rate of GPs so that all excess deaths of a GP throughout his/her career would be assessed, not just those occurring in individual years.

14.20 Professor Baker went on to point out that the collection of data resulting from the monitoring of mortality rates would not of itself be sufficient. There would have to be a regular review of the findings. He said that one argument against the monitoring of mortality rates was that it would require too great an investment of time and other resources and that GPs were already over-stretched. It might, he said, also be contended that such monitoring was unnecessary, since cases such as Shipman's were exceptionally rare. It might also be said that individuals determined on murder would adopt strategies to avoid detection. Nevertheless, he believed that steps should be taken to introduce a system of monitoring mortality rates.

The Response of the Department of Health

14.21 On 1st February 2000, immediately following Shipman's conviction, the then Secretary of State for Health, the Rt Hon Alan Milburn MP, made a statement to the House of Commons, in which he announced that the DoH was working with the ONS **'to find new and better ways of monitoring deaths of GPs' patients'**. Since then, the DoH has been considering the feasibility and practicability of collecting and using mortality data to monitor deaths of patients at GP or GP practice level. I shall refer to the outcome of the work undertaken by the DoH later in this Chapter.

The Inquiry's Approach

14.22 It was evident to me from an early stage that the Inquiry had to examine the possibility of setting up a system for the routine monitoring of mortality rates among the patients of GPs. I wanted to discover whether, using existing data sources, it would be possible to provide complete and accurate information on which such monitoring could be based. I also wanted to find out whether such monitoring would be capable of identifying abnormalities in mortality rates and, if so, at what level (i.e. GP, GP practice or primary care trust (PCT) level) it would be capable of doing so. If routine monitoring was likely to be capable of detecting abnormalities at any level, I wanted to know who would be best placed to organise such monitoring and by what method it could best be done. In order to assist me in answering these questions, it was clear that the Inquiry needed the services of an expert.

The Commissioning of Work from Dr Paul Aylin and His Team

14.23 The Inquiry team commissioned Dr Paul Aylin, Clinical Senior Lecturer in Epidemiology and Public Health, Imperial College of Science, Technology and Medicine, to carry out the necessary work and to report. Dr Aylin was a consultant to the Public Inquiry into children's heart surgery at the Bristol Royal Infirmary (the Bristol Royal Infirmary Inquiry) and had previously been employed by the ONS as a medical statistician. He assembled a team, all from Imperial College, consisting of Dr Nicky Best (Senior Lecturer in Statistics), Dr Alex

Bottle (Researcher) and Dr Clare Marshall (Lecturer in Statistics). Dr Aylin and his team were asked to determine:

- if there was any benefit in monitoring mortality data at local level
- at what level (i.e. GP, GP practice or PCO) such monitoring should be conducted
- how the monitoring should be done
- what method of analysis would be appropriate
- at what point there should be concern about the patient mortality rate of the unit (i.e. GP, GP practice or PCO) being monitored
- who should do the monitoring.

14.24 Dr Aylin and his team prepared a report and, in July 2003, gave a presentation of their work to the Inquiry. An account of their work has subsequently been published in The Lancet[1] and is at Appendix E to this Report.

The Inquiry's Seminar

14.25 The work of Dr Aylin and his team, together with wider issues relating to the monitoring of GP patient mortality rates, was discussed at a two-day seminar held by the Inquiry in October 2003. Participating in that seminar were a number of experts in the field. As well as Dr Aylin and his team, there were Dr John Fox (Director of Statistics, DoH), Dr David Spiegelhalter (Medical Research Council Biostatistics Unit), Dr Mohammed A Mohammed (Senior Research Fellow, Department of Public Health and Epidemiology, University of Birmingham), Dr Christopher Roberts (Senior Lecturer in Medical Statistics, School of Epidemiology and Health Sciences, University of Manchester) and Dr Goldblatt. In addition, the seminar was attended by Professor Baker, Dr Maureen Baker (representing the Royal College of General Practitioners (RCGP)), Dr John Grenville (representing the British Medical Association (BMA)) and Professor Gwyn Bevan (then Acting Head of Information, Commission for Health Improvement (CHI) and a member of the transition team for the new Commission for Healthcare Audit and Inspection (now known as the Healthcare Commission)). In addition, the Inquiry invited to the seminar representatives from a number of PCOs who had experience of carrying out work involving the analysis of mortality rates among the patients of GPs or GP practices. A full list of seminar participants is at Appendix F to this Report.

14.26 Participants in the seminar submitted written material in advance and expanded on that material during the course of discussions at the seminar. The discussions were led by Leading Counsel to the Inquiry. The seminar produced a very interesting discussion about the benefits that might accrue from the monitoring of mortality data, and about the problems that might be associated both with the monitoring process and with the investigation that must necessarily follow the detection of any apparent abnormality. The discussion concluded, as will become clear, with an encouraging degree of consensus on the way forward.

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[1] Aylin P, Best N, Bottle A, Marshall C (2003) 'Following Shipman: a pilot system for monitoring mortality rates in primary care', The Lancet, Vol 362: pp 485–491.

14.27 I am most grateful to Dr Aylin and his colleagues for the work that they have done for the Inquiry. It is innovative and, as I had hoped, it has made a real contribution to the debate about the feasibility and the value of setting up a system for the routine monitoring of mortality rates among the patients of GPs. The work of Dr Aylin and his team appears to have been well received by their peers and was the subject of much praise at the seminar.

The Work of Dr Paul Aylin and His Team

14.28 The report prepared by Dr Aylin and his team is on the Inquiry's website. Their work is well described in the published account to which I have already referred. I shall refer here to some of the main points of the system which they have devised.

Data Linkage

14.29 As I have already explained, in the past, the absence of any national system of linking mortality data held by the ONS to the GP or GP practice with whom the deceased person had been registered made it difficult to collate the data necessary to carry out an analysis of mortality rates among the patients of GPs. Even if a link was made, the resultant data was likely to be incomplete and, probably, inaccurate. Dr Aylin and his team carried out a pilot exercise aimed at linking national death registration records to the GP patient list data for five former HAs, including the WPHA. A special computer program was used to link ONS mortality data for the years from 1993 to 1999 with anonymised patient list data. Deaths were linked to the GP with whom the deceased person was registered, using patients' NHS numbers, date of birth, gender and postcode. The NHS Information Authority provided Dr Aylin and his team with patient list sizes for every GP and GP practice in the five HA areas during the years from 1993 to 2000. The data divided the patient population into three age bands (0–64, 65–74 and 75 and over). These age bands were broad, but constituted the best information available for the period.

14.30 The overall degree of success in linking death registration records to patient lists varied between each of the five HA areas. There was a low success rate (no more than 60%) for the WPHA up to 1999. This apparently resulted from loss of data at the time when two former FHSAs merged to create the WPHA. In general, the linkage improved markedly after 1997, when individual patient NHS numbers first became available. Dr Aylin told the Inquiry that this improvement suggested that data linkage in any future monitoring exercise would be more successful. The overall success rate in linking records was 92%. In 2000, it was 98%–99%.

14.31 Since 2000, the DoH has been working on the provision of a single database containing information on every deceased NHS patient, including the identity of the GP or GP practice with whom the patient was registered and the cause of death. The database is to be held by the NHS Information Authority. It has already been tested by several PCTs and it seems likely, as Dr Aylin suggested, to provide better linkage and more accurate data than was available to Dr Aylin and his team when they carried out their analysis.

14.32 When the pilot linkage exercise was carried out by Dr Aylin and his team, the patient list data for GPs whose practices were near the boundary of a HA area appeared to be

incomplete. This was probably because some of the patients of those GPs lived in the areas of neighbouring HAs. The data relating to such a patient would be contained in the database for the HA area in which s/he lived. In an attempt to overcome the problem of incomplete data, Dr Aylin and his team excluded from their analysis those GP practices with patient list sizes of fewer than 1000 patients for any of the years from 1993 to 1999. They did so on the assumption that those practices' patient lists must be incomplete. However, exclusion of some practices is not a solution which could be adopted for a national system of monitoring mortality rates. Dr Aylin emphasised that, in order to avoid the problem in the future, it would be necessary to have a national system of data linkage.

14.33 Dr Aylin and his team chose to look at annual death rates, rather than death rates over a shorter period. This was primarily because of the small number of deaths involved. Another factor was the delay between the occurrence and registration of a death and the compilation of mortality statistics nationally. In the past, there has been a considerable time lag (amounting to several months) before the relevant mortality data was available and could have been linked with patient list data. This would have meant that monitoring would have had to take place several months in arrears. Dr Goldblatt said that it should be possible in the future to obtain information about 97% – possibly more – of deaths within about two weeks of the death occurring. This would mean that analysis of mortality statistics could take place much earlier than would previously have been possible. Dr Mohammed suggested undertaking analyses on a six-monthly or quarterly basis. Dr Aylin said that this would be possible under his system. However, he would not advise more frequent analysis in view of the small numbers of deaths involved.

The System of Prospective Monitoring

14.34 Dr Aylin and his team developed a system that could be used to monitor mortality rates prospectively. The system was intended to be a screening tool for the purpose of identifying units which appeared to have mortality rates higher than would be expected. Dr Aylin and his team described the system as a 'surveillance' system. Dr Spiegelhalter observed at the seminar that surveillance would act as an 'automatic whistleblowing procedure' which would alert people to the fact that something might be going wrong. Once such a signal had sounded, a decision would then have to be taken as to what, if any, action was needed in response to it, in order to detect whether there was a problem with poor clinical practice affecting death rates or even with potential criminal activity. He distinguished the 'surveillance' of mortality data from the 'monitoring' of mortality data. The latter, he suggested, would be undertaken as part of the monitoring of a pool of information which could be examined and used for the purpose of quality improvement. Clearly, both 'surveillance' and 'monitoring' fulfil useful functions. Rather than attempting to distinguish between 'surveillance' and 'monitoring' throughout this Chapter, I shall use the word 'monitoring' to describe both.

14.35 The distinctive feature of prospective monitoring is that it involves monitoring continuously over time, rather than taking a single snapshot look and comparing performance at one time point. Data is accumulated over time and the analysis is repeated at every time point. This has particular benefits when viewing the small numbers of deaths among patients of

GPs. The aim is to detect unusual variation in the underlying mortality rate of any unit (e.g. of an individual GP) as soon as possible after it has occurred.

14.36 It should be noted that the analysis carried out by Dr Aylin and his team related to the deaths of all patients registered with the relevant GPs, not just to those deaths which the GPs had certified. The number of deaths for each GP was compared with the number of deaths which could be expected among the total patient population for that GP. It was not possible to perform an analysis by reference to the number of deaths certified by each GP. This is because there was no comparison patient population available by which to calculate the number of deaths which each GP could be expected to certify.

Statistical Process Control Charts

14.37 The method developed by Dr Aylin was derived from statistical process control (SPC) which was originally developed for use in the quality control of industrial processes. It is based on the recognition that the outputs of even the most stable and perfectly tuned production process will inevitably show some variation (known as common cause variation). This common cause variation means that, even under ideal conditions, a group of similar doctors will never match one another's performance from one period to the next.

14.38 In developing a system of monitoring, it is important to be able to distinguish 'common cause' variation from variation that has occurred as a result of a 'special cause'. A special cause is a factor extrinsic to the normal functioning of the process being monitored, which gives rise to variation over and above the common cause variation that can inevitably be expected in any stable process. Common causes will be responsible for most of the variation observed in a monitoring system and will produce 'background noise' in the monitoring of a stable process. Ideally, the monitoring system should be designed to 'signal' the fact that variation due to some special cause has or might have occurred and to indicate that steps should be taken to identify the special cause.

14.39 SPC charts were designed to detect and signal the point when an industrial process goes from being stable, in control and exhibiting only common cause variation to being unstable, out of control and exhibiting special cause variation. The degree of common cause variation may be acceptable. If it is not, action on the underlying process will be necessary to eliminate or reduce it. If the process becomes unstable – because there is some special cause variation – an investigation will be necessary in order to determine what special cause is responsible for the variation. That special cause must then be addressed as necessary. Special cause variation is not necessarily a bad thing; whether it is good or bad is a matter for judgement depending on the circumstances of the particular case.

14.40 SPC charts are created with 'control limits', representing the upper and lower limits of common cause variation. Suitable limits, like the limits for any diagnostic test, must balance the disadvantage of erroneously signalling that a special cause is present when it is not (i.e. a false positive) and the disadvantage that would result from failing to detect the presence of a special cause (i.e. a false negative). Control limits with high specificity (i.e. capable of discriminating to a high level) are the most appropriate.

14.41 The system of monitoring advocated by Dr Aylin and his team is similar to that described above, in that it aims to identify and signal when a GP's mortality rates appear to be subject to (special cause) variation over and above that variation which would be common to all GPs with similar features. The application of SPC charts involves defining when mortality rates may be considered acceptable or 'in control' and when they are deemed to have become unacceptable or 'out of control'.

14.42 Plotted on the SPC chart is the value of the chart statistic, which represents the difference between the observed outcomes (i.e. the annual mortality rates) for the relevant unit (in this case a GP or GP practice) and the outcomes which would be expected if the GP or GP practice was performing acceptably. The chart statistic is plotted against time. A pre-defined alarm threshold is set. All the time the chart statistic stays below that threshold, the mortality rates of the GP are considered to be in control and showing common cause variation only. However, if the chart statistic crosses the alarm threshold, it signals that there may be some factor affecting the GP or GP practice which has caused the mortality rate to become unstable or out of control and to exhibit special cause variation. The signal should then be followed up and investigated in order to find an explanation for it.

14.43 The earliest type of SPC chart is known as the Shewhart control chart (named after Walter Shewhart, who first devised it). By convention, the control limits on a Shewhart chart are set in such a way that 99.8% of the common cause variation would fall within these limits. A sequence of observed outcomes over time is plotted on the chart and when, at any time point, the observed outcome goes above the upper control limit or below the lower control limit, the chart signals that there is special cause variation. The chart statistic on a Shewhart chart is independent at each time point. It does not depend on or reflect historical data. There is no accumulation of previous values of the chart statistic. There is, therefore, no accumulation of evidence of any unusual variations that may have occurred over a number of time points.

Cumulative Sum Charts

14.44 By contrast, the type of SPC chart used by Dr Aylin and his team (known as a cumulative sum (CUSUM) chart) adds in 'new' observations to the previous value of the chart statistic. Thus, each observation is based on both historical and new observations. The reason why Dr Aylin and his colleagues used this approach was that they believed that what was needed was a system that would detect substandard or aberrant practice over a period of time. The effects of such substandard or aberrant practice may not be evident at a single time point. They may become obvious only when evidence of performance over an extended period is accumulated and considered. I have already mentioned that, in the report of his clinical audit, Professor Baker had recognised the potential benefits of monitoring cumulative mortality rates and had recommended that the possibility of using a cumulative method of monitoring should be investigated.

Variation

14.45 One of the problems with transferring the technique of monitoring used in an industrial process control setting to a healthcare setting is that the process going on within a GP

practice is very much more complex than an industrial process. As a consequence, the extent of intrinsic variation (common cause variation) is typically quite large. It therefore becomes very important to identify variation which is intrinsic and to distinguish it from the special cause variation which the monitoring is designed to detect.

14.46 When comparing the mortality rates for the patients of GPs from year to year, there are likely to be considerable differences between individual GPs and even between the mortality rates for patients of the same GP from year to year. These differences can be caused by several types of variation.

The Type of Variation that the Monitoring System Is Designed to Detect

14.47 When setting up a monitoring system, it is necessary to identify in advance the particular type of variation that the monitoring is intended to detect. In the case of the monitoring of mortality rates, monitoring is intended to detect unusual variations in the mortality rate or special cause variation. Such special cause variation would occur, for example, in the presence of criminal behaviour such as Shipman's or where poor quality of care by a GP was giving rise to an increased mortality rate among his/her patients. Special cause variation of this kind will exist in the case of only a small number of GPs. When monitoring mortality rates, the object is to ensure that the GPs who are subject to special cause variation are the ones who signal. It is also important to ensure, insofar as it is possible to do so, that their signals are not obscured by 'background noise' from other types of common cause variation.

14.48 In order to eliminate (or, at least, to reduce) the effect of variations other than those resulting from systematic difference between GPs, it is necessary to recognise the types of variation that are inevitable and to use statistical methods to quantify and adjust for those types of variation. Dr Aylin and his team attempted to quantify and to adjust for a number of different types of common cause variation that, if not adjusted for, would potentially have had an effect on mortality rates. Dr Best described those types of variation to the Inquiry.

Chance Variations

14.49 The first type of common cause variation that Dr Best described was the type that occurs entirely randomly, as a matter of chance. The number of deaths among the patients of a GP will vary from year to year, purely as a matter of chance. There are statistical methods, which Dr Aylin and his team employed, of adjusting for the effects of chance.

Case Mix

14.50 The second type of common cause variation is known as 'case mix'. Case mix factors are factors associated with a GP's patient population which are known to have an effect on mortality rates. The most obvious such factors are age and gender. If no adjustment were made for age, GPs with elderly patient populations would be likely to signal as having higher than expected mortality rates whereas, when the age of their patient population was taken into account, their mortality rates might be within a normal distribution. In

addition, a GP with significantly more elderly male patients than elderly female patients would be expected to have a higher mortality rate than one with equal numbers of elderly male and female patients. Another case mix factor known to have an effect on mortality is socio-economic deprivation. If no adjustment is made for that factor, GPs with a deprived population would be more likely to signal.

14.51 Dr Best emphasised that care must be taken when making adjustments for known case mix factors. Adjustments should be made only for factors that are beyond the control of the GP. Otherwise, adjustment might have the effect of masking important variations caused by systematic factors within the GP's practice, which are the very type of variations that the monitoring system is intended to detect. In this context, other participants in the seminar mentioned the dilemma as to whether to adjust for socio-economic deprivation. Mrs Catherine Scott, Specialist in Public Health, Croydon PCT, said that patients in deprived areas may not currently receive the health care they need. This can happen because of a shortage of GPs in deprived areas or for other reasons which might be associated with variations in GP performance or poor clinical practice. These are matters which, in the interests of public health, the PCT might wish to have highlighted, rather than to risk their being masked. Mrs Scott said that, in 2003, her PCT had prepared two sets of mortality data, one adjusted for socio-economic deprivation and one not. The intention was to see how useful the figures proved to be.

14.52 As mentioned earlier in this Chapter, because of the lack of data held by the NHS about patients registered with particular GPs and GP practices during the years from 1993 to 1999, Dr Aylin and his team were only able to adjust for age within three broad age bands (0–64, 65–74 and 75 and over). They used an indirect standardisation method to estimate the expected number of deaths for each GP and GP practice. They had no information on gender or on socio-economic deprivation. Thus, their adjustment was not as sensitive as they would have wished.

Variations Due to External Factors

14.53 Another type of common cause variation which must be taken into account is that caused by external factors unrelated to case mix. An example of this would be the effect of a known event such as a 'flu epidemic, or a spell of particularly harsh weather, either of which could cause a sudden increase in mortality rates.

Variations Due to Unaccounted-for Factors

14.54 A fourth type of common cause variation is attributable to factors not otherwise accounted for. Even after allowing for the effects of chance, for known case mix and for external factors, there may be other factors which could be expected to affect a GP's mortality rate but which are not known to the people carrying out the monitoring. The individual unknown factors may be small, but their combined effect may lead to significant variations. Indeed, work carried out by Dr Aylin and his team suggested that the variation in mortality rates at GP level caused by unaccounted-for factors was about twice that which would be expected as a result of chance variations alone. Dr Best explained that unaccounted-for factors are important but are often ignored by those conducting monitoring of this kind.

She described the method which Dr Aylin and his team used to adjust for this type of variation. It is unnecessary to describe it in detail. However, it is perhaps worth noting that Dr Best considered that there was a need for further work to be done in this area before a monitoring system was implemented.

The Incidence of False Alarms

14.55 When SPC charts are used in an industrial setting, they are used to monitor only a single process at a time. They have also been used for public health and surgical monitoring but, even then, such monitoring has involved only one or two processes at a time. This is very different from a national system for monitoring the mortality rates among the patients of all GPs or GP practices simultaneously. The fact that multiple units (rather than just one unit) are being monitored over time will increase the chances of getting a signal. It will also increase the chance of getting false alarms. It is obviously desirable to reduce the number of false alarms since they will divert attention and resources away from the true alarms that really require investigation. Over time, a large number of false alarms with no positive results would bring the whole monitoring system into disrepute.

14.56 It is important to define exactly what is meant by a 'false alarm'. A statistical false alarm will occur when a GP's patient mortality rate triggers an alarm but the rate is in fact in control and is not exhibiting special cause variation. By contrast, a statistical true alarm occurs where the signal is valid, i.e. the mortality rate *is* higher than would be expected after appropriate adjustments have been made for common cause variation. Many statistical true alarms will be medical false alarms, in that there will be an acceptable clinical explanation for the fact that the patient mortality rate of a GP or GP practice is statistically out of control. There will, therefore, be no reason for concern. A case such as that of Shipman would, however, be both a statistical and a medical true alarm since the mortality rate was indeed out of control and this was due to a special cause variation, namely his criminality.

14.57 The alarm threshold should be set in such a way that the number of statistical false alarms is minimised while, at the same time, the system remains sensitive to true alarms from unstable units which are really exhibiting special cause variation. Dr Aylin and his team ran computer simulations to calculate the false discovery rate (i.e. the proportion of signals occurring before a given time point that will be statistical false alarms) and the successful discovery rate (i.e. the proportion of unstable units exhibiting special cause variation that will be successfully detected before the same time point). They carried out the simulations using different alarm thresholds. They suggested that the false and successful discovery rates could form part of a cost benefit calculation to assist in setting an appropriate alarm threshold for a monitoring system. They suggested also that factors to be taken into account in making such a cost benefit calculation might include the importance attached to detecting GPs whose mortality rates showed special cause variation, relative to the importance attached to avoiding false alarms. The resource implications associated with investigating the cause of alarms would also be a relevant factor.

14.58 Dr Aylin and his team explained that it would be possible to 'tune' a CUSUM chart by identifying two (or possibly more) different thresholds. For example, a lower threshold

would pick up a lower level excess of mortality rates and would constitute an 'early warning', signalling a GP whose mortality rate was at the extreme end of the normal distribution of mortality rates for GPs. This might merit a low-level investigation. A higher threshold might also be set, with a view to sounding an alarm if the mortality rates of a GP became divergent from the normal distribution. A more detailed investigation might then be undertaken. The charts could thus be 'tuned' in such a way as to meet the goal of the monitoring exercise. For the purpose of illustrating the application of their SPC charts, Dr Aylin and his team used two different thresholds.

The Results of the Analyses Carried Out by Dr Aylin and His Team

14.59 Dr Aylin and his team used their CUSUM charts to examine mortality data for 1009 GPs (including Shipman) who practised in the five HA areas during the years 1993 to 1999. The data used was, of course, past data, although Dr Aylin and his colleagues looked at what the charts would have revealed had they been viewed contemporaneously. Data was available only as far back as 1993, so no account could be taken of any excess deaths among Shipman's patients prior to that time.

14.60 The CUSUM chart for Shipman shows that his chart statistic was above zero for 1993 indicating that he had had a greater number of deaths than would have been expected. It fell in 1994, which suggested that he had fewer deaths than expected in that year, given the age distribution of his patients. In fact, the Inquiry found that he killed 11 patients that year, but he might have had few other patient deaths. Thereafter, the chart statistic rose steadily as the excess deaths accumulated. At the lower of the two thresholds set by Dr Aylin and his team, Shipman would have triggered the alarm first during 1996. At the higher of the two thresholds, he would have triggered it first during 1997. He would have continued to signal up to 2000, despite the fact that he ceased practice in September 1998. This is because his GP practice code was taken over by a locum and Shipman's historical data continued to exert an effect. However, after the time when the locum started, a fall in the chart statistic was evident.

14.61 Dr Marshall told the Inquiry that the appearance of the chart for the period after the arrival of the locum in September 1998 highlighted two issues. First, the fact that Shipman's GP practice code had been passed from one doctor to another would not normally be known to the person or body carrying out the monitoring. This could lead to misleading results if monitoring continued. It would clearly be desirable that where, as in this instance, a single-handed practitioner is replaced by another doctor, there should be a change of GP practice code, so that monitoring could be restarted.

14.62 The second issue was what to do when a GP signalled. In this instance, the practice had continued to signal, despite the fact that the special cause variation (i.e. Shipman's criminality) had been removed and the mortality rate had returned to being in control. One option was that, once an acceptable explanation for a signal had been found, the chart should be re-set at zero. That would have the effect of 'wiping the slate clean' and the GP would then have a fresh start. The alternative would be to re-set the chart to some value greater than zero. The effect of that would be to put the GP 'on probation'. The latter approach would make a chart more sensitive to sustained excess mortality.

14.63 For illustrative purposes, Dr Aylin and his team assumed that 5% of GPs would show special cause variation. This of course does not mean that they were assuming that 5% of GPs have excess mortality rates because of criminality or poor clinical practice. They may have a statistical excess of deaths for quite innocent reasons, for example because many of their patients live in nursing homes or because they care for patients being treated in a local hospice. Again for illustrative purposes, Dr Aylin and his team set two different alarm thresholds for detecting GPs with special cause variation. Shipman was one of 33 GPs out of the 1009 monitored who would have signalled during the period of monitoring between 1993 and 1999 if the lower threshold was applied. At the lower threshold, Dr Aylin and his team calculated from their computer simulations that the false discovery rate would be 5.2%. That would mean that 5.2% of the 33 signals were likely to be statistical false alarms. They also calculated that the successful discovery rate was 96.6%. That meant that the system had a 96.6% chance of correctly identifying any GP whose mortality rate was subject to special cause variation.

14.64 If the alarm threshold were set at a higher level, then only 12 GPs (including Shipman) would have signalled. Dr Aylin and his team calculated from their computer simulations that the higher threshold had a false discovery rate of less than 0.01%. It could therefore be expected that only a tiny proportion of signals would be statistical false alarms. There is, therefore, a trade-off in setting different alarm thresholds. A low alarm threshold would have the effect of identifying a larger number of GPs who appeared to show special cause variation and would need to be investigated; some of those signals would turn out to be statistical false alarms. A higher threshold would identify a smaller number of GPs and would have a very low statistical false alarm rate. However, it might miss some GPs who would merit investigation because they had an excess of deaths.

The Lessons to Be Learned from the Work

14.65 Dr Aylin concluded by saying that the work carried out by himself and his team demonstrated that CUSUM charts could be used to monitor patient mortality rates at GP level and that they would have been capable of detecting Shipman if they had been in use at the relevant time. However, detection of excess mortality rates among the patients of GPs (unless very large indeed) would be impossible from an analysis at PCT level or higher. He recognised that, in reality, patients of group practices may receive treatment from more than one GP, so that monitoring at GP practice level might be more appropriate than at the level of an individual GP. However, he acknowledged that it would be more difficult to detect an unusual mortality pattern attributable to an individual GP if monitoring was being done at GP practice level, rather than at individual GP level. I shall return to this topic later in this Chapter.

14.66 Dr Aylin emphasised that CUSUM charts can highlight unusual patterns of mortality but cannot themselves shed any light on the reasons for them. That must be an issue for investigation. He also observed that, if monitoring is to be undertaken, there must be some infrastructure to undertake the necessary investigations. There would be no point in running the CUSUM charts and taking no notice of the signals that they produced. He suggested that those responsible for investigating the signals would need to have the

necessary information to enable them to investigate effectively. He thought that PCTs would be best suited to this task. Others do not agree with this, as I shall explain.

14.67 Dr Aylin and members of his team told the Inquiry that, when they looked at the mortality data of the 1009 GPs, there was an enormous degree of variation between them. That variation was greater than would be expected by chance alone and was only partially explained by case mix factors such as age, gender and socio-economic deprivation. Dr Aylin and his team attributed the high degree of variation in part to the poor quality of some of the historical data available to them. I have already mentioned that the data available in the future is likely to be of very much higher quality. Another factor was the inadequacy of the available information about case mix factors, which meant that a proper adjustment for case mix factors could not be made. Dr Aylin said that there is now more detailed data available. Data by electoral ward is available and can be linked with census data to give better adjustments for age, gender and socio-economic factors. Another very important element which was likely to have contributed to the variation in mortality rates was the unaccounted-for factors to which I have already referred. Dr Aylin said that a key message was that the variation caused by these factors must be adequately taken into account in any monitoring system that is implemented. It seems to me that, if a prototype system were devised and put into operation, much could be learned about variation from the experience gathered in the first year or two.

14.68 Dr Aylin said that it would be possible to set the CUSUM charts to detect either very high levels of mortality within a short time of their occurrence or more consistently low levels of mortality over a longer period of time. Dr Best observed that the crucial element needed to give the necessary flexibility to detect different types of outcome was good quality data, not only data relating to actual deaths, but good quality 'denominator data', i.e. information relating to the patient population being used to calculate the number of expected deaths. The denominator data is used to calculate the chart statistic for the CUSUM control chart. She said that this denominator data was likely to improve in the future, particularly with the introduction of electronic patient records. Dr Aylin also emphasised that, in statistical analysis, the denominator data was as important as the data relating to observed deaths. Dr Spiegelhalter agreed that the same statistical process could be used to detect both sudden changes in mortality rates and more gradual changes. It was just a matter of tuning the system to be 'interested' in different types of variation.

The Possible Framework for a Monitoring System

The Need for Analysis to Be Performed by a Central Unit

14.69 There was agreement at the seminar that the collection and linkage of data should be performed centrally. Dr Aylin said that the quality of the data contained on the current NHS system varied from area to area and there were still difficulties with patients who lived in one area but were registered with a GP practice in another area. The data would be more accurate if it were collected countrywide. Dr Goldblatt, of the ONS, agreed that there was a 'huge variability' in the quality of the patient list data available for different parts of the country. If the quality of mortality data was to be comparable in all areas, there must be a national system for linking data and for feeding it back to those responsible for clinical

governance locally, i.e. the PCTs. As I have said, the DoH plans that the database should be held by the NHS Information Authority.

14.70 Dr Aylin believed that analysis of the data could be undertaken efficiently and relatively cheaply by a small national unit. He suggested that many PCTs would not have the expertise necessary to carry out this task. The results of the analysis at the central unit could be fed back to PCTs, which would in turn pass on the results to individual GP practices. Dr Spiegelhalter agreed and said that central analysis of mortality data and dissemination of the results would be valuable in terms of efficiency and would also enable guidance to be given on the interpretation of the results of the analysis. Dr Fox told the Inquiry that the DoH had no plans to undertake any analysis of mortality data itself. At the time of the seminar, it was envisaged that this would be done by the new Healthcare Commission.

The Importance of Local Knowledge

14.71 Dr Aylin and Professor Baker both emphasised that PCTs must examine the results of the central analysis themselves and monitor them. It would not be sufficient for them merely to pass the results back to GP practices. Of course, the PCTs would know that a high mortality rate does not necessarily indicate that a doctor is failing in some way. Still less is it indicative of criminal activity. In most cases, the high rate will be explained by some characteristic of the doctor's practice or of his/her patient population. An obvious example would be a doctor who cared for patients in a local hospice or in one or more local care homes. The death rates among such patients might well account for a higher death rate among patients of the GP than would be expected in a practice where patients did not have these characteristics. This type of information specific to a GP practice is not likely to be available outside the immediate locality and may become known to a PCT only after discussions with the GP or GP practice concerned.

14.72 Professor Baker said that he expected that the first two or three years after the introduction of a monitoring system would be spent accumulating a lot of additional knowledge about practices and their patient populations. This would be a very important phase. Once the knowledge had been acquired, monitoring would move into a rather different phase of long-term observation. Professor Baker said that he hoped the point would be reached where all practices – not just those which had been flagged up as being statistically abnormal in some way – would be able to explain their mortality rate by reference to their patient populations.

The Part to Be Played by the Healthcare Commission

14.73 At the Inquiry's seminar, Professor Bevan and Dr Spiegelhalter spoke about the part which it was envisaged the Healthcare Commission might play in any future system of monitoring the mortality rates among GP patients. As I have explained, Professor Bevan was a member of the transition team which was working on the development of the future arrangements for the Healthcare Commission. Dr Spiegelhalter was an expert adviser to the Performance Assessment Subcommittee of the CHI; the CHI formerly carried out many of the functions which are now to be performed by the Healthcare Commission. Professor

Bevan said that it was expected that monitoring and surveillance of mortality rates, as well as of other indicators, would be carried out at a central analytical unit run by the Healthcare Commission. The results of the monitoring would be shared with PCTs and GP practices. Professor Bevan described how it was expected that the 'beating heart' of the Healthcare Commission would be a system of local offices. It was expected that these local offices would cover the areas of the SHAs. Professor Bevan said that discussions at the CHI had suggested that one of the key roles of the local Healthcare Commission offices would be to apply their local knowledge to the questions thrown up by the central analysis of data.

14.74 If the central analytical unit identified a statistical abnormality (whether in relation to mortality rates or any other indicator), it would inform the local Healthcare Commission office and the relevant PCT. The local office would examine any data (including clinical governance data) it held about the relevant GP or GP practice. The PCT would do the same. The findings would be shared. In the rare cases where no plausible explanation was found for the abnormality, the Healthcare Commission would conduct a targeted investigation. He suggested that its response would probably be tailored according to its assessment of the capacity of the individual PCT to carry out its own investigations. Dr Spiegelhalter thought that the usual pattern was likely to be that the routine monitoring of various indicators would result in a number of problem areas affecting a GP or GP practice arising simultaneously, giving rise to the need for investigation. However, it was possible that a single indicator (such as mortality rates) would exhibit striking variation and would of itself require investigation.

14.75 Dr Fox told the Inquiry that the description given by Professor Bevan and Dr Spiegelhalter was in accordance with the DoH's understanding of the likely arrangements for the Healthcare Commission.

14.76 Professor Bevan stressed that the primary function of the Healthcare Commission would be quality improvement. However if, in the course of its monitoring, the Commission were to find that something was seriously wrong, plainly it would have to act. He thought that the combination of monitoring and surveillance (see paragraph 14.34) would be 'quite a tricky balance to strike'. Dr Spiegelhalter hoped that the balance could be struck. He envisaged the DoH rapidly making mortality data available. The Healthcare Commission would then monitor the data, using a highly organised surveillance procedure. The results of that procedure would then be presented in a simple and informative way to PCTs and GP practices.

14.77 This was the position at the time of the Inquiry's seminars, in January 2004. In July 2004, the Inquiry wrote to the Healthcare Commission, asking for updated information about the role it was to play in the monitoring of GP patient mortality rates. In October 2004, the Healthcare Commission responded by saying the monitoring of the mortality rates was to **'be available'** through the DoH's National Programme for Information Technology, while routine assessment of individual GP rates would be the responsibility of the PCTs. It seems, therefore, that it is not at present intended that the Healthcare Commission should house the central analytical unit envisaged by Professor Bevan and Dr Spiegelhalter at the time of the seminars. It is not clear to me whether it is envisaged that the DoH would undertake the central analysis of mortality data or whether its function would, as Dr Fox

suggested be confined to the provision of linked mortality data. Nor is it clear whether the Healthcare Commission is to have the system of local offices described by Professor Bevan. In a recent letter to the Inquiry, the Healthcare Commission referred to its intention to **'manage relationships at local level'** and to **'engage with local stakeholders'**. It also referred to an intention to test a variety of ways of **'achieving the objectives for local presence'**. There was no mention of establishing local offices. Thus, there is uncertainty about which body would carry out any necessary investigation consequent upon the monitoring of mortality rates.

14.78 It is disappointing that the arrangements for the monitoring and analysis of mortality data that were envisaged at the time of the Inquiry seminar have not progressed. Indeed there is now uncertainty as to whether this function is to be carried out at all and, if so, by whom. It is also unclear who might be responsible for the investigation of the cause and significance of any data that lies outside the norm.

Recent Work on Analysing and Investigating Mortality Rates

The Pilot Project Undertaken by the Northern Ireland Eastern Health and Social Services Board

14.79 The Inquiry requested and received information about one pilot project that was being undertaken in Northern Ireland to develop a system for monitoring general practice mortality rates. The pilot project, which was being undertaken by a team from the Eastern Health and Social Services Board (the Eastern HSS Board), was conducted in association with the Department of Public Health and Epidemiology, University of Birmingham. At the Inquiry's seminar, Dr Kathryn Booth, Chair of the Northern Ireland GP Practice Mortality Regional Group, and Dr Mohammed, who assisted with the pilot project, gave further details of the project.

14.80 The Northern Ireland Central Service Agency established a database and provided each of the four Northern Ireland HSS Boards with mortality data for the GP practices in their area. Each HSS Board carried out its own pilot project. As I have said, the Inquiry heard about that conducted by the Eastern HSS Board.

14.81 The Eastern HSS Board team used Shewhart control charts to identify GP practices with adjusted mortality rates which were in excess of the upper control limit or below the lower control limit of the charts and were therefore exhibiting special cause variation. A longitudinal control chart was used to compare the mortality rate of four GP practices with their past mortality rates and with Northern Ireland average mortality rates over a period of eight years. Dr Mohammed explained that this latter technique avoided problems with case mix factors and showed changes in the pattern of mortality within an individual practice over time.

14.82 Dr Mohammed explained that, before the Eastern HSS Board pilot project started, there was great concern within the medical profession about the ultimate aim of the work. There was also concern about the possible publication of mortality data and about the way in which that data would be interpreted by patients and by the public. Dr Booth observed that, in particular, there was a fear that the data would be presented to the public in the

form of rankings. She said that another fear was that, if a practice was shown to be an outlier, members of the practice might not be allowed to contribute to any investigation into why its mortality rates fell 'outside the tramlines' and might have their names 'blackened' among their peers or with the public without having an opportunity to explain the apparent abnormality. The Eastern HSS Board team addressed the concerns of the profession by holding a series of seminars for GPs, patients' representatives and representatives from coroners' offices at the beginning of its pilot project. Members of the team sought to reassure those concerned that the object of the pilot project was primarily to improve the quality of health care. They had managed to secure support from GPs' representatives. Dr Booth said that some fears were still expressed in the course of practice visits conducted by those working on the pilot project, although both she and Dr Mohammed felt that progress had been made in persuading the profession of the value of the project.

14.83 If the mortality rate of a GP practice appeared to be exhibiting special cause variation, the Eastern HSS Board team used a pyramid model of investigation, which had been adapted from industry, in order to discover why this had occurred. The first stage of the investigation involved checking the existing data with the Central Service Agency and with the practice itself. A visit was arranged and, in advance of that visit, the practice was provided with all the data on which the team's analysis had been based. The practice was asked to carry out a check to validate the data.

14.84 The second stage of the investigation process was to check patient case mix. Members of the Eastern HSS Board team prepared information derived from the basic data about patient deaths and adjusted it for case mix factors such as age, gender and socio-economic deprivation. They would explain to the practice the adjustments they had made. Members of the practice, using their own local knowledge, would then have an opportunity to challenge those adjustments if they considered that they were inappropriate in some way. The team would invite members of the practice concerned to identify any characteristics of the practice, or of its patient population, that they considered might have had an effect on its mortality rates.

14.85 During a practice visit, members of the Eastern HSS Board team made use of a piece of software called a 'data mining tool', contained on a laptop computer. This enabled them to access a wealth of information, comparing the data for the practice year by year and also comparing the practice statistics with the Northern Ireland average. All this information was sent to the practice in advance of the visit. Before the visit, the team would analyse the data in an attempt to generate a hypothesis to explain the high (or low) mortality rates of the practice. The team would not disclose its hypothesis to the practice, since one of the purposes of the visit was to see whether the practice itself could explain the reasons for its special cause variation.

14.86 In each case where an investigation was undertaken, the team was satisfied by the end of the second stage of the investigation that the special cause variation was related to data and/or case mix factors. Dr Mohammed said that the team had not foreseen the impact of residence in nursing homes on mortality rates. This had become evident only in discussions with the practices concerned. He regarded local knowledge as the key to the investigation process. He gave two examples of this. In one case, a practice had had a

very low mortality rate for at least three of the years analysed; that mortality rate suddenly jumped up and then levelled off again. A preliminary investigation revealed that, during the first period of the analysis, the practice had been serving a university population, so that its patients were in general very young. The university then closed and the practice began to attract older patients, which explained the higher mortality rate. A second practice had a very high mortality rate which was decreasing over a period. Investigation of this revealed that the mortality rate was dropping because the practice had at one point had a very high proportion of patients who were resident in nursing homes but had subsequently stopped taking such patients. The proportion of patients who were resident in nursing homes had, therefore, dropped – hence the decrease in mortality rates.

14.87 In none of the cases which it investigated was it necessary for the Eastern HSS Board team to proceed beyond the second stage of the pyramid model of investigation. Had it proceeded to the third stage, this would have involved checking practice resources. It would have been necessary to discover from the practice and the PCT whether the practice had any specific problem with resources (e.g. poor access to cardiac surgery) which might have affected its mortality rate. If this third stage had failed to reveal an explanation for the excess, the team would have proceeded to the fourth stage of the pyramid model. This would have consisted of checking the process of care, i.e. looking at the processes of care adopted by the practice and by other agencies when treating particular groups of patients in the practice. It might, for example, have involved considering protocols in use in the practice for treating various patient groups. The fifth stage would have been reached if none of the preceding stages had provided a plausible explanation for the excess in mortality rates. It would have involved a formal investigation of the GP concerned.

14.88 Dr Mohammed said that the Eastern HSS Board's investigations were designed to generate knowledge in a systematic way. Once data was found to explain the special cause variation, the investigation was halted. As I have said, the explanations were generally dependent on local knowledge. Dr Mohammed said that, if a continuous monitoring system were implemented, those operating it would not necessarily wish to investigate every occasion when a unit crossed the control limit. If resources for investigation were limited, it might be appropriate to prioritise by investigating only those units whose chart statistics were most distant from the control limits.

The West Midlands Investigation

14.89 As I have said, the work undertaken by Dr Aylin and his team revealed that, had their monitoring system been in operation at the relevant time, 12 GPs (including Shipman) would have signalled at the higher of the thresholds applied. Having been informed of that fact, the Inquiry decided that the DoH and the PCTs on whose lists the 11 other GPs were now included should be notified of the fact that they had signalled. That would enable the PCTs to undertake any investigations they considered appropriate in order to ascertain the reason for the apparent excess in mortality rates.

14.90 Two of the investigations arising from this notification were of particular interest to the Inquiry. The first was carried out in the West Midlands by a team from Shropshire County

and Telford and Wrekin PCTs, with technical assistance from Dr Mohammed (the West Midlands team). The investigation was reported subsequently in the British Medical Journal[2].

14.91 The West Midlands team used the pyramid model of investigation which I have already described. Its first step was to check the data. The second was to check the patient case mix of the two GPs being investigated. Before starting its investigation, the West Midlands team informed the two GPs of what it was doing. The team then obtained the raw data used by Dr Aylin and his colleagues, together with the results of their analyses. The team also obtained additional information about where each death had occurred. By this means, they were able to see how many deaths had occurred in nursing homes. The team then formulated a preliminary working hypothesis that the excess of deaths might be caused by the fact that, at the relevant time, both GPs had a significant number of patients who were resident in nursing homes. Patients admitted to nursing homes are known to have a high mortality rate.

14.92 The West Midlands team held discussions with the two GPs and with the local primary care medical adviser, who had responsibility for GP performance. Members of the team examined administrative data from the practices of the two GPs. They compared the excess mortality rates for each GP with the number of deaths among their patients that had occurred in nursing homes. They carried out various analyses of the data. On the basis of their investigations, they concluded that the high mortality rates of the two GPs were attributable to a 'nursing home effect'. They judged that it was not necessary to proceed to the third stage of the pyramid model.

The West Sussex Investigation

14.93 The second investigation was conducted by Adur, Arun and Worthing PCT into five GPs, one from its own area and four from other PCTs in the West Sussex area. The investigating team provided a copy of its report to the Inquiry and Ms Julie Billett, Associate Public Health Specialist, spoke about it at the Inquiry's seminar.

14.94 The investigation was undertaken without the knowledge of the GPs in question. Ms Billett said that this was because of the background to the investigation, the possibility of negative publicity and the concerns that might have been generated locally had the fact of the investigation become known. The first part of the investigation consisted of a statistical analysis, using local data to make more refined adjustments for age and gender than had been possible in Dr Aylin's analysis. The PCT's statistical analysis, which covered only the year in which each of the GPs first signalled, confirmed that the five GPs did indeed have statistically significant excess mortality rates when compared with the age and gender specific mortality rates for West Sussex in the same years. The second part of the investigation consisted of a review of the medical records for the patients whose deaths had been certified by each of the five GPs in the year that s/he signalled. In the case of two of the GPs, problems were experienced in identifying from the patient medical records

[2] Mohammed MA, Rathbone A, Myers P, Patel D, Onions H, Stevens A (2004) 'An investigation into general practitioners associated with high patient mortality flagged up through the Shipman Inquiry: retrospective analysis of routine data'. British Medical Journal, Vol 328: pp 1474–1477.

evidence of the medical condition which the GPs had certified as being the cause of the patient's death. Those problems were attributed to serious inadequacies of the patient medical records. Indeed, such were the inadequacies of the records that the reviewers suggested that the practices might have failed to include the most recent computerised records when returning the records to the PCT after the patients' deaths. An alternative explanation was that a parallel set of notes might have been held in the nursing or residential homes in which some of the patients had resided. As a result of the gaps in the medical records, there were some concerns about the GPs' management of chronic disease. It was not established in the course of the investigation whether any other records did in fact exist. Subsequently, one of the GPs explained in a letter that his practice had been paperless for some years and that he had **'felt it unnecessary to produce a full paper discharge summary from the computer for a deceased patient'**.

14.95 At the conclusion of the investigation, the PCT decided that the likeliest explanation for the GPs' higher than expected mortality rates was that a significant proportion of their patient populations were nursing or residential home residents, with correspondingly high rates of mortality. At that stage, the fact that they had been the subject of an investigation was revealed to the GPs. It was left to the Directors of Public Health and the Clinical Governance Leads for the relevant PCTs to take up with the doctors the issues about record keeping and chronic disease management which had been identified during the course of the investigation.

Future Investigations

14.96 Adur, Arun and Worthing PCT had to devise the whole process of investigation for itself. Ms Billett said that one of the difficulties was knowing where the investigation should stop. She told the Inquiry that it would be of great assistance if there was some clear guidance available to PCTs on a structure and a process to be followed when conducting investigations. There was general agreement at the seminar that such guidance was required. Professor Baker supported the development of a structured protocol. He suggested that the potential outcomes of an investigation might be, first, that there was a satisfactory clinical explanation for the apparently abnormal findings. That outcome would require no further action. The second possible outcome might be that there was a problem with the performance of a GP or GP practice; that might result in the provision of support or remediation or in the use of disciplinary procedures. The third possible outcome might be the identification of possible criminal behaviour. Professor Baker suggested that there must be clarity about the point which an investigation had reached and why it had reached that point. He suggested that the police should have some input into the formulation of a protocol. They should advise at what point they might wish to become involved in an investigation. Dr Grenville, representing the BMA, suggested that the medical defence organisations should also be consulted in connection with the formulation of an investigation protocol.

14.97 Dr Fox, for the DoH, suggested that there were two different types of investigation that might result from monitoring mortality rates. The first would occur in the context of local routine prospective monitoring when a PCT or a GP practice was looking at data in a 'learning, improving mode'. This type of investigation would be very different from that

which would occur when a PCT had been alerted to the fact that there might be a 'problem' with a practice. Dr Fox suggested that different guidelines were needed to deal with those two types of investigation. He emphasised the importance, when a formal investigation was to be undertaken, of identifying the question which it was intended that the investigation should answer. Without that, it would be impossible to know when the question had been answered and when the investigation should be halted. Dr Fox anticipated that formal investigations would be undertaken fairly rarely. He was concerned that individuals would be involved in such investigations infrequently and would not be in a position to gain any experience of how to handle them. He suggested that it would be important to develop a bank of knowledge about how such investigations should be carried out.

14.98 Doubts were expressed about whether PCTs, which are small organisations with many other responsibilities, would have the necessary resources and expertise to conduct the investigations which would become necessary as a result of GPs signalling within a monitoring system. Ms Billett felt that the task of investigation should be undertaken by PCTs, which could bring to the task their understanding of the local factors that could influence the mortality rates of a GP practice or of an individual GP. However, she doubted whether all PCTs would have the capacity to undertake the task. The exercise had been useful for her PCT, in that it had identified problems with two GPs and had highlighted the importance of preserving the quality and integrity of the PCT's historical data systems. However, it had occupied a considerable amount of time and resources.

14.99 Professor Baker believed that an investigation of this complexity was likely to be beyond the ability of most PCTs. He accepted the value of local knowledge but felt that there was a danger of becoming focussed solely on a local explanation, rather than adopting a wider and more objective view. He suggested that local input should be blended with accumulated regional or national experience, so as to ensure that expertise and objectivity were brought to investigations. Dr Grenville referred to the high turnover of staff in PCTs and suggested that it was likely to be difficult for individual PCTs to build up the pool of expertise that would be required to undertake such investigations.

14.100 The alternative to a local investigation would be investigation by an external body. The most likely candidate appeared to be the Healthcare Commission. Ms Billett said that an investigation by an external body was likely to be perceived by GPs as more threatening. However, how such an investigation was received would depend on the way in which it was conducted. Both she and Mrs Scott agreed that their PCTs would want to have an input into any such investigation which affected a GP in their area.

14.101 In my view, it is important that real expertise and objectivity should be brought to such investigations. I recognise the need for PCTs to be involved, so that use may be made of their local knowledge. However, I do not think it would be appropriate, either in principle or in practice, for PCTs to have primary responsibility for a formal investigation into a doctor who had signalled within a monitoring system. As Professor Baker said, not only would they not have the necessary skills or sufficient opportunity to develop them, they might also lack objectivity. There would be a danger that local knowledge and reputation might be given too great a prominence and might be seen to provide an innocent

explanation for figures which should give rise to real concern. I express no view as to who should be responsible for the conduct of such investigations. I do not know how frequently they will be required. If it transpires that they are rare, as Dr Fox anticipates, a small national team should suffice, possibly organised by the Healthcare Commission. If, on the other hand, it is found that such investigations are required quite frequently, it may well be necessary to provide a facility on a regional basis. If so, those responsible in the regions must work to common methods and protocols. The existence of national or regional expertise would also provide a source of advice for PCTs who came across the possibility of a problem when collecting data in the 'learning, improving mode' mentioned by Dr Fox.

After an Investigation

14.102 Dr Spiegelhalter raised the issue of what would happen after an investigation had discovered an acceptable clinical explanation for excess mortality. If monitoring continued and the high mortality rate persisted, there would at some point be another signal. A decision would then have to be taken as to whether to investigate again (which could well be a waste of resources and upsetting for the doctor concerned) or to assume that the explanation previously identified satisfactorily accounted for the continued excess (which might be a false assumption). He said that decisions would have to be taken about the approach to be adopted in such circumstances.

14.103 I agree that careful consideration would have to be given to such a case. I would have thought that the right approach would be for a second (and possibly more experienced) investigator to review the first investigation, in the light of the fact that the high mortality rate appeared to have persisted. If s/he were satisfied with the methodology and conclusion of the first investigation and considered that the explanation then accepted also accounted for the continuance of the high mortality rate, it should not be necessary to embark upon a second investigation. However, a second investigation would have to take place if any concern remained after the review. In any event, such a review should not be undertaken locally, for the reasons I have already given.

Potential Problems with Monitoring

14.104 At the seminar, there was discussion about some of the problems that might be associated with monitoring mortality rates.

The Practicability of Monitoring at Individual General Practitioner Level

14.105 During the whole of the period covered by the analysis carried out by Dr Aylin and his team, Shipman (and, subsequently, the locum who replaced him) was practising single-handed. The analysis showed that he would have signalled during that period. However, the question then arose whether, if he had been a member of a larger GP practice (as he was until 1992), his excess deaths would have caused the practice to signal.

14.106 Dr Aylin told the Inquiry that, if excess deaths caused by one doctor were to be subsumed within a large GP practice, they would inevitably become much more difficult to detect. He

said that it would be possible to tune the CUSUM chart to pick up differences in mortality rates within a practice caused by a single doctor. However, if the alarm threshold were to be set at a level that would pick up such differences, this would result in a large number of statistical false alarms. Dr Aylin said that, with better data and with better adjustment for case mix and for unaccounted-for factors than had been possible in the statistical analysis carried out by himself and his team, it might be possible to pick up, in the mortality data for a practice of six doctors, an excess of 25 deaths caused annually by a single GP. This would be a large excess; Shipman had an excess of 25 deaths during only three years of his practice.

14.107 Dr Aylin pointed out that, if avoidable deaths were being caused by practice systems which were affecting more than one doctor, an excess mortality rate might show up more readily. He suggested that, from the point of view of quality of care delivered to patients, a GP practice was a reasonable unit of analysis. However, in terms of detecting excess mortality attributable to the actions of a single GP within the practice, it is plain that it is a blunt instrument. While I agree with Dr Aylin that monitoring of mortality rates at GP practice level may have some value, it seems to me that, in order to be sufficiently sensitive to detect an excess of deaths caused by the activities of a single GP, monitoring must be at individual GP level. Monitoring at individual GP – rather than GP practice – level would also enable a GP to be tracked throughout his/her career. This is important because of the increasing tendency of GPs to move between practices.

14.108 If monitoring at individual GP level is to be undertaken, two conditions must be met. First, there is a need to link the actual care of a patient to a named GP, so that, when the patient dies, the death can sensibly be counted as being 'attributable' to that GP for monitoring purposes. A merely administrative allocation of patients to a particular GP would be valueless. Second, it must be possible to calculate a total patient population for each GP. This could be done by making a link between named patients and that GP, or by allocating a proportion of the practice patient population to the GP by reference to information such as the number of sessions worked by the GP.

14.109 Recent changes to the arrangements for general practice have made it difficult to link a patient to an individual GP. Under the new General Medical Services Contract (and under the personal medical services contracts which have recently been introduced), patients are now to be registered with a GP practice and not with an individual GP. Thus it will not be possible, on the basis of the available data, to link a deceased patient with an individual GP for monitoring purposes. Even before the recent changes, the link between a patient and the doctor with whom s/he was registered might have been misleading, since patients might have been registered with one doctor, but their care might have been shared by other doctors within the practice. This type of shared care has become more common in recent years.

14.110 Professor Baker told the Inquiry that he could envisage the possibility of requiring some allocation of patients by a GP practice so that there would be a named GP for each individual patient. However, he felt that this might be 'asking rather a lot' of some practices and patients. He believed that it should be possible to estimate with some confidence the proportion of patients within a practice that an individual GP was caring for, by reference

to the patterns of work of members of GPs within the practice. In the longer term, he suggested that improved electronic information systems (including electronic patient records) might enable the number of patients being cared for by an individual GP to be measured directly. He pointed out that, even now, almost all consultations between a patient and a healthcare professional within a practice are recorded electronically. If anonymised data were made available, it would be possible to determine the proportion of consultations between an individual patient and each GP within the practice and to allocate patients to named GPs on the basis of those proportions. It would also be possible to obtain information about the activities of locums who had been employed within the practice. Professor Baker pointed out that this system would also enable precise adjustments to be made to reflect the age and gender of patients allocated to a particular GP. Dr Aylin endorsed Professor Baker's idea of focussing on the number of consultations between a patient and an individual GP in order to determine that GP's patient population.

14.111 Some potential drawbacks to Professor Baker's approach were mentioned at the seminar. Dr Goldblatt believed that, if information about patient consultations had to be collected before mortality data could be analysed, this would introduce a delay into the monitoring system. Dr Fox was concerned that the provision of information about patient consultations would impose an undue burden on GP practices at a time when the DoH is attempting to reduce that burden.

14.112 Professor Bevan observed that, if the information about patient consultations was being collected for the purpose of monitoring mortality rates with the sole intention of 'spotting another Shipman', it would be difficult to justify. However, the information might have a broader purpose to serve in the context of monitoring and of improvements in the quality of care. He said that there had been concern within the CHI about the 'massive gap' in the statistical information available about general practice. This was in contrast to the amount of information available in relation to hospital care. He pointed out that 90% of patient contact takes place at general practice level. He said that there might be the potential for setting up databases to collect the relevant data as part of a wider move to improve the quality of care in general practice.

14.113 Professor Baker mentioned that there were in existence at least two schemes whereby groups of practices operating similar computer systems had undertaken to collect and share data relating to a range of issues. He said that those schemes enabled searches to be conducted of databases containing information about contacts of up to a million patients with doctors and nurses. Dr Baker told the Inquiry about a number of projects being undertaken by the RCGP. She said that work was being done on a method by which data could be automatically extracted from a GP practice's computer system without any action by the practice being necessary.

14.114 If there is to be effective monitoring of mortality rates at individual GP level, some way must be found to make a real linkage between an individual patient registered with a practice and a named GP within that practice. That must be based upon the care actually provided and not on any administrative factor. I agree with Professor Baker that it should be possible to do this by reference to actual patient contact. There will, of course, be many young, healthy patients who rarely consult their doctors and who may have to be notionally

allocated to one member of the practice. However, allocation would have to be reviewed periodically so that, if a patient began to require regular care, s/he could be reallocated if necessary to the doctor providing it. I should have thought that it would be possible to do that. I should also have thought that it would be helpful to a GP's understanding of his/her own practice to have access to data about the patients whom s/he treats and their characteristics. From what Professor Bevan told the Inquiry, it appears that the data might have a wider use than just in the monitoring of mortality rates. It seems to me also that, with the advances in technology about which the Inquiry has heard, it should be possible to collect the necessary data without placing an undue burden on practices. I hope that such measures will be explored because I am firmly of the view that analysis of the collective mortality statistics of a group practice will be a very blunt instrument indeed in detecting either poor clinical practice or criminality.

14.115 Over recent years, there has been an increase in the number of locums providing care. There has also been an increase in the use of out of hours services. This will continue with the changes to the arrangements to the provision of out of hours services due in January 2005. At the seminar, Dr Aylin was asked whether he had considered how the mortality rates of locum GPs and out of hours services might be monitored. He explained that the difficulties lay, not in the statistical issues, but in collecting the necessary data linking a death with a particular locum or out of hours agency, and in determining the total number of patients cared for by that locum or agency. He suggested that it might be possible to monitor the mortality rates of patients being cared for by an out of hours agency. The patient population being cared for by such an agency could be determined by reference to the GP practices which used the agency. If a monitoring system were to be introduced, it would be necessary to explore the different possibilities for collecting this data.

Where to Set the Threshold

14.116 Another problem which was identified at the seminar was knowing where to set the alarm threshold, so as not to cause a large number of false alarms.

14.117 Dr Aylin said that he and his team had tried not to be 'too explicit' about where the threshold should be set. He said that one strength of the CUSUM methods was that the false and successful discovery rates could be calculated so that those setting the alarm threshold would know how the chart was likely to perform. That meant that the thresholds were not chosen arbitrarily. Dr Mohammed pointed out that, under Dr Aylin's proposed method, the calculation of the false and successful discovery rates depended on an assumption that the mortality rates of 5% of the GPs and GP practices being examined are out of control. He observed that, in reality, we do not know how many units are out of control. He suggested that the calculations were useful for the purposes of illustration but could not resolve the fundamental problem that the proportion of GPs with an excess mortality rate is not known. Dr Goldblatt made a similar point. Dr Best and Dr Aylin agreed that statistical calculations should not dictate where the thresholds were set. They should merely inform the selection of thresholds by others. It would be necessary to take into account practical considerations relating to resources and to the types and number of investigations which it was thought appropriate to carry out. Dr Aylin observed that the

number of true and false medical alarms signalling under the monitoring system would inform, on an ongoing basis, the decision as to where to set the alarm thresholds.

When Would Shipman Have Signalled?

14.118 Some concern had been expressed before the seminar about the fact that, on the basis of the statistical analysis conducted by Dr Aylin and his team, it appeared that Shipman would have signalled only in 1996. The time lag in collecting the relevant data would have meant that the signal could not have been detected until late 1997. This would not have been long before March 1998 when the late Dr Linda Reynolds reported her suspicions about Shipman. Her report gave rise to the first – and unsuccessful – police investigation. Doubts were expressed about the value of a monitoring system which would have taken so long to detect Shipman.

14.119 When asked about this, Dr Aylin pointed out that the period covered by his analysis had started only in 1993. Had the analysis been in operation for the whole of the period when Shipman was in practice, he could have been expected to signal much earlier. Also, the poor quality of the data and the limited adjustment for case mix factors made it less easy to detect an unusual pattern of deaths. It seems to me that, with improved data quality, finer adjustment for case mix factors and the use of the cumulative method, a serial killer or a doctor who habitually neglected his/her patients would signal within a reasonable time. However, it must be recognised that a doctor who killed a patient only occasionally, or who hastened the deaths of patients by only a short period, would not be detected by such a monitoring system.

14.120 At the presentation of their work to the Inquiry by Dr Aylin and his team in July 2003, Dr Aylin suggested that, statistically, every GP would signal at one time or another under his system. This suggestion caused a considerable amount of concern. At the seminar, he explained that his comment had been made in the context of monitoring for an infinite time period in the future. He had calculated that, using the thresholds employed in his analysis, 1.5% of GPs might signal purely by chance over a 50 year period. It would, therefore, take several thousand years for every GP being monitored to signal as a result of chance alone.

The Effect on Mortality Rates of Residence in a Care Home

14.121 The outcomes of the investigations in Northern Ireland, the West Midlands and West Sussex that I have described all highlighted the relationship between the mortality rates among patients of a GP or GP practice and the number of those patients who are resident in nursing homes. This effect may extend to patients living in residential homes also. The fact that a patient is resident in a nursing home suggests that s/he is in a poorer state of health and has a higher level of dependency than a patient in a residential home. The Inquiry was told, however, that this is not always the case; sometimes, practical considerations govern the admission of a patient to one type of home or another. For the purposes of this discussion, I shall refer to nursing and residential homes collectively as 'care homes' and assume that residence in either has an effect on mortality rates.

14.122 If the pattern of the three investigations is followed, it seems likely that many statistical true alarms will be accounted for by the fact that a higher than average proportion of the patient population of the GP under investigation is resident in care homes. Investigation of these alarms will, therefore, inevitably result in the unnecessary expenditure of resources.

14.123 One way of avoiding this would be to make a case mix adjustment in order to account for the number of patients of a GP who are resident in care homes. There are at least three problems with that approach. One problem is that adjustment might mask the existence of a high mortality rate of which the authorities should be aware. It is possible that a doctor might be responsible – through lack of care or criminal activity – for the deaths of patients in a care home. If an adjustment were to be made for care home residents, an excess mortality rate from that cause might not be detected. The second problem is that admission to a care home can, to an extent at least, be influenced by a GP. As I have said, there are dangers in adjusting for a case mix factor that is within the control of the subject of the monitoring. The third problem relates to the collection of the necessary data to enable an accurate adjustment to be made. Dr Farhang Tahzib, Director of Public Health, Adur, Arun and Worthing PCT, suggested that the fact that a patient had been admitted to a care home should be recorded on the NHS central data system. He suggested that this might be done by linking information from care homes and from the National Care Standards Commission (now part of the Healthcare Commission) with the NHS system. Such information would enable the number of patients registered with every GP who were resident in care homes to be ascertained. Ms Billett suggested that the information should also be sent to GP practices, which may be unaware that one of their patients had been admitted to a care home.

14.124 In theory, this seemed to be a good idea. However, Dr Goldblatt doubted whether it would be possible to collect the data in the way suggested by Dr Tahzib. He said that the designation of care homes as nursing or as residential homes could change quite frequently and suddenly, so that it would be difficult to keep data up to date. Also, patients were admitted to care homes for different periods of time. Some were admitted for short periods of respite care. Others were admitted only a short time before their death. Some patients moved between homes in different PCT areas. Dr Grenville confirmed these points and added that some hospital wards were very much akin to nursing homes, although they would not be categorised as such.

14.125 Mrs Scott, of Croydon PCT, said that, when preparing comparative data on GP patient mortality rates, her PCT had excluded deaths which had occurred in care homes. It was felt to be inappropriate to compare practices which had large patient populations living in care homes with practices which had no or few care home residents. The PCT had good information about the number of care home beds and about which GPs cared for patients in the different homes. The PCT was able to identify deaths which occurred in care homes. It was considering setting up a system for analysing deaths in care homes. Mrs Scott said that the main difficulty was the frequent change in the designation of care homes – even of individual beds within care homes. She said that it would require a lot of local knowledge and careful monitoring to deal with these changes.

14.126 Dr Aylin told the Inquiry that it would never be possible to adjust for all aspects of case mix. He said that the fact that it would not be possible to adjust for every single eventuality did

not prevent an analysis being performed on the basis of the available data. He suggested that there might be a case for performing analyses with and without adjustment for residents in care homes.

14.127 I should have thought that it would be feasible to collect data about persons admitted to care homes. It may be possible to identify those admitted on a wholly temporary basis, e.g. for the purpose of convalescence or respite care. I should have thought also that it would be helpful to GP practices and to PCTs to have information about the number of patients resident in care homes and also in other institutions such as hospices. Ways of analysing and comparing the mortality rates of residents in care homes and other types of institution could no doubt be devised. A first step would be to investigate with the Healthcare Commission precisely what information it holds and how up to date it is.

Other Possible Statistical Approaches

14.128 At the seminar, there was some discussion about different statistical methods that might be used in the analysis of mortality rates and that might have advantages over the use of the CUSUM charts advocated by Dr Aylin and his team. I shall deal with these very briefly.

14.129 The first discussion related to the relative merits of Shewhart control charts and CUSUM charts. Dr Aylin's main reason for favouring CUSUM charts was, as I have said, their ability to accumulate historical data. He also pointed to their efficiency in determining gradual, sustained rises in mortality and large and sudden deviations in mortality. Dr Mohammed, who favoured the use of Shewhart charts, pointed out that the longitudinal control charts showing the mortality rates of a single practice revealed evidence of the historical performance of that practice. He referred to the transparency of Shewhart control charts and the ease with which they could be understood.

14.130 Dr Roberts' view was that the fact that CUSUM charts used information from the past meant that they were better predictors of what would happen in the future. Dr Spiegelhalter also favoured the use of CUSUM charts for use in a central monitoring system. He agreed with Dr Aylin about the importance of accumulating historical data. He also favoured the more formal technique for setting alarm thresholds advocated by Dr Aylin and his team, rather than what he described as the 'rule of thumb' used to set the control limits for Shewhart charts. However, Dr Spiegelhalter favoured a slightly different approach to the use of historical data.

14.131 When plotting their annual chart statistic, Dr Aylin and his colleagues simply added up the outcomes from previous years and kept adding year by year. The effect of this was to give equal weight to historical and recent observations. An alternative approach would be to adjust previous outcomes so as to give more weight to more recent data and less weight to data in previous years. Dr Aylin and his team did not attempt to do this, since it was not clear by how much it would be appropriate to downweight information from the past.

14.132 Dr Spiegelhalter said that his preference was to discount historical data gradually. The effect of that would be to accord most weight to the most recent information and to give less weight as data became older. He advocated a gradual discounting, so as not to precipitate a sudden change by the removal of historical data.

14.133 Dr Spiegelhalter emphasised that a monitoring system need not be confined to using one statistical method. Different methods could be used for different purposes and to present the data to different groups of people. He suggested that the system devised by Dr Aylin and his team would be the most suitable for use as a quality assurance tool. It could be used centrally for monitoring large numbers of units and could provide warnings which would then be passed down to those who were to investigate them. In other words, the system could be used for surveillance purposes.

14.134 Dr Spiegelhalter suggested that, when the data was supplied to PCTs and practices, it should be presented clearly and simply. This might be best done by means of Shewhart charts. Dr Spiegelhalter said that it would be possible to move between the two statistical methods and thus to have multiple views of the data. No extra resources would be required. Dr Aylin agreed that CUSUM charts were not appropriate for feeding back direct to GPs. Other methods of presenting the information would have to be adopted.

14.135 Another issue arose in relation to the treatment on a CUSUM chart of a GP who, for a period, has a low mortality rate. The CUSUM chart is set at zero, so that if the mortality rate of a GP is less than that which would be expected, the chart statistic is plotted at zero. It is not allowed to go below zero and to build up credit by registering negative values. This is in distinction to the sequential probability ratio method for which Dr Spiegelhalter had originally expressed a preference. Under that method, the chart statistic builds up 'credit'. The danger is that it might build up too much credit so that, if the mortality rate of a practice increased, it would take longer for the practice to signal, because the deterioration would to some extent be compensated for by the previous good performance. Dr Spiegelhalter said that, when using the sequential probability ratio method, he had found that the building up of credit was a real problem and led to a lack of sensitivity. While the sequential probability ratio method had some advantages in his view, he now felt that the CUSUM chart was preferable. He also favoured the approach advocated by Dr Aylin and his team of using computer simulations and actual past data to work out the false and true discovery rates and of then leaving the decision as to where the threshold should be set to those responsible for running the monitoring system.

14.136 Dr Spiegelhalter suggested that there should be a pilot scheme to design the system, to set the thresholds and to fine-tune the way it works. He suggested that the pilot scheme should use data that resembled as closely as possible the data that would eventually be used. Once the system was implemented, it would be necessary to monitor its use closely and to adjust it as necessary.

14.137 Dr Spiegelhalter said that he would be very concerned at the suggestion, which had been put forward by some, that the monitoring of mortality rates should be left to visual comparisons of crude mortality data by PCTs. He spoke of his experience in the Bristol Royal Infirmary Inquiry and said that the hospital involved had been 'awash with data', with plenty of opportunity for visual comparison, but nothing had been done about the information shown by the data. A formal system was, in his view, required. Professor Baker expressed the view that a visual comparison would not be sufficiently sensitive or reliable. It was likely, he thought, to miss some information.

The Concerns of the Profession

14.138 A number of participants in the seminar suggested that many GPs find the idea that the mortality rates of their patients might be monitored very threatening. Dr Grenville, representing the BMA, made the point that, if 'entirely blameless' GPs were to be over-investigated, this would have an adverse effect on morale and, ultimately, on patient care. I have already mentioned the concerns of members of the medical profession about the work that has been undertaken in Northern Ireland.

14.139 Dr Booth mentioned that there had been particular concern in Northern Ireland that mortality data would be presented to the public in the form of rankings or league tables. There was general agreement at the seminar that the publication of rankings of GPs by mortality rates would be inappropriate and unhelpful. Dr Aylin pointed out that simple ranking can be dangerous. It inevitably means that one practice is at the bottom of the league table and is labelled 'worst'. It would be necessary to have some understanding of the distribution of mortality between GPs, in order to detect whether a practice was a true outlier, or whether it represented merely the tail of a normal distribution. Professor Baker and Dr Spiegelhalter agreed that rankings would be unhelpful. Dr Spiegelhalter said that there were other means by which divergent cases could be clearly spotlighted.

14.140 Dr Aylin and his team did, however, believe that rankings of mortality rates for GPs in a PCT area – appropriately adjusted for case mix factors – could have a use in communicating comparative information about mortality data to GPs, provided the rankings were presented in an appropriate way. Typically this would be done graphically by presenting individual GPs' mortality rates with a range of values (known as confidence intervals) within which their mortality rates were likely to vary.

14.141 Rankings of this kind are already produced in some areas. Mrs Scott told the Inquiry that her PCT provides comparative information about 60 or 70 performance indicators to GP practices in its area on an annual basis. For the last few years, mortality data has been one of the indicators. A practice's indicators are discussed at annual clinical governance visits.

14.142 I can well understand why GPs would feel that the publication of rankings of GPs' mortality rates might be misleading, unfair and damaging to doctors' morale and patient care. In my view, it should not happen. The data should be presented to GPs and GP practices as in a scientific study, with an explanation of the methodology and its limitations and the confidence intervals that apply. Then, assuming that GPs are able to understand and interpret the material in that form, it should be of real value to them for their clinical governance purposes at both an individual and a practice level.

The Potential Advantages of a Monitoring System

14.143 Since the issue of monitoring mortality rates has gained prominence in the wake of Shipman's activities, it is perhaps not surprising that there is a perception that the only purpose of such monitoring is to 'catch another Shipman'. However, those who are in favour of setting up a system of monitoring argue that it would have benefits extending well beyond the detection – and possible deterrence – of a murderous doctor.

14.144 There was agreement among participants at the seminar that the process of monitoring mortality data could have two distinct and separate uses. The first of these was quality improvement. Professor Baker believed that, if mortality data were available and GP practices had the necessary expertise to understand the data and to learn from it, it should be possible to use the data for local quality improvement purposes. The second use of monitoring would be for quality assurance purposes. This would involve the use of the data to observe abnormalities which could indicate a performance problem, or even criminal activity.

14.145 Dr Mohammed could not give any specific examples of improvements in quality of care that had occurred as a result of the Eastern HSS Board project, although, of course, it was early days. He suggested, however, that monitoring would assist in understanding the factors that contribute to an excess in mortality. This might result in an improvement in the quality of care and might potentially also identify criminal behaviour. He would like a monitoring system to look at both high and low mortality rates. He believed that this might lead to identification of good – as well as poor – practice and might make the process less threatening to the medical profession. Dr Aylin confirmed that it would be possible, using CUSUM charts, to look at both high and low mortality rates.

14.146 Dr Grenville observed that the monitoring of mortality rates could serve a dual purpose. It could be a 'powerful tool for improving practice'. At the same time, it might also be a tool for detecting 'another Shipman' should one appear. Dr Grenville felt that quality improvement should be the primary aim, with the detection of criminality as a 'by-product'. He wanted to ensure that monitoring provided 'the most benefit for the most people'. He felt that it would do this by improving practice. He cited as an example the situation which might arise if monitoring showed that a practice had an excess of deaths due to cardiovascular disease. He said that that information might lead to consideration of changes which should be made to primary and secondary strategies for the prevention of cardiovascular disease within the practice and within the area. If, in the process of using mortality data to improve the lot of patients, it was also possible to detect poor practice or instances (which he believed would be very rare) of criminal practice, Dr Grenville said that he would be delighted. His concern about setting up a monitoring system was that, once it was in operation, it might encourage a false belief that it would inevitably catch 'the next Shipman'. He did not think that it would necessarily do so, since, if a doctor was minded in the future to act in the same way as Shipman, s/he was unlikely to do it in the same setting of general practice. However, with that proviso, Dr Grenville could see real benefits in monitoring mortality rates.

14.147 Professor Baker felt that there was real value in GP practices receiving their own mortality data and having available the necessary information to enable them to compare their own data with that of other practices. He suggested that if, for example, a GP practice found that it was having more cardiovascular deaths than could be expected from the figures for other practices, this could be 'a good trigger' for them to look at how they were treating patients with risk factors for cardiovascular disease. Dr Baker, representing the RCGP, agreed with Professor Baker about the benefits of practices having an understanding of their own mortality rates. She believed that a system of monitoring mortality rates might act as a deterrent to a potential criminal. However, she also expressed the view that such a

system would not necessarily be effective in detecting the activities of locums or doctors engaged in out of hours work and would not, therefore, necessarily detect criminality on the part of a doctor working in those fields.

14.148 Some reservations were expressed about the extent to which the behaviour of GPs had the potential to influence the mortality rates of their patients. Dr Goldblatt pointed out that many diseases and causes of mortality are closely linked to socio-economic and other factors (e.g. the treatment received by a patient in hospital or the care received in a nursing home or the compliance of the patient with treatment) which are outside the control of the patient's GP. Some conditions are not amenable to treatment at all. It seems to me likely also that some deaths may have contributory factors that lie many years in the past, before the deceased became a patient at the GP practice with which s/he was registered at the time of his/her death.

14.149 Dr Goldblatt made the point that each individual GP has only a few deaths per thousand patients annually and only a relatively small proportion of the conditions causing those deaths are amenable to treatment or to intervention by the GP. It is only that small proportion of annual deaths which can be related to GP performance. Dr Goldblatt said that he believed that the monitoring of mortality rates among GP patients was of value, but it had to be recognised that a high level of mortality within a practice might be caused, not by the quality of care within that practice, but by some extraneous factor. He believed that the monitoring of general practice had to be complemented by the monitoring of other institutions and organisations.

14.150 Dr Roberts expressed some doubt, based on his experience of clinical trials in primary care, about the extent to which a variation in GPs' behaviour (e.g. by improving their practice) was capable of influencing the outcome for patients. He acknowledged that it might be useful for a GP to look at the deaths in his/her practice and, having seen for example that the practice had a number of deaths from substance misuse, to consider changing its system of dealing with substance misuse. However, he pointed out that that was not 'a statistical observation', by which I think he meant that it was not necessary to conduct any analysis of mortality rates in order to make the observation. Nevertheless, I suppose that an examination of mortality data might cause a practice to focus on deaths which had occurred and on the causes of those deaths in a way that it might not otherwise do. That was, as I understand it, the point that was being made by Professor Baker and by Dr Baker.

14.151 Professor Baker said at the end of the seminar that he felt optimistic about the capability of a monitoring system to combine both the quality improvement and quality assurance roles. He firmly believed that the monitoring of information about mortality was likely to be important to local quality improvement activities. He observed that quality could be measured only if there were several different ways of measuring it. This is because quality of health care is such a complex and confusing concept. Mortality, although not a very sensitive measure of quality, is, he said, an important one. It should be part of any overall scheme to assess quality. Professor Baker believed, from what he had heard at the seminar, that it would be possible to have a system which could detect doctors with high and clinically unexplainable mortality rates and could also help doctors and primary

healthcare teams to consider the mortality patterns among their population and to plan their key policies. He went on to say:

> **'I do not think it is possible for us to tell the public, let alone relatives of Shipman's victims, that we are unable to detect and will be unable to detect in the future a doctor who murders a large number of patients. I do not think that is sustainable.'**

Conclusions

14.152 Several participants in the Inquiry's seminars observed that if, in the future, there were another doctor with a criminal intent similar to that of Shipman, s/he was unlikely to pursue his/her criminal behaviour in the same way as Shipman did. That being the case, it was said there was no guarantee that a system of routine monitoring of mortality rates among GPs' patients would 'catch another Shipman'.

14.153 I recognise, of course, that a system of routine monitoring of mortality rates would not, on its own, provide any guarantee that patients would be protected against a homicidal doctor. I also agree with those who have emphasised the importance, if a system of routine monitoring is to be introduced, of ensuring that PCTs, the medical profession and the public are not lulled into a false sense of security, whereby they believe that the system of monitoring itself will afford adequate protection for patients. Routine monitoring of mortality statistics would be only one element of that protection. I have already made detailed recommendations for the reform of the systems of death certification and investigation, which I believe would provide significant protection. Indeed, it is my view that the introduction of those reforms, coupled with a system of monitoring of mortality statistics would together provide a real deterrent to misconduct, as well as a greatly improved opportunity to detect the activity of a doctor such as Shipman. For example, if the results of monitoring had been available when Dr Reynolds made her report to the Coroner, it would have been possible to ascertain immediately whether Shipman had an abnormally high mortality rate. If the information that I have suggested should be collected for death certification had also been available, it would have then been possible to pick up the abnormalities in the pattern of deaths among his patients even if they had not already come to light as a result of routine monitoring. In short, it seems to me that, if routine monitoring of mortality rates were shown to be workable, its introduction must be seriously considered.

14.154 Of course, the case for routine monitoring would be even stronger if it were shown that the monitoring of mortality rates would have benefits over and above the possibility of detecting aberrant or criminal behaviour. Quite apart from any other consideration, if GPs were able to see that the data derived from monitoring mortality rates was making a positive contribution to the quality of patient care within their own practices – and possibly more widely – the process of monitoring would appear less threatening than might otherwise be the case. It seems to me, as a lay person, that Professor Baker and others must be right when they say that it is important for GPs and GP practices to have access to, and to be able to interpret and understand, their mortality data. Of course, mortality data is not the only – or necessarily the strongest – indicator of the quality of patient care.

Nevertheless, it is an important indicator and must in my view form part of the data which should be collected in the course of clinical governance.

14.155 I recognise that there are practical difficulties in the way of setting up a satisfactory system of monitoring mortality statistics. The greatest of these seems to be the problem of providing a reliable method of linking an individual patient with an individual GP. My suspicion is that, unless that can be done, a monitoring system might be too blunt a tool to be worthwhile. However, I am optimistic that, with a will, it could be done. I agree with Professor Baker that it is simply not acceptable to say to the public – and particularly to the families of Shipman's victims – that it cannot be done or that it is not worth doing. In my view, Dr Aylin and his team have shown that it can be done and I am satisfied, having heard the views of the seminar participants, that it will be worth doing.

14.156 In my view, the analysis of mortality data is important. The value of this process was acknowledged by all participants at the seminar, although the difficulties which lie ahead were recognised. There was also agreement that the work must be done centrally. In my view, the DoH must now make provision for it to be done. At the seminar there was also agreement that the investigation of the cause and significance of outlying data should be undertaken locally but that it required considerable expertise. Such investigations must be well organised, consistent and objective. Unless such cases can be properly examined, the system will not be useful and may cause concern and resentment. It was not envisaged that an individual PCT should undertake this function. PCTs could not be expected to develop the necessary expertise, as the need for such investigations will arise only rarely. If the Healthcare Commission does not, after all, intend to set up local or regional bases, I think the work of investigation may have to be assigned to the inter-PCT investigation teams, which, in Chapter 27, I recommend should be set up for the purpose of investigating complaints and concerns. That would probably not be the ideal solution but, if training could be provided and a protocol for such investigations could be developed, I think the arrangement would be adequate.

CHAPTER FIFTEEN

The General Medical Council

Introduction

15.1 As I explained in Chapter 2, the Inquiry's Terms of Reference require it, by reference to the case of Harold Shipman, to enquire into the performance of the functions of those statutory bodies, authorities, other organisations and individuals with responsibility for monitoring primary care provision and to recommend what steps, if any, should be taken to protect patients in the future. A fundamental and essential part of the monitoring of primary care provision is the business of deciding whether any doctor practising as a general practitioner (GP) is fit to continue to do so. That task is carried out by the General Medical Council (GMC), the regulatory and disciplinary body of the medical profession in the UK.

15.2 The GMC is a statutory body with responsibility for the registration of all doctors. There are two aspects to the duty of registration: one is maintaining the register; the other is deciding who shall be on it. Deciding who shall be on the register involves first laying down the educational standards to be achieved before an individual can be admitted to the register. It also involves deciding whether a doctor's name should be erased from the register or whether his/her registration should be suspended because s/he is considered to be unfit to practise as a doctor. The GMC has the power to remove doctors from the register or to suspend their registration and, as an adjunct to that power, can also restrict the registration of an individual doctor, in effect imposing conditions under which the doctor is permitted to continue to practise. The GMC exercises its powers of erasure, suspension and restriction through its 'fitness to practise (FTP) procedures', with which the following Chapters of this Report are concerned.

15.3 It is clear that, under its Terms of Reference, the Inquiry must examine the GMC's role as the regulatory and disciplinary body for persons already practising as GPs. However, it did not appear to me that Parliament intended the Inquiry to examine, at least as anything other than background, the means by which a person becomes a GP or the standards to be achieved before that can happen. The Inquiry is not, therefore, concerned with the GMC's educational responsibilities.

15.4 Shipman was admitted to the medical register in August 1971 and practised as a GP for over 22 years between 1974 and 1998. During that time, he was reported to the GMC for various forms of alleged misconduct on three occasions, in 1976, 1985 and 1994, prior to the police investigation which resulted in his conviction for murder. On each occasion, after considering the circumstances or allegations in the light of the procedures in force at the relevant times, the GMC decided to allow him to continue in practice without restriction. Plainly, the Inquiry was expected to examine those allegations, circumstances and procedures and to consider the decisions of the GMC that affected Shipman. Out of fairness to the GMC, it was obviously necessary to examine the procedures in operation at the various times when complaints were made and to consider the decisions affecting Shipman in the context of the culture of the times and against the background of the way in which the GMC usually decided such cases at those times.

15.5 However, the Inquiry also has to make recommendations for the protection of patients in future. The procedures that were in force when Shipman was last reported to the GMC have changed a great deal; indeed, as I shall explain, they have been in an almost constant state of development and change since the mid-1990s. The GMC has very recently introduced a completely new regime of FTP procedures. In order to make recommendations for the protection of patients in future, the Inquiry has had to examine the development of the FTP procedures and the GMC's 'track record' of operating them. It must also consider the new procedures, for which there exists, as yet, no operational 'track record'.

15.6 The Terms of Reference require the Inquiry to consider the actions of all those involved in monitoring primary care provision **'by reference to the case of Harold Shipman'**. Shipman was, as is now known, a serial murderer of his patients. However, it would be simplistic to suggest that the Inquiry was expected only to make recommendations about how to protect patients from being murdered by their GPs. Shipman was many other things besides a murderer. He was also a liar and a cheat. He forged prescriptions, falsified medical records and practised various other forms of dishonesty. In the 1970s, he misused pethidine, a controlled drug, by obtaining it unlawfully and administering it to himself; he was, for a time, addicted to or dependent upon that drug. Throughout his entire time in general practice, he flouted the statutory regulations relating to the keeping and usage of controlled drugs. There is also evidence that he was reckless or careless when prescribing or administering drugs. On one occasion, it was found that he had failed to attend a patient who needed admission to hospital. Thus, to consider the GMC's procedures **'by reference to the case of Harold Shipman'** requires consideration of the GMC's procedures as they affect doctors exhibiting a wide range of problems, including misconduct, ill health due to drug addiction or dependence and substandard clinical performance. For that reason, the examination which follows must necessarily be wide-ranging and detailed.

History

Objectives

15.7 The GMC was created by the Medical Act 1858. The current statute governing its constitution, functions and practices is the Medical Act 1983, as amended (the 1983 Act). Originally, the principal purpose of the GMC was to rationalise the many different forms of medical qualification then in existence and to distinguish properly qualified medical practitioners from the large number of unqualified persons who held themselves out as offering medical services. The early GMC was also given a limited disciplinary role whereby it could erase from the medical register any doctor found guilty of **'infamous conduct in a professional respect'**. From early times, there was some recognition that the underlying objective of the GMC should be to protect the public from 'rogue' doctors. However, in recent times, that objective has been much more clearly spelled out and the GMC now accepts that the protection of patients and the public must be its paramount objective. Very recently, that objective has been given statutory recognition. By section 1A of the 1983 Act, as amended in 2002, the main objective of the GMC in exercising its functions is **'to protect, promote and maintain the health and safety of the public'**. The

Charity Commissioners, in granting charitable status to the GMC in 2001, defined its purpose as being **'to protect, promote and maintain the health and safety of the community by ensuring proper standards in the practice of medicine'**. Those statements of purpose are applicable to both of the GMC's main functions, i.e. the setting of educational standards and the exercise of its disciplinary role through the FTP procedures.

Constitution

15.8 Initially, the GMC comprised 24 members (collectively termed 'the Council'), most of whom were nominated by the medical Royal Colleges and the universities. A few were chosen by the Privy Council. All were medically qualified. The numbers increased to 29 in 1886 and, from 1926, it became the practice of the Privy Council to choose at least one non-medical ('lay') member. By 1950, the GMC had 50 members, of whom three were lay members. The method of selection and appointment changed with the coming into force of the Medical Act 1978, since which time a majority of members has been elected by doctors on the medical register. Also at that time, the number of GMC members increased. By 1989, the number had grown to 102. In June 2003, there were 104 members of whom 54 were elected, 25 were appointed by the universities and the medical Royal Colleges and 25 were nominated by the Queen on the advice of the Privy Council. By law, a majority of nominated members must be persons who are not medically qualified but, in recent years, the practice has been for the Privy Council to advise that all nominated members should be lay members. All elected and appointed members are registered doctors.

15.9 In July 2003, the number of Council members was reduced to 35, comprising 19 elected medical members, two appointed medical members and 14 nominated lay members. This change was brought about as it was recognised that effective decision-making was almost impossible for a group with 104 members. This change has had the effect of increasing the proportion of lay members on the Council from about 25% to 40%.

Development: the Merrison Committee

15.10 The change to a largely elected membership came about as the result of the recommendations of a Committee set up in 1972, under the chairmanship of Dr (later Sir) Alec Merrison (the Merrison Committee). Until the late 1960s, the GMC was financed by a single registration fee paid by each doctor at the time of registration. By the 1960s, the GMC's activities and expenditure had increased and it required increased income. It decided to impose an annual retention fee on all doctors. This led to insurrection. Many doctors refused to pay the annual fee; they argued that there should be 'no taxation without representation'. The GMC threatened them with erasure. The Government was concerned at the prospect of losing a large number of NHS doctors. At the time, there were other issues dividing the GMC from various professional bodies, such as the British Medical Association and several of the Royal Colleges. In order to give proper consideration to all these issues, the Government set up the Merrison Committee. Its Terms of Reference required the Committee:

> **'To consider what changes need to be made in the existing provisions for the regulation of the medical profession; what functions should be**

assigned to the body charged with the responsibility for its regulation; and how that body should be constituted to enable it to discharge its functions most effectively; and to make recommendations.'

15.11 The Merrison Committee reported in 1975, with two main proposals. It suggested that the profession should have the right to elect a majority of the members of the GMC, a change which was, as I have said, effected by the Medical Act 1978. Today, the majority of members of the GMC are still elected by medical practitioners. This change no doubt resolved the discontent within the profession; there was now to be taxation but with representation. However, the dominance in a regulatory body of an elected group, with an electorate to serve, inevitably gives rise to conflicts of interests and objectives. Those members elected by the profession must, at least to some extent, have the interests of their electors at heart. At times, the interests of doctors and of the public may lie in different directions. Yet, as I have explained, the main objective of the GMC should be **'to protect, promote and maintain the health and safety of the public'**. Financial matters must sometimes give rise to a potential conflict between interests and objectives. The GMC is still funded by an annual retention fee payable by all doctors. By far the greatest item of expenditure in the GMC budget is the FTP procedures. The number and variety of cases going through the FTP procedures has increased enormously in recent years. The appointment of suitably educated, experienced and trained staff and panel members sufficient to administer the FTP procedures must have led to an increased financial burden.

15.12 The Merrison Committee also proposed reforms to the FTP procedures, based upon a clear statement of philosophy that these procedures were to be designed to protect patients rather than to punish doctors. In particular, it recommended new procedures for supporting and rehabilitating doctors who were unfit to practise by reason of ill health. I shall describe these procedures in Chapter 22. Whether the GMC has struck the right balance between protecting patients and supporting and rehabilitating doctors (rather than punishing them) is an issue to which I will return in subsequent Chapters.

15.13 The Merrison Committee recommended that the GMC should be statutorily charged with the duty of promoting high standards of professional conduct. The relevant powers were provided by the Medical Act 1978. The Committee also considered the possibility that the GMC might undertake some form of periodic 're-licensure' of doctors. The position then was (and still is) that, once a doctor had qualified, it was taken for granted that s/he remained fit to practise unless and until found to be unfit as the result of FTP proceedings. Those proceedings could be initiated only following the receipt by the GMC of a complaint or report about the doctor. Re-licensure would have entailed some periodic reassessment of fitness to practise. The Merrison Committee considered any recommendations in respect of re-licensure to be beyond its remit and the presumption that a doctor will remain fit to practise throughout his/her career has, therefore, continued. However, that situation is about to change under proposals that doctors' registration should be periodically 'revalidated'. It is proposed that, once every five years, every doctor who wishes to continue to hold a licence to practise will have to demonstrate to the GMC that s/he is 'up to date and fit to practise' in his/her chosen field. I shall describe those proposals in Chapter 26.

Various Functions

15.14 As I have said, the GMC function which is of most direct interest to the Inquiry is the conduct of the FTP procedures. The revalidation of the doctors' registration is also a matter of interest. However, for the sake of completeness and lest it be thought that I am unaware of the important work done by the GMC in other fields, I shall describe its other functions very briefly before describing (also briefly at this stage) the various FTP procedures. Those other functions are:

- the setting of standards of professional competence and conduct
- the registration of doctors
- the promotion of high standards in the training and education of doctors.

The Setting of Standards of Professional Competence and Conduct

15.15 The Committee on Standards of Professional Conduct and on Medical Ethics (the Standards Committee) is responsible for the GMC's work in setting standards of competence and conduct. It seeks to define the principles that underlie good professional practice, to apply those principles to new and developing situations and circumstances, and to advise the GMC on guidance which should be issued as a whole.

15.16 From its early days, the GMC provided guidance to doctors about unacceptable conduct. Until the early 1990s, the guidance largely comprised warnings about the kind of misconduct that might lead to disciplinary action by the GMC. The GMC no longer does this. Since 1995, the emphasis has changed and the GMC has sought to provide positive advice about standards of good practice and ethics. The Standards Committee has also produced, and the GMC has promulgated, a number of other sets of guidance of both a general and a specific nature.

15.17 In 1995, the GMC issued the first edition of the publication 'Good Medical Practice', which contained a statement of the principles characterising good medical practice, together with an exposition of the 'Duties of a Doctor'. I understand that doctors find this publication extremely helpful and that it has been adopted or adapted for use in many other countries. 'Good Medical Practice' is now in its third edition and is undergoing further revision. It is said to provide the standards against which doctors will be judged if their registration is called into question under the FTP procedures. The principles and duties set out in 'Good Medical Practice' are said to form the basis of the **'professional contract between doctors and their patients'**. While I readily accept that 'Good Medical Practice' provides the standards against which a doctor is judged, it is aspirational in nature. It does not provide – whether for doctors, healthcare managers or patients – clear guidance about the standards the doctor must achieve if s/he is to avoid criticism or action on registration under the FTP procedures.

The Registration of Doctors

15.18 Section 2 of the 1983 Act provides that the Registrar shall keep two registers of medical practitioners. The first comprises the names of doctors who are fully registered and the

second contains the names of doctors who are entitled to provisional or limited registration. Provisional registration allows newly qualified doctors to undertake the general clinical training needed for full registration. A doctor who is provisionally registered is entitled to work only in certain specified settings. Doctors holding limited registration may work only under the supervision of a fully registered doctor and in certain specified types of post. It is a criminal offence for any person knowingly to hold him/herself out as being a registered medical practitioner if s/he is not in fact so registered. The GMC also operates a third register, known as the specialist register, inclusion in which is a prerequisite for appointment to a substantive or honorary NHS consultant post.

15.19 The present position is that, in general, once registered, a doctor is entitled to remain on the register unless his/her name is removed by order of a FTP panel. In the future, it is the GMC's intention to issue a licence to practise to all doctors who wish to exercise the rights and privileges of the profession. Thereafter, the GMC will require all doctors who wish to retain their licence to practise to undergo revalidation. This process will be introduced in 2005, but will take several years to be fully effective.

The Promotion of High Standards in the Training and Education of Doctors

15.20 Under section 5(1) of the 1983 Act, the Education Committee of the GMC has the general functions of promoting high standards and of co-ordinating all stages of medical education. In 1993, the Committee issued the publication 'Tomorrow's Doctors – Recommendations on Undergraduate Medical Education', which contained recommendations for the implementation of a new curriculum in medical schools in the UK. In 2002, a revised version of this work was published, describing what was expected of all medical graduates. The Committee has also published a number of treatises, including a review of the periods of 'apprenticeship' which follow the completion of a medical degree, namely the pre-registration year and the year spent as a senior house officer.

The Fitness to Practise Procedures

15.21 The statutory basis of the FTP procedures is to be found in Part V of the 1983 Act. In the past, there have been three separate types of FTP procedure:

- the conduct procedures, which were the successors of the original disciplinary procedures of the GMC
- the health procedures, introduced by the Medical Act 1978, following the recommendations of the Merrison Committee. They came into operation in 1980 and were designed to deal with doctors whose fitness to practise was impaired by ill health
- the performance procedures, which came into operation in July 1997, and were designed to deal with doctors whose professional performance was found to be seriously deficient.

15.22 Throughout this Report, I shall refer to those procedures as the 'old' FTP procedures and will use the past tense to describe them. I shall describe the FTP procedures which have recently been introduced as the 'new' procedures and will refer to them in the future tense.

Present Structure

15.23 I have already explained that the GMC comprises 35 members, of whom 21 are registered medical practitioners and 14 are non-medical or lay members. The President, who is both leader and figurehead, is elected by the members for a period not exceeding seven years and is always an eminent member of the medical profession. The present incumbent is Professor Sir Graeme Catto, a distinguished consultant physician whose current appointments include Dean of Guy's, King's College and St Thomas' Hospitals Medical and Dental School, Vice-Principal, King's College London, and Professor of Medicine and Pro-Vice-Chancellor, University of London.

15.24 The 19 elected medical members are chosen by several different geographical 'constituencies' of doctors. Two medical members are appointed by the universities with medical schools and the medical Royal Colleges. The lay members, nominated by the Privy Council, are drawn from a variety of backgrounds. During the hearings, Leading Counsel for the Tameside Families Support Group (TFSG) drew attention to the fact that a significant number of lay members had a professional background in NHS management or administration. It was suggested that they were not really 'lay' people who could represent and safeguard the interests of the general public and of patients in particular. As a result of their professional backgrounds, they would be steeped in the culture of the medical profession and of NHS management. The GMC, in reply, suggested that it was appropriate for some lay members to have a background in health administration; this gave them an understanding of the quite complex structures of the NHS which was invaluable to them in their GMC role. In any event, said the GMC, the lay members were all extremely independent, whatever their background, and were very conscious of their duty to safeguard the interests of patients and the public.

15.25 I do not feel able to express any concluded view on this interesting difference of opinion. I see the advantage of having a knowledge of existing NHS procedures. Such knowledge will be very useful to a GMC member. The knowledge can be acquired, but that takes time. It also appears to me, from the evidence I have heard from and about lay members, that some of them are very independent in their thinking, notwithstanding their healthcare background. Dr Arun Midha, who has been a member of the GMC since November 2000 and was a lay screener from July 2001 until 2004, is a case in point. Dr Midha is not a medical doctor; his academic qualifications lie in the fields of social studies and business administration. He is Associate Director (Business and Planning) of the School of Postgraduate Medical and Dental Education, University of Wales College of Medicine. Before taking up that role, he held management and advisory positions with Health Promotion Wales and the Welsh Combined Centres for Public Health (Division of Public Health). Between May 1994 and January 2002, he was Programme Manager for the public health medicine training scheme in Wales. In the past, he has been a non-executive director of an ambulance trust and the lay chair of the NHS complaints panel in Wales. Although he is not medically qualified, therefore, it can be seen that Dr Midha has a background in the field of health care. Yet it was apparent from his decisions in the FTP procedures that he applied his mind in a completely independent way. On the other hand, I can understand the concerns expressed by the TFSG. Even if the lay members who have worked mainly in NHS management are in fact independent, their backgrounds may

create the impression that they are 'members of the same club' as the doctors. They may not bring a fresh eye to their scrutiny of GMC practices and procedures. It is vital that lay members should be people of an independent mind, able and determined to safeguard the interests of the public, including patients. I think that lay members should come from a range of different backgrounds. It may be that, in the past, the mix has been rather too heavily weighted towards the NHS professionals. I think that the GMC recognised the force of the points made by the TFSG and I hope that in future it will be possible to ensure that there is an appropriate mix of backgrounds among the lay members.

15.26 The Council meets about six times a year to discuss and decide major issues of policy. However, much of the work of policy development is carried out by committees or by working groups formed by those committees. I have already mentioned the Education Committee and the Standards Committee. These committees are composed mainly of GMC members, although some also have co-opted members. There are other committees whose functions range over fitness to practise, registration, finance and resources, audit and race, equality and diversity. There is also a 'Patient and Public Reference Group', comprising members of the GMC and others, who represent the interests of patients and consumers. For example, the Patients Association, the Consumers' Association (now known as Which?) and the Patients Forum are represented on it. The object of this Group is to allow continuing consultation between the GMC and patient groups on policy issues.

15.27 A considerable body of administrative staff supports the day-to-day work of the GMC. At the head is the Chief Executive and Registrar. The present incumbent of this post is Mr Finlay Scott. Below him are the Directors in charge of four directorates, dealing with fitness to practise, registration and education, corporate affairs and policy, and resources.

15.28 The Fitness to Practise Directorate is divided into a number of Sections, each dealing with a different aspect of FTP work and headed by a senior member of staff. These senior staff are not medically qualified; they usually have a background in administration – many of them in the Civil Service or quasi-governmental bodies. The handling of the thousands of individual cases reported to the GMC every year is undertaken by teams of caseworkers under the leadership and supervision of casework managers. Again, these members of staff do not usually have any medical qualifications. Most are graduates. In addition, there are secretarial and junior administrative staff.

15.29 In the past, important aspects of the preliminary work in the processing of an individual case were undertaken by medical or lay members of the Council. In the conduct procedures, for example, complaints of misconduct were referred by office staff to a 'medical screener' (a medically qualified member of the Council), who would decide whether or not the complaint should proceed to the next stage of the procedures. This was a sifting process. If the medical screener decided that the case ought not to proceed to the next stage, it would be closed, provided that a 'lay screener' agreed. In health cases, a 'health screener', a medical member of the Council (usually one who practised in psychiatry), was responsible for the supervision of a doctor who was subject to restrictions on his/her practice. In the performance procedures, a medical member of the GMC was appointed as a case co-ordinator. He or she would take important preliminary decisions,

which might include the drafting of a statement of requirements for re-education or remediation that the doctor might agree to undertake.

15.30 In future, under the new FTP procedures, it is likely that individual medical members of the GMC will not generally be responsible for any of the preliminary stages of the FTP procedures, as they have been in the past. Insofar as sifting functions require medical expertise, they will be undertaken by medically qualified members of staff, to be known as case examiners. Members of the GMC will be mainly concerned with issues of policy and governance. They will carry much less responsibility than before for decisions on individual cases.

15.31 In the past, five committees were responsible for deciding cases brought under the three types of FTP procedures. These were the Preliminary Proceedings Committee (PPC) and the Professional Conduct Committee (PCC) (conduct procedures), the Health Committee (HC) (health procedures), and the Assessment Referral Committee and the Committee on Professional Performance (CPP) (performance procedures). In addition, the Interim Orders Committee, created in 2000, had the task of deciding whether it was necessary to suspend a doctor's registration or to impose conditions on his/her registration pending a final decision on his/her case.

15.32 Panels of the various FTP committees traditionally comprised only members of the appropriate committee; for example, a panel of the HC would comprise sufficient members of that Committee to make a quorum. However, the number of FTP cases increased and it became necessary for multiple panels of FTP committees to sit simultaneously in order to reduce the long delays which were occurring before cases were heard. In order to make this possible, in 2000, the GMC sought and obtained the power to co-opt non-GMC members to sit on its FTP committees. The persons co-opted were known first as 'adjudicators', then as 'associates'. A large number of 'associates' (both medical and lay) were recruited to sit on FTP committee panels. When the number of GMC members was reduced in 2003, many retiring members were appointed as associates. By mid-2004, GMC members were no longer sitting on panels save in exceptional circumstances; instead, panels were composed entirely of associates. In future, under the new procedures, GMC members will be ineligible to sit on FTP panels, although they will be eligible to sit on panels of the new Investigation Committee. Whether they will, in fact, do so is as yet uncertain. All other panels will be composed of non-GMC members who have undergone training and assessment.

The 'Old' Fitness to Practise Procedures in Outline

15.33 The 'old' FTP procedures were governed by a range of statutory and internal, non-statutory provisions. The primary legislation was contained in Part V of the 1983 Act. However, each set of procedures had its own set of statutory Rules. In the past, the GMC had difficulty in obtaining amendments to the Rules or securing the passage of new secondary legislation. However, the provisions of section 60 of the Health Act 1999 enabled the GMC to secure much more speedy amendment of the Medical Act and the introduction of secondary legislation. Section 60 enabled the Department of Health to make certain amendments to primary legislation, including the 1983 Act, by Order in

Council. Such an Order is subject to affirmative resolution in both Houses of Parliament. The making of regulations and rules under the 1983 Act in relation to FTP procedures and revalidation is a matter for the GMC itself, but they have to be approved by Order of the Privy Council. The GMC also has a set of internal Standing Orders, comprising procedures that have been approved by the full Council. Some of these dealt with aspects of the FTP procedures. In addition, there are internal processes and guidance governing the way in which the GMC handles individual cases. It is not clear to me to what extent these internal processes and guidance have been expressly approved by the full Council. They may be approved by the Fitness to Practise Committee or may possibly be made under powers delegated to the Chief Executive.

15.34 As I have already explained, the three separate FTP procedures were introduced at different times and to fulfil different perceived needs. Some form of disciplinary procedure to deal with misconduct has existed for as long as the GMC itself, although many changes have been made over the years. For many years, the conduct procedures dealt with doctors who had been convicted of criminal offences and with those who were alleged to be guilty of serious professional misconduct (SPM). The health procedures came into effect in 1980 to meet the need to protect the public against doctors who were unfit to practise on account of ill health, while at the same time treating such doctors in a non-punitive and supportive way so as to help them to recover and to be rehabilitated into full practice. The performance procedures were introduced in 1997 and were intended to give the GMC the power to deal with doctors whose standard of professional performance was seriously deficient but whose poor performance could not be categorised as SPM.

15.35 The concept of SPM has given rise to considerable difficulty in interpretation. In Chapter 17, I shall discuss the meaning of SPM and the various attempts that were made over the years to define it. For the moment, suffice it to say that a wide variety of different forms of misbehaviour might amount to SPM. Often, these related to the doctor's dealings with his/her patients (for example, sexual misconduct), but behaviour which brought the medical profession into disrepute or which undermined public confidence might also amount to SPM even though it did not directly involve patients. For example, dishonesty in research might amount to SPM. In connection with clinical treatment, it had long been recognised that the wilful neglect of clinical responsibilities, such as a refusal to provide treatment when necessary, might amount to SPM. But negligent, as opposed to wilful, failures in connection with clinical treatment might also amount to SPM provided that the failure in question was sufficiently serious. It seemed to be assumed that members of the GMC would recognise a case of SPM when they came across it although, in fact, the evidence suggests that the issue of whether conduct amounted to SPM gave rise to frequent differences of opinion.

15.36 Similarly, there was no accepted definition of what was meant by seriously deficient performance (SDP). As with SPM, it seemed to be assumed that members would recognise it when they came across it. As with SPM, the lack of any authoritative definition gave rise to difficulties and differences of opinion. I shall discuss the meaning of SDP in Chapter 17.

15.37 All complaints, allegations and expressions of concern reaching the GMC were considered first by a case manager. He or she would follow detailed instructions when

considering whether the matter should be closed at that initial stage or whether it should advance into the FTP procedures. If s/he decided that the case was to proceed, s/he would send it either to a medical screener or, if it was clear that the case involved issues of ill health, directly to a health screener. The medical screener would consider whether the case raised any FTP issue, be it SPM, SDP or serious impairment of fitness to practise by reason of ill health. If s/he thought that it did, the case would be transferred to the appropriate Section. If s/he thought that no such issues were raised and that the case should be closed, a lay screener would examine the papers. If the lay screener agreed that the case should be closed, it would be. From that stage onwards, the procedures differed.

The Conduct Procedures

15.38 If either the medical or lay screener decided that a question of SPM had arisen, the case was handled in the Conduct Section and went to the PPC, which decided whether the case should proceed to a hearing before a panel of the PCC. Hearings before the PCC took place in public. If the PCC panel found the doctor guilty of SPM, it had the power to administer a reprimand, to impose conditions on the doctor's registration (such as practising under supervision or undertaking further training), to suspend the doctor from practice for up to a year or to erase his/her name from the medical register.

The Health Procedures

15.39 When a case was referred to the Health Section (by either a caseworker or a screener), it would be considered by a health screener. In the past, two medical members of the GMC acted as health screeners. From March 2004, two medically qualified case examiners were appointed to act as health screeners in place of the GMC members who had previously fulfilled this function. A very large proportion of all cases dealt with in the health procedures involved psychiatric problems of one sort or another. The health screener would write to the doctor inviting him/her to be examined by at least two medical examiners, usually psychiatrists. On receipt of the examination reports, the health screener would decide whether the doctor's fitness to practise appeared to be seriously impaired and, if so, s/he would devise a list of conditions (based on the recommendations contained in the examination reports) to which the doctor would be invited to agree. These might include restrictions on the circumstances of practice (such as not practising single-handed) and would always include a requirement that the doctor submit to medical supervision. If the doctor was continuing to practise, there would be a requirement that a professional supervisor should be appointed.

15.40 If the doctor agreed to the proposed conditions, the doctor was said to enter the 'voluntary' health procedures. He or she accepted the conditions and the health screener oversaw their operation, seeking periodic reports from the medical supervisor. If and when satisfied that it was appropriate to do so, the health screener might vary the conditions or terminate them, leaving the doctor free to practise. If the doctor did not accept the conditions thought appropriate by the health screener, or if the doctor refused to be examined at all, or was unfit to agree to conditions, the health screener might decide to

refer the case to the HC, which had the power to impose conditions upon the doctor's registration (in effect, the same kind of conditions as the health screener would have suggested) or to suspend him/her from practice for up to a year. The HC sat in private. It did not have the power to erase a doctor from the medical register although it could renew and extend either conditions or suspension. In certain circumstances, it could make a direction that a doctor's registration should be suspended indefinitely.

The Performance Procedures

15.41 The performance procedures were similar in operation to the health procedures in that they might be entered voluntarily or might operate by compulsion. When it appeared to a medical screener that a doctor's professional performance might have been seriously deficient and that it was appropriate to take action, s/he might invite the doctor to agree to an assessment of his/her performance by an Assessment Panel. If the doctor agreed, the case would be passed to the Performance Section, where arrangements for the assessment would be put in motion. A case co-ordinator would be appointed. In the past, two medically qualified members of the GMC acted as case co-ordinators. From March 2004, two medically qualified case examiners were appointed to act as case co-ordinators in place of the GMC members who had previously fulfilled this function.

15.42 The Assessment Panel would comprise one lay and two medically qualified assessors, one of whom practised in the same (or a similar) specialty as the doctor under scrutiny. One medical assessor would be appointed as the lead assessor. An assessment might take some months to arrange and complete. When the assessors had submitted their report, the case co-ordinator would decide whether the doctor's performance appeared to be seriously deficient. If so, s/he might devise a statement of requirements to which the doctor was invited to agree. The statement might require the doctor to undertake training in some aspects of his/her practice and might specify limitations (e.g. a requirement to practise under supervision) on his/her practice. If the doctor accepted the statement of requirements, s/he would enter the 'voluntary' performance procedures. The case co-ordinator would require periodic progress reports and, in due course, would arrange for a reassessment to be carried out. If all was satisfactory, the case co-ordinator might decide that the doctor should be free to practise without restriction. If the doctor failed to agree to or comply with the statement of requirements, or refused to co-operate in some other way, or if the case co-ordinator did not think that voluntary procedures were suitable, the case was referred to a panel of the CPP. The panel usually sat in private. If the panel decided that the doctor's performance had been seriously deficient, it might impose conditions on the doctor's registration or suspend the doctor from practice for up to a year. It had no power to erase a doctor's name from the medical register. Both conditions and suspension could be renewed and extended. In certain circumstances, a CPP panel could make a direction for indefinite suspension of a doctor's registration.

The 'Silo Effect'

15.43 Because the three different FTP procedures came into existence at different times, they operated separately and independently of each other. Although, in some limited

circumstances, it was possible for a doctor to be transferred from one set of procedures to another, a case could not be handled within more than one set of procedures at any one time. Thus, if a doctor presented with problems that included conduct, performance and health issues, a decision had to be taken as to where they were to be handled. The GMC referred to this as the 'silo effect'. The new FTP procedures have been designed to overcome this fundamental difficulty. It is intended that all cases will be investigated using flexible powers to obtain evidence of various kinds, including expert opinion about clinical practice, medical or psychiatric reports on the doctor's health, and performance assessment reports. If conduct issues arise, they will usually be determined by a FTP panel but the panel will also be able to consider any issues of performance or health which remain in dispute or which require the imposition of conditions or other sanction.

Criticism of the General Medical Council and the Movement for Reform

External Criticism

15.44 In his book, 'The Doctors' Tale'[1], Sir Donald Irvine (a member of the GMC from 1979 and its President from 1995 until 2002) described how the GMC came under increasing criticism from many quarters from the 1980s onwards. In his Reith Lectures of 1980, entitled 'Unmasking Medicine', Professor (now Sir) Ian Kennedy, currently Chairman of the Commission for Healthcare Audit and Inspection (now known as the Healthcare Commission), was deeply critical of the GMC. He doubted that medical self-regulation would be adequate by the end of the twentieth century. He observed that, although the GMC had a duty to protect the public interest, it had no method of consulting with the public. He alleged that it dismissed far too many complaints about doctors without adequate investigation or public scrutiny. He considered that the GMC was not properly held to account by the Privy Council. He was concerned that the GMC's approach to its disciplinary procedures was governed by the amount of money it was prepared to spend on them. He suggested regular re-registration in place of the presumption that a doctor, once qualified, remained fit to practise unless and until it had been proved, on receipt of specific complaint, that s/he was unfit. He also suggested that there should be an inspectorate that would be able to look into all aspects of a doctor's professional practice. He observed that specific guidelines would be needed as to what constituted good practice.

15.45 Another voice of criticism was that of Mrs Jean Robinson, one-time Chairman of the Patients Association and a lay member of the GMC. In 1988, she published a monograph in which she was deeply critical of the opacity of the GMC procedures and of their failure to do anything to protect patients from the poor clinical performance of incompetent doctors. Professor Rudolf Klein, of the University of Bath, criticised the GMC's reactive approach to complaints of misconduct and its complete failure to tackle the problems of poor performance.

15.46 In 1989, the British Medical Journal published a series of articles by Mr Richard Smith, then an editorial assistant. These were severely critical of the GMC. It was said that the

[1] Irvine, Donald (2003) 'The Doctors' Tale'. Oxford: Radcliffe Medical Press.

GMC was too large and its membership too old and too conservative. It was too interested in internal issues and was not sufficiently concerned about issues of medical education and clinical incompetence. Also, it should have been (but was not) seen to be serving the public interest; instead, it complained when criticised in the media.

15.47 One might summarise those criticisms by saying that the GMC was 'doctor-centred'. It appeared to assume that all doctors were good, competent and conscientious until proved otherwise. It would deal with the profession's 'bad apples' for the sake of the profession. It would do so in its own way and did not welcome scrutiny. Its procedures were designed to be fair to doctors and to ensure that no doctor would lose his/her right to practise without very good cause. It did not focus on the reasonable expectations of the public and it did not see itself as having a duty to ensure that all members of the medical profession were willing and able to provide a proper professional service.

15.48 Since the time when this criticism was at its height, the GMC has made considerable efforts to change. The development of the performance procedures in the early 1990s, and the improvements in the health procedures, which I shall describe later, are examples of this. In 'The Doctors' Tale', Sir Donald Irvine described his election to the Presidency on a 'reforming ticket'. He won the election but explained that the road to reform was not always easy. To some extent, events were to push the GMC forward. The tragedies of the Shipman case, the events surrounding the failure of paediatric heart surgery at Bristol Royal Infirmary and the case of Rodney Ledward (a consultant gynaecologist, whose lack of skill had caused injury to many of his patients over a period of 15 years or so) were important agents of change in the late 1990s. However, even before then, an expression of concern about the possibility of racial bias within the GMC had led to a wide-ranging examination of the GMC's internal procedures and to many important procedural changes.

The Work of the Policy Studies Institute

15.49 In 1994, an analysis of the nature and outcome of cases considered by the PCC over a ten-year period was brought to the attention of the GMC. This analysis appeared to suggest that doctors from the ethnic minorities were more likely to be brought before the PCC than were white doctors. To its great credit, the GMC decided that these concerns must be fully investigated. The GMC instructed the Policy Studies Institute (PSI) to do the work and gave the PSI team full access to all the relevant material that was available.

15.50 Allegations of racial bias are completely outside the Inquiry's remit. However, allegations that the GMC is biased towards doctors are not. The Inquiry is aware that there is a public perception that the GMC often favours the doctor as opposed to the complainant in its decision-making processes. This is an allegation of bias in another form. The work of the PSI team was to shed a great deal of light upon the procedures of the GMC. Those procedures are of interest to the Inquiry. Only if the GMC's procedures were thorough, fair and transparent would it be possible to say whether there was bias against complainants and whether patients were being properly protected from the actions of doctors reported to the GMC for alleged misconduct or incompetence.

15.51 The purpose of the PSI study was, first, to look for evidence of racial bias in the existing GMC procedures and processes and, second, to consider whether any changes should be made to minimise the risk of racial bias in the future. The study was confined to the GMC's conduct procedures. The study team was led by Professor Isobel Allen, Emeritus Professor of Health and Social Policy, University of Westminster PSI. Initially, Professor Allen and her colleagues analysed complaints made to the GMC against doctors in the 12 month period to August 1994. A Report (the 1996 PSI Report), setting out their findings and recommendations for change, was presented to the Racial Equality Group of the GMC in November 1995 and published in 1996.

15.52 The PSI team had considerable difficulty in carrying out its work. It found that the GMC data was largely recorded by hand. There was no reliable log or database of past complaints. The way in which complaints were classified made it difficult to analyse their seriousness. Papers relating to past complaints were stored in the same files as enquiries, general correspondence and press cuttings. Papers relating to an individual doctor were not necessarily filed together. An analysis carried out by the PSI team cast doubt upon the accuracy of statistics previously produced by the GMC. As a consequence of these difficulties, the 1996 PSI Report made detailed recommendations about steps which should be taken to establish a reliable and accurate database of complaints. The Report also made many observations and recommendations about the GMC's procedures for handling complaints. I shall refer to some of these in the Chapters that follow.

15.53 On the issue of racial bias, Professor Allen and her colleagues reported that they found **'no evidence of any overt racial discrimination or bias in either the procedures or the processes relating to conduct'**. Nor did they find evidence of any form of overt racial discrimination or bias in any interview or informal encounter with GMC staff or members or in any written comment found on the GMC files. Nevertheless, the statistical analysis carried out by the PSI team clearly showed that doctors who had qualified overseas or who had a name which suggested that they belonged to an ethnic minority were more likely than those who had qualified in the UK or Ireland or who had an English or European name to be referred on through the FTP procedures, as opposed to having their case closed at an early stage. The major difference between the groups was found in the proportion of each group referred by the PPC for a hearing before the PCC. These differences could not be satisfactorily explained because of the opacity of the GMC processes.

15.54 The 1996 PSI Report made clear that the fact that there were differences in outcome between the two groups did not of itself mean that there was racial bias within the GMC. It might just have been that the complaints against overseas qualifiers and those from non-English/European countries were more serious than those against members of the other groups. However, the possibility of bias could not be ruled out. The main conclusion of the Report was that, unless all the GMC procedures for handling complaints against doctors were transparent and open, it would not be possible to demonstrate that there had been no bias. The Report recommended a number of steps that the GMC should take in order to make its procedures more open, transparent and consistent. I shall discuss those recommendations later in this Report.

15.55 In 1998, the GMC commissioned a follow-up study from the PSI, which resulted in a further Report. The aim of this follow-up study was to identify any factors which might explain

differences in the representation of overseas qualified doctors at the various stages of the GMC conduct procedures. Before beginning its follow-up study, the PSI team recommended some immediate changes to the GMC procedures. These were designed to streamline the screening process and to improve the transparency and consistency of decision-making. I shall describe these changes in Chapter 19. The PSI team carried out a quantitative analysis of complaints received by the GMC in the calendar years 1997, 1998 and 1999, and examined the results for evidence of racial bias. In addition, the study examined the screening process, including the effects of the changes to the process which had been introduced by the GMC on the advice of the PSI team. The study also examined the decision-making processes of the PPC.

15.56 By the time the follow-up study began, the GMC had made considerable progress in implementing the recommendations contained in the 1996 PSI Report. In particular, its data collection system had been computerised and the process of tracking complaints had been made much easier. However, the number of complaints received by the GMC annually had increased markedly and considerable delays were occurring in the processing of complaints. At this time, the GMC had a relatively small staff, many of whom had been employed for a long time. Skills had been passed on by personal contact and mentoring and the GMC had not at that stage developed systems which would enable it to enlarge its staff and train new personnel to deal with this increased workload.

15.57 The analysis performed by the PSI team showed that, in all three years studied, there was an unexplained discrepancy between the number of UK qualified doctors referred to the PCC by the PPC and the number of overseas qualified doctors so referred. For example, in 1999, of the cases referred to the PPC, the proportion of UK qualifiers sent by the PPC for hearing at the PCC was 33%, whereas the proportion of overseas qualifiers sent was 54%. Professor Allen and her colleagues could not account for that difference. They noted that, since the PPC did not keep a contemporaneous record of its deliberations and gave no reasons for its decisions, no firm conclusions could be reached. There were also significant, unexplained differences between UK and overseas qualifiers in the outcomes of cases heard by the PCC.

15.58 The 2000 PSI Report made a number of recommendations, which I shall discuss in later Chapters. For the moment, it suffices to say that the general thrust was that, in order to provide consistency and transparency in GMC decisions, there was an urgent need for the development of standards and criteria. In particular, there was a need for a clear definition and an agreed interpretation of SPM.

15.59 In 2002, Professor Allen and her colleagues were commissioned to carry out further work for the GMC. They conducted a preliminary analysis of the data relating to complaints received by the GMC in 1999, 2000 and 2001. Their findings were set out in a Paper. The analysis showed marked differences between the relative proportions of UK and overseas qualified doctors referred to the PPC by individual medical screeners. Some screeners referred equal proportions of UK qualifiers and overseas qualifiers, whereas other screeners referred three times as many overseas qualifiers as UK qualifiers. As the distribution of cases to the screeners was said to be random, it appeared that the screeners must be applying different standards. Again, the proportion of overseas

qualifiers referred by the PPC to the PCC was higher than that of the UK qualifiers. There were also continuing differences between UK qualifiers and overseas qualifiers in the outcomes of cases heard by the PCC. Once again, Professor Allen and her colleagues observed that it was possible that the complaints received about overseas qualifiers had been more serious than those about their UK counterparts. That would explain the disproportionate referral rates and the differences in outcomes. But, in the absence of objective criteria against which decisions could be measured, it was still impossible to demonstrate this.

15.60 Thus, in three studies, conducted over a period of nine years, the PSI found unexplained differences in the treatment by the GMC of overseas qualifiers as compared with UK qualifiers; the overseas qualifiers were more severely dealt with. This may or may not indicate that there is racial bias within the GMC. The importance of these findings, from the Inquiry's point of view, is that the procedures are lacking in transparency. It ought to be possible to refute a suggestion of bias if it can be demonstrated that decisions are taken according to objective criteria and by the consistent application of established standards. Professor Allen has repeatedly advised the GMC that it will be unable to refute the allegations of racial bias unless and until it develops objective standards and criteria. It seems to me to follow that, without such standards and criteria, the GMC will be unable to satisfy the public that it is complying with its duty to protect patients.

Recognition of the Need for Change

15.61 I have mentioned that a number of events occurred in the late 1990s (Bristol, Ledward, Shipman) which appeared to give rise to a collective public loss of confidence in the medical profession in general. I say 'collective' and 'in general' because it does not seem to me that there was any loss of confidence by individuals in the doctors who were treating them personally. Both Government and the GMC recognised the need for radical change. This has resulted in a programme of reform on three fronts. First, the constitution of the GMC has been changed; as I have already noted, the large unwieldy Council of 104 members has been reduced to one of 35 members and the proportion of lay members has been increased. Second, the GMC announced its intention to overhaul its FTP procedures. The new procedures have recently come into force. Third, the GMC intends to introduce, in 2005, a system of re-licensure to be known as revalidation. I shall discuss the proposals for the FTP procedures and revalidation in greater detail in later Chapters.

15.62 Other changes have very recently been made to the regulatory landscape. In 2004, the Healthcare Commission came into being, with responsibility for the supervision of the function of NHS bodies and private medicine. It is also responsible for the 'second stage' of patients' complaints about NHS doctors and services. Although this body will not have any direct involvement in the regulation of doctors by the GMC, it could well have an indirect effect. For example, it might refer to the GMC cases it has investigated through its involvement with the complaints procedures and where it has found cause for concern about the fitness to practise of a doctor.

15.63 Of more direct effect on the regulatory landscape was the creation in 2003 of the Council for the Regulation of Healthcare Professionals (now known as the Council for Healthcare

Regulatory Excellence (CRHP/CHRE)). This body has an overarching responsibility for the regulators of healthcare professionals, including, of course, the GMC. The powers of the CRHP/CHRE include the power to investigate and report on the performance by regulators of their functions, and to make recommendations for change. It can also give directions requiring a regulatory body to make specified rules if it considers that it would be desirable to do so for the protection of members of the public. Section 28 of the National Health Service Reform and Health Care Professions Act 2002 also gives the Secretary of State for Health powers to make regulations enabling the CRHP/CHRE to investigate complaints from individuals about the way in which a regulatory body has exercised any of its functions. The CRHP/CHRE also has the power to appeal against certain decisions of regulatory bodies that appear to be unduly lenient where it would be desirable, for the protection of the public, for the CRHP/CHRE to take action. Appeals by the CRHP/CHRE lie to the High Court. This is a wholly new concept in the field of professional regulation. Whereas, previously, only an individual aggrieved at a decision of the GMC had had the right to challenge that decision, an appeal now lies, in effect, on behalf of the public interest.

From the Horse's Mouth

15.64 In the following Chapters, I shall examine the GMC's old FTP procedures in some detail. I shall examine not only how those procedures were supposed to work but also how they operated in practice. I shall also examine in some detail the GMC's proposals for the future, in particular the new FTP procedures and revalidation. As will soon become apparent, I will be critical of many aspects of the GMC's work in the past.

15.65 The GMC's stance at the Inquiry was not that it has, at all times, been perfect. Very realistically, those representing the GMC recognised that there has been much to criticise. On the day on which the Inquiry turned to examine the work of the GMC, its Leading Counsel, Mr Roger Henderson QC, made frank admissions in relation to many of the shortcomings which had become evident in the course of the Inquiry's investigations. He accepted that the GMC procedures had failed in many respects to meet the reasonable expectations of the public and patients. His message to the Inquiry was that these deficiencies had been recognised and addressed. He spoke of the paramount duty of the GMC to safeguard patients' interests, while having due regard for the interests of doctors.

15.66 I welcomed Mr Henderson's admissions, which were clearly made with the authority of the GMC at the highest level. I recognise that they were made in the hope that the Inquiry's criticisms might be muted or even silenced in the light of the GMC's recognition of its past faults. They were nonetheless welcome for that. They are important and I propose to summarise them.

15.67 First, in respect of operational matters, Mr Henderson admitted that there had been unacceptable delay in dealing with complaints and concerns about doctors. He accepted that the GMC had failed adequately to investigate complaints and had failed to follow up complaints that had been referred to other bodies for investigation. He accepted that cases had been closed which should not have been closed.

15.68 Second, in respect of the quality of decision-making, Mr Henderson accepted that there had been a lack of consistency and that the quality of decisions had been variable. He accepted that the approach had been 'idiosyncratic rather than systematic' and the resulting disparity between the outcomes of cases 'unacceptable'. Mr Henderson attributed the lack of consistency, in part, to the 'absence of satisfactorily planned and structured training'. He said:

> **'It may have been thought invidious for elected Council members to require training whether as screeners, members of the PPC or of the PCC. Such an old-fashioned approach is long outmoded and is recognised as being wholly out of keeping with the needs of today and tomorrow. The philosophy of voluntary, well-meaning, judgmental concern can be no substitute for suitable training of suitably qualified people guided by systematised, coherent and carefully planned procedures enshrined in clear text on the subject of appropriate supervision and audit.'**

15.69 Mr Henderson drew attention, very properly, to the attempts that had been made to provide training and guidance for those making decisions but accepted that they had not been sufficient. He said that the GMC now recognised the need for structured training for decision-makers. While I accept and agree with all that Mr Henderson said about training and guidance, I observe that he did not mention the need for clear standards and criteria as the basis for decisions.

15.70 Mr Henderson suggested that another cause of inconsistency and poor quality in decision-making was the fact that it had not in the past been the practice for GMC panels or committees to give reasons for their decisions. He said that 'the giving of reasons is salutary'. He said (and I agree) that the discipline of having to give reasons improves the decision-making process. He pointed out, in defence of the GMC's failure to give reasons in the past, that the Privy Council had, until recently, approved its practice. That had now changed, although Mr Henderson conceded that, even in recent times, the reasons given were not always what they should be.

15.71 So far as screening decisions were concerned, Mr Henderson admitted that there had been disparity between outcomes. He attributed this to a failure by the GMC to appreciate the true nature of the screening process until advised about it by Mr Justice Lightman in the case of R v General Medical Council ex parte Toth[2] in 2000. Until then, Mr Henderson said, screeners had wished to bring their professional judgement to bear on cases in a way that was, in fact, inappropriate. He accepted that too many cases had been 'screened out'. When referring to some of the cases which the Inquiry had examined and had found to contain inconsistent decisions, he concluded:

> **'With the benefit of proper audit and consistent training, there should have been a consistent set of results leading to more Committee decisions comprised of persons who, in turn, would, by training and documentation, have avoided some of the problems which some of those chosen cases reveal.'**

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[2] [2000] 1 WLR 2209.

15.72 Mr Henderson also acknowledged that there had been insufficient audit of GMC decisions. Indeed, he accepted that such audit of decisions as had occurred (and that had occurred only in recent years) had been 'in character more enumerative than qualitative'. In other words, audit had looked at how many cases had been dealt with, not whether they had been properly decided. He agreed that that was not good enough and that proper audit was now required. The lack of transparency in GMC decisions was now, he said, being addressed.

15.73 Mr Henderson's message to the Inquiry was that the failings of the past have been recognised and addressed. The new FTP procedures would resolve not only the difficulties caused by the 'silo effect' of the separate procedures but would also ensure that cases were properly investigated and eventually resolved by decisions taken by persons who were qualified and trained for the task.

Conclusions

15.74 Since Stage Four of the Inquiry began, there has been some speculation in the newspapers, particularly in the medical press, that the Shipman Inquiry might 'bring down' the GMC. It was suggested that I might recommend the 'abolition' of the GMC. Such speculation was ill informed. Before Stage Four began, I set out the issues that the Inquiry would examine. The future existence of the GMC was not among them. The Inquiry published a Consultation Paper in October 2003, in which the views of respondents were sought on a wide range of issues. Those issues did not include the 'abolition' of the GMC or the ending of self-regulation for the medical profession. It is unthinkable that I would make such wide-ranging recommendations without giving proper notice.

15.75 The Inquiry's Terms of Reference are wide and certainly require me to examine the GMC's performance of its FTP functions. They are, I think, wide enough to permit me – indeed to require me – to consider whether those functions should be carried out in a different way or even by a different body. They are wide enough, I think, to permit me to suggest that the GMC should organise itself in a different way, so that it might better fulfil its primary duty to protect patients. What they do not permit, in my view, is any consideration of whether the GMC should continue to exist or whether self-regulation of doctors should be ended. In my view, if those matters are to be considered, the task must be undertaken by a body charged with examination of all the GMC's functions. This Inquiry has focussed on the FTP procedures and on revalidation. The GMC has other important functions, which this Inquiry has not touched upon.

15.76 I have just referred to the 'self-regulation' of the medical profession. Throughout its evidence and in its submissions to the Inquiry, the GMC has been at pains to point out that the regulation of the profession is now a complex operation in which many other bodies play a part. These include the NHS bodies which employ or contract with doctors, the Healthcare Commission which has wide-ranging responsibility for the audit and inspection of healthcare services and the CRHP/CHRE. The GMC says, and I accept, that it must work in partnership with those other bodies. The GMC is dependent upon other bodies (and patients and other healthcare professionals) reporting to it their complaints

and concerns about doctors. Nonetheless, the GMC plays the key role as the keeper of the register. The GMC decides who can practise as a doctor and who cannot.

15.77 In recent years, the GMC has been the subject of much public criticism, most of it stemming from the way in which it has dealt with or failed to deal with doctors who have been guilty of some form of misconduct. The FTP procedures are the public face of the GMC and the most likely point of contact with the GMC for ordinary members of the public. The fact is that the public has come to regard the GMC with suspicion and distrust because it perceives that the GMC acts, not in the interests of patients, but in the interests of doctors. Indeed, many members of the public have the impression that the GMC is a representative body, akin to a trade union. Paradoxically, the GMC also comes in for criticism from the profession, where the perception is that the GMC is unfair to doctors and too hard on them. These issues of 'ethos and attitudes' go to the heart of whether the GMC is in fact acting, as it claims to act, in the interests of patient protection. Consideration of these issues has required a careful and detailed review of what the GMC does and how it operates in practice.

15.78 Examination of the ethos and attitudes of the GMC has been a vital part of the Inquiry's work. However, practical matters are also important. A body cannot work effectively for the protection of patients if its procedures and practices are inefficient. One of the criticisms levelled against the GMC is that there has at times been unacceptable delay in dealing with complaints and in bringing doctors before a disciplinary committee. Mr Scott and Mr Antony Townsend, who was Head of the Conduct Section from 1993 to 1995, accepted that until the mid-1990s, the GMC's administrative systems were old-fashioned and inadequate. Much has been done to improve them and to reduce the delay that previously occurred. The GMC now operates according to service standards.

15.79 Besides examining attitudes and procedures, the Inquiry has had to consider the FTP procedures themselves and whether they are effective as a means of protecting patients from doctors who misbehave or fail to practise at an acceptable level. Much of the Inquiry's investigation was designed to discover that. Before that investigation had even begun, the GMC had recognised that its current procedures were not effective and that they must be changed. As the Inquiry was doing its work, the GMC was developing its new FTP procedures. They have now been introduced.

15.80 In its evidence and submissions to the Inquiry, the GMC sought to assure the Inquiry (and indeed the public) that the new FTP procedures will be very different from the old. I hope that they will. But, in seeking to make recommendations for the better protection of patients in the future, I must form a view as to whether the GMC will, in the event, be willing and able to ensure that all is indeed different. It is axiomatic that the best indicator of future attitude and performance is past attitude and performance. Changes of practice and performance are, of course, possible, as the GMC has already demonstrated. Changes of attitude are more difficult to bring about. In the following Chapters, I shall set out in detail how the FTP procedures have worked in the past and the conclusions I have reached about the ethos of the GMC in the past. I shall also consider the evidence relating to the way in which the new procedures have been developed and are likely to operate in the future. I shall consider whether that evidence demonstrates a change of ethos within the

GMC. Finally I shall consider what steps or further steps should be taken by the GMC to ensure that patients and the public receive the protection they deserve from doctors who, for one reason or another, are not practising as they should.

CHAPTER SIXTEEN

The General Medical Council's Handling of Shipman's Case in 1976

Introduction

16.1 Following Shipman's conviction, in January 2000, on 15 counts of murder (carried out by injecting each of his victims with an overdose of diamorphine, an opiate drug), it came to light that, in 1976, he had been convicted of a series of offences in connection with another opiate drug, pethidine. These offences included not only unlawful possession of the drug but also obtaining pethidine by deception and forgery. The offences had been committed over a period of about 14 months. Many people, shocked at this discovery, suggested that the General Medical Council (GMC) ought to have erased Shipman's name from the medical register in 1976. It was said that, if the GMC had 'struck him off' the register then, Shipman would not have been able to perpetrate his later crimes. In fact, he had been permitted to continue practising. It has not, so far as I am aware, been suggested that the GMC should have recognised Shipman as a potential murderer, only that he should have been dealt with much more severely for the offences he had committed at that time.

16.2 In this Chapter, I shall describe the disciplinary procedures operated by the GMC in 1976 and will consider the way in which Shipman's case was handled. So far as I am able, I shall examine the reasons why it was handled as it was. Because I wished to set the handling of Shipman's case in context, the Inquiry sought disclosure of the files of all the drug-related cases considered by the GMC's fitness to practise (FTP) committees in the years 1975 to 1980. I wished to examine cases of a similar type to Shipman's, so as to see whether the way in which his case was dealt with was in any way exceptional. I also wished to understand the policy considerations that lay behind the decision in his case and to gain some insight into the criteria applied by the GMC when considering cases involving drug-related offences. After examining these issues, I shall explain my conclusions about the reasonableness of the GMC's decision in Shipman's case.

The General Medical Council Staff in Post in 1976

16.3 In 1976, the GMC's administrative staff was headed by the Registrar, Mr Martin Draper. It seems that he had been at the GMC from about 1950 or 1951. In 1976, Mr Robert Gray was Assistant (later Deputy) Registrar. He had previously worked in colonial, then university, administration. He had joined the GMC in November 1971. From that time until about June 1976, and from a date in 1980 until his retirement in February 1988, Mr Gray was Head of the GMC's Discipline Division. In that capacity, he was responsible, under the supervision of the Registrar, for dealing with administrative matters relating to the disciplinary procedures of the GMC. Also working in the Discipline Division was an administrative assistant, Mr Adrian Williams (who was employed between December 1970 and May 1977), and a second administrative assistant, who has not been identified. The Discipline Division also had secretarial and typing staff. Mr Gray gave oral evidence to the Inquiry. Mr Williams provided a witness statement. Mr Draper's state of health was such that he

could not assist the Inquiry by providing a statement or attending to give evidence. He died in August 2004.

The General Medical Council's Procedures in 1976

The Power of the General Medical Council to Act in Respect of a Conviction

16.4 In 1976, the GMC was governed by the Medical Act 1956, as amended by the Medical Act 1969 (the 1956 Act). At that time, the only FTP procedures in operation were the conduct procedures. The health procedures were not introduced until 1980 and the performance procedures did not come into effect until 1997.

16.5 In 1976, the amended section 33 of the 1956 Act provided:

> **'(1) Where a fully registered person –**
>
> **(a) is found by the Disciplinary Committee to have been convicted (whether while so registered or not) in the United Kingdom or the Republic of Ireland or any of the Channel Islands or the Isle of Man of a criminal offence; or**
>
> **(b) is judged by the Disciplinary Committee to have been (whether while so registered or not) guilty of serious professional misconduct,**
>
> **the Committee may, if they think fit, direct that his name shall be erased from the register or that his registration therein shall be suspended (that is to say, shall not have effect) during such period not exceeding twelve months as may be specified in the direction.'**

The Disciplinary Committee (DC) of the GMC therefore had jurisdiction under section 33 to take disciplinary action in respect of a criminal conviction or in respect of conduct amounting to serious professional misconduct (SPM). The procedures for dealing with conviction cases and with cases involving complaints of SPM ('conduct cases') were different. Shipman came before the GMC by reason of his conviction. I shall, therefore, confine my description of the GMC procedures at the time largely to the procedures relating to conviction cases.

16.6 It should be noted that, in 1976, the term **'convicted ... of a criminal offence'** did not include a finding of guilt in respect of which a doctor was placed on probation or was discharged conditionally or absolutely. Nor did it include a criminal offence for which a doctor had been cautioned by the police, despite the fact that a police caution would not have been administered in the absence of an admission of guilt.

16.7 The GMC's primary source of information about convictions was the police, who were required by a Home Office Circular of 1973 to report to the GMC convictions which might reflect on a doctor's suitability to continue in his/her profession. In particular, the police were required to report offences involving violence, indecency, dishonesty, alcohol or drugs. Although the police were not obliged to report findings of guilt where a doctor had been made the subject of a probation order or a discharge (and where there was,

therefore, no 'conviction'), Mr Gray told the Inquiry that, in practice, they usually did so. If a finding of guilt in respect of which a probation order or discharge had been imposed was brought to the GMC's attention, the GMC might elect to proceed by treating the matter as a complaint of SPM.

16.8 All conviction cases, other than those for minor motoring offences not involving alcohol, drugs or injury to others, were referred by the GMC staff to the Penal Cases Committee (PeCC). The PeCC was the predecessor of the Preliminary Proceedings Committee (PPC). It had the task of deciding which cases should go forward 'for inquiry' (i.e. for hearing) by the DC. The DC was the equivalent of the present Professional Conduct Committee (PCC).

16.9 The General Medical Council Disciplinary Committee (Procedure) Rules Order of Council 1970 (the 1970 Rules) provided that cases involving convictions should be submitted by the Registrar to the President of the GMC or to a member ('screener') nominated by him. However, in practice, the President and the staff had an arrangement whereby all cases of conviction (save the most serious, which went to the President) were referred by staff directly to the PeCC without the intervention of the President/screener. When notification of a conviction came into the GMC office, the staff would usually attempt to obtain information about the circumstances of the offence for which the doctor had been convicted. This information would most commonly come from the police or the Home Office. When the staff considered that there was sufficient information, the case would be placed on the agenda for the next meeting of the PeCC. Meetings of the PeCC took place three times a year.

The Penal Cases Committee

16.10 The PeCC consisted of the President of the GMC (or a member of the GMC nominated by him) who chaired the Committee, together with one elected, medically qualified ('medical') member of the GMC, one lay member and three medical members drawn from the GMC's Branch Councils for England and Wales, Scotland and Ireland respectively. In April 1976, Sir John (later Lord) Richardson, a consultant physician, was President. Other members of the PeCC were Professor (later Professor Sir) William Trethowan (a consultant psychiatrist), Dr Derek Llewellyn (a general practitioner (GP) from the England and Wales Branch), Dr William Fulton (a GP from the Scotland Branch) and Dr Thomas Murphy (Ireland Branch). The lay member, Miss Ruth Cohen, had retired the previous year and had not yet been replaced. The legal quorum was three. The PeCC was advised by a legal assessor, who was present at all its meetings.

16.11 By rule 6(1) of the 1970 Rules, the PeCC, having considered a case, was required to determine either:

> **'(a) that no inquiry shall be held in the case by the Disciplinary Committee, or**
> **(b) that the matter in question shall, in whole or in part, be referred to the Disciplinary Committee for inquiry either at the next meeting of that Committee or at such future meeting as the Penal Cases Committee or the President may determine'**.

The Inquiry was told that no written criteria existed to guide members of the PeCC in deciding whether a case should be referred to the DC. Mr Gray told the Inquiry that he did not believe that any criteria were necessary. He was of the view that the group of people involved was so small and their involvement in the work so regular that they knew upon what principles to act. The 1970 Rules themselves provided no criteria; they appear to have given the PeCC an unfettered discretion. I shall return to the issue of principles and criteria later.

16.12 Rule 6(3) provided that:

> **'Before coming to a determination the Penal Cases Committee may if they think fit cause to be made such further investigations, or obtain such advice or assistance from the Solicitor or Counsel instructed by him, as they may consider requisite.'**

16.13 The first possible outcome of a case considered by the PeCC was a referral to the DC for inquiry at a public hearing. The second possible outcome was no referral to the DC. The third possible outcome was a request for further information or legal advice. If such a request was made, the PeCC would adjourn consideration of the case until the information or advice had been obtained. It was also possible, in certain circumstances, for the PeCC to make a 'provisional determination'. This option was not relevant to Shipman's case and I shall not, therefore, consider it further. It is important to note that the PeCC had no power to suspend a doctor's registration pending determination of his/her case by the DC, even if the doctor appeared to pose a danger to patients. Nor did it have any power to impose conditions on a doctor's registration.

16.14 I shall now consider briefly the various possible outcomes.

Referral to the Disciplinary Committee for Hearing

16.15 If the PeCC decided to refer a case to the DC, the doctor would be notified of that fact, and of the matters to be considered by the DC and the arrangements for the hearing. He or she would be given the opportunity of submitting evidence to the DC.

No Referral to the Disciplinary Committee

16.16 If the PeCC decided not to refer a case to the DC, the 1970 Rules required the Registrar to inform the doctor of the decision of the PeCC in such terms as the PeCC might direct. On occasion, the PeCC used this provision to direct that a letter be sent to the doctor concerned, warning him/her about his/her future conduct. The January 1976 edition of the GMC publication 'Professional Conduct and Discipline' (known as the Blue Book) set out a description of some circumstances in which warning letters would be sent:

> **'Warning Letters**
>
> **Not every conviction or allegation of professional misconduct necessitates an immediate reference to the Disciplinary Committee for formal inquiry, although repeated offences may do so. It is the usual practice to send warning letters to a doctor who has been convicted for**

the first time of offences such as driving a motor car when under the influence of drink, or whose professional conduct appears to have fallen below the proper standards, in order that the doctor may reconsider his habits and conduct.'

It seems to me that one would not have expected, on reading this passage from the Blue Book, that a warning letter would be used in a case as serious as one involving multiple offences of obtaining controlled drugs, illegally and dishonestly, in the context of professional practice.

16.17 Mr Gray explained that, in general, warning letters were sent by the PeCC in conviction cases, rather than in conduct cases. This was because, in conduct cases, the misconduct would not usually have been proved by that stage. Thus, a letter warning a doctor about his/her conduct would not have been appropriate. The exception to this would be if the doctor had admitted the misconduct, for example if s/he had been charged with criminal offences and had pleaded guilty but had been conditionally discharged so that s/he had not, technically, been 'convicted'. Mr Gray told the Inquiry that a 'hierarchy' of warning letters had developed, depending on the PeCC's view about the seriousness of the doctor's behaviour. The Inquiry's examination of the outcomes of cases dealt with by the PeCC at its meetings in the mid-1970s showed that warning letters of various degrees of severity were considered appropriate for a variety of offences. For example, the PeCC gave instructions in a case of theft/shoplifting for a 'letter of disapproval' to be sent, in a case of drink driving for a 'warning letter', in the case of a failure to provide a specimen of blood or urine and of theft of a credit card for a 'severe warning letter' and, in another similar case, a 'strong warning letter'. However, no criteria were developed and no written guidance prepared.

16.18 The 1970 Rules provided that, where a decision had been taken not to send a case to the DC and the GMC subsequently received notification of a further conviction or a complaint of SPM against the same doctor, it was open to the GMC to deal with both the previous conviction and the new conviction or complaint of misconduct together, as if the earlier decision not to refer to the DC had not been made.

Request for Further Information

16.19 As I have indicated, the 1970 Rules gave the PeCC the power, if it thought fit, to cause further investigations to be made, or to obtain legal advice, before taking a final decision. This would plainly be a useful power if members felt it impossible to make a decision without obtaining a further piece of information or clarifying their legal position. However, the Inquiry's examination of cases involving convictions for drug-related offences considered by the PeCC in the mid- to late 1970s suggests that the power to adjourn for further investigations was being used for a rather different purpose, namely to exercise a degree of continuing supervision over a doctor who had been abusing alcohol or drugs. I shall discuss this use of the power to adjourn in greater detail later in this Chapter.

Procedure

16.20 The PeCC sat in private and made its decisions on the basis of written evidence and submissions. It dealt with a large caseload at each meeting, often as many as 30 or 40

cases. No witnesses were called to give evidence. The doctor who was the subject of the proceedings was not invited to attend. In the case of a complaint alleging SPM, the PeCC would usually have before it a response from the doctor, explaining his/her conduct. The 1970 Rules required that, before a case involving a complaint alleging SPM was sent to the PeCC, the doctor should be given the opportunity to furnish such an explanation. In conviction cases, however, there was no requirement at that time to invite the doctor to provide an explanation unless and until the case had been referred by the PeCC to the DC. The reason for this lay in the different procedures for dealing with convictions and complaints. In cases involving an allegation of SPM, the explanation given by a doctor for his/her conduct might be a relevant factor to be taken into account by the PeCC when deciding whether that conduct amounted or might amount to SPM. However, a conviction was treated by the GMC as conclusive evidence that the doctor was guilty of the offence of which s/he had been convicted. The 1970 Rules, therefore, reflected the intention that any explanation from the doctor relating to the circumstances of his/her conviction should, in general, be relevant only to the issue of what sanction was to be imposed by the DC. Despite the fact that there was no requirement in the Rules that a doctor should be asked to provide an explanation in a conviction case before the case was considered by the PeCC, the Inquiry's examination of the files of drug-related conviction cases dealt with by the PeCC in the mid- to late 1970s shows that doctors were often asked to provide an explanation and most did so. Indeed, in several cases where it appears that no such request was made, the doctor nevertheless proffered an explanation.

16.21 The minutes of the PeCC contained only a bare recital of the decisions reached. The PeCC was not required to give any reasons for its decisions.

The Disciplinary Committee

16.22 The DC consisted of the President (or another member of the GMC nominated by him), together with 18 other members of the GMC, at least six of whom were elected medical members and at least two of whom were lay members. The legal quorum was five. By 1976, it was no longer the practice (as had been the case until 1973) for the President to chair both the PeCC and the DC. Instead, the President chaired the PeCC, and the DC was chaired by a medical member, Mr (later Sir) Robert Wright, who had been nominated for this purpose by the President. The DC was advised by a legal assessor. Its hearings were held in public save in exceptional circumstances. Its deliberations were, however, conducted in private. Hearings of the DC were reported in the press and in public journals. Its procedures resembled in many respects those of a criminal court. Doctors who were the subject of proceedings before the DC were invited to, and usually did, attend the hearing. In general, they were legally represented, usually by solicitors and counsel instructed by their medical defence organisations. The doctor could give evidence and call witnesses. The DC's caseload for a single meeting was such that it could give more lengthy and detailed consideration to each case than could the PeCC.

16.23 In a conduct case, the allegations (or some of them) might be denied and the DC might hold a full hearing. The DC would have to make findings of fact and decide whether the facts which it had found proved amounted to SPM. If so, the DC would go on to consider the appropriate sanction. In a conviction case, the DC would be concerned only to

establish the gravity of the offence and to take account of any mitigating circumstances, before imposing a sanction. It was common for testimonials and other evidence about the doctor's character to be adduced by those representing him/her. The DC would take account of any adverse finding against the doctor which had been made by the DC in the past.

16.24 There were four courses of action open to the DC at the conclusion of a hearing in a conviction case or following a finding of SPM. The first was to admonish the doctor and conclude the case. The second was to postpone judgement, thereby effectively placing the doctor 'on probation'. Postponement could be *sine die* or to some specified future date or meeting of the DC. The third possible course was to direct that the doctor's registration should be suspended for a period not exceeding 12 months. The fourth option was to direct erasure of the doctor's name from the medical register.

16.25 I shall now consider briefly those four courses of action.

Admonishment and Conclusion of the Case

16.26 Admonishment by the DC would constitute a public warning. It might be reported in the press. It would form part of the doctor's FTP history. If an enquiry was subsequently made about that history, the enquirer should have been informed about the warning or supplied with a copy of the relevant DC minutes in which it was recorded.

Postponement of Judgement

16.27 Although the 1970 Rules provided for the postponement of judgement by the DC, they did not give any guidance as to the circumstances in which the power to postpone should be exercised. Assistance could, however, be derived from the Blue Book current at the time. The January 1976 edition stated:

> **'The primary duty of the Disciplinary Committee is to protect the public. In any case the Committee must therefore first consider whether the public interest requires it to remove the doctor's name from the Register, or to suspend his registration. Subject however to this overriding duty to the public the Committee considers what is in the best interests of the doctor himself. Largely for this reason the Council has evolved a system of postponing judgment, especially in relation to offences arising from abuse of drink or drugs, in order that the doctor may satisfy the Disciplinary Committee that he is able to conduct himself properly and to overcome any addiction to alcohol or drugs. In severe cases of addiction, however, the Committee may consider it necessary to order suspension while the doctor undergoes treatment.'**

The Blue Book went on:

> **'Postponement of Judgment**
>
> **In any case where judgment is postponed, the doctor's name remains on the Register during the period of postponement. When postponing**

judgment to a later meeting the Committee normally intimates that the doctor will be expected before his next appearance to furnish the names of professional colleagues and other persons of standing to whom the Council may apply for information, to be given in confidence, concerning his habits and conduct since the previous hearing. The replies received from these referees, together with any other evidence as to the doctor's conduct, are then taken into account when the Committee resumes consideration of the case. If the information is satisfactory, the case will then normally be concluded. If however the evidence is not satisfactory, judgment may be postponed for a further period, or the Committee may direct suspension or erasure.'

It should be noted that the Blue Book referred only to the DC, it made no reference to the fact that the PeCC might use its power to adjourn in order to postpone judgement on a doctor who had abused alcohol or drugs.

16.28 I shall discuss the use of the DC's power to postpone judgement at greater length later in this Chapter.

Suspension

16.29 In cases where the DC had elected to suspend a doctor's registration, it was open to it to resume consideration of the case before the end of the period of suspension. It could then, if it considered it appropriate, extend the original period of suspension or order erasure. Before resuming consideration of the case, the DC could, as when postponing judgement, ask the doctor to give the names of referees from whom information might be sought as to his/her habits and conduct since the suspension had been imposed. This information would be taken into account when the DC resumed consideration of the case. The Blue Book made clear that only if there was evidence that the doctor had not conducted him/herself properly, or that s/he was addicted to drink or drugs and had not responded to treatment, was the DC likely to order further suspension or to direct erasure at a resumed hearing. Again, it should be noted that, when the DC resumed consideration of a case following a period of suspension, the GMC staff did not attempt to find out about the doctor's conduct from an independent source. The doctor produced his/her own referees. Usually, in a case in which the doctor had been convicted of offences in connection with drugs of addiction, s/he would be expected to produce one or more reports from the consultant psychiatrist in charge of his/her treatment.

Erasure

16.30 The most severe sanction which could be imposed by the DC was erasure of a doctor's name from the medical register. No guidance appears to have been issued as to what type of case might warrant erasure and what factors might appropriately be considered in mitigation of the offence or conduct. If imposed, erasure prevented a doctor from practising and remained effective unless and until the doctor made a successful application for restoration of his/her name to the register. An application to restore could be made once ten months had elapsed after the original erasure order took effect. If the

first application for restoration was unsuccessful, a further period of ten months had to elapse before another application could be made. There was no limit on the number of applications for restoration that could be made. The January 1976 edition of the Blue Book pointed out that:

> **'The names of many doctors which have been erased have subsequently been restored to the Register, after an interval.'**

16.31 It was clear, therefore, that erasure was not necessarily intended to be permanent. The Blue Book explained that the DC examined every application to restore on its merits, having regard, among other considerations, to the nature and gravity of the original offence, the length of time since erasure and the conduct of the applicant in the interval.

Differences between the Proceedings and Powers of the Disciplinary Committee and of the Penal Cases Committee

16.32 To summarise, the main differences between the proceedings and powers of the PeCC and those of the DC were that the DC held a formal hearing in public and the PeCC held a meeting in private. The doctor usually attended and was represented at a hearing before the DC; indeed, it would be likely to create a poor impression if s/he did not attend. The doctor was not invited to attend meetings of the PeCC. Nor was s/he represented at such meetings. The PeCC made its decision on the basis of written material only. A hearing before the DC was likely to be reported in the press and any person making a specific enquiry of the GMC should have been told the outcome. The proceedings of the PeCC were confidential. The DC had the power of erasure and suspension; the PeCC did not.

Offences Involving Drugs and Dishonesty

16.33 The January 1976 edition of the Blue Book set out examples of certain kinds of offence and of types of professional misconduct which had in the past given rise to disciplinary action by the GMC. This was intended as guidance to doctors about what type of behaviour was unacceptable. The Blue Book made clear that the examples were not exhaustive. The issues of whether a particular course of conduct amounted to SPM, and of the gravity of a conviction, were, it was said, matters to be determined by the DC after considering the evidence in each individual case. There was no suggestion that the PeCC should concern itself with such issues.

16.34 The examples given in the Blue Book which are relevant to Shipman's case include the following:

> **'(iii) Abuse of controlled drugs**
>
> **Disciplinary proceedings have been taken in cases in which a doctor has been found to have prescribed or supplied drugs of addiction or dependence otherwise than in the course of bona fide treatment.**
>
> **Disciplinary proceedings have also been taken against doctors convicted of offences involving drugs which were committed in order to gratify the doctor's own addiction, or where a doctor has been convicted**

> **for driving or being in charge of a motor vehicle when under the influence of a drug or has treated patients when under the influence of drugs.'**

and

> **'(vii) Offences involving dishonesty, indecency or violence**
>
> **Disciplinary proceedings have been instituted against doctors convicted of criminal deception (obtaining money or goods by false pretences), forgery, fraud, theft, indecent behaviour or assault. A particularly serious view is taken of such offences if committed in the course of a doctor's professional duties or against his patients or colleagues.'**

Shipman's case involved the prescription of controlled drugs otherwise than in the course of *bona fide* treatment, allied with offences of criminal deception and forgery, perpetrated over a significant period of time and committed to gratify his own addiction or dependence. The reader of the Blue Book might well have expected that a **'particularly serious view'** would be taken of such conduct.

The Report of the Merrison Committee

16.35 In 1975, the Report of the Committee of Inquiry chaired by Dr (later Sir) Alec Merrison into the Regulation of the Medical Profession (the Merrison Report) was published. For some time before publication of the Merrison Report, there had been mounting concern about the capacity of the existing regulatory system to deal adequately with the problem of sick doctors. The problem was twofold. First, the GMC could act only if a doctor had been convicted of a criminal offence or if s/he was found guilty of SPM. Even then, the sanctions available to the DC were limited. For example, the GMC considered itself powerless to act where a doctor was known to be a chronic alcoholic (and thus a risk to patients) but had not been convicted of a criminal offence and had not committed any act amounting to SPM. Thus, it was felt that the existing procedures failed to provide adequate protection for patients.

16.36 The other problem was that, in cases where it was possible to use the GMC's disciplinary procedures to deal with sick doctors, those procedures were punitive in nature and, in the case of proceedings before the DC, were conducted in public. Many people felt that this was an inappropriate – even an inhumane – way of dealing with doctors who were suffering from a physical or mental illness. Mrs Jean Robinson, who later became a lay member of the GMC, said of this period:

> **'There was great uneasiness that doctors who were unable to cope because of mental or physical illness – some in a pathetic state – had in the past been hauled up before a public hearing which was the equivalent of a criminal trial. I myself thought it outrageous that the body which set the standard for medical confidentiality was not preserving it for doctors themselves, by allowing them private hearing and supervision for health problems (such as mental illness) ...'**.

16.37 Sir Donald Irvine, who was a member of the GMC from 1979 and President between 1995 and 2002, told the Inquiry that, in the 1970s, there was serious under-reporting by doctors of colleagues who were known to be a risk to patients because of an illness. The prime cause of that under-reporting was the threat of GMC action against the sick doctor, which could only (at least officially) be punitive. There were also concerns about the local arrangements for dealing with sick doctors which were, according to Sir Donald, 'patchy, ill co-ordinated and largely ineffective'.

16.38 The Merrison Committee had before it no reliable statistics showing the size of the problem but was confident that it was **'not small'**. The GMC had given evidence to the Committee to the effect that the largest category of cases of psychiatric illness arose from an addiction to drink or drugs which was **'associated with'** and **'accentuated the results of some other concurrent personality disorder'**.

16.39 The Merrison Committee had no doubt that there was an urgent need for the GMC to be given powers to deal with sick doctors. Its Report stated:

> **'The need for the GMC to have power to control the right to practise of sick doctors is so overwhelming and so obvious that it seems to us amazing that the GMC has continued for so long without such a power. There are very sick doctors, and by no means all of them have enough insight into their condition to retire from practice before they endanger their patients. Those who do continue to practise can be completely stopped from doing so only if they commit a criminal offence or do something which constitutes serious professional misconduct. That is not a rational way of ordering matters.'**

16.40 The Merrison Committee recommended the establishment of a Health Committee (HC) and arrangements for a stage of 'conciliation' before a formal hearing by the HC. The purpose of this conciliation would be to give a doctor the opportunity to agree to an examination by an expert and to enter into voluntary undertakings as an alternative to the case proceeding to a formal hearing. If the doctor complied with his/her undertakings, there would be no need for a formal hearing by the HC. The hope was that many doctors would be capable of rehabilitation. The Merrison Committee recommended that, if rehabilitation failed, the HC should have power to impose conditions on, or to suspend, registration. However, the Merrison Committee did not recommend that the sanction of erasure of a doctor's name from the register should be available to the HC. The GMC's health procedures, modelled on the recommendations contained in the Merrison Report, were introduced by the Medical Act 1978 and came into effect in August 1980.

16.41 The Merrison Committee emphasised, in its general discussion of the GMC's FTP procedures, the underlying purpose of those procedures:

> **'The GMC's actions towards those unfit to practise should be directed to the protection of the patient, not the punishment of the doctor. This should, in our view, be the case even where the question of his fitness to practise arises on account of professional misconduct. For a doctor to have his name erased from the register, and to be in effect deprived of**

> **his livelihood, is a very serious penalty, but that it is a penalty is a side effect rather than a purpose of regulation ... certainly an atmosphere of punishment may ... discourage members of the profession or of the public from notifying the GMC of matters which ought to be brought to its attention; especially, for example, of mental illness which also involved professional misconduct ...'**.

16.42 Shipman's case was dealt with by the GMC in 1976. Sir Donald Irvine observed that, by then, there was a **'huge sense of relief'** in the medical profession at the prospect of the introduction of more satisfactory ways of dealing with sick doctors. In particular, it was felt that, once the new health procedures were introduced, doctors would be more confident about reporting colleagues who were a risk to their patients and in need of help.

16.43 Dr Llewellyn told the Inquiry that, as a member of the PeCC, he had regarded the introduction of the health procedures as 'essential'. Without them, the PeCC would sometimes have no choice but to refer a sick doctor to the DC. This, he said, 'could often only harm the doctor'. He said that, when the health procedures came in, the profession felt much easier because doctors were 'being treated fairly'.

16.44 Once the health procedures were introduced in 1980, the GMC was able formally and openly to adopt a rehabilitative approach to cases in which a doctor's criminal behaviour or misconduct appeared to result from physical or mental illness. In 1976, preparations were being made for the forthcoming changes. This was a time of transition for the GMC. The events connected with its handling of Shipman's case must be viewed in that context.

16.45 Mr Alan Howes, who was involved with the conduct procedures more or less continuously between June 1980 and 1994, told the Inquiry that it was difficult, looking back, to put oneself into the context of the time immediately following the publication of the Merrison Report. The Report had just averted a huge threatened revolt within the medical profession in connection with the GMC's proposal to impose an annual retention fee. Mr Howes said that 'anything the GMC did in those days so far as the profession was concerned was certainly treading on eggshells'. He said that the work of the GMC FTP committees at that time had to be viewed in this context. He also said that such issues as 'protecting the public interest' were not in the forefront of people's minds in the 1970s. I interpose to say that, if that is right, it should not have been the case. It appears from the passage I have cited at paragraph 16.41 that the protection of patients was certainly at the forefront of the minds of those on the Merrison Committee. Indeed, the Blue Book said that the primary duty of the GMC was to protect the public.

16.46 Mr Howes went on to say that, in the late 1970s, the GMC's FTP committees were 'struggling with a process which everybody knew was not working satisfactorily for sick doctors'. The GMC was waiting for new legislation to introduce the health procedures and, in the meantime, the PeCC (and probably the DC too) was struggling to do the best it could with cases with a health element. He said that, once members of the PeCC saw that a doctor's problems were rooted in an illness, they would have focussed on the illness, not on other factors of the case, unless they saw them as extremely relevant to the doctor's current or future medical condition.

16.47 The Merrison Committee had also recommended that the PeCC should be replaced by a Complaints Committee. Its main function would be **'to consider, on the information available, whether prima facie evidence had been assembled that a doctor was not fit to practise'**. As the final filter of complaints, the Complaints Committee would not hold hearings but would either **'refer cases for further action or direct that the matter be closed, arranging for all interested parties to be informed in either case'**. The Merrison Committee did not appear to envisage that the Complaints Committee would make substantive decisions or impose sanctions. It would, however, be given the power to order temporary suspension of a doctor's registration where the doctor posed a serious danger to the public. In the event, the PeCC was replaced by the PPC which, as I will later explain, continued, as the PeCC had done, to adjudicate on cases to a limited extent. The Merrison Report also recommended that the GMC should establish a small investigating unit to collect evidence in connection with complaints made against doctors.

Standards, Thresholds and Criteria

16.48 Although the 1956 Act and the 1970 Rules provided a very wide discretion as to the manner in which the GMC performed its disciplinary function, and although no standards or criteria were formally laid down for the exercise of that discretion, it does appear that some underlying principles existed to guide the DC and the PeCC. As I have explained, the Blue Book said that the primary duty of the GMC was to protect the public; subject to that overriding duty, the DC would consider what was in the best interests of the doctor concerned.

The Primary Duty to Protect the Public

16.49 Plainly, the protection of the public (and, in particular, of patients) was, or should have been, an important criterion for consideration by both the PeCC and the DC. If no public or patient protection issues arose, both Committees would be free to give priority to the doctor's own best interests. In a case where the doctor was, or appeared to be, addicted to drugs, the Committees would, no doubt, wish to consider how s/he should best be rehabilitated. In the case of the PeCC, it would be relevant to consider whether it was in the doctor's best interests to be dealt with sooner and in private, rather than later and in public. Common sense would dictate that it would almost always be better for the doctor to be dealt with sooner and in private. However, if the PeCC were to be loyal to the GMC's primary duty, it would have to take proper steps to find out whether the doctor's continuance in practice did or might present any risk to patients or the public. It would seem to me obvious that, if any such risk existed, the case ought to have been referred to the DC for the possible application of the wider range of sanctions available to that Committee. Yet there was a fundamental problem for the PeCC in considering the issue of risk and patient protection. The PeCC reached its decisions on the basis of outline information only. It might decide to refer a case to the DC **'for inquiry'**. The understanding was that only at that inquiry stage would the full facts become known. Only at that stage would the doctor appear before members of the GMC and only then would the DC have an opportunity to make a full assessment of whether the doctor did or might present a risk to patients. Thus, if the PeCC were to decide to deal with a case itself, there would be a danger that it would reach a conclusion based on incomplete and inadequate information.

The Seriousness of the Offence or Complaint

16.50 As with any body involved in operating a disciplinary process, the PeCC was concerned about the seriousness of the misconduct with which it had to deal. In deciding whether to refer a case to the DC **'for inquiry'**, the PeCC would take into account the seriousness of the allegation of misconduct or of the convictions under consideration. There were no written standards, thresholds or criteria, nor even any guidelines, to assist members of the PeCC in assessing seriousness. The passage from the January 1976 edition of the Blue Book, which I quoted at paragraph 16.16, seemed to be saying (although not with complete clarity) that some single convictions or allegations of misconduct would be serious enough to warrant referral; others would not. However, if an offence was repeated, the case might be referred to the DC even though a single offence of the same nature would not be. It is not clear whether that meant that the case would be more likely to be referred if the doctor were convicted, on one occasion, of multiple offences than if s/he had made repeated appearances before the courts. Also, the Blue Book gave no indication of how serious the offence or series of offences must be before referral would be warranted. Bearing in mind that the powers of the DC to impose any sanction on a doctor for misconduct (where no conviction was recorded) were limited to cases in which the DC found the doctor guilty of SPM, it seems to me that the only sensible threshold for referral, in a conduct case, would have been whether there existed a reasonable prospect of establishing SPM. In later years, when the GMC did have some written criteria, that was the threshold standard of seriousness for referral to a disciplinary hearing. By analogy, it seems to me that, in respect of convictions, the only sensible measure of seriousness would have been whether the conduct underlying the convictions was of a seriousness equivalent to conduct which could amount to SPM.

16.51 However, even if such a standard had been explicitly laid down, it would not have been easy to apply in practice. The Inquiry has been told that opinions on what amounts to SPM can differ quite widely. In Chapter 17, I shall describe how, in the context of a discussion about the operation of the PCC (the successor to the DC) during the years in which he was a member, Sir Donald told the Inquiry that debates about whether conduct amounted to SPM gave rise on occasion to strong disagreement and generated much 'heat' and 'emotion'. In the 1970s, there was very little guidance as to what kinds of conduct did or did not amount to SPM. That has remained the case ever since.

16.52 In due course, I shall examine the extent to which the PeCC applied any consistent criteria of seriousness when deciding whether or not to refer a case to the DC. As I shall show, analysis of the cases examined by the Inquiry shows that many conviction cases were not referred by the PeCC to the DC despite the fact that, on any view, the underlying conduct was serious. Shipman's is a case in point. Convictions involving multiple offences of obtaining controlled drugs by deception (which must necessarily have entailed dishonest conduct) must, in my view, have been sufficiently serious to require referral. Moreover, the material published by the GMC at the time would have caused both doctors and public alike to expect that they would be referred. Yet some such cases were referred to the DC; some were not.

16.53 Many cases of doctors convicted of drug-related offences were indeed referred by the PeCC to the DC. At the PeCC meeting held in January 1976, of the 14 cases of doctors

convicted of drugs offences, nine were referred to the DC, and one was adjourned to the next meeting, when it was adjourned again and eventually closed without referral to the DC. The outcome of the other four cases is not known but it does not appear that they were referred to the DC. At the PeCC meeting of April 1976 (at which Shipman's case was considered), of the nine drug-related conviction cases, only one was referred to the DC. The rest (save for one, of which the outcome is not known) were either adjourned or were closed with a warning letter.

16.54 Examination of the facts of the cases considered at the January and April 1976 meetings of the PeCC suggests that it was not the seriousness of the conduct underlying the offences that determined whether a case was referred to the DC. For example, five of the doctors referred to the DC by the PeCC at its January 1976 meeting had been convicted of controlled drugs offences, committed over a significant period of time. All had become addicted to the drug in question. In each case, there appeared to have been an element of dishonesty in the obtaining of the drug. On the other hand, the cases of three other doctors and of Shipman himself involved convictions for offences of a similar degree of seriousness and yet were not referred to the DC by the PeCC at its April 1976 meeting.

16.55 An examination of the files in these cases suggests that the factor that made the difference was whether the doctor produced some evidence that s/he was undergoing psychiatric treatment or was at least under some form of medical supervision. In 1976, as I have indicated, there was no requirement in the Rules that a doctor convicted of offences should be asked for his/her explanation of the circumstances of the offence(s) for which s/he had been convicted before the PeCC met to consider his/her case. However, the practice of asking such doctors for their explanation and of giving them the opportunity to produce medical and other evidence before the PeCC hearing was growing. As we shall see, Shipman himself was given that opportunity and took it. I can see that, to some extent, the PeCC was taking account of its duty to protect patients; it was relying upon the material supplied by the doctor to assess whether the doctor was fit to practise. However, it appears from the cases that the Inquiry has examined that, if any helpful material was produced, the PeCC would very readily be prepared to conclude that the doctor was not a risk to the public and could be allowed to continue in practice, subject either to a period of continued medical supervision (which would be achieved by adjourning consideration of the case to a later meeting) or by closing the case with a warning.

The Maintenance of the Honour and Reputation of the Medical Profession

16.56 Dr Llewellyn told the Inquiry that, in deciding whether or not to refer a case to the DC, the PeCC would also consider whether the doctor's conduct had brought the profession into disrepute. I would have expected it to do so, as the GMC has always recognised the importance of maintaining the honour and reputation of the medical profession and the confidence of the public in the profession and in the GMC's regulation of it. One of the reasons why the DC (later the PCC) has always sat in public and has always allowed publication of its decisions has been to maintain public confidence in the performance of its disciplinary function. Where a doctor has been convicted of criminal offences, the facts underlying the convictions are in the public domain. They may not have received the attention of the national press but they will be known in the locality in which the doctor lives

and/or practises and are highly likely to have come to the attention of his/her patients. Assuming that the GMC handles the doctor's case in a way which properly protects the public and the doctor's patients, the confidence of the public in the GMC will be enhanced by publication of the decision. If such a conviction case is dealt with in private, there is a danger that members of the public who know about the conviction will think that the GMC has done nothing.

The Penal Cases Committee's Use of the Power to Adjourn

16.57 I have mentioned that the PeCC's power to adjourn a case was given for the purpose of allowing it to make further investigations or to obtain legal advice. However, it is clear from the cases the Inquiry has examined that the power was sometimes used in order to exercise a degree of control over a doctor who had been abusing alcohol or controlled drugs. The case might thereby remain under the jurisdiction of the PeCC for a year or more. Sometimes, the PeCC would adjourn a case more than once, even when there was evidence on the second or subsequent occasion that the doctor had relapsed. In a case where the doctor had not yet sought psychiatric treatment, the PeCC would sometimes direct that s/he should do so and would adjourn the case to a later meeting, requiring a report to be produced from a psychiatrist for consideration on that occasion. If the doctor was already under the care of a psychiatrist, the PeCC would express its expectation that the doctor would remain under medical supervision during the period of adjournment. The doctor would usually be asked to provide the GMC with the name of the supervising psychiatrist and with the names of other professional colleagues who could provide confidential information about his/her progress. If the doctor failed to co-operate with the GMC or relapsed into drug taking or alcohol abuse, the possibility of referring the case to the DC remained open. However, as will appear from the following two examples, the focus of the PeCC appears to have been upon the rehabilitation of the doctor.

Dr JA 04

16.58 In the case of Dr JA 04, the doctor had been convicted, in the mid-1970s, of obtaining morphine by deception, apparently for his own use. He was dealt with at the Crown Court and asked to have a large number of offences taken into consideration. As soon as his offences had come to the attention of the police, he had obtained psychiatric treatment and was able to put a report before the Judge when being sentenced. He was fined. The case came before the PeCC. Plainly, the underlying conduct was serious enough to warrant referral to the DC. At the time when his case came before the PeCC, the doctor was practising as a GP and was under psychiatric supervision. He had parted company with his former partner and had been practising as a single-handed GP. He was seeking another partner. I would have thought that the fact that he was practising alone gave rise to a risk to patients. However, the PeCC adjourned consideration of his case for eight months, saying that he was to remain under medical supervision. In the interim period, the doctor was, of course, free to practise and the supervision was of his state of health, not of his practice. There appears to have been an assumption that there was no risk to the doctor's patients.

16.59 At the time it next considered the case, the PeCC had before it material which ought to have given rise to concern for the welfare of the doctor's patients. The doctor's own letter gave a glowing account of his rehabilitation. He had acquired a new partner who, he said, had been made **'fully aware'** of his conviction. All was going well, he said, in every respect. However, the new partner told the GMC that, although Dr JA 04 had told him, at an early stage, that he had been convicted of a drugs offence, he had deceived him as to the true extent of his criminality, of which the partner had only just become aware. This had caused difficulties between them. Also, the partner said that Dr JA 04 had put a prepared reference for the GMC before him for signature. The partner had refused to sign it because the contents were not true. He expressed concern about Dr JA 04's state of health and was not able to offer a **'proven opinion'** about whether or not Dr JA 04 had given up the use of drugs. Also, the report of the treating psychiatrist was quite guarded about the truth of the doctor's claim to be off drugs and about the prognosis for rehabilitation. Some favourable references were received from medical colleagues, but they appeared to be friends of the doctor. In addition, the GMC had received a letter from a practitioner holding an important medical office in the locality in which the doctor practised. This letter had expressed concern on the part of the local medical community that the doctor had been convicted of a serious offence and yet the GMC had **'taken no notice'**. This material should, in my view, have rung a loud alarm bell about the safety of the doctor's patients. However, the case was still not referred to the DC but was adjourned again by the PeCC on the same terms as before. On the next occasion the PeCC considered reports and references which, again, were by no means wholly supportive. One referee asserted that the doctor was still taking drugs and expressed the view that, for his own good and for the reputation of the medical profession in the area in which he practised, the doctor should be temporarily erased from the medical register. Notwithstanding that, the PeCC adjourned the case for a further year. The Inquiry has not been able to discover how this case was eventually resolved.

16.60 Mr Howes told the Inquiry that it was difficult for him to understand why the PeCC had not referred this case to the DC at the time of its second or third consideration of the case, in view of the ambivalent reports it had received. I feel bound to observe that, on the material before it, the PeCC cannot have been satisfied that the doctor was not still using morphine or that he was not a risk to patients. In my opinion, this case demonstrates a failure by the PeCC to give proper weight to the need to protect the doctor's patients. The case should have been referred to the DC on the first occasion and, if not then, certainly when it came back before the PeCC on the second occasion. It seems that, once the PeCC had decided to keep the case to itself and to go down the 'rehabilitation route', there was a reluctance to depart from that course and little weight was given to the concerns being expressed about the doctor's conduct.

16.61 In respect of the concerns expressed by the local medical community that the GMC appeared to have taken no notice of this case, Mr Howes agreed that dealing with the case in private might have damaged the GMC's credibility. I must observe that, if the public had known how the GMC was dealing with that case, its credibility would not have been enhanced.

Dr JA 08

16.62 In another case (that of Dr JA 08), the doctor had been convicted, in the mid-1970s, of obtaining pethidine by deception. He had been self-administering the drug in large quantities, up to 1000mg per day. His case came before the PeCC. The psychiatric report, prepared for the criminal proceedings by a former colleague of the doctor, said that the doctor was not addicted to the drug and was fit to practise without any restriction on his prescribing rights. In fact, when the PeCC first considered the case, the doctor had already relapsed and was again taking large amounts of pethidine daily. In other words, the psychiatrist's report did not reflect the position as it was by the time of the PeCC's meeting. However, the PeCC was unaware of that fact and adjourned Dr JA 08's case to its next meeting, which was to take place three months later. Meanwhile, the doctor was still practising as a GP. A month after the PeCC's first consideration of his case, he was admitted to a psychiatric hospital. Shortly before the meeting of the PeCC at which his case was due to be considered for the second time, the hospital psychiatrist reported to the GMC that the doctor could soon return to work, provided that he had no access to pethidine. At that meeting, the PeCC learned that the doctor had in fact already relapsed at the time of its earlier decision. However, it adjourned the case again, this time for a year, to give the doctor **'a further opportunity to rehabilitate'**. He was free to resume general practice, with no restriction on his access to pethidine. A year later, the case was concluded, without a referral to the DC, on the basis of a further report provided by the psychiatrist who had been a colleague of Dr JA 08. The report was favourable but that psychiatrist's previous report had turned out to be inaccurate; it had advised that the doctor was fit to practise without restriction when, in fact, he was not. Yet, the PeCC acted upon the favourable opinion of the same psychiatrist. In so doing, it appears to me that the PeCC did not have the safety of patients at the forefront of its collective mind.

The Propriety and Wisdom of the Practice of Repeated Adjournments

16.63 When Mr Gray was first asked in evidence to the Inquiry about the PeCC's use of its power to adjourn for further investigation, he said that he did not recall the PeCC ever using the power in order to keep a doctor under surveillance. If the PeCC had felt that were necessary, it would have been better, he said, to refer the doctor to the DC. However, having read the papers in some of the cases decided by the PeCC in the mid-1970s, Mr Gray accepted that it had in fact been quite common practice for the PeCC to adjourn and, in effect, to put a doctor under compulsion to seek treatment and to produce reports at a later meeting of the PeCC.

16.64 Mr Howes commented on the cases heard by the PeCC in the 1970s. He said that it seemed to him that the PeCC had been using the power to adjourn in order to see whether a doctor who was under medical treatment or supervision would sustain the improvement s/he had made over a period. He described it as a 'lighter touch' than putting the doctor 'on probation', as the DC might have done. He thought it had been appropriate for the power to adjourn for further investigations to be used in this way, provided that it was short-term. He said:

> **'If the Penal Cases Committee wanted to get more information or a better picture of the doctor before deciding whether to refer to the Disciplinary**

Committee I think that was reasonable. If they were to do it for year after year, for example, that would be inappropriate.'

16.65 Mr Howes observed that the PeCC and the DC, in using their powers to adjourn and postpone, were in effect 'playing at being a Health Committee'. This was at a time when the Merrison Committee had made its recommendations and the health procedures were in the course of preparation. They had not come into effect.

16.66 Leading Counsel to the Inquiry suggested to Mr Howes that the function of the PeCC in relation to a conviction case was to look at the conviction, to assess its gravity and to decide whether it should go to the DC. The DC was the Committee charged with imposing the appropriate sanction. That being the case, she suggested that it was not the function of the PeCC to adjourn a case for the purpose of keeping a doctor under supervision, let alone repeatedly to bring the doctor back on adjourned hearings. Mr Howes agreed that, considered today, the suggestion was 'obviously a valid one'. However, he pointed out that, at the time, there appeared to have been no objections from the GMC's legal assessors. Nor had there been any objection from the medical defence organisations. In fact, as I pointed out, it was highly unlikely that the medical defence organisations would have objected as, so far as those indemnified by them were concerned, an adjournment by the PeCC would be preferable to a referral to the DC. Leading Counsel had not suggested to Mr Howes that the practice of making repeated orders to adjourn was unlawful; she had suggested only that it was not the PeCC's function to keep a doctor under prolonged supervision. The practice of adjourning so as to effect supervision might also have been unlawful but that was not the point. The point was that the practice as followed was not appropriate for the PeCC.

16.67 In the two cases I have described, I can clearly recognise the desire of the PeCC to help the doctor towards rehabilitation. However, I cannot detect the application of the supposed precondition to the GMC's freedom to do that, namely the principle that the primary duty of the GMC was to protect patients. A doctor who had been abusing controlled drugs had surely presented a risk to patients in the past. The PeCC did not seek to find out whether any harm had been suffered; I can see that such enquiries might sometimes be difficult to undertake. But, while there remained a risk of a relapse into drug taking, there must have remained some risk to patients. In my view, to allow a GP who was at risk of a relapse to continue in practice, without any real supervision, plainly exposed patients to risk of harm. It seems to me that these decisions by the PeCC to adjourn final consideration left patients at risk.

The Use of Warning Letters by the Penal Cases Committee

16.68 It seemed to me, on reading rule 6(1) of the 1970 Rules, that the function of the PeCC was to act as a filter, determining which cases should go through to the DC and which should not. However, it is clear that the powers of the PeCC were wide enough to allow it to close a case with the issue of a warning and that the GMC considered that it was proper for the PeCC to do so where appropriate. There was no internal guidance as to when that course would be appropriate. The passage in the January 1976 edition of the Blue Book, which I quoted at paragraph 16.16, suggested that it would not be used in cases of any real

gravity. Yet it is clear from some of the cases examined by the Inquiry that warning letters were used by the PeCC in cases where the doctor had been convicted of quite serious controlled drugs offences.

Dr JA 18

16.69 In one case (that of Dr JA 18), the doctor had admitted a series of about 125 offences of obtaining controlled drugs (dexamphetamine) by deception, for his own use, over a period of at least two and a half years. He had issued prescriptions in the names of patients, presented them to the pharmacy and kept the drugs for himself. It appears that, at court, he claimed that he had taken the drugs only in order to give himself the energy to work on the building of surgery premises for the new practice he had recently set up. He claimed that he had never been dependent on the drugs and had given them up as soon as he was seen by the police. He had also sought psychiatric help. He was conditionally discharged by the court but was reported to the GMC. After receiving a very favourable psychiatric report, which said that the doctor had a strong personality and was determined to stay off drugs, the PeCC closed his case with a warning letter. This case bears strong similarities to that of Shipman and was dealt with in a similar way. Unfortunately, it is not easy to see what criteria were applied as the PeCC did not record the reasons for its decisions. It does not appear from the file that the PeCC had any independent information about any possible risk to patients. From the file, it appears that the only detailed information available to the PeCC was provided by the doctor and the treating psychiatrist. When it was asked for information about the case, the Home Office Drugs Branch had said only that the case was **'simply one of a practitioner obtaining drugs for his own consumption'**.

16.70 The doctor's explanation, written on his behalf by Hempsons, solicitors to the Medical Defence Union (MDU), painted a picture that might, in itself, have given rise to some concerns for the welfare of his patients. Among other things, it was said that, at times, while he was building the new surgery, the doctor had been staying up all night, several nights a week, to do the building work and was running the practice during the day. He had taken the drugs to help him to cope with these strains. If this account was true, I find it hard to imagine what kind of condition he must have been in during the day. However, when the doctor's account and that of the psychiatrist are read together, they paint an even more worrying picture. It was said that the doctor had begun taking drugs five years earlier, while in partnership with another GP, from whom he had parted the following year. The psychiatrist attributed this parting to no more than a personality clash but the other GP was not asked for his/her account. That was before any question of building work arose. The doctor told the psychiatrist that, during the building work, he was taking about 120mg of the drug per day. He claimed that he had not been aware of any **'perceptual distortion'** on taking the drugs and had not felt any **'let down'** on cessation. He had not taken the drugs for pleasure, only for this **'strictly functional purpose'** (by which I understand him to mean to help him to cope during the building works). However, he had not stopped taking them (or obtaining them unlawfully) when the building work was finished, although he claimed to have reduced his dosage to about 60mg a day. There was no material before the PeCC from which it could have checked the truth of that assertion. The doctor's

justification for his continued consumption was the need to renovate his home in his free time while running the practice during the day. I feel bound to wonder how the PeCC could have concluded that this case did not need to go to the DC. Before reaching any conclusion about this case, I would have wished to question the accuracy of the doctor's accounts and his judgement in treating patients while subjecting himself to the punishing regime he had described. To achieve that, the case would have had to go to the DC.

Conclusions about the Criteria Applied by the Penal Cases Committee

16.71 It appears to me that, in the cases of doctors convicted of controlled drugs offences, the seriousness of the underlying conduct and of the dishonesty involved was not regarded by the PeCC as an important factor in deciding whether a case should be referred to the DC. It seems that, if any information was available to the PeCC from which it could conclude that there was an expectation of rehabilitation, the case would be closed with a warning letter and that, if the evidence suggested even a prospect of rehabilitation, the case would be adjourned to another meeting in the expectation that the doctor would remain in contact with his/her psychiatrist. No enquiries were made as to whether the doctor's drug addiction had had any adverse effect on his/her patients in the past. The police investigation would be unlikely to cover such matters. It is clear to me that, although the issue of patient protection may have been considered, the PeCC was very easily satisfied that there was no risk. In practice, the interests of the doctor in rehabilitation were not merely taken into account but were allowed to predominate.

The Approach of the Disciplinary Committee to Cases Involving Drug-Related Convictions

16.72 Examination of the files of those drug-related conviction cases that were referred to the DC shows that that Committee was very unlikely indeed to suspend a doctor from practice and even more unlikely to erase him/her from the medical register. A far more likely outcome was the postponement of the decision to a subsequent meeting, or even several postponements spanning a period of as much as two or three years. Such cases would then be closed with or without an admonishment. When a case was postponed, the doctor would be required to produce reports describing his/her treatment and progress and naming referees of whom enquiry could be made. It should be noted that, when seeking information about the progress made by a doctor who had been addicted to drugs, the GMC staff were not instructed to obtain reports from an independent source. The psychiatrist treating the doctor was usually asked to report and the doctor was asked to name referees of his/her own choosing. Among the cases examined by the Inquiry, I have found none in which the DC had concluded at a resumed hearing that the information about the doctor was sufficiently unsatisfactory to warrant suspension or erasure. From the cases examined, of which some examples are given below, it appears to me that the DC's objective was to postpone a decision in the case until such time as the doctor was rehabilitated. Throughout the process, the doctor was permitted to practise and was subject to only minimal supervision.

Dr JA 09

16.73 In the case of Dr JA 09, the doctor was convicted of a series of offences of obtaining morphine and pethidine by deception. She had issued prescriptions in the names of

patients, had presented them herself and had kept the drugs for her own use. The offences spanned a period of about 14 months. In the mid-1970s, the PeCC referred the case to the DC and the case came on for hearing two months later. It appears that a psychiatric report was produced, although this is no longer available. The minutes of the DC meeting record that the case was postponed for four months. The doctor was told that her conduct gave rise to a **'potential source of danger to your patients'**. I interpose to say that this expression was often used in decisions of the DC, from which I infer that it was indeed the view of the GMC at that time that a doctor who took drugs presented a risk to patients. The decision to adjourn was taken in order to allow the doctor to demonstrate that she was responding to treatment and would be able to fulfil the assurances of good behaviour she had given. At the next meeting, it emerged that the doctor had not kept up her medical treatment. The minutes do not record what material was before the DC but they do record that the doctor was exhorted to seek medical treatment immediately and to continue with it regularly. Notwithstanding the doctor's failure to keep up her treatment, the case was adjourned, this time for 12 months. Nothing more was said about the risk to patients and no steps were taken to ensure that the doctor's patients were not harmed. A year later, the DC learned that the doctor had not maintained regular contact with a psychiatrist in the intervening period. Again, the minutes do not record what information was available to the DC. Notwithstanding the doctor's failure in that regard, her case was adjourned for another year. She was advised that it was **'in her best interests'** to consult a psychiatrist regularly. Again, nothing was said about her patients and no steps were taken to protect them. The Inquiry has been unable to find out what happened to this case. The doctor's name does not appear in the minutes of the DC for the following year. It may be that she had died or retired. It seems unlikely that she was suspended or erased by the DC, as such an outcome would surely have been recorded in the minutes. This doctor was allowed to practise for well over a year, possibly longer, in circumstances where she must have presented some risk to patients.

Dr JA 11

16.74 In the case of Dr JA 11, the doctor was convicted of offences of failing to record in his controlled drugs register (CDR) quantities of Palfium that he had purchased on requisition. He was fined £25. In the mid-1970s, the PeCC referred the case to the DC. In a sense, this was a technical breach of the record keeping requirements of the Misuse of Drugs Regulations 1973; it did not involve dishonesty. It appears that the doctor was taking the drug himself. The DC adjourned the case so that a psychiatric report could be obtained. At its next meeting, the case was closed. The minutes do not record what information was available or why that decision was reached. Nor is there any reference at either stage to the risk to patients.

Dr JA 10

16.75 In the case of Dr JA 10, the doctor was convicted of dishonestly obtaining Dexedrine by issuing prescriptions in the names of patients who did not need and did not receive the drug. He was also convicted of offences in connection with his failure to keep a CDR. His conduct had persisted for nearly a year. At a meeting of the PeCC in the mid-1970s, the

case was referred to the DC. Two months later, the DC postponed the case for four months, requiring the doctor to identify his treating psychiatrist and other referees. The minutes refer to his dishonesty and to the risk to patients arising from his conduct. At the next meeting, the case was adjourned for a further four months on a similar basis. In the November, the case was closed; the doctor was not admonished.

Dr JA 12

16.76 In the mid-1970s, Dr JA 12 was convicted of obtaining drugs by deception and asked for 25 similar offences to be taken into consideration. It appears, therefore, that his course of conduct had extended over several months. His case was referred to the DC and came on for hearing two months later. It was adjourned for a year and the doctor was required to provide the names of his psychiatrist and referees. The following year, the DC considered a report from a psychiatrist who said that the doctor was fit to practise but recommended a further period of supervision. However, the DC decided to conclude the case, advising the doctor to continue with his supervision. It was not in a position to find out whether the doctor did do so or not.

General Comment

16.77 There are a number of common threads running through the cases of this era involving doctors who had been abusing controlled drugs. These are apparent not only in the cases I have described but also in other cases examined by the Inquiry. The first is that it appears to me that the DC used its power to postpone judgement in order to assist in the rehabilitation of doctors who had committed criminal offences as the result of a drug addiction. However, the extent to which the DC could provide adequate protection for patients in the meantime was very limited. I accept that it had no power to impose conditions on the doctor's right to continue in practice. However, it generally achieved the co-operation of the doctor in accepting treatment through the implicit threat of suspension or erasure if s/he failed to co-operate and it could have done far more to protect patients by requiring undertakings from a doctor as the price of not being suspended.

16.78 The second is that, when postponing or adjourning a case to allow an opportunity for rehabilitation, the PeCC and the DC always left it to the doctor concerned to choose the psychiatrist who would provide the report at the end of the period of postponement or adjournment. The GMC made no attempt to assemble a list of approved psychiatrists, of whose independence the GMC could be satisfied, and who could be instructed to examine the doctor and to report to the GMC. There was no requirement that a doctor's assertion that s/he had ceased taking drugs should ever be put to an objective test, as, for example, by urine analysis, although occasionally this would be done. All was taken on trust. No doubt that trust was well placed in many cases but it would be surprising if it always was.

16.79 The choice of referee was also left entirely to the doctor, who was free to request assistance from friends. As we have seen, some doctors would actually prepare a draft reference for a colleague to sign. The referee did not have to state the nature of his/her relationship to the doctor (although s/he sometimes did), or say to what extent s/he had had the opportunity to observe the doctor during the period of adjournment.

16.80 The degree of 'supervision' which took place during a period of adjournment or postponement was very light and was not, in my view, sufficient to protect patients. The only requirement was to 'remain under the supervision of' a psychiatrist. This would usually involve only limited, occasional contact. As I have said, the GMC did not at this time have the power to impose conditions and requirements that it acquired later under the health procedures. However, it could have assumed those powers had it wished to do so by inviting a doctor to give undertakings or to consent to conditions and requirements as an alternative to suspension or erasure. I have in mind such conditions as not working in general practice, working only in a supervised post and not possessing or prescribing controlled drugs. Another possible safeguard would have been a requirement that a partner or senior colleague should be asked to maintain a watch over the doctor and to provide regular reports to the GMC.

16.81 The other common thread running through all these cases is the complete absence of any attempt by the GMC to find out whether the doctor's drug taking habit had in fact given rise to any problems for patients. No enquiries were made to see whether complaints had been made to practices, hospitals or family practitioner committees (FPCs). The GMC would have no idea whether a doctor might have been sued for negligence as a result of incidents caused by his/her drug dependence. Even where the reports available suggested underlying problems within a doctor's practice, no enquiry was made. This again suggests that, at least in cases involving a doctor convicted of drugs offences, the protection of patients did not rank very high in the considerations of the GMC.

The Shipman Case

16.82 Against that background, I shall turn now to consider the GMC's handling of Shipman's case. I described Shipman's abuse of controlled drugs in Todmorden briefly in my First Report and at greater length in my Fourth Report. For present purposes, I shall confine my account to those matters which had, or might have had, a bearing on the GMC's handling of his case.

The General Medical Council Is Notified of Shipman's Convictions

16.83 Shipman was convicted and sentenced at the Halifax Magistrates' Court on 13th February 1976. The GMC was informed of his conviction by a letter from the West Yorkshire Police (WYP) dated 8th March 1976. To the letter was attached a schedule, setting out details of the offences of which Shipman had been convicted. These comprised three offences of dishonestly obtaining drugs by means of a criminal deception, two offences of forgery of a NHS prescription and three offences of unlawful possession of a controlled drug (pethidine). The schedule also recorded that 74 similar offences had been taken into consideration. Shipman had been fined £75 on each charge and ordered to pay £58.78 compensation to the local FPC, i.e. Calderdale FPC, on whose list he was included at that time.

16.84 No further details of the offences to be taken into consideration were given and it does not appear that the GMC ever sought or obtained a list. No details of the offences survive; the police and court files, which would have contained a list, have now been destroyed.

However, it is clear from contemporaneous press reports that 67 of the 74 offences concerned the obtaining of pethidine by deception and that the remaining seven were offences of forgery.

16.85 The letter from the WYP, written in March, was the first intimation that the GMC had of Shipman's involvement in criminal proceedings. Shipman had admitted the offences to the police and to an inspector from the Home Office Drugs Branch in November 1975, and was charged shortly afterwards. A doctor was under no obligation to inform the GMC of the fact that s/he had been charged with criminal offences, or indeed of his/her conviction when it occurred. Nor were the police under any duty to inform the GMC of a doctor's involvement in criminal proceedings unless and until s/he had been convicted of an offence.

16.86 In 1976, advance warning of a doctor's involvement in criminal proceedings before s/he was convicted of an offence would not have been of any practical benefit to the GMC. As I explain in Chapter 20, it had no power to take interim action, e.g. by suspending the doctor's registration or by imposing conditions on it. In 1980, the GMC acquired limited powers to make interim orders. The limited nature of those powers meant that, in 1998, the GMC was unable to suspend Shipman's registration, despite the fact that he had been arrested on a charge of murder. In 2000, wider powers were conferred on the GMC, and a new Interim Orders Committee created, as a direct result of the public concern caused by the GMC's inability to act in Shipman's case.

The General Medical Council Requests Further Information

16.87 On receipt of the letter from the police, Mr Gray endorsed it with a note to Mr Williams, requesting him to ask both the police and the Home Office Drugs Branch for further particulars and then to **'draft'** (by which I think he meant prepare the case by drafting a memorandum) for the April 1976 meeting of the PeCC. Mr Williams duly wrote to the WYP and to Mrs Susan Powrie at the Home Office Drugs Branch.

16.88 Mr Williams' letter to the WYP requested **'a brief account of the circumstances surrounding the offences'**. It concluded:

> **'The Committee will be particularly concerned to know whether the drugs involved were improperly obtained by the practitioner for self-administration or for other purposes.'**

Mr Gray explained to the Inquiry that, if Shipman had obtained drugs for the purpose of self-administration, this would mean that he had been dishonest, that he had used the drugs improperly and that he had abused his professional privileges. However, he would not have been regarded by the GMC as being a danger to the public in the same way as he would have been if he had supplied drugs to others. I shall refer to the effect of this distinction later in this Chapter.

The Response of the Police

16.89 The WYP responded by letter dated 22nd March 1976, saying that it was **'contrary to practice to supply extracts from police reports to outside bodies in cases such as**

this'. The letter did, however, offer the officer in the case, Detective Sergeant (DS) George McKeating, for interview. He would not be permitted to sign a written statement but would be able to answer questions on any matters upon which he was competent to give evidence. The letter also indicated that DS McKeating would attend a hearing on receipt of a *subpoena*. Details of the charges which would be levied for interviewing DS McKeating, and for his attendance at a hearing, were given.

16.90 Mr Gray said that some police forces were more co-operative than others in providing information. They were generally reluctant to provide information in writing about anything which had not been proved in a criminal court. Mr Williams thought that the response from the WYP was **'a bit unusual'**. His recollection was that the police were usually more helpful than they had been in this case.

16.91 Detective Chief Inspector (DCI) Bryan Dent, of the WYP Drug Squad, provided a witness statement to the Inquiry. He was a young detective in the late 1970s, so had no personal knowledge of the procedures then in force. However, he had done some research and believed that the police would have been conscious at that time of the fact that interviews with an accused person were regarded as confidential to the criminal justice process. A recent decision in the courts had, he believed, led to a policy of refusing to release transcripts of interviews or reports and other exhibits which had come into the possession of the police during an investigation. However, supplementary information would be provided if an officer was interviewed. DCI Dent suggested that this was a means, in effect, of circumventing the embargo on releasing documents. While it was not the practice at that time for an officer to sign a statement recording what had been said at the interview, s/he would reiterate the contents of the statement if subsequently subpoenaed to give evidence at a hearing.

16.92 Mr Gray saw the letter from the WYP when it came in. He told the Inquiry that the offer to provide information, although kind, was not very helpful to GMC staff at this stage in the proceedings. It was clear that DS McKeating would not be permitted to sign a statement which could be put before the PeCC. If Mr Gray had interviewed DS McKeating and had taken notes, he could not, he said, have put those notes before the PeCC since they would not have been 'evidence'. The PeCC did not hear oral evidence, so DS McKeating could not have been subpoenaed to attend before it. However, Mr Gray said that, if the case had been referred by the PeCC to the DC, DS McKeating would 'almost certainly' have been subpoenaed to attend and give evidence. In his witness statement, Mr Gray said that he could recall having had several telephone calls with police officers that had cast valuable light on the circumstances behind convictions. However, he did not telephone DS McKeating on this occasion.

16.93 It seems to me that, when considering a conviction case, it would always have been helpful to the PeCC and to the DC to have some background information from a police officer with personal knowledge of the case. A mere schedule of offences may not convey a very clear impression of the degree of misconduct. For example, the *modus operandi* of an offence is not always apparent from the schedule, and information about it may be very revealing. Also, the immediate response of a person when accused of an offence may often be revealing of his/her attitude towards it.

16.94 Mr Gray was asked whether he would have thought of interviewing DS McKeating and of submitting to the PeCC a note, setting out the evidence which the officer could be expected to give if he were called before the DC. Mr Gray replied that he had not regarded it as his function to do that and that no one had ever suggested that he should. His practice was to submit to the PeCC only 'objective, good evidence'. He would have been concerned that, if he had summarised for the PeCC the evidence which the officer was expected to give and, in the event, the officer had not 'come up to proof' when giving evidence before the DC, he (i.e. Mr Gray) would be criticised. Mr Gray said that, in any event, there was enough information from the police and the Home Office to justify the staff in referring the case to the PeCC without seeking further evidence. He said that there was enough evidence also to justify the PeCC referring the case on to the DC if it had thought fit. Had the PeCC done so, any additional information which DS McKeating could have given would, Mr Gray said, have come to light when he was called to attend the DC hearing. That is so but, as the case was not referred to the DC, the evidence was never obtained.

16.95 The fact that any information coming from a police officer to the PeCC as a result of an interview conducted by a member of the GMC staff would have been hearsay (and therefore not, in Mr Gray's view, 'objective, good evidence') does not seem to me to be a good reason for not obtaining it. If the hearsay evidence were favourable to the doctor, no harm would have been done to his/her interests; if it were damaging to him/her and the PeCC decided to refer the case to the DC, the officer could be called to give evidence and the doctor's representatives would have the opportunity to challenge what s/he said. In any event, the PeCC was willing to accept a letter written by a solicitor representing the doctor, in which the doctor's account was set out. Such a letter also constitutes hearsay evidence and would not be admissible in that form as evidence of the truth of its contents. So it appears that the PeCC was prepared to receive hearsay evidence of the doctor's account but not of a police officer's.

16.96 Mr Gray annotated the letter from the WYP with comments addressed to Mr Williams. The note read:

'... Pl (*please*) **speak. with previous pp** (*papers*) **(?one for solicitors)'**.

Mr Gray said that his note was suggesting that he and Mr Williams should discuss the possibility of asking the GMC's solicitors to take a statement from the police officer. It is not clear how such a statement would have been used or at what stage in the proceedings, although, in view of Mr Gray's evidence, it seems likely that it would have formed part of the preparation for a hearing before the DC rather than for submission to the PeCC. In the event, it does not appear that the suggested discussion ever took place, probably because a letter containing useful information was received from the Home Office Drugs Branch.

The Response of the Home Office

16.97 As I have said, Mr Williams had also written to Mrs Powrie at the Home Office Drugs Branch requesting **'a brief account of the circumstances leading up to'** the offences, together with any additional information which might assist the PeCC when it considered the case in April. Mrs Powrie responded in a letter dated 25th March 1976.

16.98 Mrs Powrie's letter informed the GMC that Shipman had first come to the notice of the Home Office Drugs Branch in July 1975. In fact, this was incorrect; Shipman had first attracted its attention in January and February 1975, when it was observed that he had collected large quantities of pethidine from two local pharmacies. Enquiries were made at that time and it was decided to maintain a watch on him and to see if anything further came to light. This information never became known to the GMC. That said, it is unlikely that it would have had any effect upon the outcome of the case, even had the GMC been aware of it.

16.99 Mrs Powrie went on to say that, in July 1975, it had been discovered that Shipman was obtaining large and regular supplies of pethidine on written requisitions for use in his practice and on prescriptions for a patient. Shipman had always collected the prescriptions for the patient, who was suffering from terminal cancer. It had subsequently come to light that he was not keeping a register of supplies of controlled drugs, whereupon he had been informed of the statutory requirement to do so.

16.100 The letter went on to relate how, in September 1975, it had been reported that Shipman had resigned from his practice and had admitted his addiction to pethidine after his purchases of large amounts of the drug had come to the attention of one of his partners. It had transpired that Shipman had also been obtaining pethidine on prescription, ostensibly for patients, and the facts were communicated to the WYP. The letter explained that, in an interview with an inspector from the Home Office Drugs Branch and a police officer in November 1975, Shipman had admitted committing the offences. He had said that he had begun to take pethidine in April 1974. The letter stated that Shipman had been receiving treatment for his addiction from Dr (Ronald) Bryson at The Retreat, York, and Dr (Hugo) Milne of Lynfield Mount Hospital, Bradford.

16.101 I explained in my Fourth Report that, in 1976, the Home Secretary had the power to make a direction in respect of a doctor who had been convicted of an offence under the Misuse of Drugs Act 1971 (MDA 1971). Under section 12 of the MDA 1971, the Home Secretary could direct that the doctor should be prohibited from possessing, supplying, prescribing or administering controlled drugs. Indeed, the Home Secretary still possesses the power to make a section 12 direction, although it has not been exercised for a decade or more. In her letter, Mrs Powrie indicated that the Home Office was considering whether action should be taken under section 12 of the MDA 1971. She said, **'... we should be glad if in this connection you would let us know the view taken by the Penal Cases Committee'**. As I explained in the Fourth Report, the Home Office paid considerable attention to the attitude of the GMC when considering whether to make a section 12 direction, as the GMC had greater experience in the field of drug misuse by doctors than did the Home Office. The main interest and experience of the Home Office lay in uncovering the illegal supplying of drugs.

16.102 On 1st April 1976, Mr Williams responded to Mrs Powrie's letter, promising to let her know in due course the decision taken by the PeCC. On the same day, he wrote to Shipman, informing him that his conviction had been reported to the GMC and telling him that a further communication would be sent to him when the PeCC had decided whether to take any action in relation to it. This was the standard letter sent to doctors in conviction cases

and, sometimes, it was the only letter which they would receive before their case was considered by the PeCC. I have already explained that it was not the invariable practice of the GMC at the time to ask for an explanation from the doctor at this stage in the proceedings. As I have said, however, the Inquiry has seen that it was often done in drug-related cases.

16.103 Mr Williams then prepared a memorandum for the attention of Mr Gray. The memorandum was dated 1st April 1976. Attached to the memorandum was the original letter from the WYP, together with the schedule of offences. It is probable that Mrs Powrie's letter was also attached. Mr Williams referred to the letter from the WYP and the schedule of offences attached to it. He indicated that Shipman had been positively identified as a doctor on the medical register. He mentioned his request for further information from the WYP and the response which, he said, **'made it clear that they are not prepared to provide any, short of being subpoenaed'**. This was not strictly correct, as the police had offered an interview with DS McKeating. It may be that Mr Williams realised that this would not be deemed appropriate and mentioned what he believed to be the only option likely to be acceptable. Mr Williams went on to say:

> **'Fortunately Mrs Powrie of the Home Office (Drugs Branch) has furnished a useful and comprehensive account of the particular circumstances of the offences and the attitude taken by the police will not therefore be detrimental to the information that we can provide for the Penal Cases Committee.'**

16.104 Mr Williams expressed uncertainty as to whether the total fine imposed on Shipman had been £225 or £600. Finally, he sought Mr Gray's authority to send the item to the PeCC. Mr Gray endorsed the memorandum with a request that Mr Williams should telephone the Magistrates' Court and find out how much Shipman had been fined. Mr Williams did so and learned that the total fine had been £600. I find it puzzling that Mr Gray should be concerned to find out how much Shipman had been fined and yet did not attempt to obtain a fuller account of Shipman's criminal conduct. In any event, Mr Gray was satisfied that the information was sufficient to go to the PeCC. He told the Inquiry that the information provided by the Home Office constituted what seemed to him to be 'a sufficiently complete story'. Accordingly, no further consideration was given to enlisting the assistance of the GMC's solicitors to obtain further information from the police at that stage.

Limitations on the Investigations Made for the Purposes of the Penal Cases Committee

16.105 In a witness statement to the Inquiry, Mr Gray said that, with a conviction case, the GMC needed to:

> **'... seek sufficient evidence of the circumstances** (*i.e. of the offences*) **to enable the Penal Cases Committee to assess the gravity of the case and the extent to which it revealed that the practitioner concerned was a danger to patients'**.

16.106 It seems to me that, if the PeCC had confined itself to making a decision on a broad brush basis as to whether or not a case should be referred to the DC on the grounds of either the gravity of the doctor's conduct or the risk to patients or both, it would have been reasonable for it to limit the evidence it received in the way described by Mr Gray. In a case of a doctor convicted of multiple offences involving the dishonest obtaining of controlled drugs over a period of time as the result of drug addiction, the broad brush approach should always have led to a decision to refer the case to the DC on the grounds of gravity and risk to patients. However, as I have already explained, the PeCC did not always confine itself to that type of broad brush approach; it would sometimes decide that a rehabilitative approach should be taken and that the doctor need not be referred to the DC, despite the obvious seriousness of the offences of which s/he had been convicted. In short, it would take, not a filtering decision, but the substantive decision. Quite apart from the fact that such decisions do not appear to me to have been appropriate for what was supposed to be a filtering committee, such substantive decisions would have required careful consideration of all the evidence. The PeCC would not have had access to all the evidence that would have been available to the DC.

The Evidence of Detective Sergeant McKeating

16.107 In Shipman's case, the PeCC did not have the evidence of DS McKeating that would have been available to the DC had the case been referred. If DS McKeating had been called to give evidence, he would have been able to explain Shipman's *modus operandi* and the extent of his dishonesty. He would have been able to describe the offences taken into consideration by the Magistrates' Court. DS McKeating would also have explained why, in some cases, Shipman had also been charged with forgery: on some occasions, Shipman had forged the signature of a staff member at the residential home where the patient lived. The patient was elderly and entitled to exemption from the prescription charge; if the patient had not appeared to claim exemption, the pharmacist would have wondered why. In my view, the forgery of a signature is a significant additional act of dishonesty over and above the dishonesty inherent in obtaining the drugs by deception. DS McKeating might also have mentioned Shipman's rather cavalier attitude towards his offending, which had been revealed during the interview conducted by himself and the Home Office Drugs Branch inspector. When describing to his interviewers how much of one patient's pethidine he had taken for himself, Shipman had said, **'Shall we say half for her and half for me?'** DS McKeating might also have expressed the view which he gave to the Inquiry that, from his assessment of the appearance of the collapsed veins in Shipman's arms, it appeared that Shipman had been injecting himself for much longer than the period covered by his known offending. DS McKeating told the Inquiry that it appeared to him that Shipman had been using drugs for about five years rather than the 14 months or so to which he had admitted.

16.108 What the DC would have made of this evidence is pure speculation. It may well be that Shipman (who would almost certainly have been present at the hearing) would have wished to challenge some of DS McKeating's evidence and he might well have given evidence himself. That would have given the DC a far better opportunity to assess Shipman than was available to the PeCC.

Evidence of the Possible Impact of a Doctor's Drug Taking on Patients

16.109 Another *lacuna* in the information available to the PeCC was any evidence of whether Shipman's addiction to pethidine had had any adverse effect upon his practice or patients. No enquiries were made by the GMC of Shipman's former partners or of the Calderdale FPC. It appears that it was settled GMC practice not to make any such enquiries in cases where the doctor had been abusing the drugs by self-administration and was not known to have been supplying them to others. Mr Gray said that there was a distinction between improper prescribing to others on a large scale, where the doctor had fomented addiction in patients or had otherwise endangered them, and a case where a doctor had, like Shipman, self-administered drugs. In the latter case, the PeCC was more likely to take a 'clinical' view, i.e. to regard the doctor as sick and to hope that s/he could be cured. The focus in a case of self-administration would be on the doctor and (if psychiatric evidence was available) on the psychiatrists' views of the case.

16.110 Mr Gray suggested to the Inquiry that it would have been difficult to obtain reliable evidence about whether a doctor's drug taking had had any impact upon his patients. First, he suggested that it would have been difficult to find out, in the case of a GP, which FPC to contact. I found that hard to accept and, indeed, Mr Gray later agreed in evidence that it would have been possible to trace the appropriate FPC and to find out whether it had received any relevant complaints about the doctor. Second, he said that although, in Shipman's case, it would have been possible to approach his former partners, they would probably have been 'edgy' about giving their views of Shipman because they would have known that the deprecation of colleagues was a disciplinary offence. When pressed about this, Mr Gray accepted that, if the GMC had approached Shipman's former partners and had asked whether his drug taking had impacted on his performance as a doctor, and if the former partners had answered honestly, they could not have been in danger (or sensibly have been afraid of putting themselves in danger) of disciplinary action by voicing any concerns they might have had. Mr Gray conceded that there would have been nothing (apart, he said, from 'the time factor') to stop the GMC from putting that sort of question to a doctor's colleagues as a matter of routine, in order to find out whether there were concerns that the doctor had presented a risk to patients. The 'time factor' referred to was the need to get cases onto the agenda for the next PeCC meeting. However, Mr Gray accepted that such enquiries could have been made. It is clear, however, that they were not. It was not usual practice to do so.

16.111 In his witness statement, Mr Gray suggested that, even if it had emerged that there had been problems about the quality of care that Shipman had given during his short career in general practice, it would not have been possible to prove that those problems had been occasioned by his abuse of pethidine. He sought to support his assertion by reference to the British National Formulary and the information contained therein about the speed at which the effects of pethidine wear off. He referred to the fact that there had been no complaint to the GMC during Shipman's period in general practice about his treatment of patients and that there had been no report to the GMC of any medical service committee (MSC) proceedings against him. That was indeed the case. However, there could have been (although there were not) multiple complaints about Shipman to the FPC. There could even have been (although there were not) ongoing MSC proceedings in which it was

alleged that he had been in breach of his terms of service. Since the GMC had not sought any information from the FPC, it could not have known whether or not there had been any complaints or whether there were any ongoing proceedings. All it could have been confident of was that, in respect of the period of approximately 19 months for which Shipman had been in general practice, no complaint about him was evident from the GMC's own records.

16.112 As it happens, in Shipman's case, an enquiry to the practice in Todmorden where he had worked would not have revealed any specific concerns about the safety of patients. Dr John Dacre, the senior partner, told the Inquiry that Shipman had been hardworking and that there had been no concerns about his competence. Dr Dacre was not aware that Shipman had unlawfully killed a patient in the terminal stages of cancer, as I have found he did. Nor did he know that Shipman had signed three Medical Certificates of Cause of Death in one day in circumstances which make me suspicious that Shipman was guilty of unlawful killing. Nor was he aware that Shipman had injected Mrs (now Professor) Elaine Oswald, a patient, with pethidine, shortly after she had taken some Diconal (prescribed by him), and that Mrs Oswald had suffered respiratory arrest as a result. It seems unlikely, even if the GMC staff had made enquiries of the practice, that they would have asked about Shipman's health. It seems unlikely, therefore, that Dr Dacre would have volunteered that Shipman had had a number of blackouts in the last few months of his practice in Todmorden and that, for that reason, Shipman's wife had been driving him when he visited patients. It is clear that the Calderdale FPC would have had no information about Shipman which they could have passed to the GMC, over and above that which they had been given by Shipman's former practice. If DS McKeating had been asked about issues of patient welfare, he would have told the GMC that there was no evidence of any patient being deprived of pethidine that s/he required. Neither DS McKeating, Dr Dacre nor anyone from the Calderdale FPC would have been able to give the GMC any significant clue as to Shipman's true character.

The General Medical Council Requests a Medical Report

16.113 The procedure in cases which Mr Gray considered ready to go before the PeCC was for the papers to be submitted first to the Registrar, Mr Draper. Accordingly, in Shipman's case, Mr Gray endorsed on Mr Williams' memorandum a note to Mr Draper, seeking his authorisation for the case to go to the PeCC. Mr Draper responded with a further note:

> **'Yes, but in cases like these, I think it would be helpful to invite the practitioner's observations and if he agrees, a confidential medical report? Do so now ...'**.

16.114 I have mentioned that, in conviction cases, a doctor would sometimes receive only a standard letter informing him/her of the fact that his/her conviction had been reported and was to be referred to the PeCC and promising a further communication when the PeCC had made its decision. Mr Gray said that a different letter, of the type suggested by Mr Draper, was sent when there was a suspicion that the doctor was an addict. In Shipman's case, the Home Office letter had referred to his **'addiction'** to pethidine and had mentioned that he had received treatment at The Retreat (a private hospital for the

treatment of psychiatric disorders) and that he was being treated for his addiction by named doctors whom Mr Draper would probably have known to be consultant psychiatrists. It seemed likely, therefore, that this was the explanation for his suggestion that Shipman should be asked to provide a medical report. However, an examination of the files relating to drug-related conviction cases dealt with by the PeCC in the mid- to late 1970s does not reveal any consistent pattern of requests for the doctor's explanation for the offence or **'observations'** and/or for medical reports. There were conviction cases where there was evidence that the doctor was or might be addicted but where no explanation or medical reports were requested. There were other cases where there was no evidence of addiction, but where, nevertheless, the doctor was requested to provide an explanation. It is not clear on what basis the decision to request an explanation and/or medical evidence was made. In Shipman's case, however, there was, as I have said, information that he had suffered from an addiction and was under medical care. Mr Draper obviously considered it appropriate to ask him to provide **'observations'** and, if he agreed, a medical report.

16.115 Accordingly, Mr Gray wrote to Shipman on 6th April 1976. He informed Shipman that the PeCC meeting was to be held on 28th April 1976. He invited him to submit any observations which he had on the matter of his conviction and to arrange for the GMC to receive a confidential medical report on his current condition. The letter said that any documents received from Shipman would be placed before the PeCC, together with information about his conviction.

16.116 Mr Gray told the Inquiry that where, as here, it was evident from the information in the GMC's possession that a doctor was already being treated for his/her addiction, it would be expected that any medical report requested by the GMC would come from the treating doctor. He did not recall that the GMC at that time (which was, as I have said, before the introduction of the health procedures) ever requested a doctor to submit to examination by a practitioner of the GMC's choice. The GMC did not make any stipulation about the topics which should be covered in a medical report, or about the questions that should be answered by the reporting practitioner. Mr Gray said that it would have been possible to go back to the author and query something which had been said in a report. However, he did not recall this being done 'because they were usually very good reports'. When asked whether there was ever any concern about possible lack of independence on the part of the practitioners who reported, he responded, 'I would have thought absolutely none'. He said that, when a report came into the office, the staff would read it, but would not query it, as they were not doctors. It would be attached to the papers in the case and sent with them to the PeCC.

16.117 Shipman acknowledged Mr Gray's letter, indicating that he had put the matter in the hands of Hempsons, the MDU solicitors. Hempsons sent a 'holding letter', promising to send Shipman's observations as quickly as possible.

The Evidence Provided by Shipman

The Letter from Shipman's Solicitors

16.118 In a letter dated 21st April 1976, Hempsons set out Shipman's observations about his conviction. Their letter indicated that Shipman's age was at that time about 30. It

suggested that Shipman **'did not make the right decision in going into general practice and particularly into partnership with little experience particularly on the administrative side of general practice'**. It expanded on what was put forward as the background to Shipman's drug abuse. The letter explained that Shipman had been put in charge of the ordering of controlled drugs for his practice. It was said that he had first administered pethidine to himself following a back strain, probably in the early part of 1974. (This appears to have been the first time it had been suggested that Shipman's abuse of pethidine had started in response to back pain. It was almost certainly untrue, but it was – and, indeed, still is – not uncommon for doctors in his predicament to claim that their drug use began with legitimate self-administration for pain relief.) The letter gave an account of the events surrounding the detection of Shipman's conduct and indicated that his partners had terminated his partnership immediately his drug abuse came to light. He had remained as a patient in The Retreat, in York, until 31st December 1975. It was pointed out that Shipman had admitted his conduct to his partners when first taxed with it and had subsequently admitted it to the police.

16.119 Bringing matters up to date, the letter stated that Shipman had obtained employment as a clinical medical officer, a full-time appointment in child health, with the Durham Area Health Authority (AHA). The letter said that the appointment had been made with his employers' full knowledge of the history of the matters set out in Hempsons' letter. Shipman had moved with his family to County Durham and, on the advice of Dr Bryson and Dr Milne, continued to attend outpatient appointments.

16.120 With their letter, Hempsons enclosed a psychiatric report from Dr Bryson, dated 29th January 1976, and one from Dr Milne, dated 26th January 1976. Both reports had been prepared for the purposes of the Magistrates' Court hearing. Both Dr Bryson and Dr Milne were highly experienced in their field. By 1976, Dr Bryson had practised at The Retreat for 25 years, 20 of them as a consultant psychiatrist. He had considerable experience of treating patients (including doctors and other professionals) who were suffering from alcohol and drug addiction. Dr Bryson provided two witness statements to the Inquiry, dealing with his treatment of Shipman and the contents of his report. He was not fit to attend the Inquiry to give oral evidence.

16.121 Dr Milne was a senior consultant psychiatrist and Director of the Regional Drug Unit for the Yorkshire Metropolitan area. He was not well enough to provide a statement to the Inquiry or to give oral evidence.

The Report of Dr Ronald Bryson

16.122 The report of Dr Bryson explained that he had first encountered Shipman when Shipman was admitted on 2nd October 1975 as a voluntary patient to The Retreat. Shipman had been referred there by Dr Milne. The reason for his admission was the development of an addiction to pethidine. Dr Bryson pointed out, however, that there were some **'unusual features'** to the addiction, which was **'intermittent'** and **'had not yet reached the stage of total compulsion and constant need'**. Withdrawal from pethidine had been instituted over a few days without complication.

16.123 Dr Bryson reported that, after withdrawal had been completed, it **'became obvious'** that Shipman was suffering from **'a moderately severe depressive or melancholic state'**. After discussion with Shipman and his wife, Dr Bryson had formed the view that this state had existed for **'something like 18 months previously'**. Shipman had not, it was said, recognised his illness or sought medical attention. Dr Bryson described Shipman's condition as **'endogenous depression, that is a type of depression which arises from some internal usually biochemical disturbance of brain function, rather than is precipitated by psychologically upsetting events'**. He described **'many characteristic features'** of the condition which, he said, Shipman had exhibited. Dr Bryson believed that the depressive disorder had probably pre-dated Shipman's **'attempt to keep going by unwise self-medication'**.

16.124 Dr Bryson went on to describe Shipman's background and his **'persistence and determination'** in overcoming family resistance in order to qualify in medicine. He had, it was said, found himself suited to general practice although he **'worried a lot about it and tended to over-identify with patients and their problems'**.

16.125 After Shipman had been treated with anti-depressant medication, there had been, Dr Bryson said, a **'dramatic improvement in his condition'**. He had **'not looked back since that time'**. He had **'very considerable insight into the nature of his illness'**. He had no cravings for pethidine and had not substituted **'any other form of self-medication'**. Dr Bryson observed:

> **'He has approached the problems of his future with great courage, common sense and determination, and I am impressed by the fact that he recognises the potential dangers in the future and is trying to take steps in his professional career to ensure that if he should ever become depressed, he does receive proper medical treatment, and he is also taking steps to ensure that he does not have ready access to drugs of potential danger to him.'**

Dr Bryson regarded the chance of relapse into drug dependence as **'extremely unlikely'** in view of the fact that:

> **'... if he were ever to suffer a recurrence of his illness** (*i.e. depression*) **it would be immediately recognized, and secondly the strength of his basic personality is such that having experienced this series of events, he would have the strength of character and determination to avoid a repetition'**.

Dr Bryson recommended that Shipman should continue under psychiatric supervision, **'even if at infrequent intervals'**, for several years. Arrangements had been made for this, with Shipman's full co-operation.

16.126 Dr Bryson explained to the Inquiry in a witness statement that, having observed Shipman's condition during the period of his withdrawal from pethidine, he had formed the view that Shipman had not been severely addicted. This view also derived support from Shipman's claim that he had been able to abstain from the drug for intervals during the period of his dependency. Even if Dr Bryson had believed that Shipman had been severely addicted,

however, he would not necessarily have regarded him as unfit to practise medicine for all time. His view would have depended on his patient's underlying personality. Dr Bryson said that, had he been dealing with a patient who had been severely addicted and who had a weak personality, he would have considered a relapse highly probable and would have suggested a change of career. Shipman, however, had a strong personality and Dr Bryson did not believe that he had had **'a full-blown addiction'**. As a consequence, Dr Bryson had felt that the possibility of a relapse into drug abuse was low. There was, he had recognised, a risk that this could occur if Shipman were to become depressed again. However, Dr Bryson had felt that Shipman had enough strength of personality, and enough support, to be able to deal with any further depression appropriately, rather than by self-medicating with pethidine.

16.127 Dr Bryson made no mention in his report of the effects of Shipman's drug abuse on his practice. In a witness statement to the Inquiry, Dr Bryson referred to the importance of verifying information given by a drug abusing patient. He observed that, as a group, such patients are secretive and lack insight. However, he said that he did not contact Shipman's former partners as he thought they would have been **'quite guarded'** in what they told him and that, consequently, he was unlikely to glean any useful information. Dr Bryson had considerable experience of treating doctors for addiction. This had led him to believe that former partners of a doctor, if approached, were likely to be concerned about the effect of what they said on the good name of their practice and also to be influenced by a desire not to do anything to make a future in medicine impossible for their former colleague. I infer from that that Dr Bryson believed that information from such a source was unlikely to be reliable.

The Report of Dr Hugo Milne

16.128 In his report, Dr Milne recounted how he had seen Shipman after his initial admission to the Halifax Royal Infirmary, immediately after his drug abuse had been detected. He said that, at this time, Shipman had been **'involved in the abuse of Pethidine to the extent of an addiction'** for about 18 months. Dr Milne had recommended admission to The Retreat. Subsequently, Dr Milne had discussed his case with Dr Bryson and had also seen the discharge summary prepared by Dr Bryson following Shipman's discharge from The Retreat. He had interviewed Shipman and his wife on the day he wrote the report, 26th January 1976.

16.129 Dr Milne said that, when he first interviewed Shipman in September 1975, he had become aware that Shipman had been suffering from a depressive illness for between 18 months and two years. Dr Milne believed that Shipman's pethidine abuse and addiction were a direct result of that depressive illness. He acknowledged that depressive illness was an **'unusual causation for an addiction'** but he had nevertheless been convinced of the accuracy of the diagnosis. The diagnosis had been confirmed by Dr Bryson. Dr Milne noted that, initially, Shipman was reluctant to accept his advice that he should be admitted to The Retreat, suggesting that he was **'not good enough'** to be admitted to such a hospital and wishing instead to be admitted to the acute psychiatric unit. Dr Milne attributed this to **'ideas of unworthiness and guilt'** which were part of his **'depressive psychosis'**.

16.130 As well as the unusual nature of the cause of the addiction, Dr Milne noted that there was another unusual feature. Despite the prolonged period for which he had been abusing pethidine, Shipman had told Dr Milne that he had been able to stop his drug taking in order to take his family on holiday and in order to be fit to drive his car while on duty. In fact, as I have mentioned earlier, it is now clear that, at some time prior to the end of September 1975, Shipman had stopped driving and had thereafter relied on his wife to drive him when he visited patients at their homes. This was probably as a result of the 'blackouts' which he had begun to suffer earlier that year. Mrs Primrose Shipman told the Inquiry that she thought she had been driving her husband around for only a matter of weeks before he ceased to practise in Todmorden at the end of September 1975. It does not appear that Dr Milne was aware of this history; nor was the GMC.

16.131 Dr Milne suggested that conflict between Shipman and his partners at the Abraham Ormerod Medical Centre might possibly have contributed to Shipman's depression which **'in turn released his Pethidene** (*sic*) **addiction'**. This seems to have been speculation on his part. Shipman had joined the practice only in March 1974 and his depression was said by Dr Milne to have been present for about 18 months to two years before the end of September 1975, when he first saw Dr Milne. If Dr Milne's thesis was correct, Shipman's conflict with his partners must have occurred immediately after his arrival in Todmorden since, according to his own account, he had started taking pethidine only five or six weeks later. Given the timescale, it is difficult to see how any problems in the relationship with his partners (even if such problems existed) could have made any significant contribution to Shipman's depression or dependence on pethidine. It is not clear from the report whether Dr Milne appreciated how recently Shipman had entered general practice and how shortly after his arrival at Todmorden he had begun to obtain drugs illegally.

16.132 Dr Milne said that, when he had seen Shipman on 26th January 1976, Shipman had been **'greatly improved'**; there was no longer any evidence of depression and his wife confirmed that he had made a good recovery. Dr Milne reported that, at one stage, Shipman **'did not consider his future within the Medical Profession'**, but both Dr Bryson and Dr Milne had advised him that **'this would not be reasonable'**. Dr Milne said that, when he saw Shipman on the day he wrote his report, Shipman had told him that he had applied for and been offered a job with the Durham AHA. At that stage, he had not informed his prospective employers about his past history. Dr Milne had advised him to do so and Shipman had taken his advice. Meanwhile, Dr Milne had discussed with Dr Michael O'Brien, Area Medical Officer of the Durham AHA, the question of Shipman's suitability for the job he had been offered. It had been agreed that the job offer would remain open, on the understanding that Shipman continued to see Dr Milne for **'the necessary treatment'** in the future. Dr Milne's report suggested that all these events had occurred on one day, 26th January. Although possible, this seems unlikely and it may be that they occurred over a rather longer period than that suggested by his report.

16.133 Dr Milne recommended that the Magistrates' Court should deal with Shipman by means of a conditional discharge with an undertaking to continue his treatment as an outpatient or by means of a probation order with a condition of treatment by Dr Milne. He suggested that a probation order, if imposed, should be for the maximum period of three years. It should be noted that, if Shipman had been dealt with in either of the ways suggested by

Dr Milne, he would not have been the subject of a conviction: see paragraph 16.6. In that event, the police would not have been under a duty to report to the GMC the fact that Shipman had pleaded guilty to offences at the Magistrates' Court, although, as I have said, in practice, they usually did. If the matter had come to the attention of the GMC, the GMC could not have dealt with it as a conviction. It would, however, have been open to the GMC to deal with it as an issue of SPM, had it chosen to do so.

16.134 Dr Milne had observed that there was **'no suggestion'** that Shipman had been **'unable to carry out his duties whilst on call because of the effects of Pethidine'**. In his report, Dr Milne had mentioned his discussions with Shipman and his wife. It seems unlikely that they would have volunteered information about any difficulties Shipman might have had in carrying out his duties. (It does not seem, for example, that they had told Dr Milne that, for some time, Shipman had not been driving as a result of blackouts.) Dr Milne also spoke of discussions with Dr Bryson and Dr O'Brien. Neither of them would have been in a position to know anything about the effects of Shipman's drug abuse on his care of patients. Although it was strictly true, therefore, that there had been no suggestion to Dr Milne that Shipman's patients had suffered as a result of his drug abuse, the reality was that he had not conducted any meaningful enquiry into the matter. It does not seem that Dr Milne spoke to Shipman's partners or to the Calderdale FPC.

Further Evidence

16.135 Enclosed with a letter dated 26th April 1976, which was delivered to the GMC by hand, Hempsons sent a letter from Dr O'Brien, containing information about Shipman's progress in his new job. Dr O'Brien said that Shipman had started work on 2nd February 1976, having obtained the job after interview and in open competition with other doctors. He said that the offer of the job had been made **'subject to satisfactory medical clearance'**. He said that, at that stage, Shipman had had an interview with Dr O'Brien in which he had described his recent difficulties. It is difficult to see how that account fits in with the chronology of events described by Dr Milne but, as I have said, it may be that Dr Milne's account of the timing of events was not completely accurate.

16.136 Dr O'Brien said that Shipman had told him that he had suffered from **'an episode of profound depression'**, during which he had used pethidine. He had discussed with Shipman and his wife the fact that legal proceedings and involvement with the GMC would follow. Shipman was clearly aware of the difficulties that he faced but Dr O'Brien had formed the view that **'he was capable of rehabilitation'**. Dr O'Brien said that he had discussed Shipman's case with both Dr Bryson and Dr Milne, who had confirmed his judgement. He had therefore confirmed the offer of employment on condition that Shipman should continue to have follow-up care from Dr Milne.

16.137 Once Shipman began working for the AHA, Dr O'Brien had had no further professional contact with him but he said that he had kept **'in close touch'** with professional colleagues in the district in which Shipman was working. He understood from them that Shipman had settled well into his new employment and was **'well received by both patients and professional colleagues alike'**. He had received no evidence to suggest any recurrence of **'his former difficulties'**. Dr O'Brien concluded by expressing the hope that the PeCC would be able to reach a judgement which would further Shipman's rehabilitation.

16.138 On 27th April 1976, Hempsons delivered by hand a further letter enclosing a further short report from Dr Milne, dated the previous day. Dr Milne reported that Shipman had seen him on several occasions since his discharge from The Retreat. Shipman was entirely happy in his new job and had shown no evidence of psychiatric abnormality. There was **'no evidence whatsoever'** that he was abusing any form of drug. Dr Milne did not say whether he had carried out any urine tests or inspected Shipman for syringe marks. He concluded:

> **'As far as I am concerned Dr Shipman is extremely well, and it would be to his advantage if he were to be allowed to continue in practice, and conversely it would be catastrophic if he were not to be allowed to continue in practice.**
>
> **I shall continue to see him here regularly.'**

16.139 It should be noted that although, in November 1975, Shipman had told DS McKeating and the Home Office Drugs Branch inspector that he had no intention of returning to general practice or of working in a situation where he could obtain pethidine, the GMC was never aware of this declaration of intent.

The Penal Cases Committee Meeting of 28th April 1976

Preparations for the Meeting

16.140 Shipman's case was considered at a meeting of the PeCC held on 28th April 1976. Mr Gray was present at the meeting, as was Mr Williams. Not surprisingly, by the time of the Inquiry hearings, neither had any personal recollection of Shipman's case. The minutes of the meeting are no longer available so it is not possible to say with certainty which members of the PeCC were present. The Inquiry was, however, able to contact Dr Llewellyn, who was known to have been a member of the PeCC in 1976. He could not recall whether he had been present at the meeting at which Shipman's case was considered. However, very shortly before he was due to give evidence to the Inquiry, Dr Llewellyn discovered in his attic a bundle of papers relating to the meeting. From those papers, it was clear that he had indeed been present, although he still had no positive recollection of it. Dr Llewellyn said that meetings of the PeCC were generally well attended and he would have expected all six members to be present.

16.141 On 28th April 1976, the PeCC was to consider 14 new conviction cases, including that of Shipman. In addition, there would have been some conduct cases and a number of cases which had come back to the PeCC after having been adjourned from a previous meeting. Examination of the minutes of meetings of the PeCC which took place in 1977 and 1978 (those for 1976 are not available) suggests that there could well have been approximately the same number of cases in those two categories as there were new conviction cases. Dr Llewellyn suggested that the bundle of papers for a meeting of the PeCC was usually about eight inches high.

16.142 Papers relating to the meetings of the PeCC were sent to members in several tranches. The first tranche would be despatched to their homes two weeks before the meeting. In Shipman's case, it appears that the first tranche consisted of the original letter from the

WYP, together with the schedule of offences which had been attached to it, and the letter from Mrs Powrie. There would then be a second tranche, containing the papers in cases which had not been included in the first tranche, together with some additional papers in cases which had formed part of the first tranche. In Shipman's case, the additional papers in the second tranche consisted of Hempsons' letter of 21st April and two copies (presumably the duplication was an error) of the report from Dr Bryson. Some material (in Shipman's case, the letter from Dr O'Brien and the second report from Dr Milne) would have arrived at the GMC office too late to be posted to members of the PeCC. These documents would be distributed on the day of the meeting and members would arrive early in order to be able to read the additional material. In Shipman's case, that third tranche of documents also included Dr Milne's first report, which had previously been omitted in error.

16.143 Dr Llewellyn explained that it was his practice, during the time when he had the papers for a meeting, to read them through, sometimes several times. He would annotate the papers with his provisional views as to how each case should be disposed of. In Shipman's case, he had originally written **'D.C.'**, meaning that it was his view that the case should be sent to the DC. He went on to say that, after he had read each successive tranche of papers, he would review his annotations. If his view about a case had changed as a result of the new material he had read, he would amend his annotation accordingly. He had not made any amendment in Shipman's case and concluded, therefore, that he had not changed his provisional view up to the point when he went into the meeting.

The Decision-Making Process

16.144 In the event, contrary to Dr Llewellyn's views as to how Shipman's case should be dealt with, the PeCC decided not to refer the case to the DC. Instead the case was concluded. Dr Llewellyn crossed out his original annotation and wrote beside it the word **'Close'**.

16.145 As I have explained, when Dr Llewellyn provided his first two witness statements to the Inquiry, he was not sure whether he had been at the meeting of the PeCC at which Shipman's case was considered. He said that, if he had been there, he did not remember what his view of Shipman's case had been. In his statements, he appeared supportive of the PeCC's decision to close Shipman's case and advanced various grounds on which the decision could be justified.

16.146 In his statements, Dr Llewellyn said that the task of the PeCC was to determine whether Shipman was fit to continue in practice. (I interpose to point out that such determination should in fact have been for the DC.) Dr Llewellyn explained the thinking behind the PeCC's decision as follows. He noted that the charges were serious, but that Shipman had been convicted and punished for those. No patients were directly involved. He said that the PeCC would have considered that the sentence for Shipman's convictions was adequate and would have gone on to consider his illness, i.e. his drug addiction and moderately severe depression. He mentioned the imminent introduction of the health procedures. Dr Llewellyn pointed out that Dr Milne and Dr Bryson were two eminent consultant psychiatrists. Shipman had been under their care for many months, including three months as an inpatient. They had been impressed by Shipman's efforts to become

rehabilitated. He had acquired a post in preventive medicine where he would not be required to prescribe for patients.

16.147 Dr Llewellyn also observed that the GMC was entitled to expect that the full circumstances of Shipman's drug abuse (including any effect it might have had on patients) would have been ascertained by the Home Office Drugs Branch and by the two psychiatrists who had reported. Nothing untoward had emerged about his clinical performance. Dr Llewellyn said that there was no evidence that Shipman was generally dishonest. He suggested that the sentence of the court for his dishonesty was adequate.

16.148 Dr Llewellyn went on finally to say in his statements that the PeCC would have been aware that the trauma of a referral to the DC would have added to Shipman's stress and, in a depressed patient, could precipitate further depression, even an attempt at suicide. The psychiatrists seemed to have controlled Shipman's addiction and depressive illness. He was continuing to receive outpatient treatment. His new employer was aware of his history and was keeping a close eye on him. He observed that, as **'a solution had been found locally'**, no purpose would have been served by a referral to the DC.

16.149 Once Dr Llewellyn had found the papers for the meeting, he realised, of course, that his provisional view of Shipman's case had been that it should be referred to the DC. In his third witness statement, he referred to the annotation of his papers and said:

> **'This suggests to me that at the Penal Cases Committee's consideration of Shipman's case, I may have been persuaded by my colleagues on the Committee that it was appropriate to close the case in the circumstances; or that during the consensus process my opinion was discounted.'**

16.150 In oral evidence, Dr Llewellyn explained that members of the PeCC held different opinions about doctors who abused drugs. He explained that he regarded the possibility of rehabilitating drug taking doctors to return to the medical profession as 'very slim'. He said:

> **'Yes, there are some alcoholics that are cured, there are some drug addicts who are cured but I personally would always look sideways at them. That may be unfair but that is my personal view.'**

16.151 Although Dr Llewellyn observed at one stage in his oral evidence that his own stance was that people who abused drugs were 'highly untrustworthy', it seems that he was speaking there of the time when the abuse was going on. He said later that he believed that the use of dishonest means to obtain drugs (e.g. by falsifying a prescription) during the period of abuse was 'part of the illness' and did not indicate a general propensity for dishonesty in other respects once the abuse had ceased. Dr Llewellyn said that that was why 'we (*i.e. the PeCC*) ... did not really consider the dishonest aspects, rather the clinical aspects'. However, he said that he would be sceptical about whether the abuser had truly been cured of his/her drug habit.

16.152 Dr Llewellyn said that the message of the reports of both Dr Milne and Dr Bryson had been that the prognosis was good but that there was a need for a period of supervision

lasting several years. He acknowledged that the only way that formal supervision could have been achieved was by sending the case to the DC. The DC had the power, if it chose, to postpone its decision, thereby putting a doctor 'on probation'. He said that, having read Dr O'Brien's letter, his view would have been that the news was encouraging but he would have been suspicious that Shipman might not comply with continued medical supervision by Dr Milne unless he was obliged to do so. He observed:

> **'... the only supervision for a person who is manipulative is one that has teeth; continual reporting to a responsible body who** (*sic*) **would have the mechanism to ensure that he came to them regularly and the power to punish him if he did not'**.

16.153 Obviously, it must have been difficult for Dr Llewellyn to disentangle his current views about Shipman's case (formed with the knowledge of what has happened since) and the views which he held at the time. He acknowledged this frankly and said that there were many positive aspects to the material produced on Shipman's behalf which might have caused him to have some 'thoughts in his favour' at the time. I think Dr Llewellyn's point was that, while it is clear from his annotation that he was in favour of referring Shipman's case to the DC when he went into the meeting, he might not have been as certain at the time that this was the only appropriate course, as his oral evidence about drug taking doctors might have suggested.

16.154 Dr Llewellyn explained that, during the time he was on the PeCC, there was never a vote. The process was one of consensus. Strong personalities gave the lead. Some cases would be dealt with very quickly; in others, there would be argument and, eventually, the Chairman would bring the discussion to a close and identify the view which he believed was held by the Committee or the majority thereof. If there were psychiatrists on the PeCC, they would have had strong views about Shipman's suitability to return to work, views which it would have been difficult for others on the PeCC to rebut. In saying this, Dr Llewellyn echoed the view expressed by Mr Gray in his witness statement, where he referred to the fact that Professor Trethowan, a psychiatrist, was a member of the PeCC. Mr Gray observed that **'he would I am sure have helped the Committee to conclude that the case as presented to them heralded no danger to the public'**.

16.155 The view of Dr Milne and Dr Bryson was that several years of further outpatient supervision was desirable. Dr Llewellyn agreed that, in order for the decision to close the case to have been taken by the PeCC, there must have been members of the Committee whose view was that no steps to compel Shipman's compliance with supervision were necessary. Those members must have been happy to accept that Shipman would undergo such treatment voluntarily. Dr Llewellyn wondered whether, in fact, they had thought that far ahead. He thought that the primary reason why the majority of the PeCC had decided not to refer Shipman's case to the DC was that they had felt that they could trust him.

16.156 It is hard to understand why, in the light of the recommendation for continued supervision contained in both psychiatric reports, the PeCC decided to close Shipman's case with a warning. Dr Bryson, despite his view that Shipman had a strong personality

and was facing the future with common sense and determination, thought that continued supervision was important. Dr Milne had recommended to the Magistrates' Court that it should take a course (by imposing either a conditional discharge or a probation order) that would entail either an undertaking, or an actual requirement, to continue treatment with Dr Milne. This suggestion had been rejected by the Court. It may be that the PeCC took the view that the Magistrates had concluded that supervision was not necessary. If so, that might well have been a misunderstanding on its part, as it is entirely likely that the Magistrates wished to impose some punishment on Shipman and to recoup the loss he had caused to the public funds. A fine and compensation order could not be combined with a probation order. In the light of the recommendation in the medical reports for continued supervision, it seems to me that, if the PeCC had wished to promote the rehabilitation of the doctor and to provide some protection for patients, the proper course would have been to refer the case to the DC. That Committee could have used its powers of postponement if, on learning more of the facts of the case, it had thought it appropriate to do so.

Observations on the Decision-Making Process

16.157 Dr Llewellyn's evidence cast useful light on the decision-making process of the PeCC. First, it appears that the PeCC regarded itself as having the function of deciding whether the doctor was fit to practise. I have already observed that that was the function of the DC and have expressed my concern that the PeCC did not confine itself to its filtering role but made substantive decisions in quite serious cases. When asked whether the PeCC should have confined itself to filtering cases, Dr Llewellyn said that that was 'valid thinking' and added that 'everybody had their own views on that'. I infer from that that there were differing views about whether the practice of the PeCC in going beyond its filtering role was appropriate. Yet it appears that there was no official discussion about the issue, nor any guidance as to the kind of case which it would or would not be appropriate to refer to the DC. It is apparent from other parts of Dr Llewellyn's evidence quoted above that members relied upon their own personal views and did not rely on sound professional judgement based on evidence. For example, I have in mind Dr Llewellyn's personal views about the prospects of rehabilitation of a doctor addicted to drugs. It appears that others must have had different views. Some views might be based upon medical scientific evidence and others not. It does not seem to me to be satisfactory to allow decisions to be taken on the basis of differing personal views of this kind, any of which might prevail in a particular case.

After the Penal Cases Committee Meeting

The Letter to Shipman

16.158 After the meeting, Mr Williams prepared a memorandum for the attention of Mr Gray. This recorded that the PeCC had determined that Shipman's case could be concluded. He continued:

> **'Later in the proceedings it became evident that the Committee wished letters sent to those practitioners whose cases were concluded to contain some admonitory element.'**

Mr Williams had drafted a letter to be sent to Shipman for approval by Mr Gray. Mr Gray made some revisions to the draft and sent it on for approval by the Registrar, Mr Draper. On 6th May 1976, Mr Draper wrote to Shipman. After rehearsing details of the information considered by the PeCC, the letter went on:

> **'The Committee instructed me to inform you that they take a grave view of offences arising out of an abuse of drugs and of offences involving dishonesty and to draw your attention to sections (iii) and (vii) on page 9 of the enclosed pamphlet. You would therefore be wise to assume that, if information relating to any further conviction of a similar nature should be received by the Council a charge would then be formulated against you on the basis of both the earlier and the later convictions and referred to the Disciplinary Committee of the Council for inquiry.'**

The **'enclosed pamphlet'** was the January 1976 edition of the Blue Book. The relevant sections were those quoted at paragraph 16.34.

16.159 Mr Gray said that the **'admonitory element'** of the letter to Shipman was the threat of a public inquiry by the DC if Shipman re-offended. Both Mr Gray and Mr Williams observed that, judged by the standards of the time, the letter sent to Shipman was in 'very strong terms'. The letter concluded by requesting a personal acknowledgement of receipt. Mr Gray explained that, if a doctor failed within six months to respond to a letter sent from the GMC by recorded delivery, his/her name could be erased from the register. This was (and, indeed, remains) a necessary power as it prevents a doctor from attempting to avoid disciplinary action by failing to respond to communications from the GMC. Shipman acknowledged the letter promptly and indicated that he understood its implications.

Communication with the Home Office

16.160 By a letter dated 3rd May 1976, Mr Williams informed Mrs Powrie, of the Home Office Drugs Branch, of the decision taken by the PeCC in Shipman's case. He said:

> **'In all the circumstances, and particularly in the light of a number of reports received on the practitioner's condition, the Committee determined that it would be sufficient to conclude the case.'**

No mention was made of the fact that a warning letter had been sent to Shipman, since that was regarded as a private matter between the GMC and the doctor and was not disclosed to persons or bodies outside the GMC.

16.161 The original letter from the Home Office Drugs Branch had asked for the **'view taken'** by the PeCC, not for its decision. I do not understand this to mean that the Home Office Drugs Branch wished to know what view the PeCC took about the need for a section 12 direction, only what the PeCC itself had decided to do. Mr Williams' letter expressed no opinion about the appropriateness of a section 12 direction. In evidence, Mr Gray said that the 1956 Act did not require the GMC to be a party to action by the Home Office to restrict a doctor's rights in relation to controlled drugs. He said that Mr Williams' letter had informed the Home Office Drugs Branch what the PeCC had done with the case, which was what had been requested. Mr Gray did not think that the PeCC would have expressed any view

about the possibility of restricting Shipman's rights, although it seems to me likely that the Home Office Drugs Branch would infer, from its decision to close the case, that the PeCC did not think that it was necessary to restrict Shipman's prescribing rights. At the time, the GMC itself had no power to impose any such restriction. The only way the GMC could stop a doctor from prescribing a particular type of drug was by the DC suspending his/her registration or erasing his/her name from the register. Mr Gray did not recall any attempt by the GMC to plug that gap in its powers by encouraging the Home Office to use the power which the Home Secretary possessed to make a section 12 direction.

16.162 By a letter dated 9th July 1976, Mrs Powrie informed Mr Williams that the Home Office was not proposing to take any action in the case. As I have explained in my Fourth Report, shortly before this time, the Home Office had adopted a new policy whereby section 12 directions were considered appropriate only in cases where the doctor's breach of the MDA 1971 entailed conduct which put the public at risk of harm. In effect, from about May or June 1976 onwards, section 12 directions were made only in cases where the doctor had supplied controlled drugs to addicts or had in some way caused the release of controlled drugs onto the 'black market'. Directions were not made in cases where the doctor had been taking the drugs him/herself. The Home Office was unable to explain to the Inquiry the reason for this change of policy. It is possible that the change of policy came about as the result of the publication of the Merrison Report, with its emphasis on treating drug abusing doctors as 'health cases' requiring rehabilitation. If the Report was understood to suggest that doctors who self-administered drugs were not a risk to patients, that would have been an error. The Merrison Report recommended that the powers of the GMC should be extended so that it could protect patients by imposing conditions and restrictions on a drug abusing doctor while s/he was undergoing rehabilitation. It did not suggest that patients were not at risk from such doctors.

The Effect of the Decision of the Penal Cases Committee

16.163 The effect of the decision of the PeCC was that Shipman was free to practise medicine in any field appropriate to his skills. He was able to prescribe controlled drugs in just the same way as any other doctor and without any special 'watch' being kept on his prescribing. Most importantly, he was free to return to general practice as soon as a suitable post presented itself.

16.164 Shipman was under no compulsion to continue with outpatient supervision. It is not known if he did so or for how long. Dr Milne's records are no longer available. Dr Geoffrey Roberts, a former member of the Donneybrook practice, told the Inquiry that he spoke to a psychiatrist (he was not sure whether it was Dr Bryson or Dr Milne) about Shipman's application to join the practice. That would have been in the latter half of 1977, probably August or September. His recollection was that he had been told that Shipman had had an addiction problem, that he had been treated for depression but that he had by then finished his treatment. If Dr Roberts' recollection is correct, it appears that Shipman was no longer under supervision at that time. Certainly the Inquiry has been unable to obtain any medical records that confirm the continuance of any treatment.

The Decision Not to Refer Shipman's Case to the Disciplinary Committee

16.165 The GMC submitted to the Inquiry that the decision in Shipman's case was reasonable and justifiable when judged against the practice and the standards of the time. It said that the PeCC had all the material it needed to make an informed decision. The psychiatric evidence showed that Shipman had recovered well and that the prognosis was excellent. Shipman had a job in which he would have no need to prescribe or use controlled drugs. The GMC suggested, therefore, that no useful purpose would have been served by referring the case to the DC.

16.166 The GMC also submitted that, even if the case had been referred to the DC, erasure would not have been considered appropriate. The likely outcome would have been an admonishment or postponement of judgement. The GMC said that, if the DC had postponed judgement, it is likely that the case would have been concluded within a year or so.

16.167 On the face of it, perhaps the most surprising feature of the GMC's handling of Shipman's case is that it was not referred to the DC. This seems to suggest that the case was not regarded as 'serious enough' to warrant referral although, as I have shown, other issues besides seriousness were taken into account by the PeCC when deciding whether a case should be referred. The availability of psychiatric reports and the content of those reports seem to have played a determinative role in the decision not to refer Shipman's case.

16.168 It is instructive to consider what would have happened if Shipman's case had been referred to the DC. Is it right, as the GMC suggests, that, even if the case had been referred, the outcome would have been much the same? To some extent this is speculative because the evidence available to the DC would probably have been different from that considered by the PeCC. DS McKeating might have given evidence throwing a more serious light on Shipman's conduct. Shipman might have given evidence, either to refute, qualify or explain some aspect of DS McKeating's evidence, or to underline some aspect of the psychiatric opinions. It is quite possible that, with the benefit of that additional evidence, the members of the DC would have formed a less favourable opinion of Shipman than did the PeCC.

16.169 Mr Gray was of the view that, if the case had been referred to the DC, the result would have been the postponement of a decision. As I have explained, postponement of a case by the DC generally appears to have led eventually to closure of the case with or without a reprimand. Mr Gray observed that it was 'fortunate' for Shipman that Mr Draper had decided that Shipman should be invited to provide a medical report. Had that invitation not been issued or accepted, Mr Gray believed that, on the basis of what had happened in other similar cases, the PeCC either would have adjourned the case for him to do so or would have referred the case on to the DC. If the case had been referred to the DC, the overwhelming likelihood is that the same medical evidence as was before the PeCC would have been collected by Shipman's solicitors and sent to the GMC before the meeting of the DC. The outcome would have been postponement. In effect, Mr Gray was saying that Shipman was fortunate because, if he had not received the invitation to submit a medical report, he would have had to undergo the increased trauma of a public appearance; yet the eventual outcome would have been similar.

16.170 In his witness statement, Mr Williams said that Shipman's was the sort of case that would generally have been referred to the DC. He thought that one reason it might not have been referred was the existence of favourable psychiatric reports. He believed that this must have been a **'borderline'** case. He found it difficult to say what might have happened had the matter been referred to the DC. He said that he was not always able to predict the decisions of the DC. He guessed that Shipman's registration might have been suspended but emphasised that this was simply a guess.

16.171 Statistics provided for the Inquiry by Professor Isobel Allen, Emeritus Professor of Health and Social Policy, University of Westminster Policy Studies Institute, and my own examination of drug-related cases dealt with by the DC in the late 1970s, suggest that it is extremely unlikely that Shipman would have been erased from the register. Suspension would have been a possibility but the cases examined suggest that it too would have been unlikely.

16.172 It seems to me that, to some extent, the outcome before the DC might well have depended upon the extent of any further investigation. If there had been little or no further investigation, the most likely outcome before the DC would have been very similar to what actually happened at the PeCC, namely closure with a reprimand. I have said that, if more evidence had been available, the DC might have taken a more serious view of Shipman's conduct than did the PeCC and might have formed a less favourable view of his rehabilitation and prognosis. In that event, I think the likely outcome would have been postponement for a period of 'probation'. As I have little doubt that Shipman would have behaved himself well while under observation, I agree with the GMC that it is likely that the case would have been concluded within a year or two at most.

Possible Criticisms of the General Medical Council's Handling of Shipman's Case

16.173 In examining the GMC procedures of 1976, I must be careful to avoid the benefit of hindsight and the knowledge that Shipman was to become a mass murderer. I shall consider his case as one of a drug abusing doctor about whom no later information is available.

The Failure by the General Medical Council to Erase Shipman's Name from the Medical Register

16.174 I have already observed that, when the fact of Shipman's previous convictions for drug offences became known, many people expressed the view that the GMC should have erased his name from the medical register in 1976. The combination of Shipman's abuse of controlled drugs over many months and his dishonesty in acquiring the drugs should, it was said, have made it clear that he was unfit to practise. There were expressions of shock and surprise in the media and elsewhere that Shipman's medical career should instead have been permitted to continue virtually without interruption.

16.175 In preparation for this part of the Inquiry, Alexander Harris, the solicitors representing the Tameside Families Support Group, circulated a questionnaire to those families and

friends of Shipman's victims for whom they act. The questionnaire sought views on, *inter alia*, the GMC's handling of Shipman's case in 1976 and the way in which doctors convicted of drugs offences should generally be dealt with. The majority of those responding to the questionnaire believed that doctors in Shipman's position should not be permitted to continue in practice. Several made the point that, since doctors inevitably have access to drugs, it is inappropriate for a doctor who has abused drugs in the past to continue in practice. Miss Suzanne Brock, the granddaughter of Mrs Edith Brock, held this view. She gave oral evidence to the Inquiry. She said that she considered that the GMC should have permanently erased Shipman's name from the register in 1976 because of the continuing temptation to abuse controlled drugs that he would inevitably face if he remained in practice.

16.176 It does not appear to be generally known that there is a substantial number of doctors practising in the UK today who have, in the past, been addicted to drugs and who have committed drug-related criminal offences. The way in which Shipman's case was handled was in many ways typical of the way in which most such cases have been dealt with over the past 25 or 30 years. In 1978, Parliament, acting on the recommendations of the Merrison Committee, effected the creation of the GMC health procedures. Since then, it has been official policy that, whenever possible, doctors who have become addicted to, or dependent on, drugs should be permitted to return to practice once rehabilitated. Such doctors have frequently resorted to dishonest means in order to obtain supplies of their chosen drug. Inevitably, therefore, many have convictions for criminal offences involving not only the unlawful obtaining or possession of drugs but also dishonesty. There has never been any suggestion that they should be treated differently from those who have no such convictions. As a result, they have been, in general, treated as 'health cases' and dealt with by way of the GMC's health procedures, which, in accordance with the recommendations of the Merrison Committee, do not involve the possible sanction of erasure.

16.177 It may be that the need to have a sufficient number of doctors available to staff the NHS was a factor behind the policy adopted by Parliament in 1978. It may also be that it was recognised that the practice of medicine can be a stressful occupation and that, because of a doctor's ready access to drugs, it gives rise to unusual temptations to abuse them. Presumably, when it passed the Medical Act 1978, Parliament was satisfied that many drug abusing doctors could be successfully rehabilitated and returned to practice without significant risk to patients. Whatever the underlying considerations, Parliament acted upon the recommendations of the Merrison Report in 1978 and the GMC's health procedures came into effect in 1980. In 1976, it must have been evident that this would happen soon.

16.178 Despite the policy which has been in place for over 25 years, it seems that it is by no means universally accepted that drug abusing doctors are capable of rehabilitation and can go on to lead useful and valuable professional lives. The real problem is that there is a gap between the public perception of official policy and the reality. In my view, the public must be made aware that it has been the policy of the GMC to encourage and assist drug abusing doctors to rehabilitate and to return to unrestricted practice. The public must also be made aware that this policy has been endorsed by Parliament. If there is real and

widespread concern about this policy – as seems to me likely – it must be brought into the open for public discussion and possible change. It may well be that, after examination of all the relevant evidence, the outcome of such a public debate would be the confirmation of current policy, with proper emphasis on patient protection during rehabilitation. It may also be that such debate would result in a general call for patients to be made aware of their doctor's past history of drug abuse, so that they can make an informed choice as to whether they wish to be treated by him/her. I shall say more about these matters later in this Report.

The Failure of the General Medical Council to Suspend Shipman

16.179 The Inquiry is aware that some people took the view that, although it would have been unduly severe to erase Shipman's name from the medical register, his registration should have been suspended until it was clear that it was safe for him to practise. Suspension was a sanction available to the GMC at the time. However, suspension was regarded as a punitive sanction rather than a rehabilitative one. I can understand why that was so, although I personally think that suspension need not necessarily be inconsistent with rehabilitation, provided that it is made plain to the doctor what is expected of him/her during the period of suspension. Depending on the nature of the doctor's problem, that might be an intensive period of psychiatric treatment or, if appropriate, re-education in some field of medicine. However, Shipman had already undergone intensive psychiatric treatment. Moreover, at the time when his case was considered, he was practising in a field of medicine in which he was exposed to far less temptation to abuse drugs than while in general practice. I can understand why the GMC, which took a rehabilitative approach to cases such as his, should have regarded suspension as inappropriate.

The Failure by the General Medical Council to Place Conditions on Shipman's Registration

16.180 Many of the families and friends of Shipman's victims believed that, even if Shipman's name had not been permanently erased from the register, his continued registration should have been subject to stringent conditions and he should have been closely monitored. Some said that such safeguards should have remained in place throughout the time he remained in practice. It was suggested that monitoring in cases such as his should have included random blood tests and regular medical examinations to check for other signs of a return to drug abuse. In addition, there should have been periodic inspections of prescriptions, medical records and other aspects of the doctor's clinical practice. Suggested conditions on registration included prohibitions on prescribing or administering controlled drugs and on single-handed practice, together with requirements that the doctor should work only under close supervision or in a setting other than general practice. The Inquiry heard oral evidence from Mrs Theresa Deeley, the daughter of Mrs Edna Llewellyn, who felt that the GMC should have continued to monitor Shipman throughout his career after he had been allowed to return to practice. She said that, because of his past history of drug convictions, he should not have been allowed to work as a single-handed practitioner at any stage of his career. This view was shared by Mrs Sally Freeman, the daughter of Mrs Margaret Waldron, who added that Shipman should have been denied access to controlled drugs for the remainder of his career.

16.181 Other responses to the Alexander Harris questionnaire suggested that conditions on practice might have been imposed for lesser periods, ranging from two to ten years. Mrs Sheila Caldecott, the daughter of Mrs Angela Tierney, told the Inquiry that, if Shipman's addiction had been caused by work-related stress, the GMC should have given serious consideration as to whether it was appropriate to allow him to return to general practice where he would have access to controlled drugs. She thought that Shipman should not have been allowed to continue in general practice but should instead have been confined to administrative or teaching posts without access to controlled drugs. She considered that a doctor such as Shipman might be allowed to return to general practice if, after a period of time, s/he could show that s/he had been successfully rehabilitated.

16.182 In fact, as I have explained, the GMC had no power in 1976 to impose conditions on Shipman's registration, nor to undertake any monitoring of his progress or practice. The DC was able to exercise a limited degree of influence over a doctor by postponing judgement and I have already suggested that it could have done far more by seeking undertakings from doctors to cover the period of postponement of its judgement. However, even if such undertakings had been required and given, they would have been restricted in time to the period of postponement and could not have been kept in place for more than a year or two at the most. Short of erasing Shipman's name from the register, the DC had no means of exercising any long-term control over him or his practice.

Collection and Verification of Evidence

16.183 It should, I hope, be apparent, from the cases I described earlier, that the way in which Shipman's case was handled was not in any way exceptional for the time. The underlying approach to cases of drug addiction was to take such action as would encourage the doctor's rehabilitation, provided that this created no obvious and immediate risk to patient safety. However, no enquiries were directed at discovering whether such a risk existed. If Shipman's case appears to have been dealt with more 'leniently' than others of similar gravity, that is explained by the supportive content of the psychiatric reports and the report from his new employer.

16.184 Very little evidence about Shipman's offences was collected before the case was put before the PeCC. Ideally, a committee making any decision on a case should have had a full picture of the facts. If a filtering decision only was to be made, it might have been reasonable to act on the basis of limited information, provided that there were clear guidelines about the type and gravity of case to be referred and that, where any doubt existed, it was resolved in favour of referring the case on to the next stage. However, if the PeCC were to be permitted to make a final decision on a case, other than one in which it was clear that no form of disciplinary action was appropriate, it needed a full picture of the facts. The justification for making so few enquiries about the circumstances of the case was that, if the case went to the DC, further enquiries would be made. However, the converse was that, if the PeCC decided to handle the case itself, no further enquiries would be made and conclusions would be reached on the basis of quite scanty information.

16.185 In Shipman's case, no attempt was made to discover whether or not his addiction to pethidine had had any impact upon the clinical care of his patients. Also, when information

was received from Shipman's solicitors, it was taken on trust. I am not, of course, suggesting that the solicitors would have misrepresented their instructions but, as any judge or magistrate knows, matters advanced in mitigation by lawyers on instructions from a client must be subjected to some critical scrutiny. The PeCC did not even have Shipman there to ask him or his representatives any questions. Shipman was able to claim through his solicitors that he had begun taking pethidine following a back injury. This was not checked, despite the fact that he had not mentioned it to either psychiatrist. He also attributed the start of his 'addiction' to depression caused by being unsuited to general practice. He was never asked about this, nor did anyone seem to notice that his depression must have begun or worsened within a matter of weeks of his entry into general practice. He started working in Todmorden in March 1974 and he began obtaining pethidine within about six weeks.

16.186 The GMC has submitted that it would have been a disproportionate use of its resources to embark upon a full investigation of Shipman's case. His case appeared to be quite unexceptional. That I accept and it would follow that, if Shipman's case should have been more closely investigated, so should many others. However, to say that thorough investigation would not be justified seems to put a limit on the value of patient safety. The underlying principle was supposed to be that, in a drug addiction case, the GMC would adopt a rehabilitative course provided that there was no reason to believe that patients would be put at risk. I do not think that that precondition could be satisfied without a reasonably thorough investigation of the background facts and without some independent check on matters being advanced in mitigation. At the very least, there should have been enquiries made of the police officer in charge of the case, of Shipman's partners and of the Calderdale FPC. The fact that such enquiries were not made suggests to me that the safety of patients was not the paramount consideration in this case or in other cases of this kind. The paramount consideration was the doctor's rehabilitation, contrary to what the GMC claimed at the time.

Reliance on Psychiatrists Selected by the Doctor

16.187 It is clear that, in cases of drug addiction, the GMC placed very considerable reliance on psychiatric reports. It was plainly right that it should do so, although, in my view, such reports should have been considered by the DC, in the context of full information about the case, and not by the PeCC. In general, and in Shipman's case, these reports were provided by psychiatrists who had treated the doctor concerned. It does not appear that it occurred to anyone in the GMC to question the factual basis of such a report or the validity of the opinions expressed in it. However, uncritical reliance on any expert report is unwise. Some reports are much better than others. Some psychiatrists (and other expert witnesses) are more 'independent' and impartial than others. Indeed, I know from my own experience both at the Bar and on the Bench that, until recent years, many expert witnesses did not recognise it to be their primary duty to give an impartial opinion to the court – or, in this case, to the GMC. It was felt that, provided that the court – or the GMC – was not actually misled, the expert was free to put forward the best possible case for his/her client/patient. I think that, in later years, the GMC recognised this problem and, as I shall explain in Chapter 22, it became the practice of the health screeners to instruct independent psychiatrists to report to the GMC.

16.188 In Shipman's case (and in others that I examined), the GMC accepted reports that had been commissioned primarily for use in the criminal courts. In such circumstances, there must have been a temptation for the psychiatrist to say what s/he could that was favourable to the patient/client. I do not suggest that either Dr Milne or Dr Bryson was biased towards Shipman. However, it appears from the reports that both psychiatrists accepted Shipman's account of events, without any real attempt to verify the facts. It is true that both psychiatrists had met and spoken to Mrs Shipman but it is unlikely that she would have provided an account substantially at variance with her husband's, given the purpose to which the reports were to be put. It does not appear, on the face of the reports, that the psychiatrists had spoken to anyone else about the history. I say that not as a matter of criticism. My own experience suggests that it would not have been usual to do so in the 1970s, whereas today it would be. Nor does it appear, on the face of the reports, that Dr Milne carried out any objective test of Shipman's assertion that he had given up pethidine. He may have conducted a test but, if he did, one might have expected it to be mentioned. Even if he did not, I am not critical of Dr Milne. Objective tests, such as urine tests, although available in the 1970s, were much less used then than now. Today, it would be most unusual for a psychiatrist to accept the word of a patient that s/he had given up a drug; it would be usual practice to carry out objective tests at times when the patient was not expecting to be tested.

16.189 It seems to me that, in the 1970s, the GMC accepted psychiatric reports, not only as opinion evidence, but also as a reliable statement of the facts recited. It appears to have assumed that the psychiatrist would have carried out any verification necessary. The extent to which this reliance was well placed must have been variable. In my view, a rather more sceptical approach would have been preferable, particularly in cases involving drug abusers, who are known often to be deceitful and whose cases might well have involved a degree of dishonesty. It is, of course, common practice for courts of law to receive and rely upon information in psychiatric reports. However, it is usual practice in the courts for a judge to scrutinise the factual basis upon which the expert opinion is based to see whether it is consistent with other sources of information. It seems to me that the GMC did not attempt such scrutiny. This may have been because the GMC dealt only with doctors and made the assumption (sometimes erroneously) that all were essentially honest. The courts, on the other hand, deal with all manner of people, many of whom are dishonest. It would have been possible for the GMC to investigate the truth of some of the facts asserted by Shipman and, no doubt, by other doctors in other cases. It would also have been possible for the GMC to write to reporting psychiatrists to invite them to cover various specific matters, to check the veracity of doctors' assertions where practicable and to use random urine tests before reporting that a doctor was drug-free. It would also have been possible for the GMC to remind reporting psychiatrists of the purpose for which their reports were required and to warn them that their opinions might be relied on when taking decisions affecting the safety of patients and the public. Of course, this would all have taken time and cost money. Once again, the GMC's willingness to act on material that had not been subjected to proper scrutiny suggests that public protection was not paramount.

16.190 Having said all that, I accept without reservation that the psychiatrists on whose reports the PeCC based its decision were essentially right in their prognosis that Shipman was unlikely to relapse into the habit of drug abuse. There is no evidence that he ever did so.

The General Medical Council's Approach to Dishonesty

16.191 One of the assumptions underlying the GMC's treatment of cases involving drug abuse was the theory that the dishonesty which often accompanies the unlawful procurement of controlled drugs is not a personal characteristic but represents a temporary departure from the doctor's usual high standard of probity. It is an almost inevitable accompaniment to the drug abuse. The assumption is that, as soon as the overpowering need to obtain the drug has been conquered, any danger of further dishonest conduct will automatically disappear. This theory was lucidly explained by Dr Douglas Fowlie, who has been a consultant psychiatrist for many years. He said:

> **'Dishonesty in the context of an escalating drug or alcohol dependence is different to dishonesty in the absence of a dependence on drugs or alcohol. Dishonesty in the context of an escalating dependence is not something that is the focus from the psychiatric perspective. Almost inevitably, an element of dishonesty will arise where a person has a dependence on a substance ...**
>
> **It is important to be aware, when one is considering dishonesty in the presence of an escalating dependence, that one of the facets of an illness of dependence is a selectively distorted perception of one's own behaviour. As a dependence escalates, the priority of the individual is obtaining the next fix of the drink or the drug. This is the overwhelming priority and other factors external to this diminish in their importance. When the perceptions become distorted, a lack of insight develops, and the illness can cause a distortion of what the previously non-dependent individual regarded as right and wrong. One of the features of a mental illness of dependence can be dishonesty. It would not be fair to say that a person who has a dependence on drugs or alcohol and engages in dishonest conduct as a result of that dependence is someone who should, as a matter of course, be regarded as a person with a propensity to dishonesty in the absence of such a dependence.'**

16.192 That theory is not shared by everyone from whom the Inquiry heard. I shall discuss its validity with regard to drug abusing doctors in Chapter 23. However, I accept that the theory explained by Dr Fowlie was widely accepted within the GMC in the 1970s and the way in which the GMC dealt with Shipman's case must be seen in that light. I remain concerned that, in Shipman's case, the theory was applied without detailed consideration of whether it was appropriate to do so in the individual case. If dishonesty is to be explained (and excused) by the compulsion to obtain drugs which results from the doctor's addiction, it must surely be important to consider whether s/he really is addicted. If s/he is not really addicted and if s/he is able to give up drug taking at will, the doctor is surely not subject to the degree of compulsion which will excuse his/her dishonesty.

16.193 According to both the psychiatrists who reported on Shipman, his drug taking habit had not yet reached the stage of real dependence; he was able to give up taking the drug for periods: for example when on holiday. Notwithstanding that, the assumption seems to have been made by the PeCC that Shipman's dishonesty was all 'a part of the illness'. Here

again, the PeCC's thinking seems to have been focussed, not on patient protection, but on the welfare of the doctor.

Conclusions

16.194 I am satisfied that the GMC conducted Shipman's case in a way that was typical of its conduct of such cases at that time. I have drawn attention to several respects in which the procedures and underlying assumptions of the day are to be criticised.

16.195 My main criticism is that the GMC failed to give adequate protection to the public when dealing with the cases of doctors who had been convicted of offences arising out of an addiction to controlled drugs. It is clear that its approach laid greater emphasis on the interests of the doctor than on ensuring the safety of patients. I recognise that, in the years between the publication of the Merrison Report and the introduction of the health procedures in 1980, the GMC was in a difficult position. The need for the health procedures was recognised but they did not yet exist. It is not surprising therefore that the PeCC and the DC tried to fill the gap by the use of their powers to adjourn or postpone. As Mr Howes put it, they were 'playing at being a Health Committee'. It seems to me that the problem was that they did not manage to strike the right balance. The Merrison Committee had proposed health procedures whereby patients could be protected at the same time as the doctor was rehabilitated. That was to be achieved by placing conditions and restrictions upon the doctor's practice and by requiring him/her to accept supervision. Like the Merrison Committee, the GMC considered that health issues should be dealt with in private. In the period between 1975 and 1980, the PeCC took upon itself the right to deal with cases in private rather than send them to the DC for public hearing. It did so because that was in the doctor's best interests. Also, both the PeCC and the DC appear to have been determined to provide an opportunity for rehabilitation, even though they were not in a position to provide adequate protection for the public by imposing conditions, restrictions and/or supervision. In fact, in my view, they could have done far more than they did to protect the public by giving a doctor the option of accepting conditions, restrictions and/or supervision with suspension or erasure as the alternative. That was not done. The result was that the GMC gave too much weight to the interest of the doctor in rehabilitation and too little to the need of the public to be protected from a doctor who had not yet been shown to have recovered from the addiction or dependence that had led him/her into criminal conduct.

16.196 My second major criticism is that the GMC made so little attempt to investigate the background to Shipman's case and others like it. In my view, a case such as Shipman's should have been regarded as giving rise to the potential for risk to patients. The background should have been investigated with that in mind. The Merrison Report had suggested the creation of an investigating unit within the GMC. The GMC does not appear to have recognised the wisdom of that suggestion and did not undertake investigations, save in the small minority of cases that had to be prepared for a full disciplinary hearing. Instead of investigating, the GMC invited observations from the doctor and the opinions of experts and did nothing to question, scrutinise or check the assertions made on Shipman's behalf.

16.197 I also consider that, in the period before the introduction of health procedures, a case such as Shipman's should always have been referred to the DC. The PeCC did not have a full picture and should have been making decisions only on a broad brush basis. It should not have been making detailed assessments of psychiatric evidence. Those were functions properly assigned to the DC, which had a smaller caseload to consider at any one meeting, and fuller information before it. The DC also had the opportunity to see, and sometimes to hear, the doctor. The DC should always have given careful scrutiny to the content of psychiatric reports and should have looked critically at the accounts of events there recorded. These would underlie the expert opinion and, if inaccurate, would invalidate it. The GMC should have appreciated the need to obtain reports from psychiatrists independent of the doctor and should have laid down requirements as to the content of such reports.

16.198 I recognise that, even if Shipman's case had been handled as I think it should have been, it is unlikely that the outcome would have been very different from the actual outcome. I accept that Shipman's registration would probably not have been suspended and that his name would certainly not have been erased from the medical register. He would probably have been put 'on probation' for a few years at most.

16.199 I do not criticise the GMC for its decision not to suspend Shipman or to erase his name from the medical register. First, it was the GMC's practice to deal with drug abusing doctors by helping them towards rehabilitation. It had not been publicly criticised for that. Members of the public were probably hardly aware of the prevailing policy; if they had been it is by no means clear that it would have been criticised. Far from being criticised, it appears that the Government of the day accepted the philosophy underlying the Merrison Report and its recommendations for the creation of health procedures. The philosophy was that sick doctors, including those who abused drugs, must be helped towards rehabilitation in a way that provided adequate protection for patients. That did not imply that the GMC's existing rehabilitative approach was wrong in principle.

16.200 Nor, in my view, can the GMC be criticised for failing to foresee that Shipman's foray into the abuse of pethidine might be the forerunner of something far more serious. In short, I reject any suggestion that, even if the GMC procedures had been satisfactory, they could have prevented Shipman's later criminality and saved many lives. It is possible that a period of 'probation' might have delayed the resumption of his illegal use of drugs on patients and might have saved the lives of one or two of his victims. I am quite satisfied, however, that 'probation' and the limited medical supervision that would have accompanied it would not have had any profound effect upon his future conduct.

CHAPTER SEVENTEEN

Serious Professional Misconduct and Seriously Deficient Performance: Problems of Definition

Introduction

17.1 In Chapter 15, I explained that the General Medical Council (GMC) conduct or disciplinary procedures were, for many years, founded on the issue of whether the doctor concerned had been guilty of serious professional misconduct (SPM). The meaning of that phrase had been defined in general terms from time to time. However, the Inquiry was told that opinions about what types of conduct amounted to SPM varied considerably and that the debate between eminent members of the medical profession as to whether the conduct of a doctor in a particular case amounted to SPM could become both heated and emotional. As SPM was the basis of the conduct procedures, it is apparent that, if views about what amounted to SPM differed, then the standards that were applied by the GMC must have been inconsistent and its decisions unfair to some doctors. The corollary of that unfairness is that some decisions on misconduct must have been too lenient and may have failed to provide adequate protection for patients and the public. It is of vital importance that any disciplinary process should be based upon standards that can be applied consistently in all cases.

17.2 The GMC performance procedures, which were introduced in 1997, were founded on the issue of whether the professional performance of the doctor in question had been 'seriously deficient'. Although the history of cases under the performance procedures was much shorter than that of cases under the conduct procedures, it appears that there were difficulties with the definition and recognition of seriously deficient performance (SDP), as there were with SPM. The absence of any clear definition of, and standards for, SDP gave rise to the same problems as I outlined above. These problems were of such importance that I propose to devote this Chapter to a discussion of them and their histories.

17.3 I shall not discuss the concept of serious impairment of fitness to practise by reason of a physical or mental condition, which was the foundation of the GMC health procedures, as this does not appear to have given rise to similar difficulties.

Serious Professional Misconduct

'Infamous Conduct in a Professional Respect'

17.4 The term **'serious professional misconduct'** was substituted by the Medical Act 1969 for the phrase **'infamous conduct in a professional respect'**, which had appeared in the previous legislation.

17.5 In 1894, **'infamous conduct in a professional respect'** had been defined by Lord Justice Lopes in Allinson v General Council of Medical Education and Registration[1] in the following terms:

[1] [1894] 1 QB 750.

> **'If a medical man in the pursuit of his profession has done something with regard to it which will be reasonably regarded as disgraceful or dishonourable by his professional brethren of good repute and competency, then it is open to the General Medical Council, if that be shown, to say that he has been guilty of infamous conduct in a professional respect.'**

17.6 In 1930, Lord Justice Scrutton stated in R v General Council of Medical Education and Registration of the United Kingdom[2] that:

> **'... ''infamous conduct'' ... means no more than serious misconduct judged according to the rules written or unwritten governing the profession'**.

The Blue Book

17.7 For many years, ending in 1993, the GMC provided to all doctors on the medical register a guide to its functions, procedures and disciplinary jurisdiction. This guide was known as the 'Blue Book'. It described the more common types of misconduct which had in the past been regarded as grounds for disciplinary proceedings. In the main, they related to what might be termed 'wilful' or deliberate misconduct (e.g. termination of pregnancy in contravention of the law, drug abuse, canvassing for patients) or breach of medical ethics (e.g. abuse of professional confidence). Disregard of professional responsibilities to a patient (e.g. by failing to visit or to provide treatment for a patient when necessary) was also mentioned.

17.8 All editions of the Blue Book from 1975 (the earliest in the Inquiry's possession) to 1993 set out the two definitions I have quoted above and stated that, in proposing the substitution of the expression **'serious professional misconduct'** for **'infamous conduct in a professional respect'**, the GMC had intended that the phrases should have the same significance.

17.9 The Blue Book made clear that the question whether any particular course of conduct amounted to SPM was one which fell to be determined by the Professional Conduct Committee (PCC) after considering the evidence in an individual case. It emphasised that the categories of misconduct described within it could not be regarded as exhaustive. It stated (I quote from the final edition, published in December 1993):

> **'Any abuse by doctors of any of the privileges and the opportunities afforded to them, or any grave dereliction of professional duty or serious breach of medical ethics, may give rise to a charge of serious professional misconduct.'**

17.10 The 1985 edition of the Blue Book had included for the first time a statement of the standard of medical care that the public was entitled to expect. It stated:

> **'The public are entitled to expect that a registered medical practitioner will afford and maintain a good standard of medical care. This includes:**

[2] [1930] 1 KB 562.

(a) conscientious assessment of the history, symptoms and signs of a patient's condition;

(b) sufficiently thorough professional attention, examination and, where necessary, diagnostic investigation;

(c) competent and considerate professional management;

(d) appropriate and prompt action upon evidence suggesting the existence of a condition requiring urgent medical intervention; and

(e) readiness, where the circumstances so warrant, to consult appropriate professional colleagues.'

17.11 It seems that this statement had been formulated following the notorious case of Alfie Winn, which had been heard by the PCC in March 1983. In 1982, Alfie Winn, who was eight, became ill with vomiting and a high temperature. His general practitioner (GP) was called and attended three hours later. He asked Alfie to open his mouth. The boy seemed comatose and his mother said, 'He can't hear you.' The doctor replied, 'If he can't be bothered to open his bloody mouth, I shall not bloody well look at him.' He prescribed an antibiotic. Two hours later, the family called an ambulance and Alfie was taken to hospital. He died four days later of meningitis. The PCC found the facts proved and regarded the doctor's behaviour as falling below acceptable standards. Nevertheless, it considered that there had been no SPM. The doctor went on to be found guilty of SPM by the PCC in a different case the following year. During the intervening period, he had continued to practise.

17.12 Following these events, there were demands that the GMC should reduce its threshold for taking disciplinary action to 'professional misconduct', without the requirement that such misconduct should be 'serious'. The GMC set up a Working Group, which reported in 1984 that it could find no justification for lowering the threshold of SPM. The GMC instead proposed the formulation of detailed guidance on the circumstances in which failure to provide a sufficient standard of medical care might give rise to SPM. The statement contained in the 1985 Blue Book was the result. However, that statement constituted advice only, and a failure to meet the standards set out in the statement did not thereafter automatically give rise to disciplinary action by the GMC. Nor was the statement particularly detailed. The statement remained unchanged throughout the remaining period for which the Blue Book was published.

The Case of Doughty

17.13 In the case of Doughty v General Dental Council[3], an appeal from a decision of the General Dental Council (GDC) heard by the Judicial Committee of the Privy Council in 1987, the Privy Council defined SPM as:

> **'... conduct connected with his profession in which the dentist concerned has fallen short, by omission or commission, of the**

[3] [1988] AC 164.

standards of conduct expected among dentists and that such falling short as is established should be serious'.

17.14 The Privy Council said that the test that had been applied by the GDC (and which the Privy Council implicitly approved) was that:

> **'... judged by proper professional standards in the light of the objective facts about the individual patients that were presented in evidence to the Committee, the dental treatments criticised as unnecessary would be treatments that no dentist of reasonable skill exercising reasonable care would carry out'**.

17.15 The Privy Council observed further that the relevant Committee of the GDC was particularly well qualified to reach a view on whether the relevant misconduct was serious. It made clear that the findings against the appellant did not import any moral stigma. Nevertheless, the failures found were of a kind which the GDC had been entitled to consider sufficiently serious to warrant erasure of the dentist's name from the register.

17.16 The observation that the profession (in the Doughty case, the dental profession, but in other instances the medical profession) is particularly well qualified to judge what is and is not 'serious' has been repeated often in the courts. The problem is that, save in the most obvious cases, there was no agreement within the profession about what type of conduct was capable of amounting (or did amount) to SPM. In 1988, Mrs Jean Robinson, a lay member of the GMC who sat at various times on both the Preliminary Proceedings Committee (PPC) and the PCC, observed in her monograph, 'A Patient Voice at the GMC'[4], that there were frequently a number of different medical views as to whether a particular case might or might not amount to SPM. As I shall explain in Chapter 20, Professor Isobel Allen, Emeritus Professor of Health and Social Policy, University of Westminster Policy Studies Institute (PSI), and her colleagues observed similar divergences of view when they attended meetings of the PPC in 1999 and 2000. Sir Donald Irvine, President of the GMC between 1995 and 2002, told the Inquiry that, in his experience of the PCC, the most contentious and difficult parts of the decision-making process were the issues of whether a doctor's conduct (based on facts which had been admitted by the doctor or proved to the satisfaction of the PCC) amounted to SPM and, if so, what sanction should be imposed. He said that those were the issues that generated the 'heat' and the 'emotion' among members of the PCC panels when debating their decisions. These issues presented particular difficulties in cases involving allegations about poor treatment or substandard clinical practice. I shall discuss those difficulties later in this Chapter.

'Good Medical Practice'

17.17 In the mid-1990s, there was concern that the Blue Book was too negative, concerned as it was with 'bad doctors'. There was a desire to develop instead a more positive statement defining good practice. This gave rise to the development of a list of 14 'Duties of a Doctor', contained within a booklet, 'Good Medical Practice'. The booklet, which was issued in 1995 to all doctors on the register, set out the basic principles of good medical practice,

[4] Robinson, Jean (1988) 'A Patient Voice at the GMC'. London: Health Rights.

and was described as **'guidance'**. Later editions of 'Good Medical Practice' made a clear link between its contents and the fitness to practise (FTP) procedures. The edition of July 1998 stated:

> **'If serious problems arise which call your registration into question, these are the standards against which you will be judged.'**

The third and most recent version of 'Good Medical Practice', published in May 2001, is at Appendix G of this Report. The first page of the publication warns:

> **'Serious or persistent failures to meet the standards in this booklet may put your registration at risk.'**

17.18 The Blue Book had been intended to be read by doctors, not by members of the public. Indeed, members of the GMC staff were discouraged from sending copies of the Blue Book to members of the public for fear they would 'scour' it to find examples of misconduct which a doctor might have committed. Mr Antony Townsend, Deputy Head, later Head, of the Conduct Section between 1994 and 1998, said that this discouragement was 'a reflection of the culture at the time'. By contrast, 'Good Medical Practice' was made available to the public. Plainly, it was not intended that a single departure from the standards set out in 'Good Medical Practice' would necessarily be the subject of disciplinary action. The difficulty for those reading the publication in the disciplinary context – whether they were doctors, members of the public or others – was to know how **'serious'** or **'persistent'** a departure from the standards had to be before it would amount to SPM.

17.19 Professor Allen told the Inquiry that, while 'Good Medical Practice' was 'absolutely fine' for the purposes for which it was intended, it was not suitable for use as guidance about what might or might not amount to SPM. She said:

> **'... ''Good Medical Practice'' is a mixture of things which really must not be transgressed and which would be very serious, and other points which are, for example, being polite to your patients. This on its own could not raise an issue which ought to affect a doctor's registration presumably; so that you've within ''Good Medical Practice'' a lot of different things at different levels of seriousness.'**

What was needed, she said, was detailed guidance for those making decisions, with examples of different types of case which might reach different thresholds, thus creating a 'hierarchy of seriousness'.

17.20 Mr Townsend agreed that it would not be the case that a breach of one of the standards in 'Good Medical Practice' would necessarily lead to disciplinary action by the GMC. He told the Inquiry:

> **'... although ''Good Medical Practice'' was explicit, very explicit I think, about the principles of being a good doctor, what it did not and, indeed, probably could not do was define precisely how serious a departure from those principles was required before registration was called into**

question. That is a very difficult issue which the Council and many others have been grappling (*with*) **for a long time.'**

17.21 A number of witnesses spoke with enthusiasm of the 'change of culture' which was signalled by the publication of 'Good Medical Practice'. Sir Donald, who had been a member of the Working Group which produced the document, described it as **'a consensus statement that brought professional and patient views on the qualities of a doctor together for the first time'**.

17.22 Mr Townsend told the Inquiry that 'Good Medical Practice' laid much greater emphasis on patients' interests and on doctors' competence. It set out what he called 'patient-centred expectations'. He said that there had been a debate at the time of its publication about whether to continue to issue the Blue Book in parallel with 'Good Medical Practice' but it had been decided that this would 'perpetuate the old regime' whereby 'the focus was upon unacceptable behaviour rather than the delivery of patient care'.

17.23 As a member of the GMC staff, Mr Alan Howes, who was involved with the Conduct Section in one capacity or another more or less continuously between 1980 and 1995, said that he had found the Blue Book useful as a guide to the type of behaviour that could lead to disciplinary proceedings. 'Good Medical Practice' was harder to use in that way and indeed was not intended to be used for that purpose. He felt that the GMC had 'lost something' with the replacement of the Blue Book by 'Good Medical Practice', despite the fact that he could see the benefits of the latter. No document equivalent to the Blue Book has been produced since 1993. 'Good Medical Practice', in its updated form, remains the GMC's main source of guidance as to the type of conduct that might come within the definition of SPM.

The 1997 Screeners' Handbook

17.24 The 1997 Screeners' Handbook produced by the GMC advised screeners that, in reaching a view on whether a complaint was so serious as to raise an issue of SPM, the screener (whether medical or lay) should assess the information provided in the complaint against the following criteria:

'• The gravity of the doctor's act or omission.

• Whether there is more than one event or alleged victim.

• The extent of the risk to patients or the public.

• Whether the doctor appears to have acted deliberately, recklessly, accidentally, or in bad faith.

• Whether the doctor may have neglected or disregarded his or her professional responsibilities.

• Whether there have been any previous complaints to the GMC about the doctor which, taken with the current complaint, suggest a course of conduct which could amount to spm.'

This advice was helpful but there was still no guidance about how grave an act or omission had to be before it could amount to SPM. Nor was any guidance given as to the weight to be attached to the various criteria listed or as to the approach which should be taken if one or more of the criteria were satisfied.

Further Guidance

17.25 Further guidance as to the meaning of SPM appeared elsewhere. In 'A Problem With Your Doctor?', published in November 1997 and directed at members of the public, the GMC defined SPM as **'conduct which makes us question whether a doctor should be allowed to practise medicine without restriction'**. In a document entitled 'The Conduct Procedures of the General Medical Council', issued by the GMC Fitness to Practise Directorate in July 2000, SPM was defined as **'behaviour so serious it would justify restricting the doctor's right to hold registration'**. The problem with both those definitions was that they gave no clue as to the type of behaviour which was considered by the GMC as being serious enough to justify restricting a doctor's right to practise medicine or to hold registration.

The 1999 Report of the Professional Conduct Committee Working Group

17.26 Shortly after the establishment of the GMC Fitness to Practise Policy Committee (FPPC) in 1997, the Committee set up a Working Group to report on the activities of the PCC. One of the matters which the PCC Working Group considered was whether there should be any attempt to define SPM more precisely. One of the reasons for setting up the Working Group had been public criticism of some PCC decisions on the grounds that they were inappropriate or inconsistent. The report of the PCC Working Group recognised that the lack of a **'definitive interpretation'** of SPM was a factor which increased the risk of inconsistent decision-making by the PCC.

17.27 The PCC Working Group considered that a major advantage of the concept of SPM was its flexibility. It considered that the concept could be interpreted according to changing circumstances and expectations. The only alternative was, the PCC Working Group considered, to have a code of conduct, specifying every single offence with which a doctor might be charged. Members of the PCC Working Group did not believe that a code of conduct would offer any real benefits. On the contrary, they felt it would have significant disadvantages. In particular, they thought it would lead to **'interminable legal wrangling'** about whether the details of the alleged misconduct in an individual case fitted the circumstances defined in the code.

17.28 The PCC Working Group noted that SPM was sometimes described as being **'conduct ... so serious as to call into question a doctor's registration'**. Its report observed:

> **'While that is technically accurate, it is a circular statement which gives no real clue as to the kind of misconduct likely to be involved.'**

I wholly agree with the observation that this description or definition of SPM was unhelpful because of its circularity. The definition immediately provoked the questions 'And how

serious is that?' and also 'What do you mean by ''call into question''?' Unfortunately, the GMC's new FTP procedures will depend on just such a circular definition.

17.29 The PCC Working Group noted that the courts' interpretation of SPM was:

> **'... a serious falling short from the proper standards of conduct to be expected of doctors, or, in clinical matters at least ... action or inaction by a doctor of a serious kind for which no doctor of reasonable skill exercising reasonable care would be responsible ...'**.

The reference here was to the interpretation of SPM set out in the case of Doughty: see paragraph 17.13. The PCC Working Group observed that the definition **'left unanswered'** the questions of what the standards were at any one time and of what was meant by **'serious'**.

17.30 The PCC Working Group commented that one **'unintended consequence'** of substituting 'Good Medical Practice' for the Blue Book might have been **'a loss of clarity outside the GMC about the meaning of SPM'**. It commended the 1998 GMC publication 'Maintaining Good Medical Practice', which gave guidance to doctors and managers on what to do when they discovered poor practice. The publication contained examples (financial fraud, making false statements, indecency, etc.) which would justify the referral of a doctor to the GMC. The Working Group felt that the types of conduct mentioned in that publication provided a **'useful overview'** of SPM. However, my own view is that, although the 1998 guidance was better than nothing, it was not adequate because it was far too general. It was not surprising that many cases were reported to the GMC which the GMC considered were insufficiently serious to warrant action.

17.31 The PCC Working Group concluded that SPM should continue to be closely related to the need for a doctor's registration to be removed or restricted. It dismissed the possibility of widening the PCC's jurisdiction to include less serious offences, or of retaining the offence of SPM but introducing a new offence of lesser gravity, such as 'unacceptable conduct'. The Working Group observed that there was no point in the PCC hearing a case if the doctor's registration was not in question. The reason for that was that the statutory process (i.e. the quasi-criminal hearing) existed in order to ensure that a doctor was not removed from practice without due cause. Cases of lesser gravity, where the doctor's livelihood was not at stake, were, the Working Group observed, **'best dealt with in other ways'**.

The Revision of 'Good Medical Practice' in 2001

17.32 In May 2001, 'Good Medical Practice' was being revised for the second time. A draft had been prepared and consultation had taken place. Two medical organisations had raised concerns about some of the changes and additions to the text. They argued that the guidance was too vague and that it should include explicit and measurable standards if it were to be used as a template against which doctors would be assessed. Non-medical groups, however, either supported the standards and principles set out in the draft or argued for a more assertive statement on the need for doctors to comply with the guidance in all but exceptional circumstances. Neither the medical nor the non-medical groups argued that every complaint about a contravention of the guidance, however minor,

should lead to action by the GMC. However, the consultation exposed a difference in views about the point at which a failure to meet standards should be regarded as unacceptable and, therefore, as potentially warranting action on registration.

17.33 As a consequence of this difference of views, and following discussion at a Council Meeting in May 2001, it was decided that it would be helpful to draw up a series of examples or indicators of SPM to complement the guidance in 'Good Medical Practice'. This work was to be taken forward by the FPPC and the Standards Committee; it was intended that they should work together to produce examples of conduct which would call a doctor's registration into question. It was suggested that one example might be a statement that doctors must be honest and trustworthy and that a criminal conviction for theft would call a doctor's registration into question. It was hoped that the production of examples or indicators would meet some of the concerns which had been expressed during consultation on the revised edition of 'Good Medical Practice'. However, it appears that no examples of the type which had been envisaged were produced. When, in May 2004, the Inquiry asked the GMC (through its solicitors) what had been the result of the initiative and whether it had given rise to any guidance, the GMC replied that the work had been **'taken forward'** and was **'reflected'** in the draft case examiner decision form which was at that time being prepared for use after the introduction of the new FTP procedures, and in the draft document, 'The Investigation Stage Test – Guidance on Criteria and Thresholds', which had been prepared for the use of case examiners appointed to work under the new procedures. Copies of both were provided. The draft document has now been replaced by a further draft document, 'Making decisions on cases at the end of the investigation stage: Guidance for Case Examiners and the Investigation Committee', which was produced by the GMC in September 2004 (the September 2004 draft CE/IC Guidance). I shall refer to the September 2004 draft CE/IC Guidance again below and shall describe it more fully in Chapter 25.

Guidance for the Preliminary Proceedings Committee

17.34 Notes produced by the GMC for the use of members of the PPC, current in January 2002, stated that the GMC regarded SPM as **'behaviour which may raise issues about the doctor's registration and fitness to continue to practise'**. Here again, the GMC was using a definition or description of SPM which was circular in nature. The definition gave no clue as to what sort of behaviour might raise issues about registration or fitness to continue to practise. In any event, this particular wording might well give rise to misunderstanding. It could easily convey the idea that SPM was confined to behaviour for which the doctor might be struck off the register.

Guidance for Screeners

17.35 The Screeners' Handbook of November 2002 contained no specific guidance about the meaning of SPM. However, a description of SPM appeared on the screening decision form (SDF), the standard form which was at that time used by GMC staff and screeners during the pre-screening and screening processes. It is not clear whether the description appeared on the SDF as originally drafted in 1999, but it had certainly been included on

the form for the previous three or four years. It related to conduct other than sexual assault or indecency, violence, dishonesty and certain types of dysfunctional behaviour. It was intended that those categories of conduct should be regarded by the screeners as automatically capable of amounting to SPM or as 'SPM by definition'.

17.36 The description of SPM which appeared on the SDF stated:

> **'SPM is action or inaction by a doctor of a serious kind of which no doctor of reasonable skill and exercising reasonable care would be responsible.'**

Quite apart from the problems of syntax and clarity of expression, this description (which was derived from the interpretation of SPM in the case of Doughty) was not very helpful in that it was not appropriate for application to many of the classes of conduct which might potentially amount to SPM. It related solely to cases of substandard clinical practice. For such cases, the test proposed was similar to that applied by the courts when deciding civil claims for negligence made against doctors. It incorporated an additional element, not present within the definition of clinical negligence applied by the courts, namely that the action or inaction by the doctor had to be **'of a serious kind'**. But there was no guidance as to how serious the negligence had to be before it could amount to SPM. The screener was left to apply his/her own view of seriousness.

A Collection of Case Reports

17.37 At the Inquiry hearings, Sir Donald Irvine said that, when he was President, the idea of publishing case reports or case studies had been discussed. The idea was to illustrate by example the kinds of conduct that would and would not amount to SPM. It may be that Sir Donald had in mind the work to which I have already referred and which it had been intended should be undertaken by the FPPC and the Standards Committee. He said that, in the event, the work had not been carried out, a fact which he regarded as a matter for regret.

17.38 At the Inquiry hearings in December 2003, Professor Sir Graeme Catto, current President, and Mr Finlay Scott, Chief Executive, said that the GMC intended to publish a collection of case reports in February 2004. As I understood it, these were to be summaries of cases in which the decision taken by a PCC panel was regarded as good and as an example to be followed. I had hoped that these summaries would provide useful examples of the kind of conduct which did or did not amount to SPM, and also guidance on appropriate sanctions. In the event, publication of the case reports was delayed until September 2004, when five 'case studies' were published. They were disappointing and gave little or no useful guidance as to the threshold of seriousness at which conduct might be regarded as amounting to SPM, or be such as to warrant action on registration. I shall refer to the case studies in greater detail in Chapter 21.

The New Fitness to Practise Procedures

17.39 As I have mentioned, under the new FTP procedures, the test to be applied when deciding whether action on a doctor's registration is required will not be whether the doctor has

been guilty of SPM, but whether his/her fitness to practise is impaired to a degree justifying action on registration. This test gives rise to the same problems of circularity as the definition of SPM to which I referred at paragraph 17.28. How are doctors, patients or others to judge what degree of impairment will, in the view of the GMC, justify 'action on a doctor's registration'? The answer is that, unless they are given comprehensive guidance on standards, they will guess. Within the GMC, how are caseworkers, case managers, case examiners and FTP panel members to make judgements about whether action on registration is justified? The answer is that, unless they are given comprehensive guidance on standards, they will apply their own individual views and the result will be inconsistent decisions with all the adverse consequences that they bring. The GMC has undoubtedly recognised the need for guidance and, as I have said, has produced draft guidance (the September 2004 draft CE/IC Guidance) for case examiners, who will have to decide whether a case should be referred to a FTP panel. It sets out a number of circumstances in which a question of fitness to practise is likely to arise. A few examples are given. It is a step in the right direction. Coupled with the regular publication of case reports, such guidance might provide a basis for more consistent and transparent decision-making. As I shall later explain, however, I believe that more must be done to establish standards that are understood and accepted by society as a whole.

Poor Treatment and Substandard Clinical Practice

17.40 As I have explained, it is clear that there has often been considerable difference of opinion as to whether the facts established in a particular case amounted to, or were capable of amounting to, SPM. This difference of opinion has been particularly marked in cases involving allegations of poor treatment and/or substandard clinical practice. I recognise that there will always be a risk that two tribunals will reach different conclusions based on the same facts; that is why clear guidance is essential.

17.41 In the past, as I have said, the emphasis of the Blue Book was on what might be termed 'wilful' or deliberate misconduct and on breach of medical ethics. It was unusual for the GMC to take disciplinary action in respect of substandard clinical practice. Mr Townsend told the Inquiry that, while he was at the GMC, he did a small survey which showed that, in the late 1960s, only 5% of cases reaching the PCC had anything to do with clinical care. He said that cases referred to the PCC:

> **'... were nearly always about behavioural matters, about whether a person was a fit person to be a registered medical practitioner as distinct from whether they were competent to undertake the right kinds of treatment'**.

Speaking of the same era, Mr Howes referred to the 'old-fashioned' forms of misconduct with which the GMC would have been concerned then, 'such as advertising and abortion and adultery: the three As'.

17.42 Early editions of the Blue Book had, as I have said, referred to the possibility that disciplinary proceedings might be instituted in a case where a doctor appeared to have seriously disregarded his/her professional responsibility to his/her patients or to have neglected his/her professional duties, for example by failing to visit or to provide treatment

for a patient when it was necessary. Substandard treatment – in the absence of misconduct involving a conscious decision by the doctor to act as s/he did, knowing of the possible or likely consequences – was not, however, mentioned. The 1977 edition of the Blue Book specifically stated that the GMC was **'not concerned with errors in diagnosis or treatment'**.

17.43 In the 1983 edition, that statement was amplified. The relevant passage then stated:

> **'The Council is not ordinarily concerned with errors in diagnosis or treatment, or with the kind of matters which give rise to action in the civil courts for negligence, unless the doctor's conduct in the case has involved such a disregard of his professional responsibility to his patients or such a neglect of his professional duties as to raise a question of serious professional misconduct. A question of serious professional misconduct may also arise from a complaint or information about the conduct of a doctor which suggests that he has endangered the welfare of patients by persisting in independent practice of a branch of medicine in which he does not have the appropriate knowledge and skill and has not acquired the experience which is necessary.'**

17.44 In the 1985 edition of the Blue Book, there was the addition of the statement of the standards of medical care that the public was entitled to expect. I have referred to that statement at paragraph 17.10. As I have said, the statement constituted guidance only, and a failure to meet the standards did not automatically give rise to disciplinary action by the GMC.

17.45 Mr Howes said that, during the 1980s, it became more common for cases of substandard treatment to be reported to the GMC. This type of complaint was more of a 'grey area' than complaints about other forms of misconduct. Mr Howes' interpretation of the approach taken by the GMC during the 1980s and early 1990s was that:

> **'... if you** (*i.e. the doctor*) **try your very best and your very best happens not to be good enough, then that is not serious professional misconduct. Serious professional misconduct is neglecting to do what you ought to have done or in some cases doing what you should not have done.'**

17.46 In 1994, Mr Howes compiled what he has described as 'the beginnings of a training manual' (the 1994 Training Manual). No similar document had been produced in the Conduct Section previously and Mr Howes, who was by that time Head of the Section and was aware that he would be moving to another Section in the near future, compiled this document in order to pass on his knowledge and experience for the benefit of new staff joining the Section. He explained in evidence that he did not regard it as a finished document, but had envisaged that it would be improved and overhauled from time to time and would eventually be audited by someone and given a more formal status. He assumed that the 1994 Training Manual must have been approved at the time – at least in general terms – by his immediate superior, but had no clear recollection about this. The Training Manual is a valuable document since it provides a summary of the operation of

GMC procedures in 1994, as perceived by Mr Howes, who was then a very senior and experienced member of staff. Generally, the witnesses agreed that it accurately represented the practice and thinking of the time. However, as I shall explain, some doubt was expressed about the description of the GMC's approach to cases of poor treatment and substandard practice contained in it. It was suggested that the 1994 Training Manual might not accurately reflect the approach taken by the GMC to such cases.

17.47 The 1994 Training Manual stated:

> **'We cannot investigate complaints of failure to diagnose, or failure to give what the complainant considers to be correct and appropriate treatment, or complaints about evident or alleged errors in treatment, which have allegedly resulted in damage to the patient. Such matters come into the category of medical negligence, which it is more appropriate for a patient to pursue in the civil courts, particularly if the patient wants financial redress (which we cannot give). Those matters are not, however, regarded as serious misbehaviour by the doctor concerned, such as might justify action by the Council.'**

and

> **'The types of case relating to treatment which <u>may</u>** (*emphasis in the original*) **justify disciplinary procedures by the Council include cases where a doctor has allegedly failed to visit a patient when necessary, or failed to conduct an appropriate examination, or failed to conduct or arrange appropriate examinations, or absented himself/herself from his/her practice or post when the doctor was supposed to be on duty, or has been drunk on duty, or has been guilty of some other culpable failure in relation to his or her responsibilities towards one or more patients.'**

The 1994 Training Manual also stated:

> **'Experience shows that few complaints about treatment would actually be serious enough even if sustained to raise any question of serious professional misconduct.'**

17.48 The wording of the 1994 Training Manual suggested a very restrictive approach to complaints about poor treatment and substandard clinical practice. A clear distinction appeared to be drawn between **'errors in treatment'** on the one hand and **'culpable failure'** in relation to professional responsibilities for patients on the other. The idea that SPM must involve some element of 'wilful' or, at least 'reckless', misconduct appeared to be perpetuated. The 1994 Training Manual appeared to suggest that falling below reasonable standards of care (as opposed to wilfully refusing to give any care at all) would not of itself amount to SPM.

17.49 Despite the fact that he was responsible for compiling the 1994 Training Manual, Mr Howes did not believe that these extracts truly reflected the thinking of the GMC as it was in 1994. He said that, at that time, the GMC often dealt with complaints about doctors failing to treat and giving incorrect treatment. However, 'errors' were not matters for the

GMC. Mr Howes appeared confident that GMC staff and members had been able to distinguish between cases which might involve SPM and those which could never do so. He did, however, agree with me that, on occasion, it was difficult to decide whether an 'error' was 'culpable' on the one hand (and, therefore, capable of constituting SPM) or 'excusable' (therefore not amounting to SPM) on the other. Dr Krishna Korlipara, who has been an elected member of the GMC since 1984 and was a medical screener between 1998 and 2004, also said that the extracts from the 1994 Training Manual did not tally with his understanding of the tests which were being applied at the time.

17.50 In December 1995, the Judicial Committee of the Privy Council delivered judgement in the case of McCandless v General Medical Council[5]. The PCC had found Dr McCandless, a GP, guilty of SPM and had directed that his name should be erased from the register. The charges had alleged errors of diagnosis in relation to three patients and a failure to refer them to hospital. Two patients had died and one had been found to be seriously ill at the time of her eventual admission to hospital. The PCC had found that the care provided by the doctor **'fell deplorably short of the standard which patients are entitled to expect from their general practitioners'**. On appeal, the PCC's findings of fact were accepted by Dr McCandless and it was also accepted that he had been negligent. However, it was argued on his behalf that poor treatment was not enough to amount to SPM. It was said that SPM meant conduct that was **'morally blameworthy'**. This could not be determined simply by deciding whether the treatment measured up to an objective standard. The doctor might have been doing his best. He might have been overworked. It was argued that it was necessary to look at why the doctor gave the treatment he did. Counsel for Dr McCandless submitted that if the treatment fell short of a reasonable standard because he had been, for example, too lazy or drunk to examine the patient properly, then he would be guilty of misconduct. But not if he had made an honest mistake.

17.51 The Privy Council took the view that the legal authorities dealing with **'infamous conduct in a professional respect'** were of little assistance in the interpretation of SPM. It said that moral blameworthiness was not a necessary ingredient of SPM. Lord Hoffmann observed:

> **'... the public has higher expectations of doctors and members of other self-governing professions. Their governing bodies are under a corresponding duty to protect the public against the genially incompetent as well as the deliberate wrongdoers.'**

The Privy Council applied the objective test referred to in Doughty (see paragraph 17.13), saying that it was applicable to doctors as much as to dentists. That being the case, the appeal in McCandless failed.

17.52 Mr Townsend told the Inquiry that he believed that GMC procedures had been designed to deal with questions of professional behaviour and had not really been designed to deal with questions involving treatment. He said that there was no doubt that the GMC could act if, for example, a GP refused to visit a patient where there was sufficient evidence that someone needed a visit. He said that, over a period of years (even decades), the GMC had been 'pushing at the margins' of SPM to try to include substandard care. He said that

[5] [1996] 1 WLR 167.

the guidance contained in the 1994 Training Manual had been 'at the cautious end' of the interpretation of the Blue Book. However, at that time, the GMC was becoming less cautious. Mr Townsend made the point that it was because the GMC procedures were not really suitable to deal with substandard care that the performance procedures were introduced. As I have explained, under the performance procedures, the GMC could take action if the standard of professional performance of a doctor was seriously deficient. However, the advent of the performance procedures did not entirely solve the problem of which Mr Townsend spoke. There had to be a pattern of failure (or possibly of serious failure) to comply with relevant professional standards before SDP could be established. Where there was such a pattern, action under the performance procedures was appropriate. However, where the matter complained of appeared to be a single incident, the performance procedures were not appropriate and the issue was still whether the incident complained of amounted, or was capable of amounting, to SPM. Most complaints to the GMC came from private individuals as isolated incidents. Unless enquiries were made of the doctor's employer or primary care organisation (PCO) (which they rarely were), the GMC was not in a position to know whether the complaint was part of a pattern of similar incidents which might be sufficient to trigger the performance procedures.

17.53 There is no doubt that, during the early and mid-1990s, some complaints involving what might be termed 'errors' were judged by the GMC to amount to SPM. In Chapter 21, I have referred to a few examples of such cases, all involving the administration of manifestly excessive doses of drugs. It is clear that, in other cases, where the 'error' was not so obvious, there was uncertainty as to whether the doctor's conduct crossed the threshold of SPM. From 1995, it was possible to look at the doctor's behaviour against the background of the standards set out in 'Good Medical Practice'. However, as I have already said, a departure from those standards did not necessarily amount to SPM. The difficulty still lay in defining precisely how serious such a departure had to be before disciplinary action was appropriate.

Seriously Deficient Performance

17.54 The Medical (Professional Performance) Act 1995, which introduced the performance procedures, did not define the circumstances in which a doctor's professional performance should be regarded as **'seriously deficient'**. In the 1997 Screeners' Handbook, 'performance' was defined as **'any professional work undertaken by the doctor, including medical administrative work'**. Screeners were advised to consider whether there was good evidence that the doctor might be **'repeatedly or persistently failing to comply with the professional standards appropriate to the work'** s/he was doing. They were advised to consider whether there might be **'a pattern of deficient performance'** as opposed to **'evidence only of one or two incidents'** of deficient performance, which could be **'isolated lapses'**.

17.55 In November 1997, the GMC published guidance, 'When Your Professional Performance Is Questioned', about the new performance procedures. The guidance stated:

> **' ''Seriously deficient performance'' is a new idea. We have defined it as ''a departure from good professional practice, whether or not it is**

> **covered by specific GMC guidance, sufficiently serious to call into question a doctor's registration''. This means that we will question your registration if we believe that you are, repeatedly or persistently, not meeting the professional standards appropriate to the work you are doing – especially if you might be putting patients at risk. This could include failure to follow the guidance in our booklet Good Medical Practice.'**

17.56 Here again, the circular test was propounded. SDP was defined as a departure from good professional practice, sufficiently serious to call registration into question. But how serious was that? In giving judgement in the case of Krippendorf v General Medical Council[6] in November 2000, the Privy Council observed that it saw no reason to criticise the general guidance given in that passage, provided that it was not regarded as exhaustive. It observed that the third sentence of the guidance should more accurately read:

> **'This means that we will question your registration if we believe that you have been, repeatedly or persistently, not meeting the professional standards appropriate to the work you have been doing – especially if you might be putting patients at risk.'**

In other words, the Privy Council was suggesting that action on registration should be based on an assessment of past – not current – performance. It seems that the guidance was subsequently changed to accord with this suggestion. In the later case of Sadler v General Medical Council[7], the Privy Council referred to the amended guidance:

> **'Although in *Krippendorf* the Board did not criticise the phrase ''repeatedly or persistently'' in the GMC's guidance, it is important to bear in mind that that guidance is a generalisation seeking to cover a very wide range of professional performance. The professional demands made on a general practitioner are very different from those made on a consultant surgeon. A continuing failure to organise the efficient management of a general practice may (in a sufficiently bad case) amount to seriously deficient performance, but in the nature of things it must be assessed on very different evidence from that relating to shortcomings of technique in major surgery. It would plainly be contrary to the public interest if a sub-standard surgeon could not be dealt with by the CPP** (*Committee on Professional Performance*) **unless and until he had repeatedly made the same error in the course of similar operations, but as a general rule the GMC should not (and their Lordships have no reason to suppose they would) seek to aggregate a number of totally dissimilar incidents and alleged shortcomings in order to make out a case of seriously deficient performance against any practitioner.'**

Here, it seems to me, the Privy Council usefully suggested that the application of a test for SDP should be approached in the context of the type of work being done. In my view, this was the right track to follow.

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[6] [2001] 1 WLR 1054.
[7] [2003] 1 WLR 2259.

17.57 Also in the case of Sadler, the Privy Council indicated that it did not consider negligence to be a relevant or useful concept for consideration at a performance hearing before the CPP. It observed that SDP meant:

> **'... a much wider concept since ... it can extend to such matters as poor record-keeping, poor maintenance of professional obligations of confidentiality, or even deficiencies (if serious and persistent) in consideration and courtesy towards patients. It does not depend on proof of causation of actionable loss. (On the other hand one isolated error of judgment by a surgeon might give rise to liability in negligence but would be unlikely, unless very serious indeed, to amount by itself to seriously deficient performance.)'**

17.58 The 1999 version of the SDF completed by medical screeners stated that:

> **'SDP is normally indicated by a repeated or persistent failure to comply with relevant professional standards ...'**.

However, in the August 2001 version of the SDF, the words **'a repeated or persistent failure'** were replaced by the words **'a pattern of serious failure'**. This change introduced the concept of **'a pattern of serious failure'** as opposed merely to **'repeated or persistent failure'** to comply with relevant standards. This is not just a matter of semantics, as the August 2001 wording suggested that the failures themselves must be serious as well as repeated. The August 2001 wording was reproduced in later versions of the SDF.

17.59 The August 2001 version of the SDF also contained a list of **'criteria'** which, it was suggested, might assist medical screeners in assessing whether the conduct or the performance procedures were appropriate. The SDF made clear that the list of **'criteria'** was not exhaustive, but stated that it (by which was presumably meant the presence of one or more of the **'criteria'**) might be an indicator of SDP. The list of **'criteria'** was as follows:

- **'• a doctor who has a tendency to use inappropriate techniques**
- **a lack of basic knowledge/poor judgement**
- **a lack of familiarity with basic clinical/administrative procedures**
- **a doctor who has failed to keep up to date records**
- **a lack of insight**
- **a range of inadequacies:**
  - **outdated techniques**
  - **attitude**
  - **inadequate practice arrangements**
  - **concerns over referral rates**

- **poor record keeping**
- **inadequate hygiene arrangements.'**

These **'criteria'** were reproduced in later versions of the SDF. The **'criteria'** were helpful only to the extent that they pointed to relevant considerations. The actual standards to be applied were still at large, for the individual screener to make up his/her own mind about.

17.60 Following the case of Krippendorf, which I have mentioned above and which I shall describe in detail in Chapter 24, the GMC sought amendment of section 55 (the interpretation section) of the Medical Act 1983. After December 2002, when the amendments came into force, the expression **'professional performance'** included professional competence. However, it does not appear that this change was reflected in the guidance provided for screeners or more generally for members of Assessment Panels or panels of the CPP. The amendments also made clear that an assessment of a doctor's professional performance might include an assessment of the doctor's professional performance at any time prior to the assessment, as well as of his/her professional performance at the time of the assessment.

Conclusions

17.61 It appears that, in the past, there has not been a clear and common understanding about the type and seriousness of misconduct or deficient professional performance which was likely to result in action on registration. This has given rise to difficulties, examples of which I will examine in the ensuing Chapters. The GMC is about to introduce its new FTP procedures. Although, in future, these will not operate in the separate 'silos' of conduct, health and performance, as they have done in the past, the decisions that will have to be made by FTP panels will still involve issues of misconduct, deficient performance and ill health. Indeed, in future, issues of misconduct and deficient performance are likely to arise together in the same case. It is, in my view, vital that the GMC should establish clear standards upon which these new procedures are to be based. This is important for a number of reasons.

17.62 First, it is obviously desirable and fair that doctors themselves should know what type of conduct or deficiency of performance is likely to result in action on their registration and that they should be able to regulate their behaviour accordingly. Of course, it is to be hoped that most doctors would aim rather higher in their professional life than just to avoid disciplinary action, but it is only fair that they should understand the circumstances in which they might fall foul of their professional regulatory body.

17.63 Second, if, as has been the case in the past, it is to remain open to patients, relatives and others who have complaints against doctors to refer them to the GMC, they must have a clear understanding of whether the GMC is the right body to deal with their complaints. If they do not, their complaints will be rejected by the GMC, they will become disappointed and frustrated and the GMC's reputation will suffer.

17.64 Third, it is important that those with responsibility for referring cases to the GMC – such as doctors' employers, PCOs, private healthcare bodies, other healthcare professionals and

such bodies as the Commission for Healthcare Audit and Inspection (now known as the Healthcare Commission) – are aware of the types of case that they should refer. If they are not, they will refer the wrong cases or fail to refer the right ones, resources will be wasted and patients may be inadequately protected.

17.65 Fourth, once a case has reached the GMC, it is important that all those responsible for making decisions in the future should understand the standards to be applied and should apply them consistently. Otherwise, the system will be unfair both to the doctors against whom complaints are made and to those who make the complaints.

17.66 It is now some years since the GMC was advised that it should devise standards, criteria and thresholds for the consistent operation of its FTP procedures. Professor Allen and her colleagues so advised in 1996, 2000 and 2003. Yet the GMC has still not grasped the nettle. The problem will not go away with the new procedures; indeed, I think it will become even greater. I say at once that I recognise that the task of formulating standards, criteria and thresholds is not easy. However, it must be tackled and, in my view, the public must be involved in the process. The GMC will not command public confidence unless there is consensus about the standards that are to be applied. I shall discuss two possible approaches to the problem in Chapter 27.

CHAPTER EIGHTEEN

The General Medical Council Conduct Procedures: Initial Stages Conducted by the Administrative Staff

Introduction

18.1 I have already explained that the General Medical Council's (GMC's) old conduct procedures dealt with doctors who had been convicted of criminal offences and those who were alleged to have been guilty of serious professional misconduct (SPM). All complaints about a doctor's conduct and all information that a doctor had been convicted of a criminal offence received by the GMC were considered first by members of the administrative staff. I have already explained in Chapter 15 that complaints made to the GMC underwent a series of filtering processes. As a result of those filtering processes, the vast majority of cases were closed without reaching the stage of a public hearing by the Professional Conduct Committee (PCC).

18.2 The first of those filtering processes was conducted by the administrative staff, who applied various set criteria in order to determine whether a case should be closed at that initial stage or whether it should advance into the fitness to practise (FTP) procedures. In 2003, members of the administrative staff were responsible for closing 65% of the 3821 complaints about doctors' conduct or performance which were received by the GMC in that year. In view of the fact that so many cases were closed at this early stage, as a result of decisions taken by the administrative staff, it was clearly important for the Inquiry to examine the processes undertaken by the staff and the criteria on which their decisions were based.

18.3 In this Chapter, I shall describe briefly the processes undertaken by the administrative staff on receipt of a complaint or report about a doctor. I shall consider the circumstances in which members of staff were in the past permitted to close a case and the criteria which they were required to apply. I shall also look at the procedure for dealing with information about convictions. I shall examine the extent to which the decisions made by members of staff were subjected to audit.

18.4 I shall then proceed to consider some specific issues arising from the processes undertaken by members of staff. In particular, I shall be considering the policy of the GMC, which was current for many years, of instructing its staff to advise complainants that they should pursue their concerns through local complaints procedures. I shall also consider whether there was any, or any adequate, follow-up of such cases by the GMC. I shall go on to consider whether complaints and reports to the GMC have in the past been properly investigated. I shall consider whether there has in the past been an adequate exchange of information between the GMC and the employers and primary care organisations (PCOs) of doctors in respect of whom complaints have been made. Finally, I shall examine some problems which have arisen in connection with decisions to close cases, by reference to some individual cases which have been dealt with by the staff. To enable me to do this, the Inquiry obtained and examined a small number of cases which had recently been closed by members of the administrative staff. The intention behind examining these

cases was to gain some insight into how the processes described by the GMC worked in practice.

Witnesses

18.5 The Inquiry heard oral evidence from Mr Alan Howes (who was employed by the GMC between 1977 and 2002 and was Head of the Conduct Section from 1987 to 1994), from Mr Antony Townsend (Deputy Head, later Head, of the Conduct Section from 1994 to 1998), Mr Finlay Scott (Chief Executive of the GMC since 1994) and Mr Neil Marshall (Head of the Screening Section since March 2002). Professor Sir Graeme Catto (current President of the GMC), Dr Krishna Korlipara (a member of the GMC since 1984 and a medical screener from 1998 until 2004) and Professor Isobel Allen (Emeritus Professor of Health and Social Policy, University of Westminster Policy Studies Institute (PSI)) also gave relevant evidence.

The Screening Section

18.6 Information about convictions, together with all complaints and communications about doctors, were dealt with initially by the Screening Section. The exception was when the information or complaint clearly related to issues affecting the health of a doctor. Those cases were directed straight to the Health Section. The Inquiry was told that, as at December 2003, the staff of the Screening Section consisted of three casework managers, 29 caseworkers, 11 casework assistants and a secretary. A caseworker had the primary day-to-day responsibility for each case, with guidance from casework managers and administrative support from casework assistants.

Sources of Reports about Doctors

Convictions

18.7 The GMC receives information about doctors who have been convicted of criminal offences, or who are the subject of ongoing criminal investigations or proceedings, from a number of sources. It employs a press cuttings agency to alert it to criminal cases involving doctors that are going through the courts or have resulted in convictions. Home Office Circulars require the police to report certain types of convictions to the GMC. In addition, a doctor's involvement in criminal investigations or proceedings may be reported to the GMC by the Home Office Drugs Branch, by the doctor's employers or PCO (in England, a primary care trust (PCT)), by a member of the public or by the doctor him/herself. These systems are not foolproof and, sometimes, there is a long delay between the date of a conviction and the time when the GMC is notified of it. Some convictions have been missed altogether.

18.8 In the past, there was no professional obligation on a doctor to inform the GMC of the fact that s/he had been convicted of a criminal offence or of the fact that s/he was the subject of a criminal investigation or of criminal proceedings. As I have explained in Chapter 5, general practitioners (GPs) have been required since December 2001 to declare such

matters to the PCO on whose list they are included within seven days of the commencement of criminal investigations or proceedings, or of a criminal conviction. They have also been required to disclose, *inter alia*, the fact that they have accepted a police caution or are subject to an investigation into their conduct by any licensing, regulatory or other body anywhere in the world. However, there has been no formal mechanism whereby PCTs would automatically inform the GMC when they received such a declaration. My understanding is that PCTs would do so if they thought it appropriate.

18.9 In September 2004, as a result of discussions which took place during the course of Mr Scott's evidence to the Inquiry, the GMC decided that doctors should be placed under a professional duty to disclose to the GMC information about impending and past criminal and regulatory proceedings. The precise terms of the duty have not yet been finally decided but it is likely to include an obligation to disclose information about convictions and criminal charges brought against doctors (save for those in relation to certain minor motoring offences), about police cautions accepted and about proceedings brought against them by other regulatory bodies in the UK or elsewhere. The new duty is to be included in the next edition of 'Good Medical Practice'. Failure to comply with the duty may result in disciplinary proceedings. This change is welcome and brings the medical profession in line with other professions, including barristers.

18.10 Until 1991, the term **'convicted ... of a criminal offence'** excluded a finding of guilt in respect of which a doctor was placed on probation or was discharged conditionally or absolutely. After 1991, the exclusion applied only to findings of guilt where a conditional or absolute discharge was imposed. Such findings of guilt have, however, frequently been reported to the GMC by the police. It has then been open to the GMC, if it chose, to proceed with the case as if it were an allegation of SPM. On occasion, the fact that a doctor has accepted a police caution might also be reported to the GMC. If this occurred, the GMC might then elect to treat the report as an allegation of SPM. The new FTP procedures specifically provide that a police caution should be treated in the same way as a conviction. I shall recommend also that offences which have been dealt with by means of a conditional discharge should be treated in the same way as a conviction.

Complaints

18.11 The GMC also receives complaints about the conduct of doctors from many sources, mainly from NHS trusts, from doctors' employers, from patients and patients' families and from other healthcare professionals. Some of these complaints are serious and it has been clear from the start that, if proved, they would amount to SPM under the old conduct procedures. Others are so trivial that, even taken at their highest, they could never warrant disciplinary action by the GMC or, indeed, by any other body. Many fall somewhere in between these extremes. Some complaints do not relate to a doctor's medical practice at all, but to some personal matter involving the doctor.

Other Communications about Doctors

18.12 The GMC also receives some communications about doctors that cannot properly be termed 'complaints'. These may be requests for information or questions about medical

ethics. Some of the communications do not relate to doctors at all. Like any other public body, the GMC also receives some communications that are irrational or incoherent. All these communications must be considered by the staff and a decision taken as to whether they require positive action by the GMC. If the staff judge that they do not require any such action, they are 'closed' at this stage.

The Initial Processing of Conduct Cases under the 'Old' Procedures

18.13 The old conduct procedures were governed by the General Medical Council Preliminary Proceedings Committee and Professional Conduct Committee (Procedure) Rules Order of Council 1988 (the 1988 Professional Conduct Rules). In December 2003, the relevant instructions for staff were contained in the April 2003 edition of the FTP Casework Manual. Subsequently, new instructions were issued and were contained in the FTP Investigation Manual, the first version of which came into effect in May 2004. The FTP Investigation Manual included changes to the procedures for dealing with complaints which had been introduced after the Inquiry's hearings. Most of those changes related to new arrangements for the exchange of information between the GMC and the employers and PCOs of doctors in respect of whom complaints had been made to the GMC. I shall describe those new arrangements, which were introduced as a result of concerns expressed by the Inquiry, later in this Chapter.

18.14 In the course of the decision-making process, members of staff used specially designed standard forms to guide and record their decisions.

The Practice in December 2003

The First Steps

18.15 I shall deal first with the procedure for handling complaints involving allegations of SPM and other communications about doctors (I shall refer to them collectively as 'complaints'), as described by the witnesses in December 2003. The procedure for handling information about convictions was different and I shall describe it later in this Chapter.

18.16 When a complaint was first received, some preliminary information was entered by hand onto a case direction form (CDF) by a casework assistant. The CDF was designed to provide a record of the procedural steps taken, of the preliminary decisions made and of instructions issued about the future conduct of the case. Details of the case were entered onto the GMC's database, which was updated as the case progressed.

18.17 A number of standard procedures would then be carried out. If the complaint related to a named doctor, attempts would be made to confirm his/her identity by reference to the GMC's medical register. This was not always possible, for reasons that I shall explain later in this Chapter. If the doctor could be identified, a search of the GMC's database would be made in order to ascertain whether s/he had previously been reported to the GMC. The results of the search, together with the nature and outcome of any previous complaints found, would be recorded on the CDF. A search was also made to see whether the complainant had made previous complaints to the GMC. The case would then undergo an initial 'triage' by a casework manager.

Triage

18.18 The triage was an initial assessment, undertaken by casework managers in order to determine which cases could be closed immediately and which should be taken forward. The casework manager might decide that a communication was not a complaint at all but was an item of general correspondence. If so, it would be filtered out at the triage stage. The casework manager might be unable to take a final decision about the disposal of the complaint. He or she might require further information before doing so, in which case s/he would pass the case to a caseworker and give any necessary instructions and advice on what was to be done. The casework manager would identify cases that needed to be dealt with urgently for some reason and would give appropriate instructions to the designated caseworker. Where the casework manager felt that there was sufficient information on which to base a decision, s/he would proceed to decide whether the case should be referred to a medical screener.

18.19 There were two other matters that the casework manager would be looking out for at that stage. First, s/he would seek to identify cases where urgent interim action (e.g. suspension of the doctor from practice) appeared necessary for the protection of patients or otherwise in the public interest. After 2000, decisions about interim action were taken by the Interim Orders Committee (IOC). Members of staff could not refer a case direct to the IOC. The case had to go to a medical screener first. The casework manager would ensure that a case where interim action might be necessary went to a medical screener as soon as possible. Second, if the complaint raised a question as to whether the doctor's fitness to practise was seriously impaired by his/her physical or mental condition and this was the primary concern, the casework manager would forward the complaint to the Health Section. Subject to those matters, the casework manager would use the first part of the standard screening decision form (SDF) as a guide when making his/her decision and would record on the SDF the various steps in the decision-making process. The SDF was used to record decisions taken by staff as to whether a case should be referred to a medical screener. It also recorded the decisions taken by medical and lay screeners.

The Decision Whether or Not to Refer a Case to a Medical Screener

18.20 Rule 6 of the 1988 Professional Conduct Rules provided:

> **'(1) Where a complaint in writing or information in writing is received by the Registrar and it appears to him that a question arises whether the conduct of a practitioner constitutes serious professional misconduct the Registrar shall submit the matter to the President.'**

18.21 The functions of the Registrar, as set out in rule 6, were fulfilled by members of the GMC staff on his behalf. The medical screeners assumed the screening role previously performed by the President. In the case of R v General Medical Council ex parte Toth[1], Mr Justice Lightman described the role of the Registrar (in practice the GMC staff) in relation to rule 6 thus:

[1] [2000] 1 WLR 2209.

'At the first stage, the Registrar has a ministerial role: so long as there is a complaint (which connotes the making of some form of charge against a practitioner), the complaint is in writing and on its face the complaint raises a real question whether the conduct of a practitioner constitutes serious professional misconduct, he is duty bound to refer the matter to the screener.'

18.22 The first section of the SDF set out a long list of circumstances in which the GMC had decided that it would be appropriate for a casework manager to take a preliminary decision not to refer the case to a medical screener. These circumstances arose when:

(a) the complaint was not about a doctor

(b) the complaint related only to a minor motoring offence not involving drugs or alcohol

(c) the events complained of had occurred more than five years previously

(d) the complaint related only to fees charged for private treatment/service

(e) the complaint related only to a delay of less than six months in providing a single medical report

(f) the doctor's profession was incidental to the matter, e.g. a dispute between neighbours, one of whom happened to be a doctor

(g) the complaint related only to objections to the contents of medical reports or records where there was no suggestion that the doctor had acted unreasonably

(h) the 'complaint' was in fact an irrational/incoherent enquiry

(i) the complaint related only to patently frivolous/trivial non-clinical matters, e.g. the doctor was a few minutes late for a routine appointment

(j) the complaint related only to the fact that the doctor failed to take up a post following a verbal agreement to do so but gave two weeks' notice or more

(k) the complaint came from a third party where it was clear that the principal party did not want to pursue the matter, and there was no other reason for proceeding

(l) the complaint related only to a doctor's immigration status

(m) the complaint related only to the level or quality of service provided by a healthcare organisation where there was no suggestion that the doctor was directly responsible

(n) the complaint related only to removal from a GP list where there was no suggestion that the doctor's decision was unfair or contravened GMC guidelines

(o) the complaint related only to practice or departmental disputes where there was no suggestion that patients were being put at risk

(p) the complaint related only to failures in local complaints handling procedures

(q) the correspondence was a copy letter which did not specifically request GMC action

(r) the correspondent was explicitly seeking only an apology

(s) the complaint was anonymous and there was no reason to suspect that the doctor was an immediate threat to patients.

18.23 If any of these circumstances were judged to apply, the casework manager would close the case unless there was some other reason why the case should be considered by a medical screener. Any such reasons had to be recorded on the SDF. In deciding whether there was some other reason for referral to a medical screener, the casework manager would consider whether there was any cause to suspect that the doctor might be dangerous. The FTP Casework Manual gave guidance on the circumstances when this might arise, stating that a case should not be closed where it appeared to involve:

> **'a. persistent clinical errors;**
>
> **b. persistent failure to provide appropriate treatment/care;**
>
> **c. any single very serious clinical error or failure to provide appropriate care;**
>
> **d. any conduct which would fall into the category ''SPM by definition'' ... '**.

I shall explain the category 'SPM by definition' in Chapter 19.

18.24 The FTP Casework Manual made it clear that casework managers should be prepared to **'exercise discretion'** when assessing a case which did not meet any of the criteria set out above, but which nevertheless seemed to raise questions about whether the doctor was dangerous.

Referral Back for Local Action

18.25 If none of the circumstances listed at paragraph 18.22(a)–(s) applied, the casework manager would then go on to consider the source of the complaint. The casework manager would consider whether the complaint came from a private individual or from a person acting in a public capacity. A person acting in a public capacity was defined in the 1988 Professional Conduct Rules as:

> **'... an officer of a Health Authority, Health Board, Common Services Agency or Board of Governors of a hospital, or of a Local or Area Medical Committee or Family Practitioner Committee, or of a Hospital Medical Staff Committee or body exercising similar functions, or of a Licensing Body (that is, a University or other body granting primary United Kingdom qualifications), acting as such, or of a Government Department or local or public authority, or any person holding judicial office, or any officer attached to a Court, or the Solicitor to the Council'**.

In practice, the 'person acting in a public capacity' was usually a NHS trust or PCT. For convenience, I shall use the term 'public body' or 'referring body' instead of 'a person acting in a public capacity'.

18.26 If the complaint came from a public body, the casework manager would consider whether it appeared that all 'local procedures' had been exhausted before the complaint was referred to the GMC. If, for example, a PCT was reporting a doctor who was said to be practising to a generally poor standard, the GMC would expect the PCT to have attempted some form of remedial action (using its performance procedures) before referring the case on. If it appeared that local procedures had not, or might not have, been fully exhausted, the casework manager would contact the referring body and discuss how the case should be handled. The FTP Casework Manual stated:

> **'Where there is any question of an immediate danger to patients, the GMC may need to act. In other cases, efforts should be made to establish what local measures have been tried in order to resolve the doctor's problems – including whether the NCAA** (*National Clinical Assessment Authority*) **have been involved. One possible result of this type of discussion is that the referrer will withdraw the referral and take other measures locally first before referring back to the GMC if necessary.'**

18.27 The reference to the NCAA suggests that the requirement for public bodies to exhaust all local procedures before the GMC would take action applied primarily to cases involving potential poor performance by a doctor. Mr Marshall told the Inquiry that, sometimes, a three-way discussion took place between the GMC, the NCAA and the referring body. He said that, in all cases where the complaint came from a public body (not just where there was uncertainty as to whether local procedures had been exhausted), there was personal contact with the referring body in order to discuss how the case should be dealt with.

18.28 Where the complaint came from a private individual, the casework manager would consider whether that person had made use of any available complaints procedures before approaching the GMC. In general, the GMC would not consider a complaint from a private individual unless local complaints procedures had been exhausted. If the complaint related to a doctor working in the NHS, the casework manager had to consider whether there was any reason to believe that the complainant had referred the matter to the appropriate NHS complaints body and had exhausted that body's complaints procedures before making a complaint to the GMC. If the complaint related to a doctor in private practice, the individual would be expected to have made use of any available complaints procedures, including reference to the National Care Standards Commission (NCSC, now part of the Commission for Healthcare Audit and Inspection, which is known as the Healthcare Commission). There were other local complaints procedures to which certain complainants were expected to direct their complaints in certain circumstances, but I shall refer only to those relating to NHS and private treatment. If it did not appear that the individual had made use of the available complaints procedures, the case would be closed at that stage unless there was any cause to suspect that the doctor was dangerous. If there was no cause to suspect that s/he was dangerous, the complainant would be advised to direct the complaint to the appropriate complaints handling body.

18.29 It should be noted that the test applied by the staff at this stage (in cases where it appeared that the local complaints procedures had not been exhausted) was not whether (in the words of rule 6) **'a question arises whether the conduct of a practitioner constitutes**

serious professional misconduct'. The test applied by the staff was the higher test of whether there was cause to suspect that the doctor was dangerous. In other words, even if a question did arise as to whether the conduct of a practitioner amounted to SPM, the case would be closed unless there was cause to suspect that s/he was dangerous. It appears to me that the practice that I have outlined above was unlawful, given the mandatory wording of rule 6. The criteria which GMC staff were instructed to use when deciding whether there was any cause to suspect that the doctor was dangerous are set out at paragraph 18.23. I shall discuss the practice of referring complaints back to local complaints procedures in greater detail later in this Chapter.

18.30 Communication with an individual complainant at this stage, and at all other times up to and including the consideration of a case by the Preliminary Proceedings Committee (PPC) and its referral to the PCC, would in general be by letter. It would be unusual for the GMC to initiate any telephone contact.

18.31 If there was evidence that the local complaints procedures had been used and exhausted, or if they were not available because the relevant time limits had expired, the casework manager would go on to consider the next stage in the decision-making process. The FTP Casework Manual advised that, if the individual concerned had referred his/her complaint to local complaints procedures but was dissatisfied with its progress through those procedures, the GMC should usually take the complaint forward, rather than try to force the individual to persevere with a process with which s/he was unhappy.

Initial Screening

18.32 At this point, the casework manager had the option of submitting the case to a medical screener for what was known as 'initial screening'. This was a fast track system for cases which the GMC staff believed could not amount to SPM or seriously deficient performance (SDP) but where the complaint was about treatment or other matters involving clinical judgement, so that some input from a medical practitioner was considered necessary before a final decision to close the case could be taken. If the medical screener agreed that the case should be closed, the confirmation of a lay screener was necessary before this could be done. I shall consider this process of initial screening when I go on to examine the screening process in Chapter 19.

Preparation of the Case for Referral to the Medical Screener

18.33 If a case passed through the initial triage (and initial screening, where appropriate) and was to be taken forward, it was allocated to a caseworker who would then be responsible for preparing the case for consideration by a medical screener. The casework manager would have given an indication of any preparatory steps to be taken. Mr Marshall said that these steps might include the obtaining of medical records or an expert opinion, if it were obvious that these were required. The caseworker would write to the complainant (if a private individual) and would seek his/her consent to disclose the details of his/her complaint to the doctor who was the subject of the complaint. If consent was forthcoming, the complaint would be disclosed and the doctor's response invited. If not, the case would be closed unless, as the FTP Casework Manual stated, **'the public interest requires that**

... (*the GMC*) **... pursue the case irrespective of the enquirer's loss of interest'**. Consent to disclose was presumed when a complaint was made by a public body.

18.34 The caseworker would also assess the available evidence and would consider whether there was any further information which could be obtained that would be of assistance to the medical screener in deciding what action to take in respect of the complaint. I shall deal with the gathering of information before screening in more detail later in this Chapter.

18.35 Before submitting the case to the medical screener, the caseworker would prepare a memorandum, summarising the nature of the allegation, the evidence available in support and, usually, the views of the caseworker as to the appropriate course of action. If the caseworker's view was that the case was likely to be sent to the PPC, s/he would prepare a draft letter to be approved by the medical screener and then sent to the doctor after screening. The letter would inform the doctor of the charges which s/he might have to face.

Later Closure of a Case

18.36 It sometimes happened that the first communication received by the GMC did not make clear the precise nature of the complaint. Clarification might have been needed in order to ascertain this. Once the matter had been clarified, closure of the case might have been appropriate on one of the grounds set out at paragraph 18.22(a)–(s). Closure of the case might also have been appropriate for other reasons which had become known or had arisen while the complaint was under consideration. Accordingly, it was possible for staff to close a case without reference to a medical screener at any stage after the initial assessment or triage and before screening. The grounds for doing so were (in addition to those referred to at paragraph 18.22(a)–(s)) that:

- the complaint had been withdrawn
- the doctor could not be identified despite all reasonable efforts to identify him/her
- the doctor had died
- there had been no response from the doctor and his/her name had been erased from the register under section 30(5) of the Medical Act 1983, whereby the name of a doctor who fails to respond within six months to an enquiry about his/her address may be erased.

18.37 In the past, the staff would also close a case when the complainant refused to provide a statutory declaration in support of his/her complaint. A statutory declaration is a formal affirmation that the contents of a written statement are true. It must be made in the presence of a solicitor or of a person within other limited categories. However, the GMC's requirement for a statutory declaration in support of a complaint was abolished in November 2002. It applied only to private individuals. No statutory declaration was required from a person acting in a public capacity.

Earlier Practice

18.38 The system for the initial stages of processing conduct cases which I have described above was of relatively recent origin. Until the late 1990s, the way in which cases were

processed was far less structured. Little data was stored on computer and staff did not have available to them the detailed guidance and the standard forms which were developed during the period between 1999 and 2003.

Changes in Practice after December 2003

18.39 Some changes in office practice have occurred since the Inquiry hearings. As I have said, in May 2004, the FTP Casework Manual was replaced by the FTP Investigation Manual. At the same time, the standard CDF and SDF were replaced by the initial processing and assessment form. It is unnecessary for me to refer in any detail to the contents of these documents, which will be superseded by new guidance and forms prepared for the use of staff when implementing the new FTP procedures.

The Procedure for Dealing with Convictions

18.40 The procedure adopted when a conviction was notified to the GMC was rather different from the procedure following the making of a complaint about a doctor. The 1988 Professional Conduct Rules (as amended in November 2002) provided that all convictions, with the exception of two classes of case, must be referred to a medical screener. The first exception related to minor motoring convictions (i.e. motoring convictions not involving drugs or alcohol). Where information was received about a conviction which the Registrar considered to be a **'minor motoring offence'**, the case should not proceed further. Such cases would be closed in the office without reference to a medical screener. The second exception related to conviction cases where a custodial sentence (but not a suspended sentence) had been imposed. After November 2002, these were referred direct to the PCC for hearing, unless the staff (exercising the powers of the Registrar) were of the opinion that a direct referral would not be in the public interest.

18.41 If, following a criminal investigation, no charges were brought or charges were dropped, or if a criminal trial resulted in an acquittal, the GMC might, nevertheless, wish to pursue the case if issues about the doctor's fitness to practise had been raised in the course of the criminal investigation. This might also be the case if a criminal court had imposed an absolute or conditional discharge (which, as I have explained, would not have ranked as a 'conviction'), or if the doctor had been cautioned for a criminal offence. In that event, the case would follow the same procedure as that for a complaint.

18.42 After 2000, on receipt by the GMC of information about a conviction, or about an ongoing criminal investigation or ongoing criminal proceedings affecting a doctor, a casework manager would give urgent consideration to whether it would be appropriate for the case to be referred to a medical screener for possible referral to the IOC. However, before 2000, the GMC had no power to make interim orders in respect of a doctor who was being investigated or was facing trial for a criminal offence. This *lacuna* in the GMC's powers was rectified as the direct result of the GMC's inability to suspend Shipman from practice in 1998 when it was discovered that he was under investigation for murder. On reflection, it is surprising that, until Shipman's case, the GMC had apparently not felt the need for such a power and had not previously requested its provision. I refer to this matter in more detail in Chapter 20.

Audit

18.43 In the period from 1996 to 2001, the annual number of convictions reported and complaints received by the GMC rose from about 1500 or 1600 to 4500. The GMC office had considerable difficulty in managing this increased workload and this resulted in lengthy delays in dealing with cases. Mr Marshall told the Inquiry that, by 2000, it had been recognised that the GMC had no effective way of managing cases. It was reliant on caseworkers to report any problems that arose. Many of the cases in the system had been open for a long time without any real action being taken on them. An exercise, known as the Case Review Audit and Management Information Project, was undertaken. Mr Marshall managed the Project for 12 months. In effect, it amounted to a 'spring clean' of open cases. It involved considering whether further action was necessary and reviewing cases. As a result of the exercise, many cases were closed. At the same time, an audit process was instituted, whereby 10% of cases processed by the GMC staff were audited in an attempt to discover whether proper procedures had been followed and whether those procedures could be improved. That work led to the implementation of a structured work flow procedure for screening and to the preparation of the FTP Casework Manual and of other instructions for caseworkers. In time, the case review element of the Project ceased, as the backlog of open cases was dealt with. However, audit continued and was carried out by a newly formed Fitness to Practise Directorate (FPD) audit team.

18.44 In July 2000, service standards came into effect for the first time. These service standards identified periods within which certain elements of the FTP procedures should be completed. Targets for completion of cases within the service standards were set and regular reports of performance against the standards were required by the Council.

18.45 From January 2003, the FPD audit team carried out audits of random samples of cases at four different stages of progress. These were described as 'screening audits' (presumably because they were audits of work done in the Screening Section). They did not, however, relate to the work of the screeners. One hundred and ten cases every four weeks were selected for audit. The purpose of the audit was to check that all the appropriate procedural steps had been taken. In particular, a check was made to ensure that service standards had been met, that the case file had been well ordered and that the database had been appropriately maintained to reflect the progress of the investigation. If errors were found, auditors identified any appropriate corrective action which should be taken, and the execution of that corrective action was also the subject of audit.

18.46 Decisions to close a case at the triage stage were also audited and any errors taken up with the relevant casework manager. Until the end of 2003, 10% of cases closed at triage were audited. This was subsequently increased to 50%. During December 2003, 144 cases were closed at triage. One half (72) of those cases were audited. Four cases were identified as having been closed incorrectly (although, in one case, after further discussion with the casework manager, it was decided that his action had been justified). Three cases were reopened. Two of those cases had been inappropriately referred back to local complaints procedures. One (a sensitive case involving a complaint by a father whose children had been removed from his care after a court hearing at which the doctors complained of had given expert evidence) had been closed on the ground that the

complainant was not suggesting the doctors had acted unreasonably. In fact, although it appears that he had not said this in so many words, it was clear that he was alleging unreasonableness. There were nine further cases where an inappropriate reason for closure had been recorded on the SDF, although the auditor was satisfied that the closure was justified for other reasons. It occurred to me that, in view of the fact that three of the 72 cases examined were found to have been incorrectly closed, it would have been wise to examine the other 72. However, I do not think that that was done.

Advice to Refer a Complaint to Local Complaints Procedures

18.47 I have said that, in general, the GMC was not in the past prepared to consider a complaint from a private individual about medical treatment unless and until any complaints procedures available locally had been exhausted. Instead, complainants would be advised to pursue the complaint through local procedures. Until October or November 2002, the policy did not extend to complaints about private treatment, only to complaints relating to NHS treatment. After that time, however, complaints about private treatment were also referred back to the complaints procedures of the private doctors or organisations concerned.

Criticism of the Policy

18.48 The policy has been the subject of controversy for many years. In 1988, Mrs Jean Robinson, then a lay member of the GMC, drew attention to it in her publication 'A Patient Voice at the GMC'[2]. She complained that the **'hidden policy'** of the GMC for the previous 15 years had been that complaints about NHS treatment made by private individuals were not considered by a GMC screener but were instead referred straight back to the complainant with advice to pursue the complaint through NHS complaints procedures. The GMC would consider such complaints only if they had been investigated and found proved by a NHS authority. Instead of deciding itself in which cases it should act, the GMC relied on NHS authorities to report, at the conclusion of the complaints procedures, any case which appeared to them serious enough to warrant the attention of the GMC. Mrs Robinson expressed concern that this policy was adopted in all cases involving NHS complaints, no matter how serious the allegation against the doctor and no matter whether a question of SPM did or did not arise. Mrs Robinson questioned whether the policy complied with the GMC's Rules. The relevant rule was rule 6 of the 1988 Professional Conduct Rules, the terms of which I set out at paragraph 18.20.

18.49 Mrs Robinson observed that there were arrangements in place for reports to be made to the GMC by NHS authorities in the case of complaints against GPs, but not in respect of complaints against hospital doctors. She pointed out that, at the time she was writing, NHS hospital complaints procedures were unsatisfactory and rarely resulted in a report to the GMC. She said that, as a result, **'hospital doctors have been largely immune from GMC action on clinical standards'**. Mrs Robinson was also critical of the procedures for dealing with complaints against GPs. I have described in Chapter 6 the complaints

[2] Robinson, Jean (1988) 'A Patient Voice at the GMC'. London: Health Rights.

procedures which were in force at the time when Mrs Robinson was writing and it is clear that her criticisms were justified.

18.50 Briefly, the position was that complaints about a breach by a GP of his/her terms of service were heard by medical service committees (MSCs) of family practitioner committees (FPCs). Reports of all cases in which a breach had been found proved were sent to the Secretary of State for Health (SoS), who would report appropriate cases to the GMC, after taking the advice of the Medical Advisory Committee. From 1992, the SoS delegated his/her powers to the Family Health Services Appeal Unit (FHSAU) and, from 1996, the FHSAU's functions were exercised by the Family Health Services Appeal Authority (FHSAA) (later the FHSAA (Special Health Authority)). The Department of Health (DoH) issued a list of criteria setting out the types of case that should be reported to the GMC. These were cases involving a neglect or disregard of professional responsibilities to patients, cases where there had been a NHS Tribunal decision that a doctor's name should be removed from the FPC's medical list, and other cases involving irregular certification, improper charging or claims for fees or canvassing or gaining of patients by unethical means. In addition, advice was given to consider reporting cases of misconduct which had been **'seriously prejudicial to the medical care of patients'**. There was also reference to the possibility that cases of dishonesty by doctors might amount to SPM and should be reported. After 1992, family health services authorities (FHSAs), the successors to FPCs, were encouraged to report appropriate cases directly to the GMC (rather than to rely on the FHSAU/FHSAA to do so).

18.51 Despite the list of criteria issued by the DoH, which was in existence at the time of Mrs Robinson's concern, it was not at all clear that all proven complaints that might amount to SPM would necessarily find their way back to the GMC. Mrs Robinson's contention was that the chances of a GP being reported to the GMC following a complaint to his/her FPC were slim. She pointed out that NHS complaints procedures could take a long time to be completed. Even if a complaint was eventually referred back to the GMC after completion of the procedures, there was often a long delay before this occurred. A doctor who was dangerously incompetent might have caused further damage to patients while the complaint was being processed.

18.52 Mrs Robinson pointed out that some patients and their families might be unequal to the task of pursuing a complaint through NHS complaints procedures and some might find that they were already outside the time limit (then only eight weeks) for doing so. Some might not realise that it was necessary for them to follow the formal complaints procedures (as opposed to the informal conciliation procedures which were being encouraged at the time) in order to have any prospect at all of their cases being referred back to the GMC. At the time when Mrs Robinson was writing, the standard letters written by the GMC to complainants advised them that they could bring their complaints back to the GMC at the conclusion of the NHS complaints process. Previous versions of the letter had not contained that information. Mrs Robinson said that the standard letter had been amended at her insistence. Recipients of earlier versions of the letter might, however, have believed that they could not approach the GMC again, even if they had received no satisfaction from local complaints procedures.

18.53 The effect of the GMC's policy was to make it likely that some cases of seriously substandard clinical practice would not be considered by the GMC. This could occur because complainants, disappointed at the initial response from the GMC, gave up and did not pursue their cases further. But, even if they pursued their complaint locally, it could founder in a number of ways. If the complaint was found proved, it might not be referred to the GMC by the relevant NHS authority. Even if it were referred back to the GMC, two to three years might have passed, after which time witnesses might be no longer available or might be unwilling to give their evidence for a second time. In such cases, disciplinary action by the GMC would be impossible. Furthermore, throughout that time, the doctor would have been free to treat patients.

18.54 Mrs Robinson observed that the GMC sought to justify its policy by reference to the stringent time limits within which complaints against GPs had to be made. It was said that, by the time the GMC had considered and rejected a complaint, the complainant might have lost the opportunity to complain locally. It was therefore better for him/her, the GMC suggested, to be referred to the local procedures immediately. Mrs Robinson pointed out that it would be perfectly possible for the GMC to refer a complaint to a medical screener for consideration, while at the same time writing to the complainant to inform him/her of the time limits for making a complaint locally. Thus, the complainant's position could be satisfactorily safeguarded. When Mrs Robinson's suggestion was put to Mr Howes, who was employed in the Conduct Section more or less continuously between 1980 and 1994, he told the Inquiry that the perception within the GMC at the time Mrs Robinson was writing was, rightly or wrongly, that to start two procedures simultaneously would have been a 'nonsense' and unfair to doctors. I feel bound to observe that it does not appear to have been uppermost in the GMC's mind that what was required was a procedure that would best protect patients, while also being fair to doctors. In any event, it appears that the GMC sometimes did allow two sets of procedures to be in operation at the same time. Mr Townsend, Head of the Conduct Section from 1994 until 1998, told the Inquiry that there were occasions when NHS authorities reported to the GMC serious cases with which they were currently dealing in their complaints procedures. The GMC kept open the possibility of starting its own procedures to run in parallel with local procedures if the public interest demanded it. It may be that the situation described by Mr Townsend did not apply in the 1980s and early 1990s.

Evidence to the Wilson Committee

18.55 Until 1993, and despite the serious concerns raised by Mrs Robinson, the system continued whereby a member of staff would direct complaints about NHS treatment back to complainants without referring them to a medical screener. GMC statistics show that, in the year to 31st August 1993, 160 complaints (i.e. about 10% of all complaints received by the GMC) were dealt with in this way. In July 1993, a pilot scheme was introduced whereby such complaints were referred to a medical screener for consideration, rather than being immediately referred back to the complainant by members of the GMC staff. At the time the change was made, the reason behind it was said (in the Annual Report of the PPC presented to the Council in November 1993) to be that the time limits within which complaints could be made to NHS bodies had been relaxed, giving more time for the GMC

to deal with complaints. This was plainly not the reason, as the change in time limits had taken place in 1990 and extended the time limits only from eight to thirteen weeks. In any event, Mr Scott told the Inquiry that the change of system resulted from the fact that, in 1993, the GMC was invited to submit evidence to the Independent Review Committee, chaired by Professor (later Sir) Alan Wilson (the Wilson Committee). The Wilson Committee was considering reform of the NHS complaints procedures. The preparation of evidence for submission to the Wilson Committee caused members of the GMC to reflect on its existing practice of allowing members of staff to refer cases back to complainants without the intervention of the medical screeners, and to change it. It may be that the change resulted from concerns as to whether the policy then in operation complied with the GMC's Rules. In my view, it did not. Rule 6 of the 1988 Professional Conduct Rules required the Registrar (in practice, a member of staff) to send to the President (medical screener) any complaint which appeared to raise a question of SPM. It was not for members of staff to close such cases themselves after advising complainants to use local procedures.

18.56 In September 1993, the PPC sent a memorandum of evidence to the Wilson Committee on behalf of the GMC. The memorandum discussed the GMC's policy of referring complaints to the NHS complaints procedures, a policy which was described by the PPC as **'helpful to complainants'**. The memorandum described how complainants to the GMC were informed, where appropriate, of the existence of the NHS complaints procedures and were offered the opportunity of using those procedures and/or of writing again to the GMC. It observed that the majority of such complaints then proceeded under the NHS complaints procedures. In fact, the PPC had no means of knowing that. The GMC took no steps to find out what subsequently happened to cases which had been referred back to complainants. All the PPC could have known was that the majority of complainants did not approach the GMC again.

18.57 The memorandum made clear that the GMC wanted to retain the ability, if it regarded it as appropriate to do so, to proceed with a complaint that was reported to it, without referring it to local complaints procedures. It would do that, it was claimed, if the complaint seemed to raise a question of SPM or of serious impairment of health that the GMC had a statutory duty to consider and act upon. That statement of current practice was not accurate because, as I have indicated, staff did not refer to medical screeners all complaints from individuals that appeared to raise a question of SPM but only those in which the local complaints procedures had been completed. If the local complaints procedure had not been completed, the case would be accepted into the GMC procedures only if it appeared to the GMC that the doctor was a risk to the public.

18.58 The PPC expressed concern to the Wilson Committee that NHS bodies were not referring to the GMC all cases which should have been referred. The memorandum pointed out that only one or two complaints which had been decided by MSCs had been referred direct to the GMC by FHSAs. FHSAs sometimes dealt with serious MSC cases without referring them to the FHSAU. Only one case which had been dealt with by the NHS Tribunal had been reported to the GMC in three years. Referrals from hospital authorities had been in single figures in 1990, 1991 and 1992. The memorandum said that the GMC had been expressing concern since 1987 at the small numbers of doctors being reported by hospital authorities. In evidence to the Inquiry, Mr Townsend said that the lack of effective

disciplinary procedures in hospitals was a source of concern during his time in the Conduct Section between 1994 and 1998. Hospital doctors tended to be dismissed for misconduct without a referral to the GMC. Moreover, he said that there was concern within the GMC that the policy of requiring complaints to be directed to local complaints procedures put the onus on complainants and NHS authorities to trigger the revival of the cases at the GMC. It was felt that this was inconsistent with the GMC's stated purpose, which was to protect the public interest.

18.59 The PPC's memorandum to the Wilson Committee also referred to the delays (said to be as long as three years on occasion) which could occur before a complaint about NHS treatment was resolved locally and its outcome reported to the GMC. Reference was made to the adverse effects on the evidence available to the GMC and examples of particularly lengthy delays were given. The memorandum referred to repeated representations which had been made by the GMC over a period of 17 years about excessive delays in NHS complaints procedures and about the effects of those delays. During that time, the memorandum said, the delays had got worse, not better.

18.60 The memorandum asked the Wilson Committee to consider means of avoiding protracted delays. The PPC requested that FHSAs should be reminded of their duty to refer appropriate cases to the GMC. There was also a request that mechanisms should be established for the reporting to the GMC of cases involving hospital doctors where it appeared that a question of SPM arose.

18.61 It is clear that, by 1993 at least (and probably long before), the GMC fully recognised the deficiencies of the NHS complaints procedures. It was also recognised that, as a result of those deficiencies, cases of SPM that should have been referred back to the GMC were not reaching it. Those cases that were eventually referred to the GMC, after passing through the NHS complaints procedures, were not arriving until long after the events to which the complaints related. Yet, despite the fact that Mrs Robinson had, in 1988, drawn its attention to the effect of the deficiencies, the GMC had persisted in its policy of sending cases back for referral into local procedures without considering whether or not they raised a question of SPM. Even in 1993, when the effects of the deficiencies of the complaints system were plainly recognised, there does not seem to have been any recognition of the fact that some complaints which had come to the GMC and been referred back to the complainant might not have gone into the NHS complaints procedures at all and may consequently have been lost to the regulatory system altogether.

The Change of Practice in 1993

18.62 The change of practice, which was first piloted in July 1993 and continued thereafter, meant that all complaints about NHS treatment were referred in the first instance to a medical screener. When the change was made, it was said to be intended that the medical screener would decide whether the complaint raised a question of SPM and that only if s/he thought that it did not would the complainant be advised to direct the complaint to local complaints procedures. That intention was expressed in the Annual Report of the PPC, presented to the Council in November 1993. Had that intention been put into effect,

GMC practice would then have been in compliance with rule 6 of the 1988 Professional Conduct Rules.

18.63 Despite the contents of that Annual Report, it is clear from the findings of the PSI, which carried out an analysis of complaints received by the GMC in the 12 month period from September 1993, that the intention claimed in the Annual Report had not been carried into effect. The PSI team found that medical screeners were applying a threshold higher than SPM for the retention of cases by the GMC. In describing the procedures, the 1996 PSI Report stated:

> **'... it should be noted here that the GMC receives frequent complaints which it feels should more appropriately be dealt with initially by other bodies, for example, Family Health Services Authority ... a Health Authority, an NHS Trust, the Prison Medical Service or the Mental Health Act Commission. The question of whether there is a *prima facie* case of serious professional misconduct may or may not arise in these cases, but the GMC does not usually pursue a complaint in these circumstances but suggests that the complainant takes it up initially with ''a more appropriate body''. The discretion of the medical screener is exercised in cases where it is felt that there could be risk to the public if the GMC failed to initiate action at the same time as suggesting that the complaint should be made to another authority.'**

18.64 It seems that the PSI team had been told that the test being applied by the screeners was not whether a complaint raised a question of SPM but whether it gave rise to a risk to the public. Provided that no such risk was considered to arise, the complainant would be advised to direct the complaint to the local complaints procedures, whether or not the case raised a question of SPM. The concurrence of a lay screener was not required when a medical screener agreed that a case should be referred back to be pursued through local procedures. This was because the case was not classified as having been formally rejected by the GMC. It should have been so classified because, in reality, the case had been closed. Of course, there was a possibility that the complainant might bring the case back but, if s/he did not, the GMC would do nothing more. The effect of this incorrect classification was that the possibility that the lay screener might decide that the case should remain in the GMC was lost. In short, the only change that had occurred as a result of the consideration of the GMC's procedures undertaken at the time of the submission to the Wilson Committee was that the 'risk to the public' test was applied by screeners, rather than by GMC staff. No doubt many Council members believed (relying on the 1993 Annual Report) that the procedures in operation were compliant with rule 6. In fact, they were not, because the medical screeners were not applying the correct statutory test. The medical screeners were members of the GMC and should have realised that the reality was that the process was not as described in the Annual Report and was not compliant with the Rules. I shall refer further to the findings of the PSI team later in this Chapter.

18.65 If there had indeed been a change in the test to be applied as from about November 1993, one might have expected to see a significant reduction in the proportion of complaints being referred back to complainants with advice to pursue them through local

procedures. However, such figures as are available suggest that there was no such reduction. In the year to August 1992, the GMC received information about 1300 convictions and complaints; 185 of those were referred back to be pursued through local procedures. In the year to August 1993, 1612 convictions and complaints were received, of which 160 were referred back. In 1994, 1626 convictions and complaints were received and 192 cases were referred back to be pursued through local complaints procedures. These figures would tend to confirm that the test applied before and after November 1993 was the 'risk to the public' test and that the medical screeners took broadly the same view on risk as the staff had done before the change.

18.66 The practice of referring a case back to be pursued through local procedures unless the facts suggested that there was a risk to the public seems to have operated even where the doctor had a previous finding of SPM against him/her. In one case examined by the Inquiry, Dr JG 03 was convicted of perverting the course of justice and was later found guilty of SPM. He had given a contraindicated drug to an asthmatic patient in the early 1990s and had lied at the coroner's inquest, claiming that he was unaware from the records that the patient suffered from asthma. It was later discovered that he had falsified the records and he was prosecuted. The GMC dealt with both matters and imposed conditions on his registration for one year. A further complaint was received about this doctor seven years later, but the complainant was advised to pursue the complaint through local complaints procedures. There is no sign in the GMC file that the progress or outcome at local level of the more recent complaint was followed up.

The Guidance Contained in the 1994 Training Manual

18.67 The Training Manual, which was compiled in 1994 by Mr Howes (the 1994 Training Manual), stated that NHS treatment (or lack of it) was primarily the responsibility of the local NHS authority and that complainants should be advised **'in the first instance'** (*emphasis in the original*) to direct their complaints to the appropriate health authority (HA) or FHSA. The 1994 Training Manual gave a number of reasons for this procedure. The first related to the time limits governing local complaints procedures. If an individual was to have his/her complaint considered under those procedures, s/he had to move fairly quickly. The second reason was the speed with which local investigations could begin, even if (as was acknowledged) they took **'some time to complete'**. Mr Howes said that the reference to the speed with which local investigations could begin related to the time when a doctor would be notified of a complaint which had been made against him/her. Under NHS procedures, s/he would be notified early on, in accordance with specified time limits. Under the GMC procedures at that time, the doctor would not be notified (and the 'investigation' would not start) until the medical screener had taken a decision to refer the case to the PPC. That, it was said, could take **'some time'**. In fact, at this period, there was no significant delay within the early stages of the GMC procedures. This was an attempt to use the possibility of delay at the GMC as a justification for sending the case into local procedures. In addition, the FHSA or HA would have, it was said, much greater access to potential witnesses and relevant records. The 1994 Training Manual also made the point that complaints about hospital treatment often involved many factors (e.g. the behaviour of nurses) which lay outside the province of the GMC.

18.68 The 1994 Training Manual reminded staff that complainants were under no obligation to make a complaint first to the local body, although this was said to be **'in most respects desirable and appropriate'**. If a complainant insisted that his/her complaint should be considered by the GMC before being referred to local complaints procedures, the case should be referred to a medical screener for a decision on whether the GMC should **'intervene'**.

18.69 In describing the action to be taken when a complaint was reported to the GMC after completion of the NHS complaints procedure, the 1994 Training Manual acknowledged that such cases might reach the GMC as long as two or three years after the events which had given rise to them. By that time, the patient concerned had sometimes died. Since, if the complaint were to be referred to the PCC, a further hearing would be required, the fact that the patient was not available to give evidence could obviously cause difficulty in a case which depended on his/her evidence. It might not be possible for such a case to proceed.

18.70 The 1994 Training Manual made clear that, when a complaint had been referred to the GMC by a FHSA or a HA, following completion of its complaints procedures, the GMC would almost always take some form of action, whether by referring the cases to the PPC (and, possibly, from there to the PCC) or by issuing a warning to the doctor. In cases where there had been an adverse finding by a MSC, if it was the first time that a doctor had been found in breach of his/her terms of service and the doctor had no known previous disciplinary history, the 1994 Training Manual indicated that the case could probably be dealt with by means of a warning. In a second or subsequent case, however, formal disciplinary action might be justified, depending on the circumstances of the case and whether evidence was still available. However, when the adverse findings of two MSCs concerning Shipman were referred to the GMC by the FHSAU in 1994, no action at all was taken. I shall describe what happened on that occasion in Chapter 19.

18.71 After 1993, when a complaint about NHS treatment was received and the GMC staff considered it appropriate to refer it back to be pursued through local complaints procedures, the staff would submit to the medical screener a memorandum (much shorter and less detailed than that usually provided when a case was to be screened), setting out the reasons for recommending that the complaint should be referred to local NHS complaints procedures. Attached to the memorandum would be a draft standard letter to the complainant. Examples of the standard letters in use in 1994 were contained in the 1994 Training Manual. The letter would inform complainants that primary responsibility for considering complaints about treatment (or lack of treatment) lay with the local NHS body. It would suggest that the complainant should make his/her complaint in the first instance to the appropriate NHS body. The letter would advise the complainant of the time limit for local complaints and would enclose a photocopy of the complainant's original letter to the GMC, so that the complainant could use it, if s/he wished, when writing to the relevant NHS complaints body. The letter would inform the complainant that, if his/her complaint were upheld, an official report would automatically be sent to the GMC if **'it is considered** (*i.e. by the NHS*) **that subsequent disciplinary action by the Council may be justified'**. The complainant would be told that s/he might write again to the GMC when the investigation

by the local complaints body was complete. At that point, the screener would be willing to consider the matter further, even if the complaint had not been upheld. The letter stated:

> **'The Council does not usually consider a case until after any appropriate local investigation, because there are practical and legal difficulties about holding two inquiries into the same events at the same time.'**

18.72 It might have been undesirable and wasteful of resources to have two concurrent enquiries (and it may have been considered 'unfair to doctors') but I am unsure what the **'legal difficulties'** would have been. The letter went on to tell the complainant that if there was some **'particular reason'** why s/he did not wish to complain to the relevant NHS authority, or if the authority was for some reason not able to investigate the matter, s/he could write again to the GMC which would consider the complaint further. The telephone number of a service providing general advice on making a complaint about a NHS doctor was given.

18.73 Although the letter was helpful in tone and content, it nevertheless placed the onus for pursuing the complaint through the NHS complaints procedures squarely on the complainant. This was at a time when the GMC was fully aware of the shortcomings of the local complaints procedures and of the fact that few cases found their way back to the GMC after being referred to those procedures. The letter contained no suggestion that the GMC might itself pass on the complaint to the NHS complaints body concerned. Nor was there any follow-up procedure to ensure that a complaint had been reported to the appropriate authority or to ascertain the outcome. The complaint might have been about unacceptable clinical practice which, if repeated, could have caused harm to other patients. Yet, if the complainant chose not to pursue the complaint further, the NHS body responsible for the doctor (in the case of a GP, the FHSA) might have remained wholly unaware that an incident had occurred or that patients might be at risk from the doctor. The GMC would take no steps to inform it.

The Work of the Policy Studies Institute

18.74 The 1996 PSI Report recommended that the GMC should review its role and responsibilities when dealing with cases where complainants were advised to direct their complaints to a local NHS body. It made the point that the GMC would often not be in a position to know, at the stage when the advice was given, whether the complaint was likely to amount to SPM. The PSI team examined a sample of 134 complaints in which, during the year to August 1994, the GMC had advised complainants to refer their complaints to a more appropriate body. They found that the complaints included complaints about dissatisfaction with treatment, about failure to take steps to make a diagnosis and about failure to diagnose and treat patients. One was an allegation of 'criminal irresponsibility' resulting in the death of a patient. The fact that these complaints (particularly one such as the last-mentioned) had not been pursued immediately by the GMC was a source of understandable concern to the PSI team.

18.75 Professor Allen, who led the PSI team, told the Inquiry that she and her colleagues were concerned that these cases appeared sometimes to be 'lost' to the GMC. They noted the onus being put on patients and their families to pursue the complaints. If they decided not

to pursue them, the complaints would just disappear. The PSI team also expressed concern at the failure of the GMC to follow up complaints so as to ascertain their outcome.

18.76 In 1996, the NHS procedures governing complaints about GPs changed. The procedures in operation from 1996 are described in Chapter 7. Professor Allen told the Inquiry that, under the pre-1996 procedures, the process of making a complaint about a GP locally was relatively easy. The complainant would complain to the FHSA. The complaint would be logged and considered and, if it appeared to relate to a breach of terms of service, it would be referred to the chairman of the MSC and the process would be underway. Under the 1996 procedures, however, complaints went to the GP practice in the first instance and many were 'resolved' there. The PCO would have no idea what the nature of the complaint or the 'resolution' was. The process of securing an independent review panel (IRP) hearing under the new procedures was, she said, 'incredibly convoluted', as a result of which comparatively few hearings were held. Professor Allen believed that some patients were discouraged from complaining because of the requirement to approach the GP practice first, a concern that was highlighted in the research carried out in the late 1990s, which I described in Chapter 7. In short, complaints about a GP were not investigated by a NHS body; the PCO had neither the power nor the resources to do so.

18.77 After 1st April 1996, the NHS complaints procedures were, for the first time, separated from the disciplinary procedures for GPs. Previously, a patient complaint might lead to a finding of a breach of the GP's terms of service and to a sanction. After 1996, even if the findings of an IRP hearing showed that a GP had been in breach of his/her terms of service, disciplinary proceedings would not automatically follow. The disciplinary process was cumbersome and very few disciplinary hearings took place at all. Also, there was a change of culture and PCOs preferred to take a remedial approach to any shortcomings in a GP's practice. After 1996, the effect of GMC policy was, therefore, to refer a doctor from a system designed to discipline doctors where appropriate (i.e. the GMC procedures) to a complaints system, the primary purpose of which was to 'resolve' the complaint, preferably by conciliation. Any recognised shortcomings in the doctor's practice were likely to be dealt with (if at all) by remediation rather than disciplinary action and the prospects of a prompt referral back to the GMC were remote. The illogicality of that situation, and its even greater potential for allowing complaints to be 'lost', does not appear to have been appreciated by the GMC.

The 1997 Screeners' Handbook

18.78 At the time of the production of the Screeners' Handbook in 1997, medical screeners (rather than the GMC staff) were still being required to consider what should happen to complaints where the likely outcome was referral to NHS complaints procedures. The Screeners' Handbook contained the following advice:

> **'If, in a complaint about NHS treatment and after appropriate inquiries have been made, it appears that**
>
> **a. The pursuit of the complaint through the NHS procedures would be the most effective way to produce information which the GMC requires**

to consider the case further and without which further GMC action would be difficult or impossible, or

b. There is no immediate threat to patient safety and it would be fairer to the doctor not to make him or her face two sets of proceedings simultaneously,

the screener may decide that the complainant should be asked to consider making a complaint through the NHS complaints procedures (or to continue to pursue one already lodged), and invited to approach the GMC once that process has been completed, whatever the outcome.'

18.79 It is to be noted, first, that the test to be applied by the medical screeners was one of **'no immediate threat to patient safety'**. This was similar to the test which had previously been applied by the medical screeners, namely whether there could be a risk to the public if the GMC did not act immediately. Second, it is clear to me from the evidence, particularly that of Dr Korlipara, that the screeners assumed that the pursuit of a complaint through NHS complaints procedures would, in all cases which did not reveal an **'immediate threat to patient safety'**, be the most effective way to deal with the case.

18.80 The 1997 Screeners' Handbook described a change in practice that was said to have been initiated following the 1996 PSI Report. If a case was **'deferred'**, by advising the complainant to pursue it through local NHS complaints procedures, the medical screener was now to set a date for review of the case. If nothing more had been heard of the case by that date, GMC staff were to write to the complainant and to attempt to establish whether local complaints procedures had been completed and, if so, with what result. On receipt of the reply, a decision would be made whether to take the case forward under GMC procedures or, if the lay screener agreed, to close the case. If the complainant did not reply, efforts were to be made to persuade him/her to provide further evidence, failing which the case would be closed. The purpose of this change was to ensure there was a positive decision to close a case, rather than it just being left in limbo with no attempt to follow it up after it had been referred back to the complainant.

18.81 Mr Townsend described the change of practice and the reasons behind it. He said that there was an appreciation within the GMC that the way its procedures had worked previously had made them seem **'more like a complaints procedure than a public interest protection procedure'**. He had left the Conduct Section in 1998 and was unable to say what the impact of the new practice had been. At some point shortly afterwards, the new practice of setting a review date and following up complaints appears to have fallen into disuse. This may have been in 1999 when, as I shall explain, a decision was taken that cases of this type should no longer be referred to the medical screener save in certain limited circumstances.

Guidance to the Public

18.82 In November 1997, the GMC issued 'A Problem With Your Doctor?', a leaflet designed to inform the public about its procedures. Under the heading 'What to do if you have a problem with your doctor', the leaflet explained, in simple terms, the procedures for making a complaint about NHS services locally. It went on to say:

> **'However, you can complain to us even if you don't complain to your health authority or GP first. Please contact us if you would like more information about our complaints procedures, or if you want to discuss a particular problem in confidence. Our staff are experienced in dealing with complaints and will give you unbiased advice.'**

This advice (which is reproduced in the current version of the same publication) seems surprising since GMC policy continued to be that complaints about NHS treatment should be referred back to be pursued through local complaints procedures unless there was an immediate threat to patient safety. Mr Scott told the Inquiry that the leaflet was intended to be helpful but had the unintended effect of giving individuals the impression that the GMC would look at 'almost any problem' with a doctor, no matter what it was. He said that the leaflet resulted from 'a genuine lack of clarity within the organisation about how to position itself in relation to other systems and in particular the NHS complaints system'.

A Further Change in Practice

18.83 In March 1999, there was another change in practice, as a result of advice given by Professor Allen and her colleagues. They suggested that the workload of the medical screeners (which was very heavy in the mid-1990s) could be made lighter by reducing the number of cases referred unnecessarily to them. They therefore suggested that those cases that were then being referred by the medical screeners automatically to local NHS complaints procedures should, in the future, be dealt with by GMC staff. Such cases should be referred to a medical screener only if the doctor was thought to pose a risk to the public. This change was implemented in March 1999 and has continued ever since. As I have said, the criterion that must now be applied by GMC staff is whether there is cause to suspect that the doctor might be dangerous. In 2000, GMC staff advised complainants in 897 cases (20% of all complaints received in that year) to direct their complaints to local procedures. In 2001 (the last year for which a figure is available) complainants in 998 cases (18.7% of all complaints received) were so advised by members of the GMC staff.

18.84 It is clear that the practice operated by the GMC after 1999 perpetuated breaches of rule 6 of the 1988 Professional Conduct Rules. The practice returned, in effect, to that followed before 1993. According to Mr Scott, the GMC had realised in 1993 that the practice of allowing staff to take the decision to advise complainants to use local procedures, without first asking a screener to consider the case, must be changed. It is not clear whether it was also realised that the practice did not comply with the Rules. Possibly the members did not realise this, as they do not appear to have appreciated that, even after the change, the practice was still not compliant since the screeners were not applying the correct statutory test. In fact, it seems that the GMC collectively thought that the screeners were applying the right test (see above), but the screeners must have known that they were not. In any event, in 1999, the GMC accepted Professor Allen's suggestion to revert to the old practice. Professor Allen and her team are not to be blamed for offering that advice. They were not lawyers. They were simply seeking to help the GMC to deal with its workload. No one seems to have considered whether the new practice was compliant with the Rules.

Complaints about Private Treatment

18.85 In October or November 2002, the practice of advising complainants to direct their complaints initially to local complaints procedures was extended to include complaints about private treatment. This meant that patients who claimed to have received substandard treatment in private hospitals, clinics and practices or from individual private doctors were from that time advised by the GMC (in the absence of any reason to suspect that the doctor in question was an immediate danger to patients) to direct their complaints to the complaints procedures of those organisations or doctors. The Inquiry has heard no evidence about private complaints procedures. However, it seems to me that the quality and effectiveness of those procedures is likely to be extremely variable. Some of the larger providers of private health care may have well-developed complaints procedures. Other providers may not. Some complaints procedures may lack independence, particularly if the doctor practises alone or within a small organisation. It is true that, since its establishment in 2002, the NCSC (now part of the Healthcare Commission) has had responsibility for monitoring and regulating private health care, including complaints procedures. If a complainant experiences problems with the complaints procedure of a private organisation or doctor, s/he can report the matter to the Healthcare Commission. He or she could also return to the GMC. However, the onus is once again on the patient to initiate such action and to persevere if at first s/he does not succeed. Otherwise, his/her complaint will be lost to the regulatory system altogether.

Subsequent Developments

18.86 As I have said, it appears that the practice of following up the progress of complaints which had been referred back to local complaints procedures was discontinued at some point, probably in March 1999. There was no mention in the November 2002 or the April 2003 editions of the FTP Casework Manual of any review or follow-up procedure. When he gave evidence to the Inquiry in December 2003, Mr Marshall said that the only follow-up would be if the GMC were to receive a further complaint about the doctor. In that event, the original complaint would be retrieved and the new complaint considered in the light of it. However, as I shall explain, many of the doctors who have been the subject of complaints which have been closed by the GMC staff were never identified by the GMC. That being the case, there would be no possibility of complaints against them being reactivated if a later complaint about the same doctor were to be received.

Evidence about the Policy from Members and Staff at the General Medical Council

18.87 Dr Korlipara said that, in his view, it was 'only right' (save in a case where a GP was considered dangerous) that local complaints procedures should be completed before the GMC took a decision whether to act. PCTs could use their knowledge of the doctor to put the complaint in context. If necessary, the patient could be protected by immediate GMC action. Where that was not necessary, the GMC would be assisted by not having to 'go through the procedures locally'. By this, I think that Dr Korlipara meant that the GMC would not have to undertake local investigations. If the case were referred back to the GMC, it could speedily arrive at a decision (on the basis of any investigation which had been

carried out locally) as to whether there were issues of SPM which required further action. Dr Korlipara recognised that the NHS complaints procedure might be long-drawn-out but, nevertheless, felt that it was 'far more commonsensical and fair' that complaints should, wherever possible, be investigated and remedied locally. He said that the GMC should investigate only those complaints which were of such gravity that patient protection was seriously compromised or there was imminent danger to patients. If there was delay, Dr Korlipara said it was for 'some other agencies' (I take that to mean the bodies dealing with complaints) to expedite their processes so that patients did not suffer.

18.88 Dr Korlipara agreed that the system put a burden on patients. He accepted that, if a complaint were to be directed back to a local complaints procedure, it would be preferable from the patient's point of view if the GMC were to make direct contact with the local PCT, NHS trust or other complaints handling body, rather than leaving it to the complainant to do so. He did not know whether the GMC had ever considered doing this.

18.89 Other witnesses also supported the need for local investigation of complaints. For example, Mr Howes spoke of the complexity of some complaints reaching the GMC; they involved not only criticism of the treatment provided by a doctor, which was a matter for the GMC, but also such problems as hospital waiting lists and complaints about the conduct of nurses and other healthcare professionals. His preference was for a system where all complaints relating to treatment were handled speedily and well at a local level and where relevant concerns arising from those complaints were reported to the GMC.

18.90 Sir Graeme Catto thought that most complaints about clinical treatment could be more effectively and conveniently investigated locally but was concerned to ensure that the GMC was kept informed and was given the opportunity to provide any relevant information it might have. He was also anxious to preserve the existing position whereby members of the public were advised that they could bring any complaint or concern directly to the GMC if they preferred to do so.

18.91 By the time Mr Scott gave evidence, the GMC was aware of the Inquiry's concerns about the practice of referring cases back to local complaints procedures. He said that the GMC was 'considering whether instead of sending it (*i.e. a complaint*) back with a suggestion that they (*i.e. complainants*) take it elsewhere that we might do that job on their behalf, subject, of course, to their agreement that we should do so'. After the Inquiry hearings, the GMC announced that, from May 2004, it would discuss at an early stage certain complaints (broadly speaking, those where the way forward was not clear) with the doctor's employer or PCO. If, following that discussion, the GMC decided not to proceed with the complaint itself, but considered that it should be dealt with locally, it would (provided the complainant agreed) refer the case direct to the doctor's employer or PCO.

18.92 It is not known how this initiative has worked in practice. However, if it were to result in cases being directly referred by the GMC to local complaints procedures, rather than the onus being placed on complainants to do this, this should at least remove the potential for complaints to be lost between the GMC and the local complaints body. That would be a considerable advance. However, it is likely that certain problems would still persist. First, if the complaint were referred into local patient complaints procedures, the onus would still remain on the complainant to pursue it to a conclusion. Second, patient complaints

procedures – with their emphasis on patient satisfaction – are not, it seems to me, a suitable means of dealing with allegations which have a bearing on a doctor's ability to treat patients safely. They are unlikely to result in a prompt and thorough investigation of the circumstances of the case. Third, it still does not appear that any provision exists for follow-up by the GMC once a complaint has been referred to a local complaints body. It seems to me that the GMC should have a mechanism by which it can be satisfied that complaints which it has passed to other bodies for investigation or other action are being properly and expeditiously dealt with. This is particularly important in relation to complaints about treatment in the private sector.

18.93 In July 2004, a significant change was made to the second stage of the NHS complaints procedures. Instead of there being a possibility of the complaint proceeding to an IRP, a complainant dissatisfied with the outcome of the first stage of the procedure can now refer the case to the Healthcare Commission. That body will consider the case and may, if it considers it appropriate, carry out its own investigation before reaching its conclusions. In some cases, there will be oral hearing. It is anticipated that there will also be changes to the first stage of the NHS complaints procedures insofar as they relate to GPs. The reference of complaints to an independent body with investigative powers at the second stage ought to improve NHS complaints handling. As the GMC will have a working relationship with the Healthcare Commission, it should, in the future, be easier for the GMC to keep a close watch on the progress of complaints going through local procedures.

18.94 I shall refer further to the GMC's intentions in relation to holding early discussions with doctors' employers and PCOs later in this Chapter.

Specific Cases

A Complaint about Shipman: Mr J

18.95 In Chapter 6, I described the way in which a complaint against Shipman, made in August 1985, about his treatment of a patient, Mr J, who had recently died, was handled by the MSC of the FPC. It was rejected without an oral hearing. In fact, a letter of complaint was also sent to the GMC at about the same time as the complaint was lodged with the FPC.

18.96 The letter, written by Mr Steven Rawlinson, Mr J's closest friend, on behalf of Mr J's mother, complained about Shipman's clinical treatment of Mr J and alleged that Shipman had breached Mr J's medical confidentiality by speaking about his condition to Mr and Mrs G, who were also patients of Shipman. It was a detailed letter, covering four pages of typescript, and closed with the words **'I await the outcome of your investigation'**. I mention that because it demonstrates what some members of the public expected (and probably still expect) of the GMC, namely that it will investigate their complaint. After a reminder from Mr Rawlinson, a member of the GMC staff replied, advising that the complaint should be pursued through local procedures. The letter did not advise Mr Rawlinson to contact the GMC again if he was dissatisfied with the outcome of the local procedures, although it did say that it was open to him to write again to the GMC on completion of the NHS procedures. In fact, Mr Rawlinson and Mrs J had already initiated a complaint locally.

18.97 The MSC did not have jurisdiction to deal with the allegation of breach of confidentiality, as such a matter was not covered by GPs' terms of service. Only the GMC could deal with that allegation. This was recognised by the GMC staff and the letter to Mr Rawlinson promised a further communication about that part of his complaint. The member of staff also wrote an internal memorandum suggesting that the issue of confidentiality should be referred to the President, who was at that time acting as medical screener. However, she drew attention to the fact that it might be difficult for Mr Rawlinson to produce evidence of the breach of confidence as he had said that Mr and Mrs G might be unwilling to give evidence against Shipman. The outcome was that a letter went to Mr Rawlinson advising him that it would be possible for the GMC to take proceedings against Shipman only if both he and Mr and Mrs G were to provide statutory declarations supporting the complaint. Mr Rawlinson now has no recollection of receiving that letter but I think it likely that he did and that he and Mrs J realised that there would be no prospect of persuading Mr and Mrs G to provide a statutory declaration supporting the complaint. That complaint went no further.

18.98 The GMC's handling of the complaint about clinical treatment was typical of the response that the GMC would have given to such a complaint over a very long period of time. Indeed, the approach would not have been markedly different if the complaint had been made in 2003. The complaint was one which, on investigation, might or might not have revealed conduct amounting to SPM. The GMC did not investigate it at all but advised the use of local procedures. As I have explained in Chapter 6, it is not clear how thoroughly the complaint was investigated locally. The complainant had no power to obtain documents. The complaint covered treatment over a substantial period of time but it is not clear whether the MSC waived the time limit and considered events that occurred more than eight weeks before the date of the complaint. I think it probable it did not. The complaint was rejected without an oral hearing. The basis of the decision is not clear, save that it appears that the MSC did not think that Shipman's treatment had contributed to Mr J's death. I cannot say what would have been the outcome if the case had been properly investigated and had not been affected by problems of time limits. In short, the GMC referred the case back into a procedure that was far from satisfactory. Shipman's treatment of Mr J may have been seriously substandard and such as to render him guilty of SPM. We will never know.

Other Case Files

18.99 The Inquiry obtained the papers relating to the last five cases which had been closed by GMC staff prior to 30th September 2003, where complainants had been advised to refer their complaints to NHS complaints procedures. The Inquiry also obtained the papers in the last five cases prior to 30th September 2003 where complainants had been advised to refer their complaints to private complaints procedures. Three of the latter cases caused me some concern. I shall discuss them later in this Chapter: see paragraphs 18.181–18.184 and 18.213–18.227. The other complaints raised issues which appeared appropriate for referral to local procedures. Whether or not that referral took place, however, was left entirely in the hands of the complainant in each case. The GMC had no means of checking that this had been done.

Comment

18.100 I regret to say that I am critical of the GMC's policy towards complaints about medical treatment made by private individuals. As I have explained, the practice by which such complaints were handled did not comply with rule 6 of the 1988 Professional Conduct Rules. But it is not the fact that the practice was unlawful which concerns me most. What most concerns me is that the policy of the GMC in respect of complaints from private individuals had the effect of virtually forcing complainants to go through local complaints procedures unless the complaint appeared to be so serious that the GMC considered that doctor presented an immediate risk to patients. The GMC has been turning away many cases without considering whether the conduct alleged might amount to SPM. It has been requiring complainants to go through a local process which requires determination and persistence and which, moreover, is not likely to result in a thorough investigation of the facts.

18.101 The GMC's claim that it is better for local procedures to be used because local NHS organisations can provide a better opportunity for investigation flies in the face of reality. The complaints procedures on which the GMC has been content to rely have suffered from a number of defects. Those defects have been well known to members and staff of the GMC for decades. Mr Howes said in evidence:

> **'I do not know anybody who thinks highly of any of the past NHS systems or existing NHS systems for dealing with complaints and concerns.'**

18.102 It must have been clear that the inevitable result of the defects in the system was that many cases where the fitness to practise of a doctor was in doubt would not return to the GMC. The implications for patient safety should have been obvious. Until relatively recently, the PCOs had no power to restrict a doctor's practice, the powers of the NHS Tribunal were rarely exercised and hospital disciplinary systems were known to be ineffective. The fact that cases of potential SPM were not getting to the GMC meant that doctors who were unfit to practise were continuing to treat patients. To the Inquiry's knowledge, the position was particularly difficult in the field of primary care. I have already mentioned the limited role of PCOs in the handling of complaints against GPs. Often, they were not aware of a complaint and, even if they were, they had no official investigatory role. Only in a small minority of cases was there any possibility of a case being referred back to the GMC. Those were cases in which an independent review took place, the report was seriously critical of the doctor and the PCO was sufficiently concerned to refer the case onwards to the GMC rather than attempting remedial measures of its own. Also, there was a small number of incidents which, for some reason or another, came to a PCO's attention and were directly investigated by it. Such an investigation might result in a referral to the GMC. But the great majority of complaints would follow the 'usual procedures' and would never be investigated at all. I shall not comment further on the position in respect of hospital cases, as the Inquiry has not examined them in detail. I accept of course that the GMC has no control over the quality of NHS complaints procedures or of those in the private sector. Yet, notwithstanding its knowledge that the procedures were defective and that it had no power to do anything about that, the GMC persisted, over a period of many years, in requiring complainants to 'exhaust' their local remedies.

18.103 In my view, the GMC policy that I have described amounted to a failure of its duty. The GMC accepted and dealt with the most serious cases but consistently failed complainants who reported matters which might well have involved SPM, but which did not, in the opinion of the GMC, give rise to an obvious risk to patient safety. This policy did not honour the GMC's primary duty to protect patients. It is clear from the evidence that a significant factor underlying the policy was the desire to be 'fair to doctors'; in practice, the effect was to protect doctors from the investigation of complaints and from the possibility of disciplinary action. The policy also enabled the GMC to avoid handling a substantial number of cases which it would otherwise have had to deal with. And, in addition to all that, the policy resulted in a practice that was manifestly in breach of rule 6 and therefore unlawful.

18.104 I can well understand the GMC's view that many complaints about doctors are, in principle, best investigated locally. Indeed, if the local resources were satisfactory, if the procedures were reasonably speedy and did not rely on the complainant to pursue the complaint and if there were proper, reliable mechanisms for referring cases to the GMC when appropriate, I would agree that a system which provided for initial investigation locally would be ideal. However, as the GMC recognises, local resources are not satisfactory, procedures are not reasonably speedy and the onus is always on the complainant to pursue the complaint. Nonetheless, the GMC has maintained its policy over many years. Part of the problem has undoubtedly been that the GMC has never had an adequate in-house investigating facility. As I explained in Chapter 16 and as I shall explain further below, in the past, the GMC has only ever fully investigated a case in preparation for a disciplinary hearing. But another aspect of the problem has been the GMC's uncertainty and ambivalence about its role and about its position in relation to NHS complaints procedures. It seems to me that the GMC does not really want to receive a wide range of 'raw' complaints; it prefers to receive reports from other organisations which have already gathered and evaluated the evidence. Then, it is easy for the GMC to decide whether any FTP procedures should follow and to carry out such further investigation as it considers necessary before the hearing. But, as we have seen, the GMC still holds itself out to the public at large as the primary recipient of all complaints about doctors.

18.105 In my view, the GMC really will have to make its mind up where it stands. One option is that it should receive only those complaints which other bodies (whether NHS or private) think should be referred – either in an uninvestigated state because they are obviously very serious or after investigation because they appear to the investigating body to raise a question about the doctor's fitness to practise. The other possibility is that it carries on as now, opening its doors to all comers. If it decides to do that, it really must give proper consideration to every complaint. It must investigate it to the extent necessary to see whether action should be taken. It is not acceptable, in my view, for the GMC to seek to keep a foot in both camps: offering to receive all complaints and then selecting for investigation only those which raise the most obvious concerns about the safety of patients.

18.106 The GMC has suggested that the problem might be resolved by the creation of a 'single portal', which, as I understand the suggestion, would provide advice to potential complainants about where to direct their complaints. It does appear that quite a number

of complaints are directed to the wrong place or are received by bodies that are not complaints handling bodies at all. For example, Professor Alastair Scotland, Chief Executive and Medical Director of the NCAA, said that it receives quite a number. Members of staff always seek to help a complainant to identify the right destination for his/her complaint or concern and sometimes contact the appropriate body to facilitate the complaint's progress. There are real attractions in this suggestion and I shall consider it in greater detail later in this Report. However, even if such a facility were to be introduced, it would still be necessary for the GMC to clarify its own role, not only in its own mind but also in the minds of the public.

Investigating the Circumstances of a Complaint

Complaints from Public Bodies and Private Individuals

18.107 The extent and quality of evidence available when a complaint comes to the GMC from a public body is, in general, very different from that which is provided by a private individual. A complaint from a private individual might consist of a letter only. The letter might not be very full or articulate. It might not deal with all the relevant issues. It might not contain details of available witnesses or of other supporting evidence. By contrast, a complaint from a public body is likely to have been preceded by some sort of investigation or inquiry. The letter of complaint will usually set out the issues clearly. It will often be supported by a body of evidence. It may be accompanied by a report of an IRP (or, under the new arrangements for the second stage of the complaints procedures, a Healthcare Commission panel) which has made findings against the doctor. The quality and extent of local investigations may be very variable. Nevertheless, it has hitherto been the practice of the GMC to rely on the evidence collected by local bodies without – certainly at the early stages of its procedures – undertaking any additional investigations of its own.

18.108 A private individual who makes a complaint about a doctor to the GMC will usually lack the necessary resources to carry out his/her own investigation. He or she will therefore expect that the GMC will conduct a thorough investigation of the complaint and that only when all the relevant information is known will the GMC make an informed decision as to what, if any, action is required in respect of the doctor. In other words, there is an expectation that the GMC will fulfil the function usually performed by an organisation which is designed and equipped to handle and adjudicate upon complaints from members of the public. The reality, however, is rather different.

The Meaning of 'Investigation'

18.109 It is important to define what I mean by the term 'investigation'. By 'investigation', I mean the gathering of information and evidence relating to the circumstances giving rise to a complaint. Such an investigation might involve:

- asking questions of the complainant and obtaining a statement from him/her
- discovering from the complainant the identity of any potential witnesses (e.g. friends and family of the complainant with knowledge of the circumstances), and obtaining statements from them

- obtaining any relevant medical records, test results and other documents
- obtaining documentary evidence about other investigations such as transcripts of inquests and (in the past) reports of IRP hearings
- obtaining a statement from the doctor complained of and from any witness of fact whom s/he may put forward
- obtaining evidence from an expert in the relevant specialty
- obtaining the comments of the complainant (and possibly other witnesses) on the account given by the doctor and his/her witnesses and vice versa
- initiating other enquiries, e.g. checking facts which have been asserted by the complainant or the doctor with third parties and/or with existing documentation.

18.110 Investigation is a task which requires considerable expertise, particularly where the matter to be investigated involves complex medical procedures or issues. Investigation can also require a degree of determination, inquisitiveness and perseverance in order to ascertain what happened or, where there is a conflict of evidence, in order to identify precisely where the differences between the accounts given by the various witnesses lie.

The Report of the Merrison Committee

18.111 The Report of the Merrison Committee, to which I have already referred, was published in 1975. The Report discussed the issue of investigation. It pointed out that, in the early period of the GMC's history, there were only three circumstances in which the GMC would take action in respect of reports that a doctor had been guilty of SPM. The first was when it received information about the alleged misconduct from a public body. The second was when it received information about the alleged misconduct from another source and when that information included all the evidence required for the GMC's purposes. The third circumstance was when there was a complainant (usually a private individual) who was prepared to assemble the evidence him/herself and to present it at a hearing of the Disciplinary Committee (the predecessor of the PCC). The Merrison Report also pointed out that, during the previous ten to fifteen years, the GMC had taken the view that, if it continued to limit its activity as previously, some types of professional misconduct that gave rise to public criticism would not be dealt with. It had therefore started to collect evidence itself and to prosecute in certain types of case. The Merrison Committee expressed the view that this action was **'entirely justified'** and should be continued **'in the interest both of the public and of the profession'**.

18.112 The Merrison Report therefore recommended that the GMC should set up a small unit, possibly under the supervision of a medically qualified official, to investigate allegations against doctors. This was because the Merrison Committee considered it important that the GMC should be able to **'... assess as quickly as possible which complaints are substantial so that action, including the dismissal of unfounded allegations, can be taken without undue delay'**. The Merrison Committee recommended that the investigation unit should operate under the personal direction of the President, who would supervise the early stages of the FTP procedures and would act as the screener. The

investigation unit would be used principally for the investigation of complaints from private individuals. Its role would be to establish **'in a preliminary and neutral way'** the facts of the case. Because members of the Merrison Committee considered that points of difficulty could often be better elucidated by a personal interview than by an exchange of letters, they suggested that discussions should take place between a representative of the investigation unit and the doctor involved and between the representative and other parties to the complaint. At the end of the investigation, the investigation unit should submit a report to the President, who would then take the decision whether the case should be either dismissed or taken further.

18.113 These recommendations, which seem to me to be eminently sensible, were never implemented. In 1988, Mrs Robinson expressed surprise that the GMC did not have its own investigation unit, and contrasted the position of the GMC with that of the Ombudsman, who had a permanent staff of experienced investigators. In 1988, as was the case until very recently, private firms of solicitors retained by the GMC would investigate and prepare cases for hearing by the PCC. The solicitors employed trained investigators, including former police officers. The Inquiry has been told, and I have no reason to doubt, that the GMC's solicitors have, in the past, carried out some extensive and very thorough investigations in preparation for PCC hearings. The cases arising out of the Bristol Royal Infirmary paediatric cardiology deaths were cited as examples of this. However, it was rare for the GMC's solicitors to be involved in gathering information about the circumstances of a complaint at a time before the complaint had been referred by the PPC for hearing by the PCC.

18.114 As the Merrison Committee recognised, the need for investigation by the GMC arose primarily in connection with complaints made by private individuals. As I have said, most complaints by private individuals about NHS treatment would be referred back to local complaints procedures for investigation. However, that would still leave complaints about private treatment (until recently), together with complaints which fell outside the time limits for local complaints procedures or those which for other reasons could not be dealt with by means of local complaints procedures.

The Lack of Investigative Powers

18.115 Until 2000, the GMC had no power to compel the production of documents or the provision of information until a case had been referred by the PPC to the PCC. Mr Howes, who was employed by the GMC between 1977 and 2002, did not think that anyone had ever put forward a proposal that the GMC should be given power to act earlier. I can only assume that that was because it was never really contemplated that investigations (other than seeking the doctor's response to the complaint made against him/her) would be carried out at a stage in the proceedings earlier than the time of referral to the PCC.

18.116 The 1994 Training Manual compiled by Mr Howes set out the position at that time:

> **'So far as sufficiency of the evidence is concerned, this is largely a matter of common sense, rather than law. For example, if a complaint alleges that a doctor has breached professional confidence in a letter sent to the complainant's employer, the Council will need to see a copy**

of that letter, so as to be reassured that the doctor did in fact write such a letter, and that it did indeed contain confidential information concerning the medical history, condition and/or treatment of the person concerned. We will also need information from the complainant about the circumstances which led to the letter being sent. Therefore, if the complainant is not able to produce a copy of the letter in question, the view taken by the preliminary screener will normally be that the evidence is insufficient to justify disciplinary proceedings against the doctor, regardless of the gravity of the allegation. The onus to produce evidence is almost entirely on the complainant, and not on the GMC, because the GMC does not have much by way of investigative powers at the preliminary stage of the procedures; its powers of subpoena are confined to cases being heard by the PCC or Health Committee. Thus for example, in the hypothetical breach of confidence case mentioned above, the Council would have no means of obtaining a copy of the letter giving rise to the complaint, nor does the Council have access to a doctor's medical records.'

18.117 In that passage, there appears to be a fundamental confusion between the GMC's lack of **'investigative powers'** during the preliminary stages and its ability to investigate at all. Mr Scott agreed that such confusion existed in the minds of some GMC staff and members. It is true, as I have said, that the GMC had no power to compel disclosure of documents or the provision of information until a decision had been taken to refer a complaint to the PCC. But, regardless of its lack of such a power, there would have been nothing, in the example given in the passage above, to prevent a member of the GMC's staff from asking the complainant's employer for a copy of the letter. It might have been provided voluntarily. Mr Howes said that the GMC would have expected the complainant to get a copy of the letter from his/her employer. If s/he could not produce the letter, he said that 'one would wonder why'. When asked why the GMC could not itself have made that sort of enquiry, he replied:

'Well, the Council could, but the Council, if you like, is not there to make out the complainant's case. The Council is supposed to be impartial and, therefore, certainly at that time, the thinking was that we should be impartial. There was no part of our job to assist a doctor with his defence against a charge and it was no part of our job to go overboard and make the case out for the complainant. The complainant had to make out the *prima facie* (*case*), we would then if we said there was a *prima facie* case take it on board and do the rest and we would pay for the costs of the case ... in front of the Disciplinary Committee, etc. We were prepared to take on a case once the complainant if you like had done their bit and made out a case.'

18.118 At a later stage, Mr Howes said:

'... we did not really regard it as our job in those days to help the complainant any more than it was our job to help the doctor with his

defence. If the complainant wished to bring a complaint against the doctor then the law allowed them to do that with certain limits, and it was our job to adjudicate on that complaint and I think we concentrated on that aspect. That is not the way the GMC looks at these matters now, but I think that is the way it was looked at then.'

18.119 There were, however, circumstances in which the GMC was prepared to initiate investigations at an early stage, despite its lack of power and the usual expectation that the complainant would provide the evidence. This is illustrated in the next paragraph of the 1994 Training Manual:

'In a very small number of cases, however, the medical preliminary screener may consider, on the advice of the office, that the matters alleged are so serious that a thorough informal investigation should be carried out locally by the Council's solicitors, who will then attempt to investigate the case and take statements, in so far as potential witnesses are prepared to cooperate. However, because the resources of the Council's Solicitors are limited, it is not possible to investigate many cases of potential serious professional misconduct in this way; screeners usually limit them to cases of considerable public interest.'

18.120 If investigations could be undertaken on some occasions, then the absence of powers was plainly not considered to be a complete bar. However, it is plain that a decision had been taken to restrict investigations to serious cases, in particular those with a high public profile. When asked for examples of cases when an investigation might be mounted, Mr Howes cited complaints of irresponsible prescribing to addicts or multiple allegations of indecency against a doctor.

18.121 Mr Townsend agreed that there was probably some confusion of thought between the absence of a power to compel people to co-operate and the inability to investigate at all. He felt that the fact that there was a real difficulty if people did not co-operate tended to make staff disinclined to attempt to investigate. The view that it was the complainant's responsibility to assemble the evidence in support of his/her complaint was another factor. He agreed that, in the 'large majority of cases', the onus was on the individual complainant to provide the evidence necessary to demonstrate a *prima facie* case of SPM. That individual would not be interviewed by GMC staff nor, save in exceptional circumstances, would other potential witnesses be approached or interviewed. Instead, the complainant him/herself would be encouraged to obtain statements from any potential witnesses.

18.122 Some witnesses at the Inquiry mentioned the fact that the Rules did not confer on medical screeners in conduct cases any specific power to investigate. The PPC, together with screeners dealing with cases where the health of the doctor was in issue (health screeners) and medical screeners dealing with performance cases, were given a specific power. It was suggested that this absence of a specific power might have discouraged staff and screeners from undertaking investigations. I do not see how this can be the case. It is clear that, if a case was considered sufficiently serious and/or high profile, investigations were undertaken. Screeners did on occasion cause further information (e.g. expert opinion) to be obtained. The absence of a specific power did not prevent them

from doing this. Moreover, I was not told that there had ever been any attempt to seek such a power. It seems to me that the lack of investigation was attributable mainly to a feeling that it was for the complainant (not the GMC) to substantiate his/her complaint. The absence of any power to compel production of documents and information cannot have helped. However, that could no doubt have been rectified had it been considered necessary or desirable to do so.

The Work of the Policy Studies Institute

18.123 The 1996 PSI Report drew attention to the lack of investigation. It suggested that the GMC should consider carrying out some investigation before a case went to a medical screener or, if not then, after screening and pending consideration by the PPC. At that time, it was not the practice even to seek the response of the doctor to a complaint made against him/her before the complaint was screened. The Report suggested that, at a minimum, this should be done where there appeared to be the possibility of a *prima facie* case of SPM. That change was instituted shortly afterwards. The Report also raised the possibility of seeking further evidence, over and above the response of the doctor. Some years later, in about 2000, the GMC extended its 'investigatory' procedures by inviting the complainant to comment upon the doctor's response to, or explanation of, the matters alleged. However, it did not and never has routinely undertaken any other form of evidence gathering such as the taking of witness statements during the preliminary stages.

18.124 As the 1994 Training Manual had made clear, when a private individual made a complaint to the GMC, s/he bore responsibility for gathering the necessary evidence in support of the allegation. The 1996 PSI Report showed that, in a significant proportion (22%) of cases in which the GMC took no action, the reason for lack of action was that the GMC had requested further evidence from the complainant but had received no response. If no response was received from a complainant, there was usually no follow-up request. Professor Allen told the Inquiry that she thought that complainants might have found such requests for further evidence intimidating. She and her colleagues were concerned at the onus being put on complainants and at the fact that complaints involving SPM might have been lost. It was for that reason that the PSI team had recommended that the GMC should consider carrying out investigations itself.

18.125 The PSI team had other concerns about the lack of investigation by the GMC of complaints made by private individuals. The 1996 PSI Report showed that by far the single most important factor in determining whether or not a complaint was acted upon by the GMC was whether the complaint came from a public body or from a private individual. In the year to August 1994, 66% of doctors referred to the PPC, and 72% of doctors who were referred by the PPC to the PCC, had been referred by public bodies. The 2000 PSI Report produced similar results. Complaints made by private individuals against doctors were referred by medical screeners to the PPC relatively rarely: 5% of such complaints were referred in 1997, 6% in 1998 and 13% in 1999.

18.126 Professor Allen and her colleagues recognised that the disparities in outcome between complaints coming from private individuals and those from public bodies could reflect the fact that complaints made by public bodies were for some reason intrinsically more

serious than those made by private individuals. If that were so, it would not be surprising that a greater proportion progressed further than the screening stage. However, they urged caution in assuming that this was the reason for the different outcomes. They believed that the differences in outcome might instead be caused by differences in the quantity and quality of evidence provided by public bodies, when compared with that provided by private individuals. If this were correct, the effect of the GMC's failure to investigate complaints would have been that some complaints from private individuals which should have been the subject of disciplinary action by the GMC were being rejected because of lack of evidence.

18.127 Mr Townsend agreed that the disparities in outcome between complaints made by public bodies and those made by private individuals were, in part, accounted for by the fact that a public body would have gathered more evidence than would a private individual. Moreover, that evidence would have been sifted. A judgement would have been taken on the probity of the evidence. Another factor was, he thought, the series of hurdles which a private individual had to overcome. These included (until November 2002) the requirement for a statutory declaration to be provided. He felt that these hurdles might have discouraged an individual from taking his/her complaint forward.

18.128 It seems to me entirely understandable that virtually all complaints received from a public body should be found by the GMC to require some sort of disciplinary action. The allegations would already have been investigated and a judgement made that the allegation was serious enough to refer to the GMC. However, it is a matter of concern that the GMC has not been prepared to undertake a **'preliminary and neutral'** investigation of complaints made by private individuals. I fear that many valid complaints will have been closed because of the failure to investigate. I recognise that to undertake such investigations would have been a costly exercise for the GMC. However, I have the clear impression that cost was not the only reason why such investigations were not undertaken. The impression I received was that complaints from individuals were suspected of being, in some way, unreliable, at least unless and until the complainant could produce sufficient evidence to amount to a *prima facie* case of SPM, backed – until November 2002 – by a statutory declaration. Also, there was resistance to any action which might be seen as 'assisting complainants' and, therefore, as 'unfair to doctors'.

Subsequent Developments

18.129 The 1997 Screeners' Handbook referred to the fact that, in more complicated cases, the GMC's solicitors might be asked to obtain evidence before a case was screened. They could interview witnesses and, although they had no power to compel the production of evidence at that stage, it was said that they were **'frequently able to secure the co-operation of individuals and authorities through personal contact'**. It does not appear that this was often done. The option of obtaining expert advice before screening was also discussed.

18.130 The version of the FTP Casework Manual published in April 2003 emphasised that the amount of evidence required by the screeners was **'minimal'**. They simply needed to have enough information to understand what the allegation was. Caseworkers were

enjoined to have this **'very firmly in mind'** when deciding what information should be collected before screening. The **'menu of evidence-collection options'** open to caseworkers at this stage included the following:

- disclosing the complaint to the doctor and inviting comments. (This practice of disclosing a complaint to a doctor before screening was, as I have said, introduced in response to the recommendation made in the 1996 PSI Report.)
- disclosing the doctor's comments to the complainant, giving the opportunity for further comment. (This practice was introduced in July 2000 in anticipation of the coming into force of the Human Rights Act 1998. Prior to that, neither the medical screener nor the PPC had had any comments from the complainant in relation to the doctor's response to the complaint.)
- if the complainant provided further comments, disclosing those comments to the doctor for his/her further observations
- obtaining medical records in an appropriate case
- making enquiries with the doctor's employers or PCO. (I shall deal with this option later in this Chapter.)
- seeking evidence or statements from potential witnesses by correspondence or through the GMC's solicitors. (This was said to be necessary in some cases to clarify the nature of the allegations against the doctor. However, staff were cautioned against holding up a screener's decision by **'chasing evidence required only at a later stage'**.)
- seeking an expert medical opinion in cases involving issues which appeared **'very complex and unusual'** and where there was no form of medical opinion already included with the complaint.

18.131 It is clear from the contents of the April 2003 FTP Casework Manual that the aim at this stage of the GMC procedures was not to conduct a thorough investigation of the circumstances of the complaint. Rather it was to ensure that the medical screener had the **'minimal'** evidence required for his/her purposes, i.e. for the purpose of deciding whether the complaint raised a question of SPM.

18.132 There were a number of problems with this approach. First, that evidence which was regarded by a member of the GMC staff as **'minimal'** but adequate might be regarded by a medical screener as insufficient to found a *prima facie* case of SPM. The case might, therefore, fail at the screening hurdle when, had more evidence been available, this would not have happened. Second, in a case involving allegations of substandard clinical practice, it is essential to establish the factual basis first, in order that any expert opinion obtained (and that any opinion formed by the medical screener) should not be based upon a misunderstanding of the facts. Third, in the absence of the full facts, a screener might be tempted to make assumptions about what had occurred. Fourth, the complaint, as initially recounted by the individual concerned, might not have been immediately recognisable as serious; this might have become evident only if the complaint had been properly investigated.

18.133 In December 2003, Mr Scott told the Inquiry that, in general, there was still limited evidence gathering prior to a screening decision. He observed that the existing procedures appeared a 'paradox'. A complaint was screened, referred to the PPC, referred on to the PCC, charges were formulated, and only at that point did the GMC set about finding evidence to support the charges. He referred to this process as 'putting the cart before the horse'. He went on to say:

> **'The more rational way may be to gather such evidence as appears to you to be relevant and then you formulate the charges accordingly. That has been an impediment I think to progress throughout the 1990s, which will not be fully resolved until new procedures come into play ... .'**

18.134 That reference to the new procedures, and the changes that would come about as a result, was echoed by other witnesses from the GMC. I shall consider the new procedures, and their implication for investigation of complaints, in Chapter 25. However, I cannot understand why, having recognised the deficiencies in their existing procedures, the GMC felt it necessary to wait for the introduction of the new procedures before instituting proper investigative procedures.

18.135 In 2003, the GMC began to recruit a team of solicitors, paralegals and support staff. Mr Scott said that he had expected that, when complete, the team would number about 20 people in all. Mr Scott did not suggest, at the time he gave evidence in December 2003, that the job of the team was to gather evidence about complaints in the early stages. Rather, the team appeared to be assuming the role previously carried out by private firms of solicitors who had been retained by the GMC to prepare cases for hearing by the PCC and, possibly, the role of counsel who had previously presented the cases to the PCC. In 2004, the GMC has advertised with a view to recruiting investigators and I assume that these people will be used to investigate cases under the new procedures.

Statutory Declarations

18.136 For many years, the GMC Rules required complaints made by private individuals (but not those made by persons acting in a public capacity), together with statements from witnesses in support of such complaints, to be supported by statutory declarations. The purpose of this requirement was to establish the *bona fides* of the complainant and his/her witnesses. It was also intended to deter the making of malicious complaints. However, its effect, as the GMC eventually recognised, was to deter genuine ones. In general, complainants were asked to provide one or more statutory declaration immediately after a decision had been taken by the medical screener that a complaint should be taken forward. If no statutory declaration was provided, the referral to the PPC would not proceed. In the case of the complaint about Shipman in respect of Mr J, the complainant was told that both the complainant's evidence and that of the principal witnesses would have to be supported by statutory declaration. In general, the complainant was required to make the necessary arrangements and to bear the cost of providing the statutory declaration. If the complainant was able to draw up the statement him/herself, the cost of swearing it was relatively modest. If, however, the complaint was more complex and the complainant required the assistance of a solicitor to draft a

statement, the cost would be substantial enough to deter many people. The very fact of having to approach a solicitor to have a statement sworn may have been intimidating to some. In the 1996 PSI Report, Professor Allen and her colleagues recommended that the requirement for a statutory declaration should be reviewed.

18.137 It is clear from the 1994 Training Manual that the GMC staff were well aware of the financial and other burdens placed on complainants in connection with the obtaining of a statutory declaration. They sought, wherever possible, to advise and assist complainants in order to keep expense to a minimum. However, there was recognition that, in most cases, it would be necessary for complainants to approach a solicitor in order for the statutory declaration to be obtained. In later years, financial assistance was available to complainants in certain circumstances. However, they had to ask for it and many were unaware that this was possible. The witnesses agreed that the requirement for a statutory declaration had had the effect of discouraging some complainants from pursuing their complaints. Mr Howes accepted in evidence that 'many, many complainants' had not provided statutory declarations when required to do so. He said that he and other members of staff had not wanted the requirement for a statutory declaration to be an undue barrier to making a complaint but it had been part of the Rules and it was not for the staff to try to bypass the requirement. Nor, he said, did the staff have any authority to say to every single complainant that the GMC would authorise and pay for the declaration. He said:

> **'... I think we were all the time pushing at the boundaries of how we could help people and in how many cases we could perhaps find money to help them and so on. But it was a question of pushing back the boundaries, particularly as there was a strong feeling I think that on the medical side of the argument that we should not be helping complainants at all in this way.'**

18.138 He said that the GMC was 'walking the tightrope between the public interest and the professional interest'. It was there to sit in judgement on a complaint, not to help the complainant or to 'side with' the doctor. If the staff bent over backwards to make sure a complainant's case was supported, the view of the medical profession might be that the GMC was clearly siding with complainants all the time. Doctors would question how they could get a fair hearing at the GMC. He said that one had to be seen to be fair and also, from the complainant's point of view, had to be seen not to be putting an 'absolutely insurmountable barrier' in his/her way. He went on:

> **'... every time that the Procedure Rules were in front of the Council for some sort of amendment, this is the sort of issue that would be raised, is it not about time we took away our insistence that they make sworn statements and this argument would then be in front of the Council and people would stand up, some of them saying, ''I think we should continue with sworn statements,'' and others saying, ''No, this is quite wrong and it is a terrible burden on complainants and unnecessary.''**
>
> **So you would get this argument and then the latest outcome was that they should not be – this requirement should at last be taken away and**

that was relatively recently. Until then the argument had always been (*won*) **from the other angle.**

I am not saying it was always profession against lay, but I think probably the argument was very much one of ''Is this fair to the doctor?'' against ''Is this fair to the complainant?'' '

Mr Howes said that the GMC was 'in an impossible position'. He went on to say that he thought things gradually improved and that the GMC now gave much more help to complainants.

18.139 The fact that many complainants failed to provide a statutory declaration must inevitably have meant that cases of potential SPM were lost to the system. In addition, it is clear that the requirement must have created the impression, in the eyes of many complainants, that the GMC was not prepared to take the complaint seriously or to 'trouble' the doctor with it until evidence of a very high standard had been produced. In short, it gave the impression that the GMC was 'on the doctor's side'.

18.140 The requirement for a statutory declaration was eventually abolished in November 2002.

Comment

18.141 It is evident that, up to now, the GMC has done little to investigate complaints made to it unless and until those complaints have been referred by the PPC to the PCC. At that point, solicitors retained by the GMC have taken over preparation of the case for hearing. The complaint has then been subjected to investigation by someone with a degree of independence and some expertise in investigation. In a very few (usually high profile) cases, investigations have been put in train at an earlier stage. The vast majority of complaints – in particular those made by private individuals and those relating to substandard clinical practice – have been closed well before that point. They have been closed without any personal contact with the complainant and without any attempt to elucidate the complaint or to find evidence that might support or refute it. In a treatment case, medical records may have been obtained and, in a complex case, expert evidence sought. Where the facts were very uncertain, however, expert evidence might be of limited assistance unless and until the facts were clearer. It seems likely, as Professor Allen and her colleagues believed, that complaints which would have amounted to SPM have been screened out as a result of lack of investigation.

18.142 The fact is that the GMC's policy has been to refer complaints about medical treatment back for local investigation by NHS bodies, in effect relying on those bodies to do the investigation for it. Until the NHS body provided the evidence to the GMC as a package, the GMC was unlikely to act. The wisdom of pursuing this policy was obviously questionable because, as the GMC itself has recognised, the quality of local investigation was very variable and much depended on the determination of the complainant to reach a proper resolution of the issues rather than a fudging of them. There is no way of knowing how many cases that should have been dealt with by the GMC were not.

18.143 The idea that the GMC should establish an investigation unit to gather evidence about complaints at an early stage in its process is not a new one. The Merrison Committee

recommended this step almost 30 years ago. Like Mrs Robinson in 1988, I was extremely surprised in 2003 to learn that, until very recently, the GMC had had no in-house investigative expertise.

18.144 It seems to me that there are a number of reasons why the GMC has not undertaken any investigation of complaints at the pre-screening stage. Part of the explanation lies, I believe, in the history to which I referred at paragraph 18.111. In the past, a private individual who wanted to bring a complaint against a doctor bore the entire responsibility for assembling the necessary evidence and for presenting the case at a hearing. More recently, although complainants still had the right to present cases before the PCC if they chose, the more usual arrangement was for the GMC to 'take over' complaints once they had been referred to the PCC. The GMC would then be responsible for preparing the case and presenting it at the hearing; the complainant's role would be that of a witness only. However, the principle that it was for the complainant to establish the basis of the case at the outset, by providing the necessary evidence, lingered on. There does not appear to have been any real appreciation of the difficulties this caused for complainants. Nor was there any recognition of the fact that, if a complainant was unable or unwilling to take the necessary steps to assemble the evidence, this might mean that a complaint of real substance was lost to the regulatory process, with a concomitant risk to the public and to patients.

18.145 There was also the view that it was the GMC's role to act as independent arbiter, not to assist in gathering evidence to support one party to the complaint or the other. It seems to have been thought that to investigate a complaint was in some way 'anti-doctor'. In an organisation where most members are elected by the profession, a member who advocated the robust investigation of all complaints might have been unpopular with his/her constituents. I have the clear impression that some members took a view that was protective of the interests of doctors and would have opposed investigation of complaints on principle. There seems to have been a failure to recognise that an investigation of the circumstances surrounding a complaint should not be partisan. Its purpose should have been, as the Merrison Committee recognised, to enquire into the facts **'in a preliminary and neutral way'**. Moreover, the notion that it would be 'unfair' to doctors for the GMC to undertake an investigation of complaints failed to take account of the imbalance in the relationship between the complainant and the doctor about whom the complaint had been made. The former lacked the resources to investigate; the latter was generally supported by expertise and funding from his/her medical defence organisation and had ready access to expert medical opinion.

18.146 I believe that another reason for the failure to investigate has been the issue of resources. Investigation is an expensive process and if all, or most, complaints from private individuals had been subjected to a reasonable level of investigation, this would have placed a considerable burden on the medical profession. A GMC member who voted in favour of employing a team of investigators might well have lost his/her seat on the Council. There has also been a lack of investigative expertise among existing GMC staff and, indeed, an apparent lack of understanding of how an investigation should be undertaken.

18.147 Another reason is the problem that I have mentioned before, namely the lack of clarity about the GMC's role. If the GMC had made it clear that its function was to consider only serious complaints which had already been identified and investigated by others, and that it was not prepared to undertake any investigations unless there was no other body available to do so, that might have represented a perfectly reasonable position for a regulatory body to take. Such a stance would have thrown into sharper focus the patchy quality of investigations carried out by NHS organisations and the virtual absence of any local investigation of complaints about a GP. But, instead, the GMC has at all times held itself out as a willing recipient of complaints direct from members of the public. I have in mind such publications as 'A Problem With Your Doctor?' and its successor, 'Referring a doctor to the GMC – a Guide for Patients'. Although, at times, these publications made oblique references to the limited jurisdiction of the GMC, the general impression they conveyed was that the GMC would receive and investigate any complaint about a doctor and would also give advice. Many complainants to the GMC, as we have seen, have been sent away to make use of local procedures. Those members of the public who were not dealt with in that way have expected that their complaints would be properly investigated and determined. They have never been told by the GMC that it is not prepared to do this. Indeed, many individuals whose complaints have in the past been rejected by the GMC will have had no idea that the only action which the GMC took in relation to their complaint was to show it to a medical screener who screened it out. For many years, there has been a gulf between public perception of the GMC as a proactive investigator of complaints against doctors and the reality. The GMC has failed to recognise this gulf or, if it has recognised it, has failed to take any action to bridge it. Moreover, it has failed to recognise that its lack of investigation has meant that some complaints which might have amounted to SPM have failed, with potentially serious implications for patient safety.

18.148 The Inquiry has been told that, under the new FTP procedures, things will be different and complaints will be investigated properly before a decision is made whether to take them forward or to reject them. I shall discuss the GMC's assertions about the future in Chapter 25, when I examine its proposed arrangements for the new 'investigation stage'.

Communications with Doctors' Employers and Primary Care Organisations

18.149 There are three main reasons why it might be helpful for the GMC to communicate at an early stage in its processes with the employer of a doctor against whom a complaint has been made or with the PCO (now the PCT) on whose list the doctor appears. First, it would enable the GMC to discover whether the employer/PCT had any information about the doctor which might assist the GMC in assessing and dealing appropriately with the complaint which had been made to it. Second, it would alert the employer or PCT to the fact that there might be a problem with the doctor. Third, it would enable the GMC and the doctor's employer or PCT to discuss and/or clarify which organisation should proceed to deal with the complaint and to carry out any necessary investigation. I shall deal with these three issues separately.

Obtaining Background Information about a Doctor

18.150 In the past, when a complaint about a doctor's conduct, or notification of a conviction, was received by the GMC, it was not the practice to make any enquiries of the doctor's employer or PCO in order to discover whether there had been any previous expressions of concern about him/her. When Shipman's convictions were reported to the GMC in 1976, no enquiry was made of the Calderdale FPC in order to find out what its staff knew about Shipman, his abilities as a doctor or his drug abuse. It is clear from the evidence received by the Inquiry that it was not the practice at the time to make such enquiries. Under the old FTP procedures, it was not usual for any routine enquiry to be made when the GMC was notified that a doctor had been convicted of a criminal offence. If any enquiry was made, it was likely to relate to the circumstances of the offence (e.g. the level of alcohol in a case of drink driving or the amount of financial loss in a case involving a fraud on the NHS). It was unlikely to relate to the possible impact which the doctor's criminality might have had on his/her practice.

18.151 So far as complaints about conduct are concerned, those that come from employers or PCTs will often be accompanied by some background information about the doctor and any past problems associated with him/her. Members of the public do not have access to that sort of information. Their complaints are likely to relate to single, often apparently isolated, incidents. In the past, however, the GMC took no steps routinely to seek background information about a doctor who was the subject of a complaint by a private individual.

18.152 At the time of their initial work at the GMC, Professor Allen and her colleagues were concerned at the lack of any contact with the doctor's employer or PCO before a complaint against him/her was screened. Professor Allen told the Inquiry that it seemed to them that a 'quick phone call' to the medical adviser at the relevant PCO would have helped to put a complaint about a GP into perspective. It appeared to me that there were two ways in which background information about a doctor might have been very valuable. First, where the complaint was about a single episode involving conduct which, if proved, would amount to substandard clinical practice (although not, or not necessarily, SPM), it would be important to know whether the alleged incident was, so far as was known, a 'one-off' episode or whether there had been previous similar incidents of which the doctor's employer or PCT was aware. If there had been, this might, in the past, have suggested that the doctor should be referred to the GMC's performance procedures or, at the very least, that there should be some discussion between the GMC and the employer or PCT (and, possibly, the NCAA) about how the problem should be tackled.

18.153 The second way in which such background information might have been valuable was in assessing the potential seriousness of a complaint about a single incident. For example, a complaint might concern what appeared at first sight to be a 'one-off' error involving the use of a piece of equipment or a particular drug. The doctor might admit the error but might claim that, through no fault of his/her own, s/he was unfamiliar with the equipment or drug concerned. An enquiry of his/her employers or PCT might reveal an earlier similar incident with the same piece of equipment or drug. The information about the earlier incident would put the later one in an entirely different light. It might suggest a pattern of poor

performance. However, it might also suggest a lack of concern for patient safety such as would amount to SPM.

18.154 The 1997 Screeners' Handbook, published to coincide with the introduction of the performance procedures, specifically provided for enquiries to be made of employers and PCOs and of officials of local medical committees and the equivalent committees in hospitals. Such enquiries were, however, to be made only at the request of a medical screener. The suggestion was that they should be made in all cases unless it was clear from the outset what action should be taken under the FTP procedures or unless there appeared to be no basis for the GMC's involvement in the complaint. Certain rules were to be observed. In particular, no approach was to be made to any person who was not already aware of the complaint unless the doctor who was the subject of it had first been informed of it. Furthermore, it was to be made clear to the person of whom enquiries were made that the GMC was simply making preliminary enquiries and that no decision about possible GMC action had been taken.

18.155 The contents of the 1997 Screeners' Handbook seemed to suggest that enquiries of employers would be made virtually as a matter of routine in any 'borderline' case involving a complaint of substandard clinical practice made by a private individual. It is clear, however, that this was not done. Indeed, cases where such enquiries were made appear to have been very much the exception rather than the rule.

18.156 One reason for the failure to follow the practice set out in the 1997 Screeners' Handbook was that there was ambivalence about whether the GMC should be making such enquiries. I have already discussed this ambivalence in connection with the general issue of investigation. It was well illustrated in the evidence of Dr Korlipara. He was a medical screener between 1998 and 2004. He said that, following the publication of the 1997 Screeners' Handbook, there was general support for enquiries to be made, both to shed further light on a single complaint and to see whether that complaint was in fact part of a more general problem. The type of single complaint where further enquiries would be made was, he said, where the complaint was potentially 'seriously unacceptable' but where details were sketchy, so that further clarification was necessary. In other words, any enquiries of a doctor's employer or PCO would not be made in order to inform a screener's preliminary assessment of the complaint. Rather, they would be instituted after that preliminary assessment, if it appeared to the screener that the complaint had, of itself, the potential to amount to SPM or SDP.

Dr KE 10

18.157 Dr Korlipara was asked about a case (that of Dr KE 10) which illustrated this approach. A widower complained to the GMC about the treatment of his late wife by two GPs. He had previously pursued his complaint through the NHS complaints procedures. This had resulted, a year after the events complained of, in an IRP report which was critical of both doctors and of the organisation and management of their practice in a number of important respects. One of the doctors was subsequently granted voluntary erasure from the medical register so that, in the event, the GMC was left with the complaint in respect of Dr KE 10 only.

18.158 The complainant's wife had been suffering from a terminal illness which presented late and in an unusual manner. It was not suggested that Dr KE 10 or his colleague had caused her death or that the course of the illness would have been changed had they behaved differently. Nor was it suggested that they should have correctly diagnosed the precise nature of the patient's condition. An x-ray obtained by Dr KE 10, which might have been expected to show evidence of the condition if present, apparently showed only degenerative changes. However, the IRP found that Dr KE 10 had failed to keep clinical notes or records of an adequate standard, had failed to consider carrying out blood tests which would have been appropriate, and had refused reasonable requests for home visits. These failures, together with those of his colleague and of the practice generally, were said by the IRP to have contributed to the failure to recognise the seriousness of the patient's condition and to treat it with appropriate pain relief.

18.159 Dr Korlipara screened the case and advised that it should be closed. He referred to the result of the x-ray and observed that Dr KE 10 was justified in reassuring the patient on the basis of the x-ray report. He was satisfied that the terminal nature of the patient's condition could not have been appreciated until two days before her final admission to hospital. He did not comment on the specific findings of the IRP in respect of Dr KE 10, merely saying that his management of the patient's condition did not raise issues of SPM or SDP. The lay screener agreed.

18.160 It is clear that, apart from the IRP report and related documentation, and a letter written on behalf of Dr KE 10 by his medical defence organisation, Dr Korlipara had no other information before him. In particular, there was no background information about the doctor from the PCT. This was despite the fact that the IRP report had raised concerns which might, I should have thought, have been part of wider performance issues. I also note that the complainant had suggested in his evidence to the IRP that there were wider problems with Dr KE 10. This suggestion might or might not have been correct, but it seems to me that it should at least have prompted some enquiries of the PCT.

18.161 In oral evidence, Dr Korlipara expanded upon his reasons for advising that this case should be closed. I shall refer to this decision further in Chapter 19. Dr Korlipara was then asked about the failure to discover whether the PCT had any other concerns about the doctor's performance. He took the opportunity to express his general views about the appropriateness of the GMC making enquiries of a PCT. He said:

> **'... the GMC traditionally has received complaints. It has not instigated complaints other than if it has seen** (*them in*) **the press or in some public domain but, by and large, complaints have been referred to it and it has looked at the complaints and upon the merits of those complaints after careful analysis comes to a conclusion whether there are any issues that would indicate such standards, either in conduct or in performance, that fall so seriously short of acceptable good medical practice that further action on the doctor's registration should be considered. If the answer is yes, the inquiry proceeds to the further stage. If the answer is no and it** (*is*) **an isolated complaint which of itself does not raise the spectre, we assume that in the case of National Health Service patients, which are**

either managed by the PCTs or its predecessors or the hospital trusts, they do have a duty and they would be doing their duty of informing us if they had any concerns unprompted.

... returning to the repeated question put to me as to whether the GMC should have initiated enquiries of its own of the PCT or the hospital trusts when the isolated complaint of itself really does not amount to any serious nature, I think it really takes it on to a newer level. People might describe it as fishing for further information of which the information (*I think this should be 'doctor'*) **against whom the complaint is made will have had no prior knowledge and yet which could be used in order to construct a case against a doctor. I am not really sure if the doctor's advocates would find that as in accordance with the natural law of fairness.**

Personally, I will have some difficulties unless some persuasive arguments are put to us in public that it is desirable and fair that additional information of which doctors have not been previously notified can be added to the complaints without the doctor having been made aware.'

18.162 In other words, Dr Korlipara was saying that it would not be fair to the doctor concerned to seek information from a PCT or NHS trust *before* a decision had been taken as to whether a complaint was likely to amount to SPM or SDP. If a decision was taken that it was likely to amount to SPM or SDP, further enquiries could be made. Otherwise, he suggested, it should be assumed that, had there been any concerns about the doctor, the PCT or the doctor's employers would have reported them to the GMC.

18.163 The problem with that approach, it seemed to me, was twofold. First, the background information might be necessary in order to answer the initial question of whether the complaint was likely to amount to SPM or SDP. Second, it might be that the PCT was dealing with a number of complaints or concerns about a doctor but was unaware of a complaint which had been made to the GMC by a private individual. The PCT might not have got to the point of reporting the doctor to the GMC. The information held by the PCT might nevertheless be of value to the GMC when deciding what to do with the complaint which it had received. Moreover, given the fact that the PCTs are relatively new organisations it would, I think, be unsafe to assume that they will always have a clear idea of what concerns they should and should not report to the GMC. From the viewpoint of patient safety, it seems to me to be clearly desirable that the GMC should have as complete a picture as possible before taking a decision on how to deal with a complaint. In any event, if there is to be a sharing of the regulatory function between the GMC and local NHS bodies, there must, in my view, be sharing of information relevant to that function. The making of assumptions by one organisation about information which may or may not be held by another does not appear to me to be in the interests of patient safety.

18.164 Dr Korlipara said that it was clear that Dr KE 10 had had many deficiencies which, although they did not in his view amount to SDP, needed correction. He said it was also clear that the practice was dysfunctional in a number of respects. He had assumed that the PCT

would have taken steps to deal with these problems. He said that it was not the GMC's role to oversee the PCT, so that it would not in his view have been appropriate for him to institute any enquiry about what had been done to address the shortcomings of the doctor or his practice. It seems to me that, in taking this rather narrow view of the functions of the GMC, Dr Korlipara failed to give proper weight to the need to protect Dr KE 10's patients. As the GMC is supposed to act in partnership with NHS bodies, it would surely have been sensible for an enquiry to be made about what steps, if any, had been taken to ensure that the doctor's deficiencies, and those of the practice, were remedied. If none had been taken, a letter of enquiry coming from the GMC might well have acted as a prompt to the PCT.

18.165 Mr Marshall said that, during the period between December 1998 and April 2000, a debate was going on in the GMC about whether background information about doctors should be sought when a complaint was received. He said that, in the light of some past cases, it had become apparent that the GMC was possibly failing in its duty to protect the public if such enquiries were not made. However, some members felt that there were difficulties in making enquiries at an early stage since this would involve disclosing to a doctor's employer or PCO the fact that a complaint had been made. It was eventually decided that discussions should take place only in certain cases, i.e. in those which were 'more performance-like cases'. Mr Marshall's evidence demonstrated the close link which was made with the GMC between the issues of seeking information about doctors from their employers and PCOs and of disclosing to those same persons or bodies the fact that a complaint about the doctor had been made to the GMC. The seeking of information was plainly in the interests of patient safety. The disclosure that a complaint was made was, however, perceived as unfair to doctors. His evidence also illustrates the existence of a conflict between the GMC's duty to protect patients and its desire to be 'fair to doctors'. It seems that, in that instance, the conflict was resolved by a compromise which went some way, but not far, towards the interest of patient protection.

Disclosure of the Fact that a Complaint Has Been Made

18.166 Early notification to a doctor's employer or PCT of the fact that a complaint has been made to the GMC has the effect of alerting that person or body to possible problems with the doctor. In the past, there was no automatic disclosure to a doctor's employer or PCO even when the complaint had been proved and the doctor had been the subject of disciplinary action by the GMC. Still less was there any disclosure of the fact that a complaint had been received and had been rejected or was in the process of being dealt with. NHS bodies would complain that the first that they knew of the fact that a doctor on their list or in their employment had been disciplined was when they read about it in the local newspaper. In December 1999, the GMC proposed in a consultation document that it should, in certain very limited circumstances, voluntarily disclose information about a doctor's involvement in its FTP procedures to employers and others with a legitimate interest in receiving that information.

18.167 The Government, however, favoured the creation of a statutory duty on the GMC to provide timely information to NHS bodies about doctors whose fitness to practise was being formally considered. As a result, from 2000, the GMC was placed under a statutory duty

to disclose to the DoH, and to any person or body by whom a doctor was employed or by whom s/he was contracted to provide services, any decision made by the GMC to refer the doctor to the PPC, to invite him/her to agree to an assessment of his/her professional performance or to invite him/her to agree to an assessment to determine whether his/her fitness to practise was seriously impaired by reason of his/her physical or mental condition. In other words, disclosure was to take place after screening of the complaint if a decision had been taken that the complaint was to be taken forward. Although a decision to refer a case to the IOC was not included in the list of triggers for disclosure, the Inquiry was told that, in practice, such a decision was treated in the same way as the other decisions specified in the new statutory provision.

18.168 At the same time, the GMC was given the power to require persons to disclose any information or documents in their possession which appeared relevant to the GMC's consideration of a case. This power could be used, in theory, to obtain information from NHS organisations, although one would have expected that such information would usually be provided voluntarily.

18.169 In addition, the GMC was given statutory power to disclose to any person information relevant to a doctor's conduct, professional performance or fitness to practise which it considered it was in the public interest to disclose. This power might be used, for example, where enquiries were made by a prospective employer about a doctor who was being considered for employment. It also enabled the GMC, if it considered it to be in the public interest to do so, to inform a doctor's employer or PCO of the fact that a complaint had been made against him/her, in advance of the stage in its procedures when it was obliged by statute to make the disclosure. This was important since, in some cases, a period of several weeks (or even longer) might elapse before a screening decision was made and the time for statutory disclosure was reached. In such cases, it might be desirable for the doctor's employer or PCO to receive advance warning of the complaint that had been made.

18.170 In evidence to the Inquiry, Mr Scott said that requests by the GMC to employers or PCOs for background information about doctors against whom complaints had been lodged were sometimes made and sometimes not. Even at the post-screening stage, where the GMC was obliged to disclose information about a complaint that had been made, the disclosure was not invariably accompanied by a request by the GMC for information from the employer or PCO. Sometimes, an employer or a PCT would volunteer information about a doctor but this was not always done. Mr Marshall said that, in the case of convictions, employers and PCOs would be notified of the fact that convictions had been reported to the GMC at the time they were referred to the PPC. If the GMC had reason to believe that the employer or PCO might have relevant information, direct questions would be asked of it. Otherwise, the GMC would rely on the employer or PCO to volunteer any information that might be relevant.

18.171 Mr Scott said that, since there was, at the time he gave his evidence in December 2003, no requirement imposed on the GMC to make a disclosure to an employer or PCO immediately a complaint about a doctor had been received, there was 'ambivalence' on the GMC's part about seeking background information at that stage. As a result, further

information was sought only if 'the decision-makers' (by which I assume Mr Scott meant the screeners) said they did not have sufficient information to make their decision without such enquiries. The reason for the 'ambivalence' referred to by Mr Scott was that, if enquiries were made of an employer or PCO when a complaint was received, this would disclose the fact that a complaint had been received before the GMC was required by statute to make that disclosure. It was thought that this was unfair to the doctor concerned. As I have explained, it is clear that the GMC had the power to disclose at an earlier stage the fact that a complaint had been made, if it considered that it was in the public interest to make the disclosure for the purpose of obtaining information from the doctor's employer or PCO. However, in most cases, it did not choose to use that power.

18.172 With the impending introduction of the new FTP procedures, the GMC had to reconsider the point at which its statutory duty to make disclosure of a complaint should arise. During the period for which the new procedures were under discussion, its proposals as to what stages of its procedures should trigger disclosure underwent considerable changes. I describe these changes – and the eventual outcome – in Chapter 25. Broadly speaking, the obligation to disclose the complaint to a doctor's employer or PCO will, in most cases, arise when the case is referred to a case examiner, who will fulfil a similar – but not identical – role to that of the current screeners.

18.173 Meanwhile, as I have explained, in May 2004, the GMC announced that it would thenceforth be making informal disclosure of the fact that complaints had been made in certain cases. The intention was to discuss certain complaints with the doctor's employers and PCO at an early stage. The purpose of these discussions would be, first, to discover whether the complaint was an isolated matter or was part of wider local concerns about the doctor and, second, to inform those with local clinical governance responsibilities that the GMC had received a complaint about the doctor. It was not intended that such discussions would take place in every case. They would not be held in cases which, in the view of the GMC, clearly did not require action, nor in those cases where it was immediately clear, because of their seriousness, that the GMC must investigate.

18.174 The type of case in which discussions should take place is one where the allegation is not of itself (even if proved) serious enough to justify action on registration, but where the GMC's view might be different if there were wider concerns at local level about the doctor's practice. In such cases, the GMC will enter into a dialogue with the doctor's employer before deciding whether to investigate further. If that dialogue discloses no wider concerns about the doctor's fitness to practise, the GMC might decide that it need not investigate further. It seems to me that these new arrangements should, if implemented consistently, bring about significant improvement in the GMC's preliminary decision-making.

18.175 However, reports in the medical press have suggested that the new arrangements have been greeted with dismay by doctors. It has been said that the informal disclosure to employers and PCOs of the fact that a complaint has been made would be 'unfair to doctors' since employers would be liable to draw adverse conclusions from the fact that a complaint had been made against a doctor. At least two medical defence organisations are reported to have challenged the right of the GMC to ask a doctor to provide

employment details for the purpose of enabling the GMC to contact his/her employers to discuss a complaint made against him/her before the time for statutory disclosure is reached. It remains to be seen whether the GMC will apply the new arrangements consistently in the face of such opposition from within the profession or whether it will apply them in only a minority of cases or whether, like the very similar arrangements that were described in the 1997 Screeners' Handbook, the new arrangements will fall into disuse.

Deciding Which Organisation Should Deal with the Complaint

18.176 An early discussion between the GMC and a doctor's employer or PCO about a complaint should enable a decision to be taken as to which organisation should assume responsibility for dealing with the complaint. I have referred at paragraph 18.104 to the advantages, in an appropriate case, of a direct referral by the GMC to the local complaints body.

Comment

18.177 It is disappointing that the GMC, which has the protection of patients as its declared objective, has been content for so long to look at individual complaints in isolation. There seems to have been a failure fully to appreciate the effect that knowledge about a previous complaint might have on the evaluation of a later complaint. It also seems that there has been a view, illustrated by Dr Korlipara's evidence, that it would be 'unfair to doctors' to seek background information which might, in some circumstances, be unfavourable to them. From the viewpoint of patient safety, it seems to me essential that, when a decision is being taken whether or not to institute disciplinary action, the person making the decision should have a full picture of all issues which may affect the doctor's fitness to practise.

18.178 I welcome the intention, expressed by the GMC, that it should have informal discussions with doctors' employers and PCOs at an early stage after a complaint has been received. If this is done, it should ensure that employers and PCOs are aware at an early stage of complaints made about doctors for whom they have a responsibility. This will alert them to possible problems with doctors and will enable them to take any necessary steps to protect patients. In addition, complaints can be a source of great distress and anxiety to doctors and it is important that their employers and PCOs are aware of the position so that they can offer any support and practical assistance which may be necessary. The arrangements should also enable the GMC to place a complaint in context and to be made aware if the problem complained of is part of a wider pattern of concerns or is more serious than it would first appear. I hope that the GMC will not be deflected from its present intention by opposition from the profession. I hope that it will use this option in the majority of cases, indeed in all save for those which are obviously trivial and which plainly do not give rise to any issues for the GMC or the local NHS body. I do not know whether the GMC intends to apply this policy to complaints about doctors working in the private sector. I hope that it will do so.

Some Problems with Cases Closed by General Medical Council Staff

18.179 Under the old procedures, about 65% of the complaints and other communications received by the GMC's Screening Section were dealt with by members of the GMC's

administrative staff, who were authorised to close them without reference to a medical screener. It was the casework managers who took the decision whether to close a case or to refer it to a medical screener. It was also the casework managers who decided what, if any, further information was required before a case was submitted to a medical screener. The casework managers worked to instructions set out in the FTP Casework (later the FTP Investigation) Manual and other documents.

18.180 As I have previously explained, the Inquiry requested and obtained from the GMC the last five cases prior to 30th September 2003 which had been closed by GMC staff and in which the complainants had been advised to refer their complaints to local NHS complaints procedures. The Inquiry also requested and obtained the last five cases prior to the same date where complainants had been advised to refer their complaints to private complaints procedures. I shall refer later in this Chapter to two of the latter cases, those of Dr KC 02 and Dr KC 05, where the doctors who were the subjects of the complaints had not been identified. I express my concerns about those cases at paragraphs 18.213–18.227.

Dr KC 03

18.181 Another within this group of five cases was that of Dr KC 03. The complaint in that case was that Dr KC 03 had sent to the complainant the results of certain medical tests, carried out in the course of the (private) treatment of a member of the complainant's family, without providing any explanation of the results. It was said that when the complainant spoke to Dr KC 03 and requested an explanation, the doctor had been abrasive and rude. The complainant asked that the doctor should be reprimanded. The case was closed by a GMC casework manager on the ground that it would be more appropriately dealt with under local complaints procedures.

18.182 Standing alone, that decision could not be criticised. However, there had been two earlier complaints made against the doctor. The first had concerned the doctor's employment practices. The second alleged that the doctor's performance in private practice gave cause for concern. In connection with the second complaint, the GMC had written to the doctor, informing him that the medical screener was considering referring the doctor for a performance assessment and seeking his observations. (This letter was written under rule 5 of the General Medical Council (Professional Performance) Rules Order of Council 1997, a provision which was repealed in 2002.) The doctor submitted an extensive reply on the basis of which the medical screener decided that an assessment would not be necessary, given the doctor's insight into his problems and his ongoing attempts to address them.

18.183 Mr Marshall explained that, when the most recent complaint against the doctor was triaged, the casework manager should have been aware that previous complaints had been made about the doctor since this was noted on the CDF. However, he said that it was not clear from the relevant documents whether the casework manager had referred to the papers relating to the previous complaints before making a decision on the current one. Mr Marshall would have expected this to be done in view of the fact that one of the previous complaints had given enough cause for concern for a rule 5 letter to be sent. The most recent complaint cast doubt on the belief that the doctor was addressing his problems

successfully. Mr Marshall said that, if the casework manager had been aware of the previous complaint, he should at least have checked with the doctor's current employers or colleagues to ascertain whether there were any ongoing concerns about his practice. After the case came to light, as a result of the Inquiry's investigations, Mr Marshall caused it to be reopened so that the GMC could make appropriate enquiries.

18.184 This was a case where a previous complaint which was plainly of relevance to the one under consideration was probably not examined. As a result, the potential significance of the subsequent complaint was not recognised and the case was closed. It is of particular concern that the GMC should have failed to make appropriate enquiries in a case involving possible performance problems with a doctor in private practice. Such problems are less likely to come to light and be dealt with in a private setting than within NHS structures. When they are revealed, therefore, they should be given especially careful consideration.

Dr KE 05

18.185 When examining GMC files relating to doctors who had been the subject of disciplinary action for drug abuse, the Inquiry, by chance, came across a number of cases where other complaints against the same doctors had been closed by members of the GMC staff. One example of such a case was that of Dr KE 05, a GP. The GMC received a letter from a HA, expressing concern about Dr KE 05's high level of prescribing of morphine. Following Shipman's conviction, the Medical Adviser to the HA had carried out an analysis of the prescribing of morphine by doctors in the area. This had shown that Dr KE 05 had been prescribing over ten times more morphine than the average amount prescribed by other doctors/GP practices in the area. The Medical Adviser reported that a rumour had been circulating that the doctor had had 'dealings' with drug addicts. The doctor had since left the area covered by the HA in question.

18.186 The GMC requested further information from the HA, and this was provided. Eleven months later, the GMC sent a 'holding' letter. After a further 11 months (and almost two years after the original complaint), a member of the GMC staff wrote asking for **'any additional documentation'** relating to the complaint. This kind of delay was fairly common in cases that were dealt with by the GMC at that time. It seems that this letter was written following a Screening Case Review which had resulted in a recommendation that, because of its subject matter, the case should be progressed **'as a matter of priority'**. The HA responded promptly, saying that it had no further documentation in its possession. Shortly afterwards, the case was closed on the ground that it was a complaint from a third party **'where it is clear that the principal party does not want to pursue the matter, and no other reason for proceeding'**.

18.187 One striking feature of this case was the absence of any investigation by the GMC. The only action initiated by the caseworker was to ask for information and documentation from the HA which had raised the concern. There appeared to have been no real understanding of the type of documentation or information that would have been of assistance. Clearly, what was required was prescribing data relating to the doctor's past and current prescribing. If the HA did not have the data, it could have been obtained from

the Prescription Pricing Authority (PPA). If the request had been made quickly enough, prescription forms could also have been obtained from the PPA. No attempt was made to do this. Moreover, there was no attempt to find out where, and in what circumstances, the doctor was working at the time he was reported to the GMC or to contact his current employers or PCO.

18.188 The GMC might not have been the appropriate body to undertake an investigation of this kind. It might have been better done by the Home Office Drugs Inspectorate. If that was the case, there was no recognition of that fact and no attempt to direct the case to the proper quarter. Instead, the GMC acted as the passive recipient of information and, when the complainant appeared to have no more information to offer, the case was closed. The fact that a member of the GMC staff considered that there was **'no other reason for proceeding'** in a case involving the possible unlawful supply of controlled drugs is extremely worrying.

18.189 Dr Korlipara acknowledged to the Inquiry that there had been a 'serious lapse' in this case. Subsequent to it, in his capacity as a medical screener, he had had to consider a further complaint against Dr KE 05. This had involved an allegation of substandard clinical practice and was not drug-related. Dr Korlipara was informed by GMC staff at the time of screening that there had been two previous complaints against the doctor. The first in time had been referred to a medical screener; Dr Korlipara saw the papers relating to that complaint and did not consider it relevant to the one he was considering. On being told that the second previous complaint (the morphine case) had been closed by GMC staff, Dr Korlipara did not look at it. Thus, he remained unaware of the complaint about possible over-prescribing of morphine until he reviewed the file for the purpose of making a written statement to the Inquiry.

18.190 The practice of not considering cases which had previously been closed by GMC staff caused me some concern. I do not criticise Dr Korlipara personally for his failure to look at the earlier complaint. I have no doubt that he was following the usual practice. However, many cases were closed by casework managers, not because they contained no allegation of substance, but because they had not yet passed through the local complaints procedures. The majority of cases closed for that reason would have involved allegations of poor treatment or substandard clinical practice. It seems to me desirable that the person performing the screening function (in future, a case examiner) should have the fullest possible picture of the history of any previous dealings which the doctor may have had with the GMC's FTP procedures before taking a decision as to whether a case should go forward. In this context, I was concerned to hear that, at one stage in the 1990s, the GMC had embarked upon the process of disposing of the documentation relating to old complaints that had been closed. Fortunately, the process was discontinued. I can well understand the desire to clear out old documents to make space for new ones. However, it does seem to me that information about all complaints about a doctor should be retained (in some form) while that doctor remains on the register.

18.191 Returning to the complaint against Dr KE 05 of possible over-prescribing of morphine, Mr Marshall said that the decision to close the case was 'clearly wrong'. The member of staff who had taken the decision no longer worked for the GMC. Since the matter came

to light, the case had been reopened and enquiries instituted. Mr Marshall described as 'minimal' the possibility that at the time when he gave his evidence, a decision to close the case would have been taken in the same circumstances. This was, first, because casework managers were better trained. Second, he said that the system of triage which had operated since October 2002 meant that new cases were considered by a relatively senior member of staff (a casework manager) at an early stage. The casework manager would give instructions about action to be taken, together with the timescale within which that action should be completed. In all cases where complaints had been referred by healthcare providers, staff had been instructed to contact the referring body to discuss how the case should be dealt with. In addition, weekly meetings between caseworkers and their casework manager were held, at which all 'live' cases were discussed, priorities agreed and weekly objectives set. Mr Marshall also said that the audit procedures for cases handled by the Screening Section, to which I have already referred, should assist in eliminating any potential inconsistencies and errors made in the closure of cases at an administrative level.

Dr KH 02

18.192 An error or omission by a member of the GMC staff which results in a failure to obtain or take note of relevant information about a doctor may have an important effect upon the course of any subsequent proceedings. One such case of an error by a member of staff came to light by chance as the result of the Inquiry's consideration of a case (that of Dr KH 02) that had entered the health procedures. In the late 1990s, a complaint was received about Dr KH 02 to the effect that he had been drunk at work. The medical screener, Dr Korlipara, referred him into the health procedures. Unbeknown to Dr Korlipara, a few months before this complaint had been received, the GMC had been notified that Dr KH 02 had recently been convicted of the unlawful possession of cannabis and cocaine. Had Dr Korlipara known of these convictions, it is likely that his decision would have been different and that the case would have been referred to the PPC. In the event, the doctor's progress in the health procedures had not been good and, at the time when this error came to light, during the Inquiry hearings in 2003, his future in medicine was in doubt.

Dr JN 01

18.193 Another case which gave rise to concerns about actions taken by GMC staff was that of Dr JN 01. A HA informed the GMC of concerns relating to Dr JN 01, a GP, who was said to be issuing, in suspicious circumstances, large numbers of NHS and private prescriptions for benzodiazepines and other drugs. Subsequently, the HA sent to the GMC information from one pharmacy which showed that the doctor had issued 329 private prescriptions for benzodiazepines over a ten-month period. The HA sent the GMC a dossier of evidence relating to Dr JN 01's prescribing and also to two further complaints (one of theft from a patient) which had been made about him.

18.194 Before the case was referred to the GMC, investigations had been undertaken by the police and by the PPA Pharmaceutical Fraud Team (PPAPFT). On receipt of the referral,

the GMC took no action itself but awaited the outcome of the other investigations. A GMC caseworker met a representative from the PPAPFT. After that, it was decided to await further information from the PPAPFT before considering what to do next. The GMC file contained conflicting information as to whether the police investigation was continuing. However, the GMC made no direct contact with the police, despite the fact that the GMC had a team of staff whose task was specifically to liaise with the police. Mr Marshall said that he thought that the failure to refer the case to the specialist team occurred because the case was referred initially as a complaint of 'strange prescribing', rather than as a conviction case.

18.195 Seven months after the report was received by the GMC, the case was closed administratively. This did not mean that it was necessarily at an end. Instead, the intention of the GMC apparently was that it would be reviewed monthly and that regular enquiries would be made of the PPAPFT to ascertain what stage its investigation had reached. The GMC's computer system permitted a case to be 'flagged' for action periodically. However, it appears that this was not done. Two months later, following an enquiry from the HA, the GMC wrote to the PPAPFT, asking about progress. After a further four months, the PPAPFT informed the GMC that it had concluded its investigations. Four months later, the GMC was told that the local PCT (which had by this time replaced the HA as the PCO) was considering evidence collected by the PPAPFT and was making further enquiries about the doctor. The GMC still took no further action and the case remained closed until it came to light a few months later as a result of the Inquiry's request for documents.

18.196 Mr Marshall acknowledged that the handling of the case by the GMC had been deficient at two points. First, he said that the case should not have been closed administratively. That closure had resulted in a failure to chase up the PPAPFT for information. Second, after contact with the PCT, no further action was taken. The explanation was, he said, 'that we (*i.e. the GMC*) have either consciously made a decision that we have had three stabs at this and this is the last time we are going to bother ourselves to do it, or it has simply disappeared from view as other priorities took over'. He said that, if the case had not been closed, it would have been reviewed every week by the casework manager and a caseworker. Because the case was closed, it was not subjected to that routine review and was not the 'nagging irritation' it would – because of its age – have been at such meetings. The impression I received was that it was probably to avoid that 'nagging irritation' that the case was closed in the first instance.

18.197 Once the failure to follow up the case came to light as a result of the Inquiry's investigations, the case was reopened. Mr Marshall said that the GMC had obtained a full update from the PCT, which continued to monitor the doctor. Officers of the PCT had told the GMC that they did not feel that patients were at risk as a result of the doctor remaining on the register and being allowed to practise unrestricted. Mr Marshall told the Inquiry that he thought that the GMC needed to ask more questions of the PCT. In particular, it needed to find out whether any explanation had ever been obtained for the 'strange lurch in prescribing activity' that had occurred. It also needed to know what the position was in relation to the other two outstanding complaints against the doctor.

18.198 Mr Marshall said that it would not have been appropriate under the old FTP procedures for the GMC to have undertaken any investigation of its own (e.g. by instructing its

solicitors to investigate) at or before the screening stage. In any event, he did not think that the solicitors would have had the powers necessary to mount an investigation of this kind. Unless an investigation had been undertaken by another body and an explanation for the doctor's prescribing habits identified, it would, he said, have been difficult for charges against the doctor to be formulated by the GMC. It would not have been clear to the GMC what the doctor should be charged with, since it was not known whether the prescribing was the result of criminality or incompetence or was entirely innocent.

18.199 The handling of this case gave rise to a number of concerns. I can well understand the difficulty the GMC faces where other bodies are engaged in investigations, particularly where the doctor concerned is unaware that those investigations are going on. It is obviously important that the GMC does not prejudice the outcome of other investigations, in particular police investigations. It is also important, however, that the GMC has a clear picture of which organisation(s) is/are investigating and which issues they are investigating. It is in my view extraordinary, in the present case, that the GMC had no contact with the police and that it neither requested nor obtained a copy of any report prepared at the conclusion of the police investigation. It might be that the GMC staff assumed that the police had decided not to prosecute the doctor. However, that fact would not mean that there were no issues that the GMC ought to address. Nor did the GMC obtain any report on the evidence collected by the PPAPFT. There seemed to be no recognition of the fact that the PPAPFT investigation would be concerned only with potential fraud on the NHS (and, therefore, only with the NHS prescriptions issued by the doctor), not with the doctor's private prescribing.

18.200 The failure by the GMC to investigate rendered it entirely dependent on the result of investigations carried out by other bodies. If, as appeared to be the case here, those results were inconclusive, it seems that the GMC regarded itself as powerless to act. This was despite the fact that the purpose of disciplinary proceedings by the GMC – to ascertain whether the doctor is fit to practise, and to protect patients – is wholly different from the purpose of the other investigations which were undertaken. Mr Marshall suggested that the problems of dealing with a case such as this would be ameliorated by the introduction of the new FTP procedures.

18.201 Another obvious concern was the premature closure of the case. The purpose of that closure may have been to avoid the very procedures which had been designed to ensure that cases were not overlooked and left inactive for long periods. The system of flagging a case for review did not appear to have been implemented. The effect was that, had it not been for the Inquiry bringing the case to light, it might have lain dormant indefinitely, despite its potential seriousness. Even when it was brought to the GMC's attention, it did not appear that the GMC was intending to embark upon any investigation of the case. Rather it seemed content to let the PCT continue its attempts to resolve it. This is despite the fact that the evidence of the private prescriptions alone must, at the very least, have raised doubts about this doctor's fitness to practise.

Comment

18.202 I do recognise that every organisation makes mistakes. The Inquiry has not carried out an audit of cases closed by casework managers; it has examined only a few cases, which

have come to its attention by chance. It is possible that the Inquiry has, by chance, alighted upon isolated incidents of poor practice. However, the results of the audit exercise recently begun, which I described at paragraph 18.46, would suggest that errors and poor practice are not uncommon. It is comforting to know that some audit is now taking place. However, while mistakes are still being found, I wonder whether the audit should not become a review and should encompass all decisions rather than only a proportion of them. It seems to me that correct decisions in these cases are important to patient safety.

18.203 The cases I have described also illustrate the real problems caused by the lack of any investigation by the GMC. Within the small selection of cases examined by the Inquiry, two potentially serious cases were found, both involving allegations of improper prescribing of controlled drugs. Both were closed without any investigation by the GMC. Either or both of those doctors could pose a continuing risk to patients.

Ascertaining the Identity of a Doctor Who Is the Subject of a Complaint

18.204 One of the first tasks which the GMC staff undertake when a complaint is received is to seek to establish the identity of any doctor named or described in the complaint, by reference to the medical register. This is not necessarily as simple as it sounds. It may appear surprising that a complainant should not be able to identify a doctor about whom s/he is complaining. However, it is not unusual for a patient in a hospital to be unaware of the identity of the doctors who treat him/her, nor for a patient attending a 'walk-in' clinic to be similarly unaware. Nor is it uncommon for a complainant to supply a name to the GMC which turns out to be wholly or partially incorrect. Identification can also be a problem where there are several doctors on the register with the same or a very similar name. It is rare for a member of the public to be in a position to quote a doctor's GMC registration number, which might be necessary to identify the doctor positively in these circumstances.

The Work of the Policy Studies Institute

18.205 When Professor Allen and her team first began their studies of the GMC procedures, they noted that a significant proportion of the doctors against whom complaints had been made had never been identified by reference to the GMC's medical register. Plainly, if the GMC's procedures were to be thoroughly examined for racial bias, it was important that the doctors complained about should be identified. A good system of identification is also necessary if the GMC is to fulfil its public protection duties. The 1996 PSI Report recommended that the GMC should enter and store on computer, for the purposes of monitoring, full details of the doctors about whom complaints had been made and that those details should be matched and linked with the medical register.

18.206 Despite this, the 2003 PSI Paper pointed out that there had in fact been an increase since 1997 in the proportion of doctors complained about whose identity had not been established by the GMC. In 1997, complaints were made against 2485 doctors, of whom 377 (15%) were not identified. By 2001, the number of doctors complained of had risen to 3999, of whom no fewer than 1019 (just over 25%) had not been identified. Professor

Allen told the Inquiry that the GMC's explanation for the increase in unidentified doctors was that it was thought unnecessary to identify doctors in cases which were closed by the administrative staff and which the GMC considered could never raise a question of SPM or SDP. Professor Allen and her colleagues noted with surprise that the GMC's categorisation of the complaints made against 22% of the unidentified doctors (in cases where there had been a categorisation of the complaint) had been **'dishonesty/criminality'**. A fairly high proportion of complaints in this category had not been sent to a medical screener. I find it worrying that so many doctors remained unidentified, especially in cases involving allegations of dishonesty or criminality. It is also a matter for concern that they were not referred to the medical screeners. Moreover, in each year, about 10% of the doctors who had not been identified had been reported to the GMC by public bodies. This was particularly surprising because it is hard to imagine that a public body would make a complaint about a doctor without being aware of the doctor's identity.

The Problems Caused by the Failure to Identify Doctors

18.207 Since Professor Allen and her colleagues were looking at the possibility that racial bias might play a part in decisions made by the GMC, the failure to identify doctors was of particular concern. In their various analyses, they had looked at the country of qualification of all doctors who were the subject of complaints to the GMC. They had then compared the outcomes of the complaints against those who qualified in the UK with the outcomes of the complaints against those who had qualified overseas. Failure to identify a doctor meant that the country of qualification of the doctor could not be identified. Professor Allen and her colleagues were concerned that no similar analysis of cases would be possible in the future if doctors and their countries of qualification were not identified.

18.208 There are other consequences of the failure to establish the identity of a doctor against whom a complaint is made. First, it means that the GMC cannot ascertain whether the doctor has any previous history of complaints made to the GMC about him/her or of disciplinary action taken against him/her. Yet there will be many cases where knowledge of a doctor's FTP history might cause the current complaint to be viewed in a different light. Second, it means that the complaint cannot be retrieved in the future if another complaint against the same doctor is received. Third, it might be that the complaint involves a person who is not on the GMC's register but is masquerading as a doctor. If no attempt is made to check that the person complained about appears on the register, the fact that s/he is an impostor will never be known.

Possible Reasons for the Failure to Identify Doctors

18.209 In his evidence to the Inquiry, Mr Scott suggested two possible reasons for the apparently high number of unidentified doctors. First, he suggested that the doctor's identity might in fact be known but the name might just not have been recorded on the GMC database. I find it surprising that this could occur since I should have thought that the name of the doctor was a vital piece of information for reference purposes. The omission to record a name on the database may have serious consequences since it will be impossible to make

a link with another complaint about the same doctor in the future. There does not seem to me to be any excuse for a failure to record on the computer database the identity of a doctor if it is known.

18.210 Second, Mr Scott said that a significant proportion of communications received by the GMC were not complaints against doctors but were pieces of correspondence raising issues which, if a doctor were involved, could become a complaint. Quite a high proportion of those did not involve a doctor at all. I can see that, in those circumstances, it would not be necessary (or, in some cases, possible) to link the subject of the complaint with a name on the medical register. However, the complaints referred to by Professor Allen (particularly those involving **'dishonesty/criminality'** and the reports from public bodies) must have involved allegations against the doctors concerned; they cannot have been just general correspondence.

18.211 Mr Scott said that there was a procedure to be followed when trying to identify a doctor. The extent to which that procedure was implemented depended on the potential seriousness of the issue that had been reported. If it was of sufficient seriousness to be a potential candidate for the FTP procedures, staff would go to some lengths to identify the doctor. If the complaint did not, on the face of it, raise an issue that would fall within the FTP procedures, then correspondingly less effort would be devoted to trying to identify the doctor. That approach does not sound unreasonable but it does not account for the failure to identify doctors about whom the complaint was of **'dishonesty/criminality'**. Moreover, examination of a few individual cases suggests that abandonment of an attempt to identify a doctor may sometimes be premature.

Specific Cases

18.212 The Inquiry examined two cases that illustrated the problems arising from a failure to identify a doctor about whom a complaint has been made. Both were closed by casework managers in late 2003.

Dr KC 02

18.213 In the first case (that of Dr KC 02), the complainant had undergone laser eye treatment at a private clinic. She alleged that, as a consequence of the treatment, she had suffered scarring to her eye. She was complaining of distortion of vision. In a letter to the complainant's GP, written after he had been notified of the complainant's dissatisfaction, the person who performed the treatment (whom the complainant understood to be a doctor) had claimed that the complainant had been warned of the risks of a poor outcome before undergoing the treatment. The complainant said that she had not been warned. She had initially directed her complaint to the General Optical Council, which had forwarded the complaint to the GMC since the subject of the complaint appeared to be a doctor.

18.214 The case was closed by GMC staff on the ground that local complaints procedures had not been exhausted. In a letter written by a casework assistant, the complainant was advised to refer her complaint to the Medical Director or Chief Executive of the clinic

where she had received her treatment. The letter also suggested that she might wish to copy her complaint to the NCSC, which would monitor the handling of the complaint.

18.215 The complainant had given the name of the person who had treated her. The name was an unusual one. Yet the caseworker who dealt with the complaint had not been able to match the name with that of a doctor appearing on the medical register. It appeared to me that this immediately raised the possibility that the person who had treated the complainant had not been a doctor at all. Of course, it might be, as Mr Marshall suggested, that the complainant had spelled the name wrongly and that this was why the name could not be found on the medical register. However, it was impossible to be sure.

18.216 Mr Marshall said that, once a decision had been taken that the GMC would not be proceeding in the case, it would have been an unnecessary expenditure of resources to attempt to identify the doctor. I can understand that, in some cases, it might not be worthwhile expending resources in this way. However, in this case, where the GMC had the address of the clinic where the treatment had been given, the task of ascertaining the doctor's details would have been relatively simple. If that was not done, the possibility remained that the person who had performed the treatment was not a doctor at all.

18.217 If the person who treated the complainant had been an impostor, pretending to be a qualified doctor when he was not, he would have been liable to prosecution. Given that the role of the GMC is to protect patients, I should have thought it would have a keen interest in detecting and initiating action against any person who impersonated a doctor. If, an enquiry having been made of the clinic, it had appeared that the person who had treated the complainant was not on the medical register, the next step would have been to report the case to the police for investigation. Indeed, had the doctor not been on the register, that fact should have triggered investigations into the clinic, its recruitment policy and its staffing arrangements. The GMC itself could not have carried out such investigations but could presumably have asked the NCSC to do so.

18.218 The complaint was primarily one of negligent treatment. Even if the treatment itself had not been negligent, then there might have been a negligent failure to inform the complainant of the risks associated with the treatment. Both would be serious matters. If the subject of the complaint was indeed a doctor, the failure to identify him made it impossible for the GMC to ascertain whether there had been any previous complaints against him. It is possible that there had been a history of past complaints of a similar nature. In addition, if the GMC received another complaint of a similar nature about the doctor in the future, there would be no means by which that complaint could be linked with the previous one.

18.219 Mr Marshall pointed out that the failure to identify a doctor was not an unusual occurrence. Often, the name of the doctor was a common one and the problem lay in ascertaining which doctor of that name was involved in the complaint. Because the situation that arose in this case was commonplace, this case would not necessarily have 'rung alarm bells' with the caseworker. Having looked at the case afresh, Mr Marshall recognised the possibility that the 'doctor' might not in fact have been registered. He felt that the GMC should look at its processes with a view to setting out criteria for the circumstances in which more vigorous attempts should be made to identify a doctor about whom a complaint had been made.

18.220 This complaint concerned treatment in a private clinic, into which members of the public could walk without referral by, or advice from, a GP. Patients in those circumstances are particularly vulnerable and I should have thought that the GMC should be especially rigorous in protecting them. I find it concerning that the GMC's processes allowed the question of whether or not the person who treated the complainant was a *bona fide* doctor to go unanswered. I note also that the complaint was referred to the clinic's complaints procedures at a time when the GMC was in no position properly to assess the seriousness of the complaint or whether the doctor (if doctor he was) presented any danger to patients attending the clinic for treatment in the future. Nor did the GMC have any knowledge of the complaints procedures in operation at the clinic or whether they were likely to identify a possible threat to patient safety, if such a threat existed.

18.221 Moreover, the onus of initiating the complaints procedure was on the complainant. She had already indicated that she had been unable to get a satisfactory response to her complaint from the clinic. It would not perhaps have been surprising if she had been unwilling to make another approach. If the GMC had forwarded her complaint direct to the clinic and had made it clear that it would be following the matter up to discover the outcome, the burden would have been removed from the complainant and there would, I should have thought, have been a greater chance of her complaint being taken seriously.

18.222 This case provided an interesting insight into the GMC's attitude to the gathering of information. During his evidence about this case, Mr Marshall made the point that it would be onerous for the GMC, and potentially disappointing for complainants, if the GMC were to enter into 'lengthy correspondence' with complainants in order to try to establish the identity of a doctor in such a case as this, where the GMC was not going to take the case forward. Plainly, it had not occurred to Mr Marshall that the GMC itself might take the initiative and might seek information from a third party, in this case the clinic. It seemed to be the case that 'investigation', to members of the GMC staff, was essentially confined to seeking information either from the complainant or from the doctor against whom the complaint had been made. This was perhaps not surprising, since it reflected what had, in general, been the practice in the past.

Dr KC 05

18.223 In the case of Dr KC 05, a member of the public wrote to the GMC, saying that she had undergone, at a private hospital, an orthopaedic operation which had had a very unsatisfactory outcome. The nature of the unsatisfactory outcome was unspecified. She was pursuing a claim for negligence against the surgeon concerned but wanted the issue of his fitness to practise to be considered by an appropriate authority. She did not name the surgeon involved or the hospital.

18.224 The case was closed by a casework manager and the complainant was advised to contact the Medical Director or Chief Executive of the hospital concerned and to ask him/her to look into the issues. She was told that she could return to the GMC if she was dissatisfied with the response. In this case also, it was suggested that the complainant might copy her complaint to the NCSC. She was not asked for the surgeon's name and the GMC did not establish his identity. The casework manager who closed the case had no idea whether

the surgeon had a history of complaints of a similar nature or a record of disciplinary action against him. The complaint of a poor outcome to the complainant's operation might or might not have been justified. If there had been a poor outcome, it might or might not have been as a result of substandard treatment on the surgeon's part. If it was, that substandard treatment might or might not have amounted to SPM. If there had been a previous history of similarly substandard practice, the opportunity of linking that history to this complaint (and possibly of discovering a pattern of SDP) was lost. Similarly, if a further complaint of the same type were received in the future, there would be no way of linking it with this one.

18.225 Mr Marshall said that he thought it would have been preferable if the GMC's letter to the complainant had specifically asked her to provide the surgeon's details so that checks could be carried out. He said, 'I think we hope that this particular complainant may come back to us.' I do not believe that the complainant would have understood from the letter which she received that an immediate return to the GMC was an option. The letter merely suggested that she could contact the GMC again if she was dissatisfied with the response she received from the hospital. Mr Marshall pointed out that an unsatisfactory outcome to an operation might not necessarily raise any issues affecting the doctor's practice and that, if there were such issues, they might not be at the appropriate threshold for the GMC to become involved, at least in the first instance. I accept that entirely, of course. The problem, it seems to me, is that, at the time the decision to close the case was taken, the GMC did not have the information necessary to make these judgements.

Comment

18.226 If the GMC is to be in a position to link a doctor against whom a complaint is made with any past FTP history which s/he may have and with any such history that s/he might acquire in the future, it is vital that a full and accurate record is maintained of the details of that doctor. I accept of course that, on occasion (particularly where the complaint relates to hospital treatment), it may not be possible to identify the doctor concerned. I also accept that there will be cases where no issue of patient safety could possibly arise or where there are other circumstances which mean that it would be a complete waste of resources to go to elaborate lengths to identify a doctor about whom a complaint has been made. However, it seems to me to be an entirely different matter where, as in the two examples I have cited, potential issues of patient safety do arise and complaints are being closed not because there is no substance in them, but because the GMC prefers to leave the task of investigating and assessing the seriousness of the complaint to local complaints procedures. In both cases, the task of ascertaining the identity of the doctor should have been perfectly simple. In both cases, the existence of a history of similar complaints could have been very significant.

18.227 Mr Marshall told the Inquiry that he thought that the GMC needed to reconsider its policy in relation to cases that were closed for referral to local procedures. In particular, there needed to be consideration of whether more energy should be expended on identifying the doctor. The Inquiry has been told that, since its hearings, the GMC has taken steps to address the problem of unidentified doctors and, certainly, the FTP Investigation Manual of May 2004 laid more emphasis than did previous similar publications on the importance of identifying a doctor against whom a complaint was made. I do not know how successful

the measures taken by the GMC have been. It seems to me surprising, however, that the GMC did not appear to appreciate – until the Inquiry drew attention to the fact – the implications for patient safety consequent upon its failure to establish the identity of such a high proportion of the doctors about whom complaints were made.

Conclusions

18.228 In this Chapter, I have examined the early stages of the GMC's 'old' conduct procedures in some detail and have been very critical of some of the practices, and of the policies which have underlain their operation. It may be said that this detailed examination of how the procedures have worked has been pointless and the criticism misplaced, because the conduct procedures have been abolished; the new FTP procedures will be much better. However, in my view, it has been important to conduct this examination because it has provided the best opportunity to understand how the procedures actually operated in the past as opposed to how they were theoretically intended to operate. There was, as I have indicated, a considerable difference between the two. For the future, I have received evidence about how it is hoped and intended that the new procedures will operate. In the nature of things, there is bound to be some shortfall between the intentions and the reality. I needed to know about any shortfall in the past in order to assess how the new procedures might actually operate in future.

18.229 The evidence has also revealed much about the attitudes and approach of the GMC over the years. Although the GMC has recognised the need for change, not only of its procedures but also of some of its old attitudes, I have needed detailed evidence of the old attitudes if I am to form a view of the chances of success for the new regime.

18.230 My overwhelming impression of the staff employed in recent years is that they are conscientious and sympathetic to patients. They did not seem to me in any way dismissive of patients' interests and concerns and I certainly detected no underlying desire to 'do patients down'. But it does seem to me that the GMC, as an institution, has been incapable of devising and operating its procedures and policies from the viewpoint of patients and patient protection. This is a thread that runs through all the issues I have discussed above. When, at the Inquiry, a problem was drawn to the attention of a member of staff, the reaction was usually to see the point and to accept that a different approach was required. An example is the feature that I have just described: the failure to identify 25% of doctors about whom complaints were received. Yet the problems were not recognised by the organisation itself until they were pointed out. I am not sure why not. There are several possibilities.

18.231 I recognise that an organisation can become set in its ways and so used to doing things in a certain way that it fails to notice that there is anything wrong with its methods, procedures and attitudes. But this cannot be said of the GMC. In the last five years, the GMC has faced up to the fact that its FTP procedures are inadequate and that they require radical reform. It has spent a great deal of time and effort devising new procedures and consulting upon them. It claims to have recognised the need to place the protection of patients in the forefront of all it does. Yet it did not see that many aspects of its old FTP procedures required change – change that did not need an Act of Parliament or the

expenditure of large amounts of money to bring about. A case in point was the practice of advising complainants to pursue local procedures and then just leaving them to get on with it. Mrs Robinson pointed out the difficulties and dangers of this practice in 1988. Yet it survived, little changed, for more than 15 years after that.

18.232 Another possibility, which I mention only to dismiss, is that members of the GMC staff do not have the intellectual resources to grapple with these problems. I have the impression that the GMC employs some extremely able staff. I do not think that is the problem. It is also apparent that leading members of the GMC, such as the current President, Sir Graeme Catto, and his predecessor, Sir Donald Irvine, are personally committed to providing FTP procedures that protect patients.

18.233 A further possibility, which I believe to be the root cause of the problem, is that there are inherent tensions between the interests of patients in having first class FTP procedures and the interests of the doctors who elect the majority of members of the GMC. There are two obvious sources of tension. One is money. The GMC is funded by doctors, and good FTP procedures, including good investigation, are an expensive business. The other is even more fundamental. I can understand and sympathise to some extent with the view of a doctor who asks why s/he should be expected to pay (and pay dearly) for a process that is designed primarily to protect the interests of another group (those of patients) which sometimes appear to be inimical to the doctor's own interests. The answer, of course, is that, if the profession wants to be in charge of its own regulation, it must pay for it and it must do the job to the satisfaction of the community at large. If the profession is not prepared to do the job in a way that properly protects the public and does not want to pay for a first class process, the Government may eventually decide that the profession will have to give up self-regulation.

18.234 Another facet of the problem seems to me to be that many doctors perceive the GMC not as their regulator but as a representative body. This perception is fostered by the way in which the majority of members are elected by the profession. If the doctors elect the members and pay for the whole operation, one can see why they expect the GMC to conduct itself in a way that favours the interests of the profession. The practice of electing members began in the 1970s following a near revolt within the profession at the introduction of an annual retention fee. The cry was 'no taxation without representation': hence the misunderstanding as to the role of the GMC. A possible solution to this is that the GMC should not be dominated by elected members but by leaders of the profession who are not beholden to an electorate.

18.235 I mentioned also that one of the problems that appeared to beset the GMC was its internal confusion about its role and its relationship with patients and the public. It has given the public the impression, in particular in its leaflets 'A Problem With Your Doctor?' and 'Referring a doctor to the GMC – a Guide for Patients', that it is a repository for all types of complaints and concerns about doctors. Yet its statutory powers and duties have been limited to dealing with complaints and concerns that give rise to a question of SPM, SDP or serious impairment to health. That was all the old FTP procedures were designed to do, although the GMC staff would also provide advice to callers. In this context and, as a further example of the way in which the GMC has reacted to concerns expressed by the

Inquiry, I notice that a new – and more accurate – description of the GMC's functions in respect of complaints and concerns has recently appeared on its website. When speaking of the old leaflets, Mr Scott said that there had been a lack of clarity in the GMC about where to position itself in relation to other systems, in particular the NHS complaints procedures. I wonder whether the 'lack of clarity' did not in reality represent a conflict of views between its members as to the function and purpose of the GMC's FTP procedures.

18.236 I shall revert to these issues again in later Chapters, when discussing problems that have been detected in the operation of the later stages of the GMC's conduct procedures. Their relevance, in case the reader is in doubt, is to the important question of whether the GMC will in fact bring a new approach and attitude to the new procedures or whether, like the leopard, it will be unable to change its spots.

CHAPTER NINETEEN

The General Medical Council's Conduct Procedures: Screening

Introduction

19.1 In Chapter 18, I described how, under the 'old' conduct procedures, when complaints and reports of convictions were received by the General Medical Council (GMC), they were subjected to a filtering process which was carried out by members of the GMC staff, exercising the legal powers of the Registrar. Only about 35% of cases survived that initial filtering process. I shall now consider the next step in the conduct procedures, which was known as 'screening'.

19.2 From the end of the nineteenth century, GMC Rules stipulated that convictions and complaints referred to the GMC should undergo initial consideration in order to determine whether or not they should be referred on for further action. Individuals who performed this function became known as 'screeners'. For many years, the President of the GMC, who was always a prominent member of the medical profession, acted as the sole screener. If, for any reason, he was unable or unwilling to do so, he would nominate another medically qualified member of the GMC to take his place. Complaints were few and it was possible for one man to consider them all. Conduct that the President regarded as potentially 'infamous in any professional respect' (later serious professional misconduct (SPM)) would go forward to a disciplinary hearing. The President himself would chair that disciplinary hearing. By virtue of his dual roles, the President of the GMC was, in effect, the arbiter of what conduct was and was not acceptable in a member of the medical profession. That this degree of power and influence should be reposed in one individual seems extraordinary to modern eyes. Of course, the system has changed but, in examining the functions of the present day screener, it is helpful to understand the origin of the role.

19.3 Over recent decades, as I shall describe, the number of screeners increased. The President ceased to undertake this role, which was thereafter performed by several individuals. After 1990, lay people participated in the screening process. Until July 2003, the Rules provided that only members of the GMC could act as screeners. When the size of the GMC was reduced, in July 2003, that changed; after that time, it was possible for non-members to be appointed to act as screeners. From mid-2004, the existing screeners were replaced by case examiners, who had been appointed for the purposes of the new fitness to practise (FTP) procedures. The intention was that they should fulfil the roles of screeners pending the introduction of the new procedures.

19.4 Cases referred on by the screeners went for further consideration to one of the GMC's FTP committees. Until 1980, that committee was the Penal Cases Committee (PeCC); after 1980, it was the Preliminary Proceedings Committee (PPC). The function of the PPC was to decide whether a case should go to the Professional Conduct Committee (PCC) (formerly the Disciplinary Committee (DC)) for a disciplinary hearing.

19.5 The importance of the screener's role as a filter was demonstrated by the statistics produced by the GMC. Screeners were responsible for 'screening out' a large proportion

of the cases referred to them. In most years from 1987 to 1998, between 82% and 89% of cases referred to screeners were screened out and closed. The public was not generally aware of this. The screening process took place in private and, as I shall explain, was not open to scrutiny by anyone, not even by other members of the GMC.

19.6 In this Chapter, I shall examine the role of the medically qualified and 'lay' screeners and the developments in the screening process which took place over the years. I shall discuss the tests applied by the screeners at various times and the guidance which was available to assist them when applying those tests. I shall discuss some individual screening decisions, including that relating to complaints against Shipman which were reported to the GMC in 1994 and some of those which have been the subject of proceedings for judicial review. I shall consider the light shed on the screening process by the work undertaken by the Policy Studies Institute (PSI). I shall also consider some specific problems which have arisen in connection with the screening process.

Witnesses

19.7 The Inquiry heard oral evidence from Dr Krishna Korlipara, who was a medically qualified screener dealing with conduct and performance cases (a 'medical screener') from 1998 to 2004, and from Dr Arun Midha, who is not medically qualified and was appointed a 'lay' screener in July 2001. Dr Robin Steel, a medical screener between 1987 and 1999, and Dr Joan Trowell, who was appointed a medical screener in 1999, provided witness statements to the Inquiry. Mr Blake Dobson, Head of Casework for the GMC's Fitness to Practise Directorate (FPD) and Head of the FPD Audit Team, also provided a witness statement. Professor Isobel Allen, Emeritus Professor of Health and Social Policy, University of Westminster PSI, provided a witness statement and gave oral evidence. During the late 1990s, she and a team of colleagues examined several aspects of the GMC's work, including the screening process.

The Role of the Screener from the 1970s until 1996

The 1970s

The Treatment of Convictions

19.8 Rule 5 of the General Medical Council Disciplinary Committee (Procedure) Rules Order of Council 1970 (the 1970 Rules) provided that all criminal convictions (save those excepted by a direction of the PeCC) should be referred by the Registrar to the President. The PeCC made an exception for minor motoring offences not involving the abuse of alcohol or drugs; no action was, therefore, taken in relation to such convictions. They were not required to go forward for screening by the President.

19.9 In practice, despite the requirement in the 1970 Rules that all convictions (save excepted convictions) should be referred to the President, it appears that this did not happen. Mr Robert Gray, Assistant Registrar in 1976, when the GMC considered Shipman's conviction, told the Inquiry that he thought that, by that time, the then President, Sir John (later Lord) Richardson, had arranged with members of the GMC staff that only the most serious convictions should be referred to him. These would include convictions for which

a custodial sentence had been imposed and second or third drink driving convictions. The purpose of referring the most serious convictions was not, as I understand it, because there was any doubt as to whether they should be referred to the PeCC; rather, it was because the President wanted to be kept informed about such cases. Other convictions (save for excepted convictions) were to be referred by staff direct to the PeCC. The effect of these arrangements was that all criminal convictions (save for minor motoring offences) were automatically referred for consideration by the PeCC.

The Treatment of Conduct Cases

19.10 By rule 5(1) of the 1970 Rules, the Registrar was also required to refer to the President any complaint made in writing that appeared to him to raise a question as to whether the conduct of the doctor in question constituted SPM. Such cases would be referred to by the GMC as 'conduct cases'. Rule 5(1) of the 1970 Rules was the forerunner of rule 6 of the General Medical Council Preliminary Proceedings Committee and Professional Conduct Committee (Procedure) Rules Order of Council 1988 (the 1988 Professional Conduct Rules), the operation of which I discussed in the last Chapter.

19.11 Rule 5(2) of the 1970 Rules provided that, in a conduct case and **'unless it appears to him that the matter need not proceed further'**, the President should set in motion the disciplinary procedures. The question whether a case did or did not **'need'** to proceed further – and of how to interpret the word **'need'** – was for the President to decide. The Rules contained no criteria to be applied when making the decision. It seems to me that it was implicit in the Rules that, notwithstanding the fact that the Registrar had referred the case for screening (and must therefore have considered that it raised a question whether the doctor's conduct amounted to SPM), the President might take the view that the complaint could not, in fact, amount to SPM. In that event, there would be no **'need'** for the matter to proceed. Other types of consideration spring to mind; for example, if the doctor complained about had already retired from practice, that might provide a sensible reason why there was no **'need'** for the complaint to proceed. The presence or absence of a '**need'** for a case not to proceed further continued to be the test to be applied by medical screeners until August 2000. The test allowed the President/medical screener a wide discretion. Despite the fact that the wording of the test was framed so as to require a case to proceed unless there was a reason why it should not, a high proportion of cases were screened out. This suggests that the screeners might have applied the test in reverse – by screening a case out unless there was an identifiable reason for allowing it to proceed. Evidence received by the Inquiry suggests that the test was indeed applied in reverse. Mr Antony Townsend, Deputy Head, then Head, of the Conduct Section between 1994 and 1998, told the Inquiry that, until the mid-1990s, the 'old view' had been that a reason had to be found for referring a case to the PPC.

After Screening

19.12 If the President/medical screener decided that a case **'need not proceed further'**, the case was closed and no further action was taken. No 'second opinion' was sought. If s/he considered that the case should go forward, rule 5(2) of the 1970 Rules required

him/her to direct the Registrar to write to the doctor, notifying him/her **'of the receipt of a complaint or information, and stating the matters which appear to raise a question whether the practitioner had committed'** SPM. The complainant (if there was one and if s/he was a private individual) would be required to provide a statutory declaration and that would be sent to the doctor. The doctor would be informed of the date of the next meeting of the PeCC and would be invited to submit an explanation of his/her conduct. Once these steps had been taken, the President/medical screener would refer the case to the PeCC.

The Screeners

19.13 Until 1973, it was normal practice for the President not only to deal with the screening of cases but also to chair the PeCC and the DC. Lord Cohen of Birkenhead, President from 1961 until 1973, fulfilled all three roles until he fell ill in about July 1973. After that time, Professor Sir Denis Hill, a prominent member of the GMC, was appointed by the President to act as medical screener. Two other members of the GMC also chaired meetings of the DC.

19.14 Over the years, there had been dissatisfaction in some quarters about the arrangement whereby the President decided whether a complaint should be referred to the PeCC, then adjudicated on the same complaint at the PeCC and again at the DC. In 1973, the GMC accepted that it was undesirable for the President to continue to fulfil all three roles. Thereafter, the new President, Sir John Richardson, chaired the DC and Sir Denis was again appointed to act as medical screener and to chair the PeCC. In 1975, the President resumed the roles of medical screener and Chairman of the PeCC. He delegated chairmanship of the DC to another member of the GMC, Mr (later Sir) Robert Wright.

19.15 In 1975, the Merrison Committee recommended that the preliminary sifting (i.e. screening) of cases should be undertaken by the President, assisted by GMC staff and by the proposed investigation unit which I mentioned in Chapter 18. The reason for entrusting the task to the President was, the Committee said, **'the vital nature of the initial sifting task'**. The Committee also recommended that the President should be a member of the new Complaints Committee (subsequently entitled the PPC), which was to replace the PeCC. This was so that the President's knowledge of a case, derived from his previous screening of it, could be available to the PPC. The Committee recommended that a person other than the President should chair the DC (which was to become the PCC).

The 1980s

The Health Procedures

19.16 The Medical Act 1978, together with the General Medical Council Preliminary Proceedings Committee and Professional Conduct Committee (Procedure) Rules Order of Council 1980 (the 1980 Professional Conduct Rules), brought into effect many of the changes recommended by the Merrison Committee.

19.17 At the same time, the General Medical Council Health Committee (Procedure) Rules Order of Council 1980 (the 1980 Health Rules) came into effect and governed the operation of

the new health procedures. They provided that the Council should appoint the President or some other GMC member to undertake the initial consideration (i.e. screening) of cases which raised a question whether the doctor's fitness to practise was seriously impaired by reason of his/her physical or mental condition. If the President chose to chair the Health Committee (HC), or if for other reasons he did not wish to be appointed as screener for health cases, he was to nominate another member of the GMC for appointment by the Council. The person fulfilling this screening role, who would be medically qualified, became known as a 'health screener'.

19.18 The 1980 Professional Conduct Rules provided that, in any conviction or conduct case where it appeared to the President/medical screener that the doctor's fitness to practise might be seriously impaired by reason of a physical or mental condition, the President/medical screener should direct the Registrar to inform the doctor of the fact and to invite the doctor to furnish medical evidence of his/her fitness to practise. That evidence would then be available to the PPC when it considered the case. The 1980 Professional Conduct Rules also permitted the President/medical screener in such a case to remit the case to the health screener for action under the voluntary health procedures.

The Treatment of Convictions

19.19 The 1980 Professional Conduct Rules required the Registrar to refer all convictions to the President/medical screener save for those (i.e. minor motoring offences not involving the abuse of alcohol or drugs) which the PPC had directed need not be referred. In principle, the President/medical screener was required to refer to the PPC every conviction case which had been referred to him. It was, however, open to him to remit a case to the health screener for action under the voluntary health procedures as an alternative to referring the case to the PPC.

19.20 The 1980 Professional Conduct Rules introduced an arrangement whereby doctors in conviction cases were invited at an early stage to submit their observations to the GMC. Those observations were then put before the President/medical screener at the time the case was screened. Where the doctor had submitted medical evidence, this might give rise to the case being remitted to the health screener rather than being referred to the PPC. Doctors in conduct cases were not asked for their observations until after the case had been screened so that, in general, the President/medical screener would not have the doctor's response to the complaint made against him/her.

The Screeners

19.21 The 1980 Professional Conduct Rules provided that the President should continue to perform the role of medical screener as before. However, if the President chose to sit either on the PCC or on the new HC or if, for other reasons, the President did not wish to undertake the screening of cases, it was open to him to **'nominate some other member for appointment'** by the Council as medical screener. Later, the 1988 Professional Conduct Rules provided that the Council **'shall appoint'** the person nominated by the President. In effect, therefore, the appointment was in the hands of the President. The 1988 Professional Conduct Rules also provided that the President could nominate (and

the Council was required to appoint) other members of the GMC to act as additional medical screeners in cases where the President or the appointed medical screener was unable to act.

19.22 In 1980, Sir Robert Wright became President. He chaired the PCC until his death in 1981. Sir Denis Hill was again appointed medical screener, both for conduct cases and for cases being dealt with under the new health procedures. He chaired the PPC. In February 1982, Sir John (later Lord) Walton became President. From the beginning of his Presidency until November 1984, he chaired the HC. Initially, Sir Denis continued as screener and Chairman of the PPC. Following the death of Sir Denis in May 1982, the President nominated Dr John Fry, a general practitioner (GP), as medical screener for conduct cases. Dr Fry also chaired the PPC. In November 1984, Sir John ceased to be a member of the HC and became screener for both the conduct and the health procedures. He was assisted by the previous medical screener, Dr Fry. Sir John also chaired the PPC. In November 1987, Dr Steel was appointed as an additional medical screener. Sir John was the last President to act as medical screener.

19.23 Sir Robert (later Lord) Kilpatrick succeeded to the Presidency in February 1989. He chose to chair the PCC. Dr Fry was appointed medical screener, assisted by Dr Steel and Dr (later Dame) Beulah Bewley. Dr Fry also chaired the PPC. From about this time, the medical screener for conduct cases became known as the 'principal' medical screener, in order to differentiate him/her from the additional medical screeners. It is apparent that, at least until this time, screening had been the province of very few members of the GMC and all involved had been personally selected by the President of the day.

Chapter XV Procedures

19.24 I have said that, under the 1970 Rules, if the medical screener decided that the complaint need not proceed further, it would be closed. That was also the case under the 1980 Professional Conduct Rules. In May 1981, an informal mechanism for warning a doctor about his/her conduct was introduced. This was intended to permit the GMC to mark its disapproval of conduct that fell short of SPM but was, nevertheless, regarded as unacceptable. The relevant procedures appeared in Chapter XV of the revised version of the GMC Standing Orders published in August 1981.

19.25 The procedures could be used if the medical screener decided that the complaint need not proceed to the PPC but nevertheless considered that the doctor appeared to have behaved in a manner that could not be regarded as acceptable professional conduct. The medical screener also had to be satisfied that the matter was not trivial and that it was desirable, in the public interest, or in order to maintain the reputation of the medical profession, that the GMC should act. In the Annual Report presented to the Council by the PPC in November 1993, the Chapter XV procedures were described as being **'designed as remedial – to encourage a doctor to review what may have led to a complaint, and preventive – to give advice aimed at avoiding recurrence in future of similar conduct'**.

19.26 Before taking action under the Chapter XV procedures, the medical screener was required to consult two members of the PPC: one medical member, who was engaged in

the same specialty as the doctor in question, and one lay member. If the doctor's conduct had not already been the subject of an investigation by a court, medical service committee (MSC) or statutory tribunal, the members consulted had to be satisfied of the adequacy of the evidence. Although it was not required by the GMC Rules, the practice was that, when the relevant complaint came from a private individual, the complainant would be asked to submit a statutory declaration before the Chapter XV procedures were started. If a preliminary decision was taken that the Chapter XV procedures should be invoked, the doctor's observations were invited. The letter seeking the doctor's observations made clear that no formal disciplinary proceedings were contemplated in respect of the matter about which observations were being sought. The initiation of the procedure effectively ruled out, therefore, the possibility of disciplinary action, even if the doctor's response was unsatisfactory.

19.27 Once the doctor's observations were received (or if s/he did not respond), it was open to the medical screener, with the agreement of the other two members, to direct that a letter should be sent to the doctor, containing such advice as the members (including the medical screener) thought fit. The letter would inform the doctor that, if another complaint were to be received subsequently, the present case would be reviewed. If an enquiry about the doctor's fitness to practise was made to the GMC subsequently, the fact that s/he had received a Chapter XV letter would not be disclosed.

19.28 The Chapter XV procedures could not be used where there had been no previous finding of fact and where the doctor did not accept that there was any foundation for the complaint. In those circumstances, there was nothing the GMC could do, since, when embarking on the Chapter XV procedures, the medical screener would have already decided that formal disciplinary procedures were not appropriate.

19.29 Statistics relating to the number of cases in which action under Chapter XV was taken were reported by the PPC annually to the Council. The statistics show that the Chapter XV procedures were used extensively, particularly in dealing with complaints of poor treatment or substandard clinical practice and with complaints involving allegations relating to the doctor's personal behaviour. Although, until 1985, the number of cases in which Chapter XV letters were sent remained below 20 a year, the numbers increased markedly thereafter. In the year to 31st August 1994 and in 1995, 6% of all doctors in respect of whom the GMC received complaints were sent Chapter XV letters. In 1997, 10% of cases screened (i.e. 192 cases) were the subject of Chapter XV action.

The 1988 Professional Conduct Rules

19.30 The 1988 Professional Conduct Rules left the screening test unchanged. The relevant provision was rule 6(3) which provided:

> **'Unless it appears to the President** (*i.e. the medical screener*) **that the matter need not proceed further, he shall direct the Registrar to write to the practitioner**
>
> **a) Notifying him of the receipt of a complaint or information and stating the matters which appear to raise a question whether the practitioner has committed serious professional misconduct ...'**.

The Period from 1990 to 1996

The Introduction of Lay Screeners

19.31 Until 1990, members of the GMC who were not medically qualified were not involved in the screening process. In 1990, the 1988 Professional Conduct Rules were amended to provide for the nomination by the President (and appointment by the Council) of a non-medical member of the GMC to act as a lay screener. In May 1990, Mr (later Sir) Roger Sims was appointed as a lay screener. In November 1991, he was joined by Sir Maurice Shock. Sir Maurice was later replaced by Professor Christine Chapman. The lay screeners did not screen cases alone. They were required to consider only those conduct cases where the medical screener had made a preliminary decision to close the case. If the lay screener did not agree with that decision, a discussion would take place between the two screeners. Ultimately, if no agreement was possible, the case would be referred to the PPC despite the views of the medical screener. Once the performance procedures were introduced in 1997, lay screeners were involved also in screening cases in which the medical screener had made a preliminary decision that the case did not raise a question either of SPM or of seriously deficient performance (SDP). It is perhaps surprising that lay screeners never played any part in the screening of convictions, particularly since, after May 1990, screeners were given a rather wider discretion in connection with their treatment of convictions: see paragraph 19.33. I shall discuss the role of lay screeners more fully later in this Chapter.

The Medical Screeners

19.32 In November 1992, Dr Steel replaced Dr Fry as principal medical screener for conduct cases and as Chairman of the PPC. Dr Bewley continued to act as an additional medical screener. Dr Michael Wilson was also appointed as an additional medical screener for conduct cases. In September 1995, Sir Donald Irvine became President of the GMC. The screening arrangements continued as before.

The Treatment of Convictions

19.33 In May 1990, the PPC made a direction giving the medical screeners further discretion in relation to convictions. The direction authorised the medical screeners to exercise their discretion in deciding whether to refer to the PPC convictions which related to any offences committed more than five years before notification to the GMC. Discretion was also given to the medical screeners not to refer a conviction to the PPC if the offence was:

> **'... an extremely minor offence which was not ostensibly related to any aspect of the doctor's professional practice and did not involve conduct likely to bring the medical profession in general into disrepute'**.

19.34 In January 1995, the PPC endorsed the direction issued in May 1990. However, the terms of the direction were slightly different from those of May 1990. On this occasion, the medical screeners were given authority to exercise their discretion when deciding whether or not to refer to the PPC:

'... convictions of minor offences not ostensibly related to a doctor's professional practice, nor involving a degree of dishonesty such as to bring disrepute upon the medical profession'.

19.35 In June 1997, a Note was produced for the guidance of new members of the PPC. The Note stated that the PPC had agreed that **'minor motoring offences such as speeding'** need not be referred to it (in fact, it had directed that such cases should not even be referred to the medical screener), but that **'other convictions must be referred'**. In fact, this Note, which was designed to be for the benefit of members of the PPC and was not apparently directed to screeners, was not consistent with the 1995 direction. By that direction, screeners had been given a discretion not to refer to the PPC other types of minor convictions, including some minor cases of dishonesty which they judged insufficient to **'bring disrepute upon the medical profession'**. This may have resulted in members of the PPC having the impression that they were receiving all conviction cases (except minor motoring offences) when in fact they were not.

The Lack of Information about Screening Processes

The Extent of Knowledge among Members of the General Medical Council

19.36 It is evident from what I have said that, up to this time, very few members of the GMC had been involved in the screening process. The process took place in private and was shrouded in a degree of secrecy. Mr Townsend told the Inquiry that screening 'had traditionally been the preserve of only a very few people'. The Council itself had 'really very limited information' about how the screening function was undertaken.

19.37 In 1988, Mrs Jean Robinson, then a lay member of the GMC, expressed concern about the lack of information about the screening process in her publication 'A Patient Voice at the GMC'[1]. She said:

> **'From the time I was appointed to the GMC, and was elected to the Preliminary Proceedings Committee, I was asking for further details of rejected cases.**
>
> **I seemed to be the only member of Council who wanted to know. My request for basic information about the majority of complaints the Council received was sometimes interpreted as distrust of the Screener, who is always an eminent and respected doctor. My view is that I do not care if the Angel Gabriel is Preliminary Screener. Members of the Council and the public have a right to know what kind of complaints the Council receives, whether some kinds are increasing or decreasing, and which get further investigation and which do not.'**

Mrs Robinson was concerned also at the lack of lay involvement in screening decisions and at the absence of anyone within the GMC with the power to review or query screening decisions.

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[1] Robinson, Jean (1988) 'A Patient Voice at the GMC'. London: Health Rights.

19.38 The lack of lay involvement in screening was addressed, as I have said, in 1990, when a non-medical member of the GMC was, for the first time, appointed as a lay screener. However, other members of the GMC continued to receive little information about the screening process. They did not see cases which had been 'screened out'. The GMC had agreed no criteria for the guidance of screeners when deciding which cases should and should not go forward. There was no internal audit or review of the quality of screening decisions. The only hard information available to members consisted of the statistics relating to the cases dealt with by the GMC, which were published on an annual basis. These statistics shed no light on the seriousness of individual allegations. They did, however, show that the proportion of complaints referred by the screeners to the PPC was small. During the period from 1993 to 1995, no more than 15% of the complaints received by the GMC each year (all of which were at that time referred to a medical screener) were referred by the medical screener to the PPC.

The Information Given to Complainants

19.39 Until 1988, the Professional Conduct Rules did not specify whether complainants should receive notification of the fact that their complaint had been screened out or, if so, what information they should be given. The 1988 Professional Conduct Rules provided that a complainant should be notified of a decision by the President/medical screener not to refer his/her complaint to the PPC. However, complainants were to have no right of access to any document related to the case that had been submitted to the GMC by any other person. Moreover, they were not to be entitled to any explanation of the reasons for the decision not to refer, if the President/medical screener directed that no explanation should be given. This power to refuse to give an explanation continued until 2000, when the Rules were changed: see paragraph 19.118. In practice, after 1988, complainants were usually given some explanation of why their case had not been referred to the PPC, although it was not always very comprehensive.

19.40 Neither doctors nor complainants have ever had any right of appeal against, or review of, a decision of a screener, save by means of judicial review. That is an expensive process and one which may be intimidating to many. It was not until 1997 that judicial review was used to challenge a screening decision. Then, for the first time, some light was thrown onto the screening process and screeners were given some idea of whether they were approaching their task in the correct way. For the first time, the GMC gave its screeners authoritative guidance. By the time several cases had gone to judicial review, the GMC and the public were able to gain some insight into the way in which the task was being performed and the criteria, if any, that were being applied.

The Approach to the Screening Process

19.41 I have referred in Chapter 18 to the Training Manual compiled in 1994 by Mr Alan Howes, who worked in the Conduct Section more or less continuously between 1980 and 1994 and was Head of the Section from 1987 until 1994. The 1994 Training Manual was intended to provide training material for new staff in the Section after Mr Howes' move from there in 1994. It provides a useful insight into the practices of the time. Part of the 1994

Training Manual set out guidance on initial procedures and on the role of the preliminary (i.e. medical) screener, based on an internal guidance note for new screeners. That guidance note is no longer available.

19.42 The guidance in the 1994 Training Manual stated that, when assessing whether an individual complaint raised any question of SPM, the staff and screeners had to consider two questions:

> **'(i) Does the behaviour which is the subject of the complaint relate to the doctor's professional work or position?**
>
> **(ii) Is the alleged behaviour so serious that it might justify taking action in relation to the doctor's registration?'**

If the answer to both questions was 'yes', the 1994 Training Manual advised that the case was **'potentially one which falls within the Council's jurisdiction'**. No guidance was given on the criteria to be used when assessing seriousness.

19.43 The 1994 Training Manual went on to say that it was then necessary for screeners to **'look at the case forensically, i.e. to consider whether the available evidence in the case** (*emphasis in original*) **would be sufficient to justify referring the matter for a formal inquiry'**. It observed that the issue of sufficiency of evidence was **'largely a matter of common sense, rather than law'**. The 1994 Training Manual then proceeded to discuss the issue of evidence in a passage which I have already quoted in Chapter 18. In short, the guidance in the Training Manual appears to have created a much 'finer filter' than was envisaged by rule 6(3), which required the screener to refer a case to the PPC **'unless it appears to** (*him/her*) **that the matter need not proceed further ...'**.

A Report about Shipman: the Cases of Mr W and Mrs B

19.44 In Chapter 6, I described the two complaints made locally about Shipman in 1990 and 1992. In the first, relating to Mr W, the Tameside MSC found Shipman to be in breach of his terms of service; he was warned to comply more closely with them in future. He had made a serious error in prescribing an excessive amount of Epilim to an epileptic patient. The MSC's finding was not reported to the GMC at the time it was made. In 1993, another MSC found Shipman to be in breach of his terms of service again, this time in respect of an elderly stroke patient, Mrs B. In 1992, he had refused to visit her in response to a request from her relatives and the MSC found that he had not put himself in a position to exercise proper professional judgement about the need for a visit. The case was referred to the Family Health Services Appeal Unit (FHSAU). In May 1994, Shipman was warned again and a recommended withholding of his remuneration of £800 was confirmed. Shipman now had two MSC findings against him. The FHSAU reported Shipman to the GMC and sent the GMC all the papers.

19.45 The GMC papers show that a caseworker prepared a detailed memorandum for submission, first to Mr Howes and then to Dr Steel, the principal medical screener. The memorandum noted Shipman's convictions in 1976 and the fact that he had been warned by the GMC on that occasion. It set out the facts of both of the more recent cases. In respect of the second case, that of Mrs B, the summary stated that the facts were in issue.

The relatives were saying one thing and Shipman another. The summary did not, however, record that the MSC had preferred the evidence of the relatives or why they had done so, matters that were clearly stated in the papers. The MSC had found that Shipman had failed to put himself in a position to find out whether Mrs B needed a visit. The caseworker said that, in view of the disputed evidence, s/he was quite sure that the case would **'not be a candidate for action within the Rules'**. Later, s/he expressed the view that it would be **'virtually impossible'** to take such action. Nor would there be **'very much point'** in taking action under the Chapter XV procedures; Shipman would only repeat his version of events. The caseworker also noted, however, that it would be unusual for the GMC to do nothing in a case where the MSC had recommended a withholding of £800, which, I infer, was considered at that time to be a substantial sum and to be indicative of a serious breach of the GP's terms of service.

19.46 Mr Howes wrote on the memorandum:

> **'The earlier case is too old for us to act now. The more recent case revolves round evidence which is now obscured by time. It would be difficult to unravel this at this stage. An error of judgment clearly occurred, but the MSC have now dealt with the matter and that seems to me to be sufficient.'**

19.47 Dr Steel noted:

> **'I am in agreement First case is too late and minor second case is borderline Nothing** (*short word indecipherable, possibly 'in'*) **Chapter XV. The latter would be flawed because of lack of admission. Agree no action.'**

19.48 At this time, the GMC was preparing for the introduction of performance procedures and was seeking to discover how many cases might arise. In this connection, Dr Steel appears to have completed a performance assessment form relating to the report about Shipman. The form asked three questions. The first was **'Is there evidence of seriously deficient performance?'** To that, Dr Steel answered **'yes'**. The second asked, **'If so, is there evidence of a pattern of poor performance (as opposed to isolated incidents)?'** To that, Dr Steel answered **'yes – only 2'**. The third asked whether there was also evidence of SPM pointing to conduct proceedings rather than performance action. To that, Dr Steel answered in the negative.

19.49 The case did not go to the PPC. In my view, it should have done. First, although Dr Steel said on the performance assessment form that the case did not show evidence of SPM, he had said in his screening decision that Shipman's conduct in the case of Mrs B was **'borderline'**. That must, in my view, mean that some people would take the view that it did amount to SPM. It seems to me certainly arguable that the facts found by the MSC in the case of Mrs B fell into the category of cases described in the early editions of the Blue Book (the GMC's professional discipline guide) as a serious disregard of professional responsibility or a neglect of a professional duty. The examples of this given in the Blue Book were of failing to visit or to provide treatment for a patient when it was necessary to do so. Moreover, the reliance on the conflict of evidence as a reason not

to proceed was quite unsatisfactory. Even recognising that, at the time, it appears to have been thought correct for screeners to consider the strength of the evidence, the medical screener's decision was plainly wrong. There had been no evidential difficulty for the MSC and there was no reason to suppose that there would be an evidential problem for the GMC if it chose to act. However, the case was closed. I cannot see from the file any sign that closure was agreed by a lay screener as was required by the 1988 Professional Conduct Rules.

Developments in the Screening Process from 1996 to 1997

A Cultural Change

19.50 Mr Townsend said that, prior to the second half of the 1990s, the 'old view' had been that reasons had to be found for referring a case to the PPC. This would suggest that, instead of a presumption that a case would go forward unless it appeared to the medical screener that it **'need not'** proceed further (as provided for by the Rules), the presumption was that a case would not go forward unless there was a positive need for it to do so. It appears that the handling of the report in 1994 about Shipman's conduct in the cases of Mr W and Mrs B was an example of this approach. Mr Townsend said that that view changed in the mid-1990s. He attributed the change in part to the publication of 'Good Medical Practice' in 1995, which he thought had represented a 'cultural change'. This cultural change had, he said, led to a 'greater willingness' on the part of both GMC staff and screeners to allow cases to go forward to the next stage, rather than ruling them out immediately. I am not sure whether that view is borne out by the statistics. Until 1999, of those doctors referred to the screeners, the percentage that were referred on by them to the PPC remained steady at no more than 15%. The proportion referred to the PPC rose sharply (to 25%) in 1999 and again the next year, but that followed (and may be explained by) a significant reduction in the number of cases referred to the medical screeners, with many more cases being closed by the GMC staff. There were other factors also which would have had the effect of increasing the proportion of cases referred to the PPC by screeners in 1999.

19.51 Mr Townsend also said that, in the mid-1990s, there had been a 'review of the legal basis of screening', prompted partly by the formal challenge of a screening decision by means of judicial review and partly by consideration in the GMC office. I think it highly likely that the judicial review to which Mr Townsend referred was the case of R v General Medical Council ex parte White[2]. I shall discuss the decision in that case, which was given in March 1997, later in this Chapter.

The 1996 Policy Studies Institute Report

The Practical Arrangements

19.52 I have already referred to research carried out by the PSI. The PSI team, led by Professor Allen, carried out an analysis of cases dealt with by the GMC during the 12 months from September 1993, which was reported in the 1996 PSI Report. At the time of that Report, screening was carried out by three medical screeners, Dr Steel, Dr Bewley and Dr Wilson.

[2] 18th March 1997 (unreported).

Most of their screening work was carried out at their homes or practice premises, not at the GMC offices. They would fit their screening work around their other professional commitments. The PSI team found that the principal screener, Dr Steel, dealt with 60% of referrals to screeners during the 12 months for which they analysed data. The GMC statistics showed that there were 2294 referrals to screeners in that period (that figure included some cases which were referred to a medical screener more than once). On that basis, Dr Steel must have dealt with about 1376 referrals. Some cases would have been very straightforward. However, in others, there might have been a considerable amount of detail. This obviously represented a very substantial workload, over and above Dr Steel's work as a GP and his commitments as a member of the GMC and Chairman of the PPC. The other screeners handled about 30% and 10% of referrals respectively. Usually, only one of the medical screeners saw each case. Sometimes, however, a medical screener would seek a second opinion from another medical screener or from another medically qualified GMC member whose specialty was relevant to the complaint. As principal medical screener, Dr Steel would give advice and guidance to the other medical screeners, both generally and in relation to specific cases. He would also act as a mentor to new medical screeners.

19.53 A medical screener would receive the case papers, together with a memorandum prepared by the GMC staff. In the case of a complaint from a private individual, the papers might consist of only a single letter. There might or might not be any supporting evidence. If the complaint was from a public body, it might contain a large bundle of evidence collected during a local investigation, together with a report of a MSC hearing. The PSI team noted that the GMC staff would often write long memoranda, containing many comments and giving very clear views about the way in which the case should be handled. I interpose to say that the caseworker had done so in the 1994 case involving Shipman. The screener would record his/her decision on the top sheet of the case papers. The decision might consist of a single word, denoting agreement with the course of action proposed in the memorandum. On occasions, the screener might write a longer comment, giving reasons for his/her decision. In the 1994 Shipman case, Dr Steel gave brief, but intelligible, reasons. There was no obligation for a medical screener to state his/her reasons and, in many cases, they did not. There was no standard form for the screener's response.

Possible Screening Outcomes

19.54 The 1996 PSI Report explained that, if the medical screener was able to make a decision on the information available, there was a range of possible outcomes. First, the medical screener might decide that the complaint raised a *prima facie* case of SPM and should be referred to the PPC. Second, s/he might decide that the complaint did not raise a *prima facie* case of SPM but that the doctor's behaviour nevertheless appeared to have fallen below acceptable standards. In that event, the medical screener might decide that a letter of advice should be sent to the doctor in accordance with the Chapter XV provisions; I have already described the procedure for this. Third, the medical screener might decide that the complaint did not raise a *prima facie* case of SPM and that no further action should be taken in relation to it; in this event, the case would be referred to a lay screener. Only

if the lay screener confirmed the decision of the medical screener to take no further action would the case be closed. If the lay screener disagreed with the medical screener, the case would be referred on to the PPC.

19.55 The analysis carried out by the PSI team in the late summer of 1995 showed that just over half the cases dealt with by the screeners during the year to 31st August 1994 had resulted in one of the three outcomes I have described. The remainder of the cases referred to the medical screeners had been dealt with in a variety of other ways. There was a significant proportion of cases in which a medical screener had approved the recommendation of the GMC staff that a complainant should be advised to direct his/her complaint to NHS or other local complaints procedures. At the time of the PSI research, there was also a sizeable proportion of cases in which the medical screeners had felt unable to make a decision. In such cases, the medical screener would request the staff to seek further information or would ask for the papers to be shown to another screener or a medical expert. Decisions as to whether further information was required were, at this time, left to the medical screeners, rather than being taken by the staff at an early stage. Requests for further information were often made by GMC staff to complainants and sometimes went unheeded. As I explained in Chapter 18, Professor Allen and her colleagues were worried that cases were getting 'lost', particularly when the onus was placed on complainants to take their cases back to local complaints procedures or to provide further information.

19.56 If there appeared to be an issue relating to the doctor's health, a medical screener might send the case to a health screener, who would advise whether it was suitable to be dealt with under the voluntary health procedures. If it was adjudged suitable, it was open to the medical screener to remit the case to the health screener. This course did not require the agreement of a lay screener.

After Screening

19.57 If the medical screener judged that a case warranted no further action, s/he would often approve a draft letter of response to the complainant, which would have already been prepared by a caseworker. If the case was judged suitable for referral to the PPC, the caseworker would write to the complainant (if s/he was a private individual), asking him/her to provide at least one statutory declaration in support of his/her evidence. Upon receipt of the statutory declaration, a letter would then be written to the doctor (pursuant to rule 6 of the 1988 Professional Conduct Rules), notifying him/her of the receipt of the complaint and setting out details of the charges that s/he would face before the PPC. At the time of the PSI Report in 1996, that would be the first time that the doctor had been informed by the GMC of the complaint and had been asked to respond to the complaint. At the time of the screening decision, the screener would not usually have before him/her any response from the doctor. If, however, the referral to the GMC had been preceded by a local investigation, it is likely that the doctor's response to the allegations would appear in the papers relating to that investigation. In those circumstances, it would be available to the screeners.

The Outcomes of Cases Handled by Different Medical Screeners

19.58 The PSI team examined the outcomes of cases handled by individual medical screeners. The principal medical screener, Dr Steel, had been the only medical screener in 67% of

the cases that went forward to the PPC. Comparable figures for the other two screeners were 14% and 6%, respectively. (These percentages do not add up to 100% since some cases had been seen by two – even all three – medical screeners.) In fact Dr Steel had been involved at some stage of the screening process in 77% of the cases which went to the PPC. There was clearly extensive reliance by the other screeners on his advice. Professor Allen and her colleagues concluded, from the discussions they had had with screeners and staff, that cases that appeared more serious were sent to Dr Steel, as principal medical screener. By reason of their seriousness, those cases would be more likely to be referred to the PPC. Thus, it was not surprising that Dr Steel had referred a higher percentage of cases to the PPC than might have been expected had the cases been distributed randomly between screeners.

Reasons for Rejecting a Case

19.59 I have said at paragraph 19.54 that one of the possible outcomes of the screening process was said to be that the medical screener would decide that the complaint did not raise a *prima facie* case of SPM and that no further action should be taken in relation to it; in this event, the case would be referred to a lay screener. The PSI team was told by members of the GMC staff that there were two distinct grounds on which a complaint might be rejected by the screeners as 'not SPM'. The first was where the complaint was judged insufficiently serious or as not relating to professional misconduct (i.e. not occurring in a professional context). The second was where the allegation, if made out, would have been capable of amounting to SPM, but there was, in the screeners' view, insufficient supporting evidence to enable it to be proved. The PSI team observed that, when noting their decisions on cases, screeners rarely commented on the seriousness of the complaint or on the quality of the evidence.

19.60 The Annual Reports of the PPC show that, in 1997, screeners rejected 54% of the 1919 cases referred to them on the grounds that they were **'Not SPM/SDP'** and 18% on the grounds of **'Insufficient evidence SPM/SDP'**. Of the 1203 cases involving allegations of poor treatment, 57% were rejected on the grounds of **'Not SPM/SDP'** and 20% on the grounds of **'Insufficient evidence SPM/SDP'**. Of the 142 decisions made by screeners in cases involving allegations of dishonesty and criminality, 23% were rejected as **'Not SPM/SDP'** and 11% on the grounds of **'Insufficient evidence SPM/SDP'**. The 1998 statistics show that the screeners rejected 28% of the cases referred to them on the grounds of insufficient evidence of SPM or SDP.

The Criteria Used by Screeners

19.61 Professor Allen and her colleagues noted that there were no guidelines or written criteria for assessing the seriousness or gravity of a complaint, or for assessing the adequacy or weight of the evidence in support of it. In an attempt to establish how the screeners were making their decisions, they discussed with GMC staff and screeners what criteria the screeners were using in order to determine whether a complaint raised a *prima facie* case of SPM. The discussions revealed that SPM was generally regarded as having a **'high threshold'**, although some people regarded the threshold as higher than did others. The PSI team reported that there was a **'consensus'** that a decision was reached by:

> **'(a) ... considering the nature of the allegation and assessing its seriousness or gravity, (b) weighing up the amount, type and nature of the evidence, with particular attention to whether there are witnesses or other corroboration, (c) looking at the past relevant history of the doctor concerned and (d) always bearing in mind that the doctor's fitness to practise is under consideration with the ultimate sanction being the removal of the doctor's registration'**.

Other factors considered by some (but not all) of those involved were:

> **'(e) the importance of assessing the extent to which there was risk to patients or to the public, and (f) whether the action or actions were committed deliberately or with intent rather than by accident or default'**.

It would appear from this that some members of staff or screeners did not have in mind the GMC's primary duty of protecting patients.

19.62 Professor Allen and her colleagues noted that it was clear from the criteria identified by members of staff and screeners that the weight and quality of the evidence was generally believed to be an important factor in determining whether a complaint raised a *prima facie* case of SPM. They noted also that some of the people to whom they had spoken gave more weight than others to the question of whether the allegation **'would stand up in a court of law and could be proved beyond all reasonable doubt'**. They believed that this emphasis on the weight and quality of the evidence might have accounted, at least in part, for the rejection by screeners of a high proportion of complaints from private individuals. In cases brought by such individuals, the evidence was likely to have been sparse, and less well ordered and presented than evidence produced by public bodies. There might have been no witness statements or other corroboration.

19.63 Professor Allen and her colleagues recommended the development of guidelines about what constituted SPM, both generally and in particular types of case. They recommended that a **'hierarchy of gravity'** should be developed for each category of behaviour that might amount to SPM. They also suggested that the GMC should develop and put into use a method of demonstrating how screening and other decision-making had been carried out in a particular case. The object of these recommendations and suggestions was, first of all, to promote consistency in the treatment of all complaints at all stages of the decision-making process. The PSI team was also anxious that the GMC should be in a position to demonstrate, if called upon to do so, precisely how – and by reference to what criteria – a particular decision had been reached. In other words, the PSI team wanted the GMC's decision-making to be made more 'transparent'. Only in that way would the GMC be able effectively to defend itself against any allegation of bias, whether racial or otherwise. The PSI Report noted, however, that there was **'no enthusiasm'** among those whom they had interviewed for developing such written guidelines or criteria or for applying techniques of structured decision-making.

Changes to the Arrangements for Screening following the 1996 Report

19.64 The 1996 PSI Report recommended a number of changes to the arrangements for appointing and training medical and lay screeners. In particular, it recommended

increasing the number and diversity of background of the medical screeners. It suggested appointing as medical screeners some doctors who had dedicated time available to carry out the task of screening, i.e. who would not have to fit in screening around other professional commitments. It also recommended the introduction of training and refresher courses for all screeners and of feedback to them of information about the results of their screening.

19.65 In November 1996, two new medical screeners, Dr (later Professor) Hilary Thomas and Dr Pearl Hettiaratchy, were appointed. Another lay screener, Mrs Rani Atma, was appointed in February 1997. This increase in numbers was partly in response to the recommendations contained in the 1996 PSI Report and partly because of an anticipated increase in the screeners' caseload. The performance procedures were to be introduced in July 1997 and it was recognised that this would place further demands on the screeners, in particular the medical screeners.

The Case of White

The Complaint

19.66 In March 1997, the first judicial review of a screening decision took place in the case of R v General Medical Council ex parte White[3]. The case arose out of the death of a young child who suffered from *spina bifida*. In September 1993, when the child was about 12 months old, he became unwell and his parents took him to hospital. It was thought that he had a urinary infection. He had been vomiting and was dehydrated. He was kept in overnight and was allowed home late the next day. The day after that, his condition deteriorated and his parents summoned their GP. He arrived at about 3pm, examined the child, observed that the child's chest was **'a bit noisy'**, advised that he should take Calpol and fluids and promised to revisit the next day. Shortly after the GP's departure, the child's condition deteriorated further. The child was taken to hospital but died at about 4pm. The cause of death was bronchopneumonia.

19.67 In due course, the parents made a complaint about the GP to the GMC. Initially, they were advised to pursue their complaint locally, but the time for so doing had expired. Then the GMC wrote asking if the parents really wished to pursue their complaint. They did; their medical expert considered that the GP's failure to realise that the child was critically ill at 3pm amounted to **'gross professional misconduct'**. The case was referred to Dr Steel, who screened the case out. The letter explaining his decision, written in November 1995, said that, before disciplinary action could be justified, there had to be clear evidence (to the standard required by a criminal court) that the doctor had failed to put himself in a position to assess the child's condition, or evidence that he had deliberately disregarded his responsibilities to the child in some way. As it appeared that the doctor had examined the child and had exercised his clinical judgement, the screener took the view that there was no evidence of SPM. On 3rd January 1996 (which, I observe, was shortly after the decision of the Privy Council in McCandless v General Medical Council[4], to which I referred in Chapter 17), the parents' solicitors replied saying that the screener's approach

[3] 18th March 1997 (unreported).
[4] [1996] 1 WLR 167.

was wrong. Their point was that negligence, if serious enough, could amount to SPM. The doctor had examined the child but had failed to realise that the child was dying, although the signs must have been obvious. A month later, the GMC replied, saying that the case had been reconsidered but that this had led to the same conclusion as previously. Errors in diagnosis, made in good faith, did not of themselves raise an issue of SPM. The fact that the child had died within a **'certain'** period following examination could not, of itself, be regarded as evidence of SPM. Mr Justice Collins, who heard the application for judicial review, was critical of that reply because, as he observed, it suggested that negligence *per se*, in the absence of bad faith, could not raise an issue of SPM. That was wrong and he could understand why the parents had sought judicial review.

The Judicial Review

19.68 In the course of the proceedings for judicial review, the caseworker's memorandum was produced; in it, the caseworker had expressed the view that, as it was clear that the doctor had examined the child, it could not be said that he had failed to put himself in a position to assess the child or had deliberately disregarded his responsibilities to him. Mr Townsend, who was then the Head of the Conduct Section, noted on the file that, unless the doctor should **'beyond doubt'** have made an immediate referral to hospital, no question of SPM arose. (I interpose to observe that it appears from this that Mr Townsend was of the view that the screening process was intended to apply a very fine filter and that only clear cases of SPM should be referred to the PPC.) The note of Dr Steel's screening decision said that he agreed with Mr Townsend. This was a one-off failed clinical judgement. He continued:

> **'It can be seen in hindsight the baby was poorly but there is no evidence that the doctor disregarded responsibilities.'**

19.69 In an affidavit sworn for the judicial review proceedings, Dr Steel set out all the criteria that he generally took into account in deciding cases at the screening stage. He then applied those criteria to the facts of the case and said that he had formed the view that the doctor had made an error of clinical judgement, which might give rise to a claim in negligence. However, although he was **'well aware'** that negligence might be so serious as to amount to SPM, in his judgement this was not such a case. The Judge accepted that Dr Steel had approached the matter in the way he described in his affidavit, despite the fact that this was not the way in which his views had been represented in correspondence. He decided that the approach did not disclose an error of law and dismissed the application for judicial review.

19.70 It is worth noting that rule 6(3) of the 1988 Professional Conduct Rules, which governed the screener's decision, was not analysed in the judgement. It does not appear that the applicant's case was based upon the GMC's failure to apply the correct statutory test. Rather, the argument was that the screener had wrongly directed himself that negligence, however serious, could not amount to SPM. Once the Judge was persuaded that the screener had not thought that and had applied his mind to the seriousness of the negligence, the case was over. It was not until the case of R v General Medical Council ex parte Toth[5] that the meaning of rule 6 came under scrutiny at judicial review.

[5] [2000] 1 WLR 2209.

The 1997 Screeners' Handbook

19.71 In July 1997, the GMC issued, for the first time, a Screeners' Handbook (the 1997 Screeners' Handbook). According to the Annual Report of the PPC, presented to the Council in May 1997, the Handbook was intended to **'set out explicit, published criteria for the main screening decisions'**. Presumably, it was intended to meet the PSI recommendations. Its production was timed to coincide with the introduction of the new performance procedures. The Preface, written by Dr Steel, indicated that the purpose of the 1997 Screeners' Handbook was to assist the GMC in its work and to explain to those outside the GMC the principles which were applied by screeners when making decisions. Mr Townsend, who was Head of the Conduct Section at the time the Handbook was published, said that the fact that the 1997 Screeners' Handbook was a public document was a 'noticeable change', part of a move by the then President of the GMC, Sir Donald Irvine, to 'open up' the GMC's decision-making processes. It seems to me, having read the judgement in the case of White, in which extracts from Dr Steel's affidavit are cited, that the contents of the Handbook were to some extent informed by that case.

19.72 The 1997 Screeners' Handbook explained the framework within which the screeners worked. It emphasised that:

> **'Complaints are screened out rather than in, that is, the fitness to practise procedures are based on the premise that the GMC will take action, but, if it cannot, it must justify not doing so.'**

Mr Townsend observed that the Handbook reflected the change in the approach to screening which I have already mentioned. He said:

> **'... previously, at least psychologically I think, the question had been ''Does the complaint jump over the first hurdle to enable it to proceed to the PPC?'' That was replaced with the view, which I think is reflected quite clearly in the first edition of the Screeners' Handbook, that there had to be cogent and explained reasons why a case was not to proceed; in other words, that the screening was a coarse sieve simply to get rid of the complete non-starters as distinct from a more sophisticated filter.'**

19.73 The 1997 Screeners' Handbook gave guidance on the order in which issues of health, conduct and performance should be considered by the screeners and on the various steps open to screeners to obtain further information or advice or expert opinion before taking a decision. The 1997 Screeners' Handbook advised:

> **'In each case, the medical screener's initial task is to consider whether a question of spm arises in relation to a doctor's conduct. The GMC's Rules state that a case which appears to raise a question of spm shall normally be referred to the PPC.'**

The reference to the **'GMC's Rules'** is presumably a reference to rule 6(3) of the 1988 Professional Conduct Rules and to the fact that a case should be referred to the PPC unless it appeared to the medical screener that it **'need not proceed further'**. Rule 6 is not quoted in the Handbook.

19.74 Screeners were advised that, in order to keep abreast of what the PCC considered to be SPM, they should read the minutes of the PCC as they were published. They were also advised that they should be aware of any Privy Council decisions concerning the meaning of SPM. (It was not long since the important decision in McCandless.) They were further advised to assess the information provided in the complaint against the following criteria:

> **'• The gravity of the doctor's act or omission.**
>
> **• Whether there is more than one event or alleged victim.**
>
> **• The extent of the risk to patients or the public.**
>
> **• Whether the doctor appears to have acted deliberately, recklessly, accidentally, or in bad faith.**
>
> **• Whether the doctor may have neglected or disregarded his or her professional responsibilities.**
>
> **• Whether there have been any previous complaints to the GMC about the doctor which, taken with the current complaint, suggest a course of conduct which could amount to spm.'**

These were most of the criteria that had appeared in Dr Steel's affidavit in the case of White and which had, in effect, been approved by the Judge (although without his having considered the statutory provision). Dr Steel had also included **'the detail and nature of the evidence and the length of time since the relevant events occurred'**. Those were not included as criteria in the 1997 Screeners' Handbook. The Handbook contained no guidance about how grave a negligent act or omission had to be before it was capable of amounting to SPM. Nor was any guidance given as to the relative weight to be attached to the various criteria listed above.

19.75 It was noted that the existence of previous complaints, incapable of substantiation, should not be taken into account. Previous complaints could be taken into account only if, for example, they indicated that the complainant was malicious or disturbed, or if they indicated that the doctor might be the subject of some form of vendetta. They could also be taken into account if they had already been the subject of formal GMC disciplinary action. Thus an unsubstantiated complaint of indecent assault would be left out of account if a second complaint of a similar nature were received. There does not appear to have been any recognition of the possibility that an unsubstantiated account might be true or any realisation that the receipt of more than one complaint of a similar nature, even if unsubstantiated, ought to give rise to concern.

19.76 Screeners were advised that, if a question of SPM arose, if the case complied with the necessary procedural requirements (one such requirement would be the provision by a complainant of a statutory declaration) and if no further evidence in support was required at the screening stage, the case should be referred to the PPC as soon as possible. There were two circumstances when that should not be done. The first of these was where referral to the PPC should, for some good reason, be deferred and this could be done without harm to the public interest. Deferral would be appropriate, for example, where a case was to be referred back to local complaints procedures or for investigation by the

police or some other organisation. The second circumstance was that some wholly exceptional reason existed why the PPC did not need to consider the complaint. This might arise where the doctor was terminally ill or where there was a risk that the bringing of disciplinary proceedings would amount to an abuse of process.

19.77 The 1997 Screeners' Handbook also dealt with the situation where a screener found that a case raised a question of SPM but that there was insufficient evidence to support the allegation. In this connection, screeners were advised:

> **'... it is not the role of the screener to attempt to decide whether any, or all, of the facts alleged in a case are true. It is for the PCC alone to make findings of fact.**
>
> **It is not possible to lay down precise criteria about the type, the quantity or the apparent quality of evidence required to justify referral of a complaint to the PPC, as that will inevitably depend on the nature and circumstances of each case. In many cases it will be sufficient to inform the complainant what further information or evidence (which may simply be a sworn statement) appears to be required, and ask the complainant to provide it.**
>
> **In all cases where it appears to the screener that a question of spm arises the screener must bear in mind that:**
>
> - **The Rules simply require that it must appear to the screener that there is a ''question whether the practitioner has committed spm''.**
> - **The screener should not, at the screening stage, attempt to resolve conflicts of evidence between the doctor and the complainant.**
> - **The PPC has the power to adjourn a case for further evidence, and evidence may also be obtained following referral of a case by the PPC to the PCC.**
> - **If in doubt, and if further inquiries or consultation with other screeners cannot resolve the doubt, the case should be referred to the PPC.'**

19.78 It appears that the 1997 Screeners' Handbook recognised that Dr Steel's inclusion (in his affidavit in White) of the consideration of the detail and nature of the evidence as one of his criteria had been wrong. Screeners were advised that complaints involving allegations that were obviously irrational, or self-evidently untrue, need not be taken forward, even if a question of SPM would arise if the allegations were true. However, screeners were also reminded that they must not, in any other circumstances, attempt to decide whether any, or all, of the facts complained of were true. They were warned that if there was **'*any* doubt at all'** as to the rationality of an allegation, the case should be considered as one which appeared to require action by the GMC, but where there was insufficient evidence to proceed at that stage. Further evidence should then be sought until it became clear whether or not there was a valid issue about the doctor's fitness to practise for the GMC to consider.

19.79 The 1997 Screeners' Handbook stated that, where further information was requested from a complainant and the request had not been complied with, there should be an effort to persuade the complainant to provide the necessary information, bearing in mind that GMC action might be necessary to protect other patients or the public and that the complainant might not be the only person affected. This advice reflected the concerns of the PSI team that complaints were being 'lost' because of the failure on the part of complainants to respond to requests by the GMC to provide further information.

19.80 The 1997 Screeners' Handbook also signalled a change of procedure in relation to the informing of doctors about complaints made against them. Up to 1997, doctors were not in general informed of complaints unless and until a decision had been taken to refer a case to the PPC and (in the case of a complaint by a private individual) unless and until a statutory declaration had been obtained from the complainant. At that stage, the doctor would be invited to submit any explanation s/he had to offer. (The position in relation to convictions was different: see paragraph 19.20.) The 1997 Screeners' Handbook advised that screeners were to decide, at an early stage, whether a complaint should be copied to the doctor. In most cases, that would be done before a decision was taken whether to refer the case to the PPC. The effect of this was that, from 1997, screeners would often have the doctor's response to a complaint available to them when considering a complaint. At that time, there was no opportunity for the complainant to see and comment on the doctor's response. A complaint would not be copied to the doctor before screening if it was clear from the outset that the case should be referred to the PPC. In that event, the doctor would be informed about the complaint and asked for his/her response at the same time as s/he was notified that the case had been referred to the PPC.

19.81 The contents of the 1997 Screeners' Handbook make it plain that the GMC had recognised that, in the past, the screening process had not been carried out in accordance with the Rules. The filter applied had been far too fine; too many cases had been 'screened out'. The 1997 Screeners' Handbook represented a real attempt to change that culture. However, it appears that some aspects of the advice that were designed to change the culture were either ignored or quickly fell into disuse. Moreover, there was no attempt to keep the advice up to date and to remind screeners of the principles on which they should act. Despite the many important changes that took place in the following years, the Inquiry has been told that no further version of the Screeners' Handbook was produced until as late as November 2002.

Developments in the Screening Process since 1998

19.82 Additional medical screeners were appointed, making a total of seven in post during most of 1998 and 1999.

The Case of Toth

The Complaint

19.83 Despite the advice given in the 1997 Screeners' Handbook, it is clear that some screeners at least did not apply the tests it set out. In March 1998, a medical screener considered a

complaint by the father of Wilfred Toth, a five year old boy who suffered from glycogen storage disease. Wilfred had become hypoglycaemic and his father, Mr Arpad Toth, had called the family's GP, Dr Jarman, who made a home visit. Mr Toth alleged that he and his partner had told Dr Jarman of Wilfred's condition and of their opinion that he was in urgent need of intravenous glucose. Dr Jarman failed to administer glucose and instead treated Wilfred with sedative drugs. Dr Jarman later denied that he had been informed of Wilfred's condition or of his need for intravenous glucose. Mr Toth alleged that his untreated condition led to Wilfred's death a week later. Mr Toth had complained in the first instance to the local Family Health Services Authority (FHSA). A MSC hearing had followed, at which the MSC found Dr Jarman in breach of his terms of service in failing to take account of Mr Toth's knowledge of Wilfred's condition. No sanction was imposed. Some time later, a claim for damages in respect of Wilfred's death was settled on payment by Dr Jarman of the sum of £10,500, a sum which implies an admission of full liability. Mr Toth complained to the GMC about Dr Jarman's conduct.

The Screening Decision

19.84 Having considered the papers, the medical screener decided not to refer the case to the PPC. A lay screener confirmed that decision. A letter was written to Mr Toth (on 23rd March 1998, i.e. within a year of the production of the 1997 Screeners' Handbook) explaining the decision:

> **'There is a clear conflict of evidence between your version of events and that of Dr Jarman's** (*sic*) **on the** (*matter of disclosure of the need for intravenous glucose*)**. The standard of proof which the GMC works to, by law, is that of beyond reasonable doubt ... Therefore, unless you are able to provide further evidence of a legal standard ... the members have concluded that there is no prospect of your allegations being proved to the required standard, and no further action can be taken.'**

I interpose to say that either the medical and lay screeners or the caseworker who drafted the letter, or possibly all three, seem to have been unaware of the contents of the 1997 Screeners' Handbook insofar as it related to the approach which screeners should take where there existed a conflict of evidence. If aware of it, they had not heeded its contents. Mr Toth made further representations but, four months later, the same medical screener made a second decision confirming the first decision. On that occasion, the lay screener was not consulted.

The Judicial Review

19.85 Mr Toth sought permission to apply for judicial review in respect of both decisions. The GMC obtained legal advice on the application. The advice was received in August 1998 and was to the effect that the screeners had not followed the correct procedure in making their first decision. It was not the role of the screeners to resolve conflicts of evidence. Moreover, the medical screener had had no jurisdiction to reconsider the complaint after the first decision had been made. Nor, as the Judge subsequently found, was the second decision valid, since no lay screener had concurred in it. Having received that advice, the

GMC consented to an order quashing the decisions and directing a reconsideration of the case by a different medical screener. The case went before the High Court because Dr Jarman objected to the reopening of his case on the grounds that it would be unfair to him. Judgement in the case was given in June 2000.

19.86 The Judge, Mr Justice Lightman, considered the meaning of the words used in rule 6(3) of the 1988 Professional Conduct Rules to describe the duty of the screener. That duty was, as I have said, to decide whether the matter **'need not proceed further'**. He contrasted that duty with the function of the PPC, which was, by section 42(2) of the Medical Act 1983, to decide whether the case **'ought to be referred for inquiry by the Professional Conduct Committee or the Health Committee'**. He said that the screener's role was:

> **'... to decide whether a negative state of affairs exists, namely whether the complaint need not proceed further (as in the ordinary course it would) to the PPC: the only conclusion on the merits of the complaint required of him before he allows the complainant to proceed is that (as the screener is required to inform the practitioner) the matters stated ''appear to raise a question whether the practitioner has committed serious professional misconduct'' '**.

19.87 The Judge construed the 'need' referred to in rule 6(3) as being 'the need to honour the legitimate expectation that complaints (in the absence of some special and sufficient reason) will proceed through the PPC to the PCC'. He went on to say:

> **'The absence of ''need'', of which the screener must be satisfied before he can halt the normal course of the complaint to the PCC, connotes the absence of any practical reason for the complaint so proceeding and that for the complaint to proceed to the PCC would serve no useful purpose. There may be no need because there is nothing which in law amounts to a complaint; because the formal verification** (*i.e. the statutory declaration*) **is lacking; because the matters complained of (even if established) cannot amount to serious professional misconduct; because the complainant withdraws the complaint; or because the practitioner has already ceased to be registered. Wider questions as to the prospects of success of the complaint as to whether the complainant is acting oppressively or as to the justice of the investigation proceeding further do not lie within the screener's remit. So far as they may go to the issue whether the complaint ought to proceed they fall within the remit of the PPC. It is not for the screener to arrogate to himself the role of the PPC and decide whether the complaint ought to proceed further, still less to arrogate to himself the role of the PCC and weigh up conflicting evidence or judge the prospects of success. He must respect the role assigned by the Rules to the PPC (for which the PPC is armed with investigative powers) and recognise that his duty is only to act as a preliminary filter before the more substantive role as filter is exercised by the PPC.'**

19.88 He observed further:

> **'In the exercise of their respective jurisdictions the screener and PPC should be particularly slow in halting a complaint against a practitioner who continues to practise; as opposed to one who has since retired, for the paramount consideration must be the public's protection in respect of those continuing to practise; and they should at all times bear in mind the role of the HC whenever questions arise of impairment of fitness to practise by reason of physical or mental condition.'**

19.89 The Judge's conclusion, in the end, was that it would not be unfair to Dr Jarman if the screener's decision were set aside and Mr Toth's complaint were reopened. However, the importance of the case lay in the Judge's analysis of rule 6(3) and of the screening function. In effect, it threw retrospective light on the process of screening as it had been carried out during the past 30 years, and possibly even longer. It demonstrated that screeners had exceeded their powers when they had based their decision on their view of whether the complaint amounted to SPM (as opposed to whether it could do so) and of whether the evidence was sufficient to prove the case. That is not to criticise them personally. They were not lawyers. They had been doing the job as others had done it before them. But it is surprising that, until 1997, nobody in the GMC had apparently felt handicapped by the absence of any guidance as to how screeners should approach their important task.

19.90 Following the decision in Toth, which was handed down in June 2000, the screening test was changed in August 2000: see paragraph 19.120. However, no corresponding change was made to the 1997 Screeners' Handbook. Mr Robert Nicholls, a lay member of the GMC who was Chairman of the PPC between November 1999 and June 2003, told the Inquiry that it was his impression that the proportion of cases referred by the screeners to the PPC increased after the decision in Toth because screeners became more cautious about closing cases. That impression is not borne out by the statistics. It is true that the GMC statistics show that the proportion of cases referred by screeners to the PPC rose from 30% in 1999 to 39% in 2000. However, the proportions dropped back again to 27% and 25% in 2001 and 2002. In 2003, 33% of cases were referred. However, the numbers of referrals went up from 466 in 2000 to 600 in 2001. It may be that it was this increase in numbers which gave Mr Nicholls the impression that the proportion of cases referred had increased.

Further Work by the Policy Studies Institute in 1998

19.91 In 1998, Professor Allen and her colleagues were commissioned to carry out a follow-up study. Before starting that follow-up study, they conducted an 'intervention phase', during which they advised the GMC on certain changes of procedure which should be introduced, including changes to the screening procedures. The idea of the intervention phase was to identify changes which should be made to the procedures before the PSI team carried out the research which was to form the basis of its 2000 Report.

19.92 In an attempt to cut down the screeners' workload and to avoid duplication of effort, it was agreed that, from March 1999, screeners should not be sent cases which were

considered by the GMC to be clearly outside its remit. Instead, those cases would be dealt with by the GMC staff without reference to a screener. This process of 'filtering out' cases by the GMC staff had the effect of increasing (in fact, almost doubling) the proportion of cases referred to screeners which were sent on by them to the PPC. The PSI's figures show that, in 1999, the screeners referred 25% of the doctors they dealt with to the PPC; in 2000, the proportion was 22%. In 1997 and 1998, the figures had been about 11% and 12%. In the GMC FTP statistics for 1999, this increase was attributed in part to a change in the approach to evidence, which, it was said, had taken place in March 1999, as a result of legal advice (possibly advice received in connection with the case of Toth). From March 1999, screeners no longer considered whether there was **'sufficient evidence to substantiate the allegation'**. Instead, they **'could decide to close a case only if there was no prospect of obtaining probative evidence'**. There does not appear to have been any amendment of the 1997 Screeners' Handbook to reflect this changed approach. However, if such a change of approach had been instituted in March 1999, it might have contributed to the increased proportion of cases referred by screeners to the PPC.

19.93 In September 1998, it was agreed between the GMC and the PSI team that, unless there appeared to be a risk to the public, screeners should be sent cases only when there was sufficient information available to enable them to make a substantive decision. Members of the administrative staff, rather than the screeners, would assume primary responsibility for identifying any further information that was required and for obtaining it. Only when that had been done would the case be submitted to the medical screener, if appropriate. It was also agreed that, in the absence of a perceived risk to the public, cases involving doctors whose identities had not been established would not be sent to the medical screeners. Before 1998, virtually all complaints received by the GMC were referred to the medical screeners. As a result of these various changes, the percentage of complaints received by the GMC which were referred to the medical screeners decreased. The PSI's figures show that, in 2001, only 41% of complaints went to the medical screeners. The GMC's own figures reveal that the percentage dropped to about 35% in 2003.

19.94 In addition, the GMC agreed that a more structured approach to screening should be adopted. Standard forms, to be known as screening decision forms (SDFs), were designed by the PSI team in consultation with the GMC. The SDFs were intended for use by caseworkers and screeners as a prompt to ensure that they followed the essential steps of the decision-making process. They were intended also to be a record of that process and, thus, a tool for analysis in the future. It was hoped that they would promote clarity, consistency and transparency.

19.95 The structure of the SDFs divided complaints into four main categories, namely:

(a) complaints which were suitable for closure by GMC staff without reference to a medical screener

(b) reports of convictions, which were to be referred by medical screeners to the PPC except when they were referred into the health procedures

(c) complaints which 'by definition' raised issues of SPM ('SPM by definition' cases). These comprised complaints involving dishonesty, dysfunctional conduct, sexual

assault or indecency and violence. A requirement was introduced that all such complaints should be referred automatically by medical screeners to the PPC unless the screener felt that there were overwhelming reasons for not doing so.

(d) complaints which required the exercise of discretion on the part of the screeners in deciding whether or not they should be referred to the PPC or to the performance procedures ('SPM or SDP by discretion' cases).

19.96 Cases falling within category (d) were, in the main, complaints about poor treatment/substandard clinical practice. Screeners were permitted to exercise their discretion in deciding whether to refer such cases to the PPC. The purpose of the introduction of 'SPM by definition' was to reduce the proportion of complaints in respect of which screeners were permitted to exercise discretion and, thereby, to promote consistency and to guard against bias and accusations of bias. I shall describe the history of the operation of the 'SPM by definition' category later in this Chapter.

19.97 The SDFs also required medical screeners to record, in relation to those cases referred to them, an assessment of whether they believed that there was a current or imminent risk to the public arising from the complaint or conviction. The primary reason for this was to assist in the decision whether an interim order (suspending or imposing conditions on a doctor's registration pending his/her appearance before a FTP committee) might be necessary. At the time the SDFs were first introduced, medical screeners were also required to record their assessment of the seriousness of the doctor's alleged conduct using a four-point scale. This assessment was intended to form the basis for analysis of screening decisions in the future. If the medical screeners decided that a case did not raise an issue of SPM or SDP, they were required to record their reasons on the SDF.

The 2000 Policy Studies Institute Report

The Analysis of Screening Decisions

19.98 Initially, GMC staff and screeners had difficulty in getting into the habit of recording the relevant data on the SDFs. The 2000 PSI Report described the introduction of the SDFs as **'a painful process'**. There was a four-month 'pilot exercise' in the early part of 1999. The SDFs were then brought into use on a permanent basis. In the early part of 2000, Professor Allen and her colleagues analysed the contents of the SDFs completed by the medical screeners during the period from 1st July to 31st December 1999.

19.99 The PSI team analysed 792 SDFs which had been completed during that six-month period. By that time, the number of medical screeners was seven. The analysis revealed significant variations between the medical screeners in the outcomes of their screening. One medical screener referred 10% of cases that s/he screened to the PPC, while another referred 36%. This suggested that the threshold at which medical screeners felt it appropriate to refer a case on to the PPC differed from screener to screener.

19.100 The analysis also demonstrated striking differences between medical screeners' assessments of risk and seriousness. Two medical screeners considered that there was a current or an imminent risk to the public in one third or more of the 'SPM by definition' cases they screened, while two others considered that there was no risk at all in any of the

cases they dealt with. In relation to 'SPM by discretion' cases, two of the medical screeners (the same two who had identified a risk in a high proportion of 'SPM by definition' cases) considered that more than 40% of cases they screened posed a risk. By contrast, three screeners thought that less than 10% of their cases posed a risk. One medical screener rated nearly 90% of 'SPM by definition' cases that s/he screened as **'very serious'**, while another assessed only 20% of such cases as **'very serious'**. Classification by medical screeners of 'SPM by discretion' cases as **'not at all serious'** ranged between 28% of the cases handled by one medical screener and 70% of cases screened by another.

19.101 It was difficult to draw any firm conclusions from the variations observed because, as became evident during the PSI study, the distribution of cases to screeners was not random. Thus, the differences could have been explained by bias in the distribution of cases, i.e. by some screeners deliberately being given a greater number of serious cases than others. It could also have been that, by chance, certain screeners were allocated cases of a higher degree of risk and seriousness than those allocated to other screeners. However, the PSI team regarded it as unlikely that either of those possibilities could alone have accounted for the wide range of assessments which they observed. They regarded it as likely that the variations were at least partly due to the fact that different screeners were applying different standards and criteria when judging 'seriousness' and 'risk'.

The Need for Agreed Standards and Criteria

19.102 The marked variations between screeners in terms of the outcomes of the cases screened, and the extent to which they differed in their assessments of the risk and seriousness of cases, caused Professor Allen and her colleagues to reiterate the need (which they had identified in their first Report) for all those involved in the GMC's FTP procedures to have a common understanding of the standards, criteria and thresholds to be applied at the various stages of the procedures. They believed that the lack of any such common understanding had led to inconsistency in the past. The analysis of SDFs which they had conducted suggested that screeners were applying their own personal interpretations of the threshold for SPM. As a result, cases which might have been referred to the PPC by one screener were considered not to raise an issue of SPM by another. This lack of consistency applied equally to decisions of the PPC, as I shall explain in Chapter 20.

19.103 The PSI team identified a need for detailed guidance that could be understood both by doctors and by the general public. Professor Allen told the Inquiry that, while the GMC's publication 'Good Medical Practice' was 'absolutely fine' for the purposes for which it was intended, it was not suitable for use as guidance about what might or might not amount to SPM. She said:

> **'... ''Good Medical Practice'' is a mixture of things which really must not be transgressed and which would be very serious and other points which are, for example, being polite to your patients. This on its own could not raise an issue which ought to affect a doctor's registration presumably; so that you've within ''Good Medical Practice'' a lot of different things at different levels of seriousness ...'**.

19.104 What was needed, she said, was detailed guidance for those making decisions, with examples of different types of case which might reach different thresholds, thus creating a 'hierarchy of seriousness'. The 2000 PSI Report recommended that:

> **'The GMC should ensure that all those involved in the fitness to practise procedures have a common understanding of what does and does not constitute serious professional misconduct. Guidelines should be drawn up to ensure that a clear and agreed definition can be put into operation by all GMC staff, screeners and members of committees. These guidelines should make clear a) what factors should be taken into account in determining the outcome of cases; b) what standards should be applied in reaching decisions; c) at what point cases ''reach the threshold of serious professional misconduct'' and represent a departure from the standards of conduct expected of doctors ''sufficiently serious to call into question a doctor's registration''.'**

19.105 The PSI team recognised that the existing confusion and inconsistency about the threshold for SPM gave rise to problems not only within the GMC. It also presented a difficulty for members of the public and public bodies who might wish to make a complaint against a doctor. Accordingly, the 2000 PSI Report recommended that:

> **'The GMC should develop clear protocols defining the types of cases which do and do not come within the jurisdiction of its fitness to practise procedures. These should be made public and should be available to anyone who wishes to complain about a doctor.'**

19.106 Professor Allen told the Inquiry that it was clear that there was confusion both inside and outside the GMC about the types of case that were suitable for referral to the GMC. This was why she and her colleagues thought it appropriate for there to be clear protocols, setting out what was and was not likely to raise an issue of SPM or SDP. This would assist the GMC by relieving it of the burden of a lot of inappropriate complaints. It would also spare members of the public the disappointment of having their complaints rejected.

Problems with Complaints about Poor Treatment and Substandard Clinical Practice

19.107 Professor Allen and her colleagues considered that particular problems existed in applying the concept of SPM to complaints about poor treatment and substandard clinical practice. I agree with that view. SPM is an appropriate expression when the conduct in question comprises, for example, indecent assault, fraud or the dishonest acquisition of controlled drugs. In the context of clinical practice, the word 'misconduct' seems to imply a deliberately or recklessly wrongful act or omission. However, the law is clear that negligence, if serious enough, can amount to SPM. It seems to me that such an expression as 'deficient clinical practice' would more comfortably embrace failures which included acts or omissions that were negligent, as well as those which were deliberate or reckless.

19.108 Professor Allen reported that, during the period from 1997 to 1999, complaints about poor treatment and clinical practice accounted for about 70% of all the complaints that came to the GMC. She told the Inquiry that there was room for different interpretations

where allegations about treatment and clinical practice were concerned. Different interpretations resulted in inconsistency. At the time of writing its 2000 Report, the PSI team found **'undoubted confusion and inconsistency'** in the way that such complaints were handled. Professor Allen and her colleagues therefore recommended that clinical failures should be graded on a hierarchical scale, ranging from those which could never give rise to a question of SPM to those which would always do so. Criteria should be established by which the seriousness of a complaint should be measured. They believed that these steps would result in a much greater consistency of approach to complaints about clinical treatment.

The Reasons Given by Medical Screeners for Their Decisions

19.109 Some limited insight into the approaches of different medical screeners was given by their recorded reasons for concluding that a case did not raise an issue of SPM. Some wrote only brief comments; others gave much more detailed reasons. The most common reason (given in 26% of cases) for screening out a case was that there was **'no evidence of serious professional misconduct'**. Usually, no further reason was given. In 10% of cases, the reason given was that the case did not reach the **'threshold of SPM'**. In some cases, no further explanation was given and it was consequently not clear on what basis the medical screener had made his/her judgement.

19.110 The second most common reason (20% of cases) for screening out a case was that the treatment or management of a patient had been **'reasonable'** or **'appropriate'**. Medical screeners who gave this reason often offered a clear account of the factors that they had taken into account. By this time, the practice had been instituted of seeking a response to a complaint from the doctor complained of before the screening stage. Medical screeners who gave 'reasonableness' or 'appropriateness' as their reason for rejecting a complaint often referred to the doctor's response.

The Relevance of the Quantity and Quality of Evidence to Screening Decisions

19.111 As I have already said, the 1996 PSI Report had shown that by far the single most important factor in determining whether a complaint went forward for action by the GMC was whether the complaint came from a public body or from a private individual. Complaints from public bodies were much less likely than those from private individuals to result in a screening outcome of no SPM or SDP or of insufficient evidence.

19.112 The analysis of screening decisions in the years 1997, 1998 and 1999 carried out by the PSI team showed that this pattern was continuing. Professor Allen and her colleagues pointed out that complaints from public bodies usually contained far more evidence than those from members of the public. This was because those complaints were likely to have been subject to some form of previous investigation or inquiry, whereas the GMC would not, in general, have taken any steps to investigate a complaint made by a private individual. The result was that medical screeners were usually judging complaints from the two different sources on the basis of very different material. The PSI team noted that medical screeners were required only to decide whether a complaint raised an issue of SPM. In other words, if the allegation (if true) would amount to SPM, the case should go

forward to the PPC. The PSI team suggested that medical screeners might have attached more weight to the greater level of evidence presented by public bodies than to the apparently less well-supported allegations made by members of the public, despite the fact that the complaints from the two different sources might have raised similar issues. Also, many complaints from public bodies related to matters in respect of which there had already been findings made against the doctor by another body, such as an independent review panel (IRP). The PSI team suggested that these findings might, in some circumstances, have been regarded by medical screeners as adding weight to their judgement that a complaint raised an issue of SPM.

19.113 I can see why the PSI team was concerned about these findings and thought that they might show that medical screeners were attaching weight to the amount and orderliness of the evidence available. That would have been wrong. However, I do not think that it should be assumed that they were doing that. It seems to me likely that a higher proportion of cases referred by public bodies would be of a serious nature, simply because the public body had exercised an informed judgement about whether the case should be reported to the GMC. However, I can also see that, if the screeners had become accustomed to seeing well-prepared cases reported by public bodies giving rise to serious issues, there would have been a danger that they would underestimate the seriousness of the allegations contained in poorly prepared cases coming from private individuals. They may also have been fortified by the judgements of other bodies although, it must be said, they did not always follow them. It seems to me that the real problem was that the GMC did not investigate complaints that came in a 'raw' uninvestigated state. Such evidence as was available from private individuals was likely to be scanty and might well be poorly presented. It is not at all surprising that more of such cases should fail at the screening stage.

A Change in the Chapter XV Procedures

19.114 In 1999, the Fitness to Practise Policy Committee (FPPC) of the GMC decided that use of the Chapter XV procedures should be discontinued. Documents considered at the relevant meeting recorded that the reason for this was that the **'rather cumbersome process'** could take **'several months to reach a conclusion'**. This was undoubtedly the case. However, Professor Allen and her colleagues noted in the 2000 PSI Report that it had been clear for some time that some cases which raised issues of SPM had not been referred to the PPC but were instead being dealt with under Chapter XV. They said that the FPPC had shared their concern about this, and that this concern had been a factor in the decision to discontinue the Chapter XV procedures. The fact that the medical screeners might have been using Chapter XV procedures to deal with cases that raised issues of SPM would be particularly concerning as, for the Chapter XV procedures to have been invoked in the first place, these must have been cases in which the evidence was not disputed by the doctor concerned. Such cases should plainly have been referred to the PPC.

19.115 The July 2000 Standing Orders contained a revised version of Chapter XV. This provided for cases where the medical screener considered that the doctor's conduct or professional performance did not raise a question of SPM or SDP but where the conduct

appeared to fall short of acceptable standards as laid down in 'Good Medical Practice' or other published GMC guidance and where it was desirable in the public interest that the doctor should be given advice. In such cases, the revised version of Chapter XV provided that the medical screener should consult a lay screener on the question of whether the doctor should be given advice and, if so, on the terms of the advice to be given. If the screeners decided to send a letter of advice, this was done. There was no opportunity, as there had been under the old Chapter XV procedures, for the doctor to object. Letters of advice were confidential, save that complainants were told that a letter had been sent and were informed of the terms of the letter. A letter of advice did not form part of the doctor's FTP history, either for internal GMC purposes or in response to an external enquiry about the doctor's FTP history.

Other Changes Occurring in 1999

19.116 In November 1999, during the time that the PSI team was carrying out its study, Dr Steel retired as a medical screener and as Chairman of the PPC. Meanwhile, the GMC had decided, in anticipation of the coming into force in October 2000 of the Human Rights Act 1998, that the functions of the screeners and the PPC should be separated. From November 1999, screeners (medical, health and lay) were no longer eligible to sit on the PPC or to attend meetings of the PCC as observers. The President was to be the Chairman of the PPC or, if he chose not to act in that capacity, some other GMC member was to be appointed by him. Mr Nicholls became acting Chairman of the PPC on Dr Steel's retirement. His appointment as Chairman was confirmed in January 2000. In August 2000, the Rules were changed to reflect the changes in constitution which had already been put in place. From November 1999, the role of 'principal screener' was abolished and all medical screeners were instead given equal status.

After the 2000 Policy Studies Institute Report

19.117 The 2000 PSI Report was considered at a Council meeting on 11th and 12th July 2000. The briefing paper prepared for the meeting noted that the changes which had been made to the screening process in response to the 1996 PSI Report had **'produced substantial improvements in the robustness of the procedures'**. No direct mention was made of the variations between screeners' decisions which had been revealed by the analysis of the SDFs reported in the 2000 PSI Report. Nor was there any specific mention of the recommendation which had been central to the 2000 PSI Report, namely that it was essential, in order to achieve consistency and fairness, that standards, criteria and thresholds should be agreed and applied by all those charged with making decisions about what constituted SPM. The briefing papers for the Council meeting did, however, acknowledge that the 2000 PSI Report had concluded that GMC processes did **'not match the principles of good decision making'** and that there were **'anomalies in outcomes identified in the quantitative analysis'**. Members of the Council were invited to agree that the recommendations contained in the 2000 PSI Report should be addressed by the FPPC as a matter of urgency. I shall consider later in this Report what, if any, progress has been made on the central recommendation relating to the establishment of commonly agreed standards.

19.118 Also in July 2000, the GMC introduced a procedure whereby, before a complaint was screened, the doctor's response to the complaint was disclosed to the complainant and the complainant's comments on the doctor's response were invited. Since 1997, screeners had had the complaint and (usually) the doctor's response, but had had no comment on the doctor's response from the complainant. This could have had a somewhat one-sided effect. From July 2000, a practice was introduced whereby the complainant was invited to comment and any comments submitted by him/her were sent to the doctor for his/her further observations. The complainant's comments, as well as the doctor's further observations, would be made available to the medical screener. At about the same time, the 1988 Professional Conduct Rules were changed to remove the power of the medical screener to direct that an explanation should not be given to a complainant of a decision to reject his/her complaint.

19.119 In August 2000, the 1988 Professional Conduct Rules were amended to provide that the GMC should appoint to act as medical screeners the President (unless he wished to sit on the PPC, the PCC or the HC or for any other reason did not wish to act as a medical screener) and **'such other medical members of the Council as the President shall nominate'**. The 1988 Professional Conduct Rules (as amended) also required the President to nominate (and the Council to appoint) the lay screeners.

A Change in the Screening Test

19.120 I have already said that, after the judgement in Toth had been delivered in June 2000, steps were taken to amend the statutory screening test. This was effected on 3rd August 2000, when rule 6(3) of the 1988 Professional Conduct Rules was amended to read:

> **'The medical screener shall refer to the Preliminary Proceedings Committee every case submitted to him under this rule unless –**
>
> **(a) he decides that a question as to whether the practitioner's conduct constitutes serious professional misconduct does not arise, and a lay member appointed under rule 4(5) agrees ...'**.

The only other exceptions to the general rule were cases in which no statutory declaration had been provided by the complainant and cases referred by the medical screener to the health procedures. These cases did not have to be referred to the PPC.

19.121 It does not appear that this important change in the screening test was reflected in any amendment of the 1997 Screeners' Handbook. It seems that either the screeners must have continued to use the Handbook (despite the fact that it was by this time out of date in a number of respects) or that the Handbook must have fallen into disuse. Subsequent events suggest that the screeners (or some of them) were probably unaware of the change in the rule 6(3) test which had occurred in August 2000.

The Case of Holmes

19.122 The case of R v General Medical Council ex parte Holmes and others[6] was decided by Mr Justice Ouseley on 27th April 2001. It concerned applications for judicial review, challenging, *inter alia*, decisions by medical and lay screeners and by the PPC.

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[6] [2001] EWHC 321 (Admin).

The Complaints

19.123 The case concerned complaints by the partner, Ms Caryl Nancy Holmes, and the parents (I shall refer to the three of them as 'the claimants') of Mr Derrick Marcus Dean, who died on 26th July 1995, aged 34, from a colloid cyst on the brain. The complaints related to the standard of care given to Mr Dean by his GP, Dr Rahman, and by a deputising doctor, Dr Sengupta. Mr Dean had seen Dr Rahman at his surgery two days before his death. On the evening before he died, he had been seen at his home by Dr Sengupta. He had subsequently been admitted to hospital where he died. The precise nature of the failure of the standard of care alleged by the claimants is not clear from the judgement. It seems likely that the claimants alleged failure by both doctors to appreciate the seriousness of Mr Dean's condition.

19.124 Ms Holmes made a complaint against Dr Sengupta to the FHSA. A complaint was added later against Dr Rahman. In March 1996, the MSC decided that Dr Sengupta had breached his terms of service but that Dr Rahman had not. Ms Holmes appealed to the Secretary of State (SoS) for Wales against the decision in Dr Rahman's case. In June or July 1998, the SoS for Wales notified the claimants that he had allowed the appeal and had found that Dr Rahman had breached his terms of service. The SoS for Wales directed that Dr Rahman's case should be referred to the GMC. The claimants then requested the GMC to consider Dr Sengupta's conduct also. Thus the GMC was seized of two complaints, both backed by a finding of a breach of terms of service. I do not know whether the breach by one doctor was more serious than that by the other, although it appears that the punishments imposed were different.

19.125 Some time between January and March 1999, the complaint against Dr Rahman was considered by three screeners: two medical screeners and one lay screener. They decided that the case should not be referred to the PPC. Dr Sengupta's case was considered by the same medical screeners and by a lay screener. In Dr Sengupta's case, the medical screeners decided that the case should not proceed. However, the lay screener disagreed and the case was therefore referred to the PPC. On 9th September 1999, the PPC decided that the complaint against Dr Sengupta should not proceed to the PCC. The claimants challenged that decision of the PPC; I shall deal with that part of the case in Chapter 20. They also challenged the decisions of the screeners in Dr Rahman's case.

The Decision of the Screeners in Dr Rahman's Case

19.126 At some stage, probably in the course of the judicial review proceedings, the GMC disclosed a number of documents that shed light on the reasons for the screeners' decision in Dr Rahman's case. The first was a note from a caseworker, which had probably formed part of the memorandum usually prepared by members of staff for the assistance of the screeners. In the note, the caseworker observed:

> **'Dr Rahman has been punished more harshly than Dr Sengupta. Though he should have arranged some follow up for Mr Dean, I do not think his actions constitute SPM and recommend no action in his case.'**

19.127 There was then an annotated comment from the lay screener, indicating her agreement with the observations of the caseworker. There was also a comment from a medical screener, Professor Thomas, who wrote:

> **'I think it is very difficult for us to consider a case which has not been referred to us and although this turned out to be a brain tumour neither hearing has considered this a serious breach (withholding £500). I would value the view of a GP. These events were three years ago – no history of either doctor? I am inclined to no action. In any case if we took one and not the other I think the Welsh Office** (*i.e. the Office of the SoS for Wales*) **would be rather surprised. Would Dr Steel kindly review. Many thanks.'**

19.128 I pause to note that the three years' delay in Dr Rahman's case was attributable almost entirely to the time taken (from August 1995 to June 1998) for the complaint to pass through the NHS complaints procedures. The remaining period of six months or so was attributable either to a delay on the part of the Welsh Office in referring Dr Rahman's case to the GMC or to the time taken by the GMC in dealing with the complaint. I cannot see why the delay should have been relevant to the screening test. Nor do I understand why it would be difficult to consider either case on account of the way in which it had been referred. Nor is the reaction of the Welsh Office a relevant consideration. In short, the first medical screener did not appear to have in mind the relevant considerations.

19.129 Dr Steel was the principal medical screener at the time and a GP. It was common for him to be consulted when another medical screener was uncertain how to proceed. He reviewed the case and commented:

> **'This is a lengthy read. I agree no action, not SPM as Coloid** (*sic*) **cyst is a very difficult diagnosis and Dr Rahman was GP with MRCP** (*Membership of the Royal College of Physicians*)**. I especially note the letter from hospital 2 weeks before the final consultation and I note original (?) case was no breach. Dr R & Dr S reprimand only. Happy to discuss.'**

Quite apart from the fact that Dr Steel appears to have reached a concluded view that Dr Rahman's treatment did not in fact amount to SPM, rather than expressing a view as to whether or not it could do so, he appears to have made two other serious errors. First, it cannot be relevant that a doctor is or is not a Member of the Royal College of Physicians. Second, it cannot be relevant that a MSC had decided in Dr Rahman's case that there was no breach. That decision had been shown to be wrong by the subsequent decision of the SoS for Wales. It appears that Dr Steel was still exercising a wide discretion when screening cases and did not have in mind the advice given in the 1997 Screeners' Handbook.

19.130 The decision was taken to close the case. A letter to the Welsh Office dated 8th March 1999 was drafted but, it seems, was never sent. This letter included the following passage:

> **'The members** (*i.e. the screeners*) **have carefully reviewed the actions of both Dr Rahman and Dr Sengupta in this matter. The members accept that there were shortcomings in the care that Mr Dean received from both doctors. However, they are satisfied that they are not of the gravity of**

serious professional misconduct and could not, therefore, justify the restriction or removal of their right to practice (*sic*) **medicine.**

The members have asked me to explain that a single error in the treatment or management of a patient's condition does not usually constitute serious professional misconduct. Only in cases where it can be shown that the doctor has seriously neglected or disregarded his or her professional responsibilities to a patient could issues of serious professional misconduct or seriously deficient performance arise.'

19.131 The decision not to proceed with the case against Dr Rahman was communicated to the claimants by a letter dated 22nd October 1999. They had been informed about the decision of the PPC in relation to Dr Sengupta three weeks earlier. The claimants, through their solicitors, then attempted to obtain the documents relating to the taking of the decisions. Those attempts continued until the end of July 2000 when, **'with profuse apologies'**, the GMC wrote saying that the minutes of the PPC were not discloseable. It is not clear whether the documents to which I have referred above were disclosed at that stage or later. The GMC's decision was not communicated to Dr Rahman himself until 29th December 1999. It is not known when the Welsh Office was notified, but it seems that, at some time, the SoS for Wales became aware of the decision.

19.132 The letter from the GMC to the claimants said:

'The members have considered the case against Dr Rahman very carefully and understand that Mr Dean had seen him a number of times regarding his headaches. The members were satisfied that Dr Rahman's actions were reasonable in the circumstances prior to July 1995.

The members accept the findings of the Welsh Office in respect of Dr Rahman's consultation on 24 July 1995. However, the members did not feel that the errors made on this occasion constituted serious professional misconduct.

They have asked me to explain that an issue of serious professional misconduct can arise where there is evidence that a doctor has seriously neglected or disregarded his or her professional responsibilities towards a patient. However, a complaint about an alleged error by a doctor while treating a patient – even where the alleged error has had tragic consequences – does not in itself raise an issue of serious professional misconduct.'

The Judicial Review

19.133 On 26th October 2000, the claimants issued judicial review proceedings, challenging the GMC's decisions in relation to both doctors. The doctors were joined in the proceedings as interested parties. Grounds of opposition were filed by the GMC and the doctors. In December 2000, the claimants were granted permission to apply to the Court for judicial review. That was about six months after the decision in the case of Toth. Very shortly after, the GMC informed the doctors' solicitors that it was minded to concede the claim because

of doubts as to the lawfulness of the decisions of the screeners (in Dr Rahman's case) and of the PPC (in that of Dr Sengupta). Subsequently, the GMC decided to consent to the quashing of the two decisions on the grounds that, in reaching those decisions, the wrong legal tests had been applied. A consent order was agreed between the GMC and the claimants. The doctors opposed the application. The hearing therefore took an unusual form, with the GMC and the claimants arguing that the decisions of the GMC were wrong and should be quashed and the doctors contending that the correct legal tests had been applied by the screeners and the PPC.

19.134 In his judgement, Ouseley J adopted the analysis of the legislative framework contained in the judgement of Lightman J in the case of Toth. Counsel for the GMC argued that the decisions of the screeners had not been compliant with the language of the 1988 Professional Conduct Rules. He submitted that the documents from which I have quoted, in particular the draft letter to the Welsh Office, were not couched in **'the language of preliminary consideration'**, but contained expressions of judgement. Thus, in the letter to the claimants, it had been indicated that the screeners accepted the findings of the Welsh Office in respect of Dr Rahman's consultation on 24th July 1995 but **'did not feel that the errors made on this occasion constituted serious professional misconduct'**. In the draft letter to the Welsh Office, the screeners were said to **'accept that there were shortcomings in the care that Mr Dean received from both doctors'**, but to be **'satisfied'** that these shortcomings were **'not of the gravity of serious professional misconduct and could not, therefore, justify the restriction or removal of their** (*i.e. Dr Rahman's*) **right to practice** (*sic*) **medicine'**.

19.135 Ouseley J inferred that the caseworker who wrote the letters would have been informed of the basis of the decision by the screeners and would have reflected it faithfully in her letters. He noted that the GMC had produced no evidence that the correct test had been applied, observing that **'if there had been clear evidence of the test being consistently applied ... I would have had it, even if the individual case itself could not be remembered'**. He concluded that the decision in Dr Rahman's case was probably arrived at by applying the wrong test. It was probable, he said, that the medical screeners reached the conclusion that Dr Rahman's actions did not constitute SPM, rather than the conclusion that the actions of Dr Rahman were incapable of constituting SPM. In the Judge's view, the terms of the letters sent by the GMC contained explicit judgements as to the quality of the acts as not constituting SPM, rather than judgements as to whether they were capable of doing so. Ouseley J went on to deal with the documents disclosed by the GMC:

> **'The caseworker's reference and the annotations by Professor Thomas and Dr Steel cannot be dismissed as simple annotations when one is trying to reach a conclusion as a matter of fact as to the basis upon which the decision making body reached its decision. Not merely do they not contradict the approach which is clear from the letter of 22nd October 1999, they support the inference which I have drawn. None of the material brings in the true test.'**

It is most discouraging to realise that, as recently as 1999, errors as fundamental as this were being made by the GMC. Not only had the screeners applied the wrong test, but the

administrative staff had apparently not noticed the errors and had not queried the reasons when drafting the letters.

19.136 It appears to me that these errors were not isolated failings in the application of the Rules to given situations but were indicative of a fundamental misunderstanding of the Rules and of the functions of a screener on the part of the medical screeners. I am driven to the conclusion that, in screening cases before 1999, the screeners habitually applied the wrong test. It also appears to me to be likely that screeners often took into account completely irrelevant factors. These endemic failings underline the need not only for the training of screeners, which was recognised by Mr Roger Henderson QC for the GMC at the Inquiry, but also for clear and agreed standards, criteria and thresholds to be promulgated. I recognise that it is not easy to ensure consistency of approach by different people undertaking a task such as screening. However, in the interests of fairness and consistency, it is obvious that preliminary decisions should be made in a structured way and reasons given so that they can be audited and analysed. The case of Holmes shows that, as recently as 1999, the GMC's screening work was seriously flawed.

The Case of Woods

The Complaint

19.137 The case of Woods v General Medical Council[7] came before the High Court in June 2002, although the material events took place in 2001. The claimant was the mother of a baby boy who had died and whose body had been sent for post-mortem examination to the Alder Hey Children's Hospital. Some of his organs had been retained without the claimant's consent. Following the publication, on 30th January 2001, of the Report of the Royal Liverpool Children's Hospital Inquiry (the Alder Hey Inquiry Report), the names of certain doctors who had been criticised in that Report were reported to the GMC. The medical and lay screeners decided not to refer the cases of two of the doctors to the PPC. The reason given by the GMC for these decisions was that the Alder Hey Inquiry Report did not raise issues of SPM relating to the two doctors. The claimant brought proceedings by way of judicial review, challenging the decision of the screeners. She also challenged the decisions of the PPC in respect of nine other doctors who had been referred by the screeners to the PPC but had not been referred on by the PPC to the PCC.

19.138 It is not clear when the relevant screening decisions were taken. However, solicitors for the claimant sought an explanation of them and the GMC's letter of explanation (which was undated) arrived on or about 16th August 2001. That was more than a year after rule 6(3) of the 1988 Professional Conduct Rules had been amended to change the screening test.

The Judicial Review

19.139 Leave to apply for judicial review was granted and the case proceeded to a hearing before Mr Justice Burton. The medical screener had provided a witness statement describing the process and reasoning by which he had reached his decision. That witness statement had been approved by the lay screener. The witness statement made clear that there had

[7] [2002] EWHC 1484 (Admin).

initially been disagreement between the screeners. The medical screener had been confident that the case did not raise an issue of SPM or SDP. The lay screener had disagreed with that view. After lengthy discussions, they had agreed that the case should not go to the PPC. The Judge observed that there was nothing wrong or unusual about the fact that there had been disagreement between two independent-minded screeners. He noted, however, that the eventual agreement was said to have been reached by the lay screener **'on balance'** although it was also said that both screeners had, in the end, been **'convinced'** of its correctness.

19.140 From the medical screener's witness statement, it was clear that he had applied the screening test that had been in force before August 2000. He described the medical screener's role as being to decide whether a complaint **'need not proceed further'**. The lay screener appears to have accepted that that was the test that he had also applied. Burton J drew attention to the fact that the change to rule 6(3) since the case of Toth had removed the reference to the word **'need'** in the screening test and that the question of whether it appeared to the screener that the matter **'need not proceed further'** had gone. That had been the old rule. As to the test that should be applied, the Judge observed that it appeared to him significant that, in practice, the screening process led to the formulation (by the medical screener, or by the staff, on the instructions of the medical screener) of a charge or allegation. The charge or allegation was then sent to the PPC for consideration. The medical screener had, therefore, to be satisfied that a charge could be laid. It appeared to Burton J that the decision to be made by the medical screener at that stage might simply be **'whether there is no arguable case'**. Burton J also observed that, although the 'old' test had been a narrow one, it might have been said to **'allow for an element of subjectivity or proportionality'**. By contrast, the 'new' test was **'effectively, no arguable case'**. It was clear that the wrong test had been applied. Burton J was not satisfied that, had the correct test been applied, the screeners would necessarily have reached the same decision. He therefore directed that the case should be reconsidered by the screeners, applying the correct test.

19.141 It is obviously a matter of concern that it was possible for two screeners, in the middle of 2001, to apply the old screening test so many months after it had been replaced. This was despite the regular screeners' meetings and training sessions which the Inquiry was told had been taking place since 1997. The hearing in this case took place in June 2002. The date of the medical screener's witness statement does not appear in the judgement. It may be that it was prepared some time before the hearing took place. However, it seems clear that it cannot have occurred to either the medical or the lay screener at any stage up to the time of the hearing in June 2002 that the statement was based on a fundamental error as to the screening test to be applied. The medical screener in question had been appointed a medical screener in July 2000, the month before the new screening test came into effect. He was said by the Judge to have screened over 400 cases by June 2002. Presumably, he had applied the wrong test in all those 400 cases. In many cases, it may be that the error would have had no effect on the outcome. However, it seems likely that there would have been many cases where the error might have made the difference between a complaint being referred to the PPC and being closed at the screening stage.

19.142 It seems to me that, if these two screeners were both under a misapprehension as to the correct test to apply, it is unlikely that they were the only two in that position. It is also likely

that others within the GMC would have read the medical screener's witness statement; yet it appears that no one noticed the error. There was not, of course, an up-to-date Screeners' Handbook at the time. I have not been shown any guidance for screeners which was available at this time. One might have expected that having had to concede the errors made in Toth and Holmes would have been a chastening experience for the GMC. One might have thought that, having sought and obtained an amendment of the Rules to effect a change in the test to be applied by screeners, the GMC would have given a high priority to the education and training of screeners so as to enable them to apply the test correctly and consistently. Yet it appears that this was not done.

Further Work by the Policy Studies Institute

19.143 In further work undertaken during 2002, Professor Allen and her colleagues analysed the outcomes of screening decisions made during the period from 1999 to 2001. The results appeared in their 2003 Paper. They compared the outcomes for individual screeners. This exercise showed variations in outcome as between medical screeners, with two **'hawks'** sending an average of 30% of cases screened over the three years to the PPC and two **'doves'** sending an average of less than 20%. Professor Allen and her colleagues had previously recommended that a system of random distribution of cases to screeners should be put in place. They were told that, as a result of that recommendation, a **'cab rank'** system of distribution of cases to the screeners had been in operation from the beginning of 2000. From that time, there should not have been any difference in the types or seriousness of cases handled by each individual medical screener. The PSI team suggested that, if it was indeed the fact that the distribution of cases was entirely random, the variations in outcome amounted to evidence that the medical screeners were not all applying the same standards and criteria to their decision-making.

19.144 The PSI research was directed primarily at identifying any differences between the treatment by the GMC of doctors who had qualified in the UK and the treatment of those who had qualified overseas and, if any such differences were apparent, at analysing the possible reasons for those differences. Professor Allen and her colleagues identified differences in the treatment of the two groups but had difficulty in analysing the reasons for those differences because there was **'no discernible common agreement on the criteria and threshold to be applied in reaching a judgment on the seriousness or gravity of cases'**. They pointed out that this lack of a common agreement had led to problems in ensuring consistency. These problems extended both to the treatment of different cases within the same stage (e.g. screening) of the conduct procedures and to the treatment of cases at different stages of the procedures (e.g. as between the screening and PPC stages). The PSI team referred back to the recommendations contained in its 2000 Report and observed that the continuing differences between the outcomes of FTP cases involving doctors who had qualified in the UK and those who had qualified overseas suggested that the development of guidelines to be used in the decision-making process was **'a matter of priority'**.

19.145 As I have said, during their research, Professor Allen and her colleagues had primarily been concerned to discover whether there was any racial bias in the GMC's FTP procedures. Plainly, if there was inconsistency in decision-making, it would be

impossible for them to reach any reliable conclusions on that issue. However, consistency in decision-making is also important more generally in the interests of fairness to every doctor who is the subject of complaint. Professor Allen told the Inquiry that, on the available evidence, it could not be asserted that every doctor was treated by the GMC in the same way by reference to the same criteria and the same standards. This was because there were no generally agreed or applied criteria or standards. I would add that consistency is also important from the point of view of patient protection. If there is a 'right' threshold at which action should be taken, the public may be exposed to risk if action is not taken at that threshold in some cases. Also, unless the threshold is clearly stated, the public will feel aggrieved when the lack of clarity leads to inconsistency in decision-making.

Another Change in the Screening Test

19.146 On 1st November 2002, following the decision in Woods, the screening test was changed again. Rule 6(3) of the 1988 Professional Conduct Rules was amended to read:

> **'The medical screener shall refer to the Preliminary Proceedings Committee a case submitted to him ... if he is satisfied from the material available in relation to the case that it is properly arguable that the practitioner's conduct constitutes serious professional misconduct.'**

Dr Midha told the Inquiry that this test altered the 'presumption' upon which screening decisions would be made. I think that he meant that whereas, before November 2002, a case had to be referred to the PPC unless the screeners agreed that no question of SPM arose (a negative test), under the new rule, the screener had to be positively satisfied that it was arguable that the doctor's conduct constituted SPM. In fact, the change was very slight. The language had changed but the threshold to be crossed before the case was referred to the PPC remained very low. Put another way, if carried out in accordance with the Rules, screening remained, as had always been the intention, a very coarse filter.

19.147 Also on 1st November 2002, the 1988 Professional Conduct Rules were amended to remove the requirement for a complainant to provide a statutory declaration in support of his/her complaint.

The November 2002 Screeners' Handbook

19.148 On this occasion, a new Screeners' Handbook (the November 2002 Screeners' Handbook) was issued at the same time as the change in the screening test. This was the Handbook that was in use at the time of the Inquiry hearings in December 2003. It incorporated an *aide memoire* on the interpretation of the new screening test. Screeners were advised that they should first ask whether it was properly arguable that the alleged misconduct was capable of constituting SPM. In answering the first question, screeners were advised that:

> **'i It should be assumed the allegation is true;**
>
> **ii An assessment should be made of the allegation's seriousness not credibility;**

iii The argument does not need to be likely to prevail before the PCC;

iv The issue is properly arguable if a claim can reasonably be made that the practitioner's behaviour fell seriously short of the standards of conduct expected among doctors.'

19.149 Screeners were told that, if they were of the view that it was properly arguable that the alleged misconduct was capable of constituting SPM, they should then consider whether it was properly arguable from the material available in relation to the case that the practitioner had committed SPM. In considering this question, screeners were urged to remember that:

'(i) This question addresses the factual allegations;

(ii) It identifies possibilities not probabilities;

(iii) It is based on the identification of a possibility less than any real or realistic prospect of the allegation being sustained;

(iv) Properly arguable means reasonably arguable. An allegation is not properly arguable if it is absurd, frivolous, vexatious or repeats an earlier allegation (whether made by the same or different complainants);

(v) Conflicts of evidence should not normally be resolved;

(vi) Implausible accounts unsupported by other evidence can legitimately be rejected.'

19.150 Screeners were cautioned that the evidential element of the test did not establish a **'high hurdle against the progress of a case'**. They were told that they must not make any attempt to resolve conflicts of evidence. The November 2002 Screeners' Handbook stated:

'There will be very few cases where the allegation(s) against the doctor are either fanciful, incredible or incapable of being supported by the evidence.'

19.151 I have already mentioned in Chapter 18 that the November 2002 and April 2003 versions of the FTP Casework Manual and the May 2004 FTP Investigation Manual advised that the amount of evidence required by the screeners was **'minimal'**.

19.152 In deciding whether conduct was or was not capable of amounting to SPM, screeners were told that they should bear in mind the relevant GMC guidance when exercising their discretion whether to close a case or to refer it to the PPC. The November 2002 Screeners' Handbook stated that staff would ensure that the screeners' attention was drawn to the appropriate guidance. In many cases, the 'guidance' would be the relevant passage from 'Good Medical Practice'. The November 2002 Screeners' Handbook made it clear that deviation from the published guidance would not necessarily give rise to issues of SPM. It stated:

'The key will be the degree and/or nature of deviation from that guidance.'

The Handbook further advised (in language that came perilously close to encouraging the screener to make a 'judgement' on the evidence) that:

> **'Screeners should bear in mind that if they determine that a doctor deviated from best practice, as set out in our guidance, but not by so much as to call his or her registration into question, a closing letter containing advice to the doctor may be the logical outcome.'**

19.153 The Handbook contained no criteria by which screeners were to assess the **'degree'** or the **'nature'** of the deviation from the relevant guidance that would be sufficient to call a doctor's registration into question. In my view, the use of the expression 'to call the doctor's registration into question' may have caused some confusion, in that it might have suggested to some screeners that the conduct had to be so serious as to give rise to the possibility of erasure from the register. In fact, if SPM were proved, the PCC could impose lesser forms of sanction than erasure, including the imposition of conditions. In the recent past, it became increasingly common for the GMC to use the concept of conduct which was 'serious enough to call registration into question' as an equivalent of SPM. In my view, the use of this expression did not help screeners to decide whether the conduct amounted to SPM.

19.154 In making a decision on a case, the November 2002 Screeners' Handbook advised that a medical screener had a number of options. First, s/he could (with the agreement of a lay screener) close the case. If s/he decided that that course was appropriate, s/he could elect to send a letter to the doctor, giving advice as to his/her future conduct. Second, the medical screener could refer the case to the PPC. Third, if the medical screener believed that there were grounds to suggest that the standard of the doctor's professional performance might have been seriously deficient, s/he could refer the case for a performance assessment. I shall discuss that option further in Chapter 24. Fourth, the medical screener could refer the case to the health procedures.

19.155 A fifth option for the medical screener was to request further information. However, screeners were advised that they should do this only in circumstances when further information was necessary in order to clarify what the allegation was. Screeners were warned not to request further evidence that was not necessary for this purpose. The November 2002 Screeners' Handbook stated that, if they did, and evidence was obtained in response to their request:

> **'... we** (*i.e. the GMC*) **leave ourselves open to the charge that the screeners, in seeking evidence, must have intended to take that evidence into account in making their decision and that in doing so they went beyond their legal powers and applied the wrong test (by weighing the evidence)'**.

19.156 I understand entirely why the GMC wished to discourage requests for further evidence about an allegation. However, it would have been unfortunate if screeners had been discouraged from asking that staff should find out, for example, whether other complaints of a similar nature had come to the attention of the doctor's employer or the primary care organisation on whose list s/he was included. Complaints should not be considered in

isolation; additional information might well show that an apparently isolated complaint of poor clinical practice was in fact a sign of SDP. However, it may be that, in the future, the GMC will obtain such information as a matter of routine, at least in certain cases. I shall return to this issue later.

19.157 The November 2002 Screeners' Handbook advised that, once a decision had been made to refer a case to the PPC, the medical screener should not request that further information be obtained before the case proceeded. By making the decision, the medical screener had fulfilled his/her role and had no further part in directing the case. It was open to the medical screener, in exceptional cases, to request a second opinion from another medical screener or to call for a case conference of several screeners. However, screeners were enjoined to exercise these options only when **'absolutely necessary'**, since they would have the effect of prolonging the screening process. Under the GMC's service standards, screeners had two weeks to consider each file and come to a decision. In exceptional cases (i.e. those which were highly complex or which contained large amounts of information or documentation), screeners could agree with GMC staff a longer timescale for an individual decision. Medical screeners were also advised that they should consider whether it was necessary to take steps to protect the public interest by suspending or imposing conditions on a doctor's registration, pending the final determination of his/her case. If they believed that it was necessary to take such steps, they were required to refer the case to the Interim Orders Committee.

19.158 The November 2002 Screeners' Handbook advised that a SDF should be completed and the screener should give clear reasons for his/her decision. Those reasons should relate solely to the test which screeners were required to apply. If a case was to be closed, the medical screener should approve the letters to be sent to the complainant and the doctor. The November 2002 Screeners' Handbook reminded medical screeners that the explanations to the various parties should be identically worded, except where technical terms might need to be explained to a complainant.

19.159 The November 2002 Screeners' Handbook made clear that one of the functions of caseworkers and case managers in the Screening Section was to ensure that screeners' decisions were made in accordance with the law and with the statutory process. An agreed protocol was attached to the Handbook, setting out the circumstances in which it would be appropriate for a member of staff to ask a screener to reconsider a decision which might have been made for reasons which were not legally defensible. This might arise if the medical screener requested that staff should obtain information that was not necessary for the purpose of the screening decision. More frequently, it would arise if the reasons for the decision given by the medical screener demonstrated that s/he had taken into account matters which should not have formed part of the decision-making process. An example would be if it was clear that the screener had 'weighed up' the evidence or had speculated about how the PPC or PCC might dispose of the case. The protocol pointed out that a decision taken in these circumstances might be vulnerable to challenge by judicial review. In a case where there was real concern about the potential for judicial review, the protocol suggested that the advice of the GMC's solicitors might have to be sought before a final decision was taken on the case. This was, no doubt, intended to avoid a repetition

of the situation in Toth and in Holmes, where it was immediately evident to the GMC's advisers that the decisions of the screeners were unsustainable.

The Treatment of Convictions

19.160 On 1st November 2002, rule 5(1) of the 1988 Professional Conduct Rules was amended to read:

> **'Where information in writing is received by the Registrar from which it appears to him that a practitioner has been convicted of a criminal offence in the British Islands or has been convicted of an offence elsewhere which, if committed in England or Wales, would constitute an offence**
>
> **(a) in a case of conviction for an offence which the Registrar considers to be a minor motoring offence the case shall not proceed further;**
>
> **(b) in a case of conviction where a custodial sentence has been imposed (but excepting any case where the sentence was suspended), the Registrar may refer the case direct to the Professional Conduct Committee for inquiry unless it is his opinion that such direct referral would not be in the public interest;**
>
> **(c) in any other case of conviction including any case which the Registrar has determined not to refer direct to the Professional Conduct Committee under rule 5(1)(b), the Registrar shall refer the case to the medical screener.'**

This change gave explicit legislative authority to the longstanding direction by the PPC that convictions for minor motoring offences need not be referred to the PPC or, indeed, to a medical screener. The amended rule appears to have created an expectation that convictions leading to an immediate custodial sentence would usually be referred directly to the PCC and that all others, save those for minor motoring offences, would be referred to a medical screener.

19.161 The November 2002 Screeners' Handbook dealt with the screening of convictions. It stated:

> **'A subset of conduct cases relate to doctors convicted of a criminal offence ... When we receive notification of a conviction, staff will refer the case to a screener (unless the doctor in question was imprisoned, in which case the matter will be referred direct to the PCC), who must in turn refer it to the PPC unless:**
>
> **a. it appears to the screener that the doctor's fitness to practise may be seriously impaired by a physical or mental condition and that action under the health procedures should be taken in preference to action under the conduct procedures; or**

b. the conviction is for a minor motoring offence (not involving the use of alcohol or other drugs), or a conviction for a minor offence not involving dishonesty.'

The Problem of Finding Out How Conviction Cases Were Dealt With

19.162 There is a real problem in discovering the number and nature of convictions reported to the GMC and in tracing how those convictions have been dealt with. In the GMC's annual FTP statistics, cases dealt with by medical screeners are divided into broad categories. There is no separate 'conviction' category. Some of the categories (e.g. dishonesty, sexual assault/indecency and violence) will presumably include both conviction cases and conduct cases. It is not possible, on reading the statistics, to distinguish between the two. In 2003, 28 cases involving allegations of dishonesty against doctors were closed by screeners, out of 125 such cases considered. It may be that in none of the 28 cases had the doctor been convicted of a criminal offence. It may be that a sizeable proportion had been convicted. It is impossible to tell from the annual FTP statistics. It was only when cases were referred to the PPC that the GMC statistics identified the number of conviction cases dealt with and their outcome. In my view, this is unsatisfactory. It is important for members of the GMC and the wider public to know exactly how the GMC deals with doctors convicted of criminal offences. Transparency is particularly important where concerns exist, as they do, about the disparity of treatment between different groups of doctors.

Remission of Cases to the Health Screener

19.163 Since the introduction of the health procedures in 1980, the Professional Conduct Rules have permitted medical screeners, in both conviction and conduct cases, to remit an appropriate case to a health screener to be dealt with under the voluntary health procedures, as an alternative to referring the case to the PPC. A large proportion of the cases where this course of action is considered involve abuse by a doctor of alcohol or controlled drugs.

19.164 According to the GMC annual FTP statistics, in 2001, the medical screeners remitted 31 cases (out of 2235 cases screened) to the health screener. In 2002, 13 out of 2239 cases were so remitted. In 2002, 13 out of 1884 doctors whose cases were dealt with by the medical screeners were referred into the health procedures. In 2003, the figure was seven out of 1304 doctors. It is not possible to say how many of these cases (if any) involved convictions. In any event, it is clear that in the recent past, the medical screeners have referred only a small proportion of cases into the health procedures.

Audit of Screening Decisions

19.165 While carrying out the work preparatory to their 1996 Report, Professor Allen and her colleagues had advised that screeners should receive training and should be provided with information about the results of cases they had screened. This had not happened up to that time. In response to that recommendation, regular meetings of screeners and screening casework managers were instituted. These were used to discuss issues of

common interest arising from the screening process, as well as specific screening cases, suitably anonymised. In addition, training sessions and workshops for screeners and screening caseworkers were introduced.

19.166 From about the end of 2002 or the beginning of 2003, screeners began to receive statistics about their own screening outcomes. The statistics showed how many cases the screener had closed and how many s/he had referred to the PPC. Screeners were able to compare this information with anonymised information about the screening outcomes of colleagues. The object of this was to inform individual screeners and also to enable the GMC staff to identify screeners who appeared to be outliers in some way. When the new system was introduced, it was intended that, if an outlier was identified, an explanation would be sought and any necessary remedial action taken. The Inquiry has no information about whether such action has been taken in respect of any screener. Screeners were also informed of the outcomes of the PPC's consideration of cases they had referred there.

19.167 In September 2002, Mr Blake Dobson joined the GMC. He was given responsibility for developing a programme for auditing GMC casework which could be applied to both the existing and the new FTP procedures. In January 2003, Mr Dobson became Head of the FPD Audit Team. The Team consists of three caseworkers and an administrative assistant, as well as Mr Dobson.

19.168 In August 2003, the audit of screening decision-making began. A random sample of two cases per medical screener was audited each month. The audit involved examination of the caseworker's memorandum to the screener and of the screening memorandum setting out the screener's decision and any other comments made by the screener on the file. The auditors also checked that the relevant part of the SDF had been correctly completed and was consistent with the screening decision.

19.169 A check was made to ensure that the reasons for the decision accorded with the screening test to be applied. If there was evidence which suggested that the basis of the decision was questionable – because the screener appeared to have applied the wrong test, for example, or because s/he had taken into account matters which should not have formed part of the decision – the file was referred to Mr Dobson and, if he had concerns, it was passed to the Director of the FPD.

19.170 This procedure was a most welcome development. Until its introduction, scrutiny of a screener's decision would occur only if proceedings for judicial review were taken. However, the scrutiny was still not complete. It checked that the reasons given complied with the legal test (which was plainly important) but it did not involve any evaluation of whether the decision itself was correct in all the circumstances of the case.

19.171 More recently, in May 2004, the Fitness to Practise Committee set up an Investigation Audit Sub-Group, with a view to establishing and developing a programme of audit for the investigation stage of the new FTP procedures.

19.172 There was, in the past, discussion about the appraisal of screeners. These discussions were not taken forward, largely because of the imminent changes in the arrangements for screening.

Some Problems with the Screening Process

19.173 As I have already explained, the judicial reviews have provided examples of cases in which screeners have applied the wrong screening test and have taken irrelevant considerations into account. It appears that those errors were made as the result of ignorance of the correct test and the considerations relevant to it. However, in the course of its investigations, the Inquiry has also become aware of a number of situations in which screeners have been unwilling to abide by internal GMC decisions.

'Serious Professional Misconduct by Definition'

The General Medical Council Agrees to Automatic Referral to the Preliminary Proceedings Committee

19.174 As I have explained, Professor Allen and her colleagues were anxious to promote changes in the GMC procedures which would secure greater consistency in decision-making. Accordingly, in the period before the start of their follow-up study in 1999, Professor Allen agreed with the GMC that there were a number of categories of cases which should 'by definition' be regarded by the medical screeners as SPM. The categories to which it was agreed that this approach should apply were complaints about dishonesty, about dysfunctional behaviour (e.g. abusive behaviour, soliciting money from patients, persisting in practice when the carrier of an infectious disease, etc.), about sexual assault and indecency and about violence. Cases falling within these categories were to be referred automatically by the medical screener to the PPC, unless the medical screener considered that one of two exceptions applied. These exceptions were, first, where the doctor was terminally ill and not in active practice and, second, when there was no tenable basis for taking action because the complainant had declined reasonable requests for further information, there was no probative evidence to support the allegation(s) (or any prospect of obtaining any) or the complaint was self-evidently untrue or irrational. The types of behaviour which amounted to 'SPM by definition' were clearly indicated on the SDFs which were introduced at that time to assist screeners in the decision-making process.

The Impact of Automatic Referral

19.175 The introduction of the 'SPM by definition' categories led initially to a dramatic increase in the number of complaints of dishonesty, dysfunctional behaviour, sexual assault and indecency, and violence referred by the medical screeners to the PPC. In 1997 and 1998, only about half of all complaints about dishonesty and criminality referred to the medical screeners – and far fewer complaints relating to the other categories of 'SPM by definition' – had been referred by the medical screeners to the PPC. By contrast, during the period from July to December 1999, 93% of all cases within the 'SPM by definition' categories were referred to the PPC. In the other 7% of cases, the reason given by the medical screeners for not referring the case was that **'there was no probative evidence to support the allegation nor any prospect of obtaining any'**.

19.176 The 2000 PSI Report welcomed the consistency of approach which the introduction of the 'SPM by definition' categories had produced. Indeed, it suggested that there was an

argument in favour of the GMC staff referring all complaints of dishonesty, dysfunctional behaviour, sexual assault and indecency and violence straight to the PPC on receipt, without any intervention at all by the medical screener. Professor Allen and her colleagues pointed out that, for such cases, consideration by both the medical screener and the PPC seemed to be an unnecessary duplication of effort. It also caused delays, which were a cause of concern, particularly when a case appeared to raise a question of risk to the public.

A Surprising Retreat

19.177 As I have said, the GMC had agreed to the introduction of 'SPM by definition' and suitable SDFs had been designed by the PSI team in consultation with the GMC. Mr Scott said that there had been a 'very strong commitment' to 'SPM by definition' and 'huge enthusiasm' about implementing the new procedure. In July 2000, a meeting of the Council considered the 2000 PSI Report. The briefing papers for the meeting referred to cases of 'SPM by definition' and indicated that such cases would normally be referred by the medical screeners to the PPC. This and other changes had, it was said, **'produced substantial improvement in the robustness of the procedures'**. Anyone reading those papers would have understood that the system whereby certain types of complaints were regarded by definition as constituting SPM and were referred to the PPC more or less automatically was in operation and producing benefits.

19.178 The same impression would have been gained by anyone reading the November 2002 Screeners' Handbook, which stated:

> **'In cases where the alleged behaviour is characterised as SPM by definition – and assuming that the screener agrees with the categorisation – the screener would have no choice but to refer the case on (rather than close it), unless exceptionally the low evidential test is not met.'**

19.179 When they undertook their work in 2002, Professor Allen and her colleagues understandably assumed that virtually 100% of cases in the 'SPM by definition' category and all convictions (save those specifically excepted) would have been referred by the medical screeners to the PPC. As far as they were aware, the system was still in operation as agreed with the GMC in early 1999 and they had not been informed otherwise. It was with surprise, therefore, that they discovered that, in the dishonesty/criminality category, only 47% of cases which had gone to the medical screeners in 2000 had been referred to the PPC, rising to 74% in 2001. In both years, a fifth of the cases that had not been referred to the PPC had been screened out on the ground that they did not raise a question of SPM. This is hardly consistent with their being categorised as 'SPM by definition'. In addition, 19% of cases in the dishonesty/criminality category in 2000 and 7% in 2001 had been referred by screeners to the health procedures. In the dysfunctional behaviour category, only about 70% of cases seen by the medical screeners had been referred by them to the PPC in 2000 and 2001. Again, this proportion fell significantly short of the almost 100% which had been expected.

19.180 When Professor Allen asked about these findings, members of the GMC staff explained that there had been a change of practice in mid-2001. From that time, she was told, there was no longer a requirement that complaints falling within the 'SPM by definition' category should be referred to the PPC in the absence of overwhelming reasons why this should not be done. Instead, medical screeners had been using their own discretion when deciding whether or not to refer such cases to the PPC. The contents of the SDF had even been changed to facilitate this. It is clear from the statistics that, even in 2000, medical screeners (or some medical screeners at least) had not in fact been implementing the policy in accordance with the agreement reached the year before.

19.181 Professor Allen told the Inquiry that the change of practice had seemed to her 'such an extraordinary thing to do'. Automatic referral had been an agreed policy. She had asked the GMC for an explanation for the change but had not been given one. She was, however, told that the change of practice would be reversed so as to restore the system which had been agreed upon in March 1999.

19.182 Dr Korlipara, a member of the GMC and a medical screener between 1998 and 2004, was asked about this change of practice. When he was shown the categories of conduct which it had been agreed should be treated as 'SPM by definition', he said that, if a screener was satisfied as to the strength of the allegation and if there was *prima facie* evidence to support the allegation, the screener had to refer such cases to the PPC. If one of those categories applied, he said, 'There is no question at all, they would go to the PPC.' However, when asked about the specific example of theft, Dr Korlipara said that there were circumstances in which he had decided that a case of theft need not go to the PPC. The example he gave was:

> **'If it was a small amount of money or National Health resources which is, you know, taking paracetamol or something like that having been stolen, which is technically correct, I may not take the issue further.'**

19.183 He said that he would exercise some discretion in order to distinguish between the 'frivolous' and the 'rather more serious'. Dr Korlipara did not appear to appreciate that, by doing this, he was undermining the procedure laid down for screening complaints that had been identified as amounting to 'SPM by definition'. Nor, apparently, did he appreciate that this could be a source of unfairness to doctors. If a doctor's case was screened by one of Dr Korlipara's colleagues, who was adhering to the 'SPM by definition' rule, that case would be sent to the PPC; if, however, the same doctor's case was screened by Dr Korlipara, it would be closed. Dr Korlipara's response also failed to take account of the fact that different people might take very different views about whether the theft of money (even a small amount of money), or the theft of drugs from the NHS, could ever be regarded as 'frivolous'. Indeed, the 'SPM by definition' procedure was aimed at reducing the inconsistency flowing from the fact that individuals may have differing views about the approach to be adopted to certain types of misconduct, including dishonesty.

19.184 It appears that there was what Mr Finlay Scott, the GMC's Chief Executive, termed a period of 'incomplete compliance' with the 'SPM by definition' procedure by medical screeners. During that time, medical screeners (or some of them) were not sending all the cases within the relevant categories to the PPC. The medical screeners then indicated to

members of the GMC staff that they wanted the SDF changed, and the GMC staff complied. Those changes were made without the knowledge of the Council or the FPPC and without the knowledge of Mr Scott. The first he knew of it was early in 2003, when Professor Allen drew his attention to what had occurred.

19.185 The changes to the SDF consisted of moving various types of conduct from the list of types of misconduct to be regarded as 'SPM by definition' and placing them in the list of types of conduct which might raise an issue of SPM. In the latter ('SPM by discretion') case, the screener would be permitted to exercise his/her discretion in deciding whether the conduct did raise an issue of SPM. The types of misconduct which were moved from one list to another were:

(a) in the category 'dishonesty'

- false certifications
- false reporting
- false claims about effectiveness of treatment

(b) in the category 'dysfunctional conduct'

- abusive behaviour
- driving under the influence of alcohol/drugs (where there had been no conviction)
- failure to report dysfunctional colleagues
- soliciting money from patients.

The provision of a misleading reference, which had previously been designated as a type of conduct to be regarded as 'SPM by definition', did not appear at all on the new version of the SDF.

The Reasons for the Retreat

19.186 In March 2003, after the change in the agreed policy on 'SPM by definition' had come to light, Mr Neil Marshall, who had been the Head of the Screening Section since March 2002, prepared a briefing paper for a meeting of the FPPC. He advanced two reasons for the change of practice. First, he said that the screeners had felt that some cases falling into the categories of conduct designated as 'SPM by definition' might form part of a pattern of poor performance, so that a referral to the performance procedures would be more appropriate than referral down the conduct route. If screeners were constrained to refer cases to the PPC, the opportunity of referring for a performance assessment would be lost since the PPC could not make such a referral. I can see that 'abusive behaviour' might possibly be part of a wider pattern of poor performance. However, I must say that I cannot see how such behaviour as soliciting money from patients, false certifications, false reporting and false claims about effectiveness of treatment could ever be considered as examples of SDP.

19.187 Second, the screeners had, it was said, been concerned at the loss of their discretion to close cases involving complaints about these categories of behaviour on the grounds that

the complaints did not raise a question of SPM. I must say that I find it very worrying that any medical screener should have considered that allegations of conduct such as soliciting money from patients, making false claims about the effectiveness of treatment or writing false certificates or reports could ever fail to raise a question of SPM. This is especially so since all the medical screeners were required to do was to refer such cases automatically to the PPC. The PPC provided another filtering process before a case went to the PCC. The screeners were not required to make a final judgement as to whether the conduct complained of amounted to SPM or required a public airing before the PCC.

19.188 Mr Marshall's paper set out the history of what had occurred and the steps that were to be taken to reinstate the agreed policy. In that paper, the issue of the medical screeners' concern about loss of discretion was further illustrated:

> **'... the Screeners felt that they had lost the discretion to close cases where the allegation, as stated by the complainant, might well be very serious, but where other relevant information seemed to suggest that the doctor's failings had been of a less serious nature. The example often quoted was where allegations of indecency made by the complainant seemed to the Screeners to be more a case of poor communication as to the reasons for an intimate examination being carried out.'**

19.189 As it happens, indecency was not one of the types of behaviour that was removed from the list on the SDF of misconduct to be regarded as amounting to 'SPM by definition'. Nevertheless, it seems clear that, on occasion, screeners rejected such claims on the grounds that they did not amount to SPM. To dismiss an allegation of indecency as a problem of **'poor communication'**, without hearing evidence from the doctor and from the patient, seems highly unsafe. In effect, a screener who refuses to refer such a case to the PPC is making a value judgement about the truth of, and about the weight to be attached to, the complainant's complaint and the doctor's response. That is not the function of a screener. Mr Scott told the Inquiry that, although he did not have the full facts, the conversations he had had with medical screeners suggested that they would have sought to exercise discretion in 'probably quite a small number of instances' of complaints of indecency. However, the GMC's FTP statistics for 2002 show that, of 65 cases involving allegations of sexual assault and indecency against doctors considered by the screeners, no fewer than 25 were closed by them. The other 40 such cases were referred by the screeners to the PPC. In 2003, 17 out of 40 such cases were closed by the screeners.

19.190 Mr Scott referred to an 'understandable frustration' on the part of the screeners at being part of a 'mechanical processing system' and the wish of those individuals to 'add value' by exercising their discretion. Mr Scott observed that there had been a tendency for screeners (especially those who had been used to sitting on the PCC) to 'slip into' the weighing of evidence and, in effect, to step beyond their role as screeners. He said that there was also a danger that medical screeners, who were experienced doctors (and, therefore, experienced decision-makers), would 'reach into their own experience' to see whether there might be 'an alternative explanation' for the conduct complained of. He did not believe that this was in any sense motivated by 'a positive desire to explain it away' but

he thought there might be a 'subconscious influence there'. He was not able to say whether the 'subconscious influence' invariably operated in favour of the doctor against whom the complaint had been made.

Restoring the Status Quo?

19.191 Mr Marshall's paper revealed that, at a meeting of the screeners held after receipt of the 2003 PSI Paper, there was a division of opinion among them about whether the changes to the categories of behaviour which had been designated as 'SPM by definition' (i.e. the removal of the types of conduct listed at paragraph 19.185) should be reversed. The matter was put to the FPPC, with a recommendation that all the categories of behaviour listed at paragraph 19.185 should be reinstated as 'SPM by definition'. In March 2003, a decision was taken to reinstate the policy which had originally been agreed in March 1999.

19.192 In fact, in August 2003, when the SDF was amended, only some of the types of behaviour listed at paragraph 19.185 were reinstated as 'SPM by definition'. Despite the decision of the FPPC, certain types of conduct (i.e. abusive behaviour, driving under the influence of alcohol/drugs, failure to report dysfunctional colleagues and soliciting money from patients) were left in the 'SPM by discretion' category. The offence of providing a misleading reference was not replaced in either the 'SPM by discretion' or the 'SPM by definition' category. That was the position at the time of the Inquiry hearings in December 2003.

19.193 In March 2004, the full Council was asked, in effect, to ratify the FPPC's decision to restore the policy in relation to 'SPM by definition' and to agree the types of complaint or allegation that should, for the purposes of screening, be regarded as 'SPM by definition'. The briefing paper for the Council stated:

> **'In mid-2001, changes were made to the SDFs and several sub-categories were removed from SPM by definition. However, in March 2003, the former Fitness to Practise Policy Committee, following discussion at a screeners meeting, restored the 1997** (*presumably 1999*) **position.'**

19.194 In fact, as I have said, the 1999 position had not been **'restored'**, since five of the types of behaviour which had in 1999 been classified as 'SPM by definition' were no longer so classified. There might have been a good reason why some of the categories were not restored, although I cannot think of any reason why soliciting money from patients or providing a misleading reference could ever fail to raise a question of SPM. However, the concern is that the Council was under the mistaken belief that the *status quo* had been restored when it had not.

19.195 This briefing paper made clear that the category of 'SPM by definition' applied only for the purpose of screening, and did not apply to the PPC or the PCC. Thus, it remained possible for the PPC to decline to refer to the PCC a case involving conduct amounting to 'SPM by definition'. The Council proceeded to approve the list of cases to be regarded as 'SPM by definition', thereby affirming the list set out in the August 2003 SDF.

Observations

19.196 Mr Scott told the Inquiry that he had three concerns about the manner in which the policy agreed in March 1999 had been changed unofficially. First, he felt that the change had been a retrograde step. Given the fact that there was concern about possible bias within the GMC, he felt that it was necessary for the organisation to 'seize every opportunity to place itself above suspicion'. He said that he 'deeply regretted' that an opportunity to do this had been missed during the period for which the policy had been unofficially changed.

19.197 Second, Mr Scott said that he felt that he had failed in communicating to other members of the GMC staff the importance that he attributed to the SDF as originally conceived and to the concept of 'SPM by definition'. He had been involved in the drafting of the SDF and felt strongly about it. Third, Mr Scott was disappointed that it was not, as he put it, 'so blindingly obvious to everyone' that the categories designated in the original SDF were (as they were described) types of behaviour which, by definition, must amount to SPM.

19.198 I can well understand Mr Scott's concerns. Bearing in mind that it was the inconsistencies in screeners' decisions that led to the introduction of the concept of 'SPM by definition', the unilateral decision of the screeners to revert to the old practice of exercising discretion in such cases calls into question their suitability as decision-makers in a disciplinary process where consistency of standards and treatment is essential.

Random Distribution of Cases to Medical Screeners

19.199 With effect from January 1997, the GMC had agreed with the PSI team to implement a system of random distribution of cases to screeners. The reason was to eliminate any possibility of bias in allocation. Removal of this bias would permit reliable analysis of screening decisions. Under this system, cases were to be allocated to screeners on the basis of the final two digits of the doctor's GMC registration number.

19.200 When Professor Allen and her colleagues began to carry out their analyses in 1999, no one told them that the agreed system was not being fully applied. However, it soon became obvious that it was not. Moreover, some screeners were screening a lot more cases than others. Professor Allen and her colleagues were given no clear explanation as to why the system was not being applied. Nor were they told what system of distribution was in fact being applied. Professor Allen told the Inquiry that it 'was difficult to get a straight answer' about the matter.

19.201 After discussions between the PSI team and the GMC, it was agreed that, from January 2000, a 'cab rank' system of distribution of cases to screeners would be undertaken, in an attempt to eliminate any possibility of bias in allocation. The PSI team recommended that a continuing check should be kept to ensure this was being done. The 2003 PSI Paper showed that the new arrangements for allocation had not had the effect of equalising the numbers of cases dealt with by each medical screener. In 2001, the two most active screeners dealt with twice as many cases as the two least active screeners. Pausing there, I do not see how that could easily be avoided without causing delay; some screeners would have more time to devote to the task than others. However, provided that some sort

of 'cab rank' system of distribution was being faithfully implemented, the fact that the distribution between screeners was numerically unequal would not affect its randomness. The PSI team carried out no check to ensure that the distribution of cases to screeners was being operated on a random basis. It was assured by the GMC that that was so.

19.202 It was left to the members of the PSI team to find out for themselves in 1999 that the agreed system of distribution was not being implemented. If they had not carried out their work, everyone (except those immediately concerned with the allocation of cases) would have assumed – wrongly – that the system of distribution by GMC registration number was being operated faithfully and that the distribution was random.

19.203 Mr Scott said that, in the past, cases had tended to be allocated according to the specialty of the medical screener. For example, a GP would deal with complaints against GPs. When the new system was introduced, the medical screeners (or some of them) were unhappy, as they thought it more appropriate to continue with the old system. Medical screeners therefore asked to be given certain types of case. They passed cases between themselves. Some undertook more work than others. All these factors led to anomalies in the operation of the new system. Mr Scott said that there was 'a lack of understanding', on the part of those involved, of the reason behind the change of system.

Assessment of the Seriousness of the Allegations Contained in a Complaint

19.204 I have said that the 2000 PSI Report contained an analysis of medical screeners' assessments of the seriousness of the allegations in the complaints screened by them between July and December 1999. That analysis revealed significant variations between individual medical screeners in their assessment of seriousness. The analysis was made possible by the inclusion on the SDFs used by screeners of a section where the medical screener was asked to indicate his/her assessment of the seriousness of the case, using a four-point scale.

19.205 Subsequently, this section of the SDF was removed. It seems that this occurred at the same time as the changes were made to the categories of behaviour which were designated on the SDF as 'SPM by definition'. That would have been in mid-2001.

19.206 Mr Scott told the Inquiry that he had not been aware at the time that this change had occurred. He did not know how it had come about but did not think that it would have been as a result of unilateral action on the part of members of the GMC staff. Although it is not entirely clear, it seems highly likely that the change came about as a result of the wishes of the medical screeners (or some of them). It is difficult to see who else could have initiated it. It appears that, for some reason, they must have thought that the assessment of seriousness was unnecessary or unhelpful and must, therefore, have suggested to the staff that the relevant section should be removed from the SDF. Mr Scott said that he thought it would have been appropriate for the GMC to have discussed with Professor Allen in advance the likely impact that the change would have on subsequent data collection and analysis.

19.207 The removal of the relevant section of the SDF has had the effect of preventing the type of retrospective analysis which was carried out by the PSI team in 2000. It has also prevented

the GMC from conducting any continuing internal audit of screeners' assessments of 'seriousness' during the relevant period. It has, of course, been possible to carry out audits or analyses of the outcomes of screeners' decisions, e.g. of the proportions of cases closed by individual screeners or referred to the PPC. However, cases can be closed for a number of reasons not related to the seriousness of the behaviour alleged.

19.208 The apparent inconsistencies in the assessments of seriousness by individual screeners revealed by the PSI analysis in 2000 were marked. I should have thought that the GMC would have wanted to carry out further analyses to see whether a greater degree of consistency had been achieved, for example, as a result of the introduction of the 'cab rank' system of allocation. I would also have thought that assessments of seriousness would be highly relevant to the development of standards and criteria which Professor Allen and her colleagues had called for in each of the PSI Reports.

Comment

19.209 Each of the three changes mentioned above was introduced for very good reasons and with the approval of the GMC. One objective was to ensure that the PSI research would produce useful results. Professor Allen's brief was to discover whether or not there was any racial bias within the GMC procedures. That, in itself, was an important objective and it is disappointing that the screeners should have had so little understanding of or respect for that objective as to sabotage it in the way they did. However, the changes were also intended to have, and would have had, a wider beneficial effect. The introduction of 'SPM by definition' should have produced greater consistency of decision-making, to the benefit of all doctors who might be the subject of complaints to the GMC. Random allocation of cases to screeners would have enabled the GMC to scrutinise the work of different screeners and to identify outliers for self-correction or further training. The recording of degrees of seriousness would have had a similar beneficial effect and would also, as I have said, have formed a useful basis for work on standards and criteria. It is not only disappointing, but also worrying, that an important stage of the conduct procedures was being undertaken by a group of people who had no collective appreciation of the purposes and advantages of the changes introduced and who were prepared to give instructions to staff to alter the systems without referral to the appropriate committee or to Council.

19.210 It is also disappointing that the staff who received instructions to change the system from that which had been agreed should have bowed to the wishes of the medical screeners without drawing these wishes to the attention of Mr Scott. However, I do recognise that, in an organisation such as the GMC, it would be difficult for members of staff to question the propriety of an instruction given by a group of Council members.

19.211 These incidents do, however, clearly demonstrate that the GMC has been unable to control the exercise of discretion by medical screeners. It may be that the history of screening, founded in the exercise of a personal discretion by the President and perpetuated to some extent by the presidential selection of screeners for appointment, explains their attitude. It may be, as Mr Scott suggested, that medical screeners, being experienced decision-makers, were not prepared to take part in a process that allowed

as little exercise of discretion as screening should. It seems that the GMC has now realised that screening by members wishing to exercise an autonomous discretion is not appropriate.

19.212 Another feature that I find disappointing is the lack of candour displayed by the GMC when Professor Allen discovered that agreed systems either had not been fully implemented or had not remained in force. I sensed that Professor Allen felt rather embarrassed at having to report to the Inquiry that she had not been told that the agreed systems were not in force and that, when she found out about this, she had been given no explanation.

19.213 A further cause for concern is the fact that the Chief Executive of the GMC was obviously not aware of what was happening in such an important area of its FTP procedures. Members did not know that the directions given with proper authority were not being carried out. That this can happen (more than once) makes it difficult to place reliance on policy statements of the GMC. One cannot be sure that the declared policy is actually being carried out. I have said that the GMC is about to introduce new FTP procedures. The role of screening will be undertaken by case examiners, who will be susceptible to management in a way that screeners were not. However, concerns will remain that there may be a gap between what the GMC decides should be done and what happens in practice.

The Inquiry's Examination of Cases

19.214 In order to examine how the screening process worked in practice, the Inquiry decided to examine a number of individual case files. Requests were made for production of the files in the five or ten most recent cases in various categories. Most of these requests related to the decisions of Dr Korlipara, who had been suggested by the GMC as a witness suitable to describe and deal with screening issues. In this section of this Chapter, I shall comment upon those decisions, sometimes individually, sometimes collectively. I shall begin with a general account of Dr Korlipara's evidence.

The Evidence of Dr Krishna Korlipara

19.215 Dr Korlipara, a practising GP, has been an elected member of the GMC since 1984 and was a medical screener between 1998 and 2004. During his time on the GMC, he has sat on several Committees, including the PPC and the PCC. When he started as a medical screener, he 'shadowed' Dr Steel, who acted as his mentor. Dr Steel reviewed and discussed with Dr Korlipara some of Dr Korlipara's early screening decisions and Dr Korlipara was also able to read the files in some of the cases in which Dr Steel had made the screening decision.

19.216 For the first few months after Dr Korlipara began screening, the workload was heavy. In some weeks, he would deal with 18 to 20 cases. However, the workload then diminished, no doubt as a result of the measures introduced on the advice of Professor Allen and her colleagues and of the appointment of further medical screeners. It has continued to reduce since. In 1998, there were no target times for turning round screening decisions. As I have indicated, these were later introduced.

19.217 In his oral evidence, Dr Korlipara explained how he used the SDF to guide his decision-making. He agreed that the form had had the effect of directing screeners to make decisions in an orderly fashion. He also claimed that the SDF had:

> **'... helped to introduce consistency so that there is common understanding to all the screeners of the various criteria to be looked at before making a decision and to that extent, it has removed the different screeners working to the different possible criteria'**.

19.218 There seemed to be two problems with this claim. First, while the SDFs no doubt assisted in ensuring that screeners applied their minds to the correct questions in the correct order, they contained no standards or criteria to be applied when making a decision. The SDF contained a definition of SPM (see paragraph 19.220) and of SDP. It reminded screeners that they should not take into account the weight of the evidence or the intent of the doctor when reaching a decision on whether the case raised a question of SPM. It also offered assistance in assessing whether it would be appropriate for a case to proceed by way of the performance (as opposed to the conduct) procedures. A number of features that might have been indicative of SDP were listed on the form. However, there were no standards or criteria by which to judge whether an allegation amounted to SPM.

19.219 The second problem is that the 2000 PSI Report and the 2003 PSI Paper have shown that there were wide variations in the outcomes of cases between screeners in 1999, 2000 and 2001, i.e. after the introduction of the SDFs. Dr Korlipara acknowledged that the 'clear message' of the 2000 PSI Report had been that there was a lack of consistency between screeners. He said that he was anxious that consistency should be improved. He suggested that this could be done by more training, more agreed criteria and regular audits of screening decisions. He said that progress in these matters had been slower than he would have liked. He said that it was hoped that a measure of consistency would be introduced with the advent of the new case examiners.

19.220 The definition of SPM included on the SDF was:

> **'... action or inaction by a doctor of a serious kind of which no doctor of reasonable skill and exercising reasonable care would be responsible'**.

Dr Korlipara described it as 'a good working definition'. However, he felt that SPM went 'a little way beyond that'. He would use the definition 'only as the starting basis'. He told the Inquiry that:

> **'... we** (*i.e. the screeners*) **have to ask ourselves whether the doctor's conduct is so serious departing from acceptable conduct that it seriously compromises the ethical standard that the profession has accepted and is so** (*un*)**acceptable that the registration of the doctor, in theory, ought to be in some way affected'**.

19.221 I have sympathy with Dr Korlipara's attempt to define SPM; it is not easy. The definition of SPM in the SDF is appropriate only in cases of alleged substandard treatment and, in such cases, the definition is not unhelpful. However, SPM embraces many different types of misconduct, of which providing substandard treatment is only one. I can understand why

Dr Korlipara would wish to describe SPM differently. The description given by Dr Korlipara of the test which he would apply when screening a case suggested that he was still (in December 2003) making decisions of the kind condemned as wrong in Holmes, i.e. by deciding whether the alleged conduct *did* amount to SPM, as opposed to whether it was *arguable* that it did. This is not a matter of personal criticism. It merely illustrates the very real problem faced by the screeners who had no standards, criteria and thresholds to apply when making their decisions. Dr Korlipara was a very experienced member of the GMC and had been a screener for five years. If he was not applying the correct test, it seems likely that there were other, less experienced, screeners who, despite the training they had undergone, had still not fully understood their role and were also operating a screening threshold higher than that permitted by the Rules.

Initial Screening Decisions

19.222 I mentioned in Chapter 18 that, under the procedures in operation as at December 2003, a casework manager had the option of submitting a case to a medical screener at an early stage for initial screening. This fast track system was used for cases which did not appear to the GMC staff to raise a question of SPM or SDP but where the complaint was about the adequacy or inadequacy of treatment or about the exercise of clinical judgement, so that some input from a medically qualified person was considered necessary before a final decision to close the case was taken. If the medical screener agreed that the case should be closed, the confirmation of a lay screener was necessary before this could be done.

19.223 In order for a case to be dealt with in this way, it had to fall within one of the categories set out in Section B of the SDF. These were as follows:

(a) the patient was demanding specific treatment/drugs and there was no suggestion that the doctor had acted unreasonably

(b) the patient was complaining simply on the basis that s/he was still ill and there was no suggestion that the doctor had acted unreasonably

(c) the patient was complaining about the side effects of treatment, where these were within acknowledged parameters and there was no suggestion that the doctor had misled the patient

(d) the patient was (only) asking the GMC to intervene in his/her treatment/care

(e) the complaint was about (only) the cosmetic outcome/failure of cosmetic surgery

(f) the complaint was about conflicting diagnoses, where there was no suggestion that the doctor had acted unreasonably

(g) the complaint was about a single and isolated error, and there was no risk that the error would lead to a serious/untoward outcome for the patient

(h) the complaint was about a failure to visit, where there had been no risk of a serious/untoward outcome for the patient and an appropriate alternative had been suggested.

19.224 The Inquiry requested the production of the files in the last five cases before 30th September 2003 that Dr Korlipara had screened out on an initial assessment of their merits. The GMC was able to find only three cases that had been dealt with by Dr Korlipara in this way during the previous 12 months. One of these, KD 01, did not in fact appear to have been an initial screening decision at all. The complaint had been received by the GMC in June 2001. The complainant had at first been advised to direct his complaint to local complaints procedures. He would not accept that advice, as he was dissatisfied with the way his complaint had been dealt with at local level. The complaint came back to the GMC and was closed by a caseworker in error in October 2001. It was reopened in February 2002 and medical records and other information were sought. The complaint was seen first by Dr Korlipara in October 2002. At that stage, he asked for an expert opinion. When that was available in November 2002, he closed the case (with the agreement of a lay screener) on the ground that it did not amount to SPM or SDP. Its closure was not, therefore, for one of the reasons set out in Section B of the SDF.

Dr KD 02

19.225 The other two cases related to cosmetic treatment. In the first (KD 02), the complainant was dissatisfied with the outcome of laser treatment she had undergone for facial capillaries. The letter of complaint did not allege substandard procedures or any worsening of her condition. It complained essentially of a breach of contract. If the complainant's account was true, the doctor's conduct was not entirely satisfactory. However, in my view, the decision to close the case was reasonable.

Dr KD 03

19.226 The other case concerned a Dr KD 03, against whom two complaints had been received, two years apart. In the first complaint, the complainant said that she had requested liposuction to improve the shape of her abdomen but, on the advice of the surgeon, had undergone an abdominoplasty (a procedure colloquially known as a 'tummy tuck'). She was dissatisfied with the outcome. She alleged that there was no improvement in the shape of her abdomen and that its appearance was worse by reason of the scarring. The doctor had said that, after the operation, she would have thin white scars, whereas, in fact, as she claimed, she had an unsightly purple scar running from one side of her abdomen to the other. A year after the operation, the doctor had agreed that the outcome had been 'not as planned' and had offered to carry out liposuction, free of charge. However, the complainant would have been obliged to pay the hospital charges. A letter written on the doctor's behalf said that the operation in dispute had been successful and that the only really satisfactory way forward was for the patient to lose weight by dieting. In any event, it was said, the doctor had counselled the patient about the 'realistic outcomes' of the surgery. There were, therefore, two contentious issues: first, whether the outcome was outside the range of what would be regarded as acceptable, and second, whether the doctor had warned the patient of the realistic outcomes or whether, as she claimed, he had told her she would have 'thin white scars'.

19.227 I have mentioned earlier that one of the grounds listed on the SDF that might justify the closure of a case at an early stage was that 'the complaint was about (only) the cosmetic

outcome/failure of cosmetic surgery'. That was the ground on which the medical screener (not Dr Korlipara) was invited to consider the closure of this case. The medical screener closed the case on that basis, saying that it:

> **'... falls completely outside the jurisdiction of the GMC. The outcome of a procedure in medicine can never be guaranteed. It appears that the doctor acted reasonably and has now offered to rectify the situation. If** (*the patient is*) **unhappy I suggest she approaches the Management of the local hospital.'**

19.228 The lay screener agreed that the case should be closed. The letter informing the patient of the decision did not say that the complaint had been rejected because it fell within a category of cases that the GMC had already decided, as a matter of principle, could not give rise to a complaint of SPM. Instead, it informed the complainant that the screeners had found **'nothing to indicate that** (*the doctor*) **seriously neglected or disregarded his professional responsibilities towards you. It appears that** (*the doctor*) **discussed all your options with you and obtained your informed consent before proceeding with the operation.'**

19.229 In short, the screeners had decided that the case did not in fact disclose evidence of SPM. The statutory provision at the time of the screening decision required that the case should proceed to the PPC unless the screeners decided that a question of SPM did not arise. It appears to me that a question of SPM clearly did arise. First, the decision to advise upon the operation might have been quite wrong or the technique by which it was performed might have been entirely incorrect. Also, there was a dispute about whether the doctor had advised the patient about 'realistic outcomes' or whether he had told her that she would have 'thin white scars'. If the doctor had given over-optimistic advice which had induced the patient to embark on surgery, that should, I think, have raised a question of SPM. Moreover, the decision to close the case was reached on the basis that the account advanced on the doctor's behalf was to be preferred to that of the complainant. It had been made plain in the case of Toth that screeners should not attempt to resolve conflicts of evidence. Leading Counsel to the Inquiry asked Dr Korlipara whether, in cases of this kind, it was the practice to ask the complainant to provide a photograph of the outcome. That would at least enable the GMC to obtain an opinion as to whether the result fell outside what was reasonable. It appears that photographs are sometimes available and sometimes not but it is not usual practice to request them in cosmetic cases.

19.230 Leading Counsel was also anxious to discover why it was the GMC's policy that complaints that concerned only the cosmetic outcome of cosmetic surgery were to be closed. Dr Korlipara said that he did not know why this category of cases was included on the list of cases to be closed but said that, as he understood it, screeners could exercise discretion and keep open a cosmetic case if they thought fit. He thought that perhaps this category of cases ought to be removed from the list. During the writing of this Report, the Inquiry team noticed that the wording of the relevant provision of the SDF had been changed at some time between July 2000 and August 2001. The version of the SDF in use in July 2000 stated that a complaint might be closed if **'the complaint is about (only) the cosmetic outcome/failure of cosmetic surgery and there is no indication that the**

care delivered was substandard'. By August 2001, the last clause had been deleted. Thus, screeners were encouraged to close cases without any real consideration of the issues, simply on the ground that the complaint related to the outcome of cosmetic surgery. It is clear that Dr Korlipara was aware that he could keep a case open if he thought fit. However, the change in the wording would result in a tendency for more cosmetic cases to be closed at an early stage than would have been the case before the change was effected.

19.231 When invited to comment on the merits of the decision itself, Dr Korlipara said that, if he had been the medical screener, he would have reached the same conclusion. He could not believe that any surgeon would have told the patient that she would be left with only thin white scars; that simply could not be guaranteed. The difficulty with that reply is that what was said was precisely the matter in issue in this case. When that was pointed out, Dr Korlipara expressed the view that, even if the doctor had unwisely made promises that he could not fulfil, it would not necessarily amount to SPM or SDP. I interpose to say, 'perhaps not necessarily', but at least it would raise a question of SPM. Dr Korlipara was then asked what his reaction would have been if a doctor had deliberately overstated the prospects of success in a cosmetic procedure with the intention of gaining private business. His response to that was that the idea 'would stop him in his tracks'. I infer from that answer that Dr Korlipara would have regarded that as a very serious matter; he had not apparently thought of the case in that way. Yet, on the basis of the information available to the GMC at the time the case was closed, that could quite possibly have been the position. Dr Korlipara was then asked (hypothetically) whether it would have made any difference to his view of the case if he had known that the hospital had had a number of other similar complaints about the doctor. That, he said, would have 'turned the case on its head'. It has not been the practice of the GMC to make such enquiries of local employers or primary care trusts (PCTs). Dr Korlipara appeared to accept that, in this type of case, there might be a case for making enquiries of the authorities in the locality in which the doctor practised.

19.232 The second complaint involving Dr KD 03 came from a patient who had undergone the removal of a facial lesion. He was dissatisfied with the outcome. The case was closed, following a decision by Dr Korlipara, with which the lay screener agreed, that the case involved only the cosmetic outcome or failure of cosmetic surgery and that there was **'nothing in the complaint which raises an issue of SPM/SDP'**. Interestingly, in the light of the previous complaint, this complainant also alleged that the doctor had advised him that he would be left with a 'faint white scar'. In his written statement to the Inquiry, Dr Korlipara said that he was informed of the earlier complaint when considering the later complaint. In that event, he appears not to have noticed the rather striking similarity between the two cases. In the second case, the patient complained that instead of a 'faint white scar' one centimetre long, he had been left with a scar that was 1.6cm long and 1.5mm wide, which he described as a 'thick red indentation'. It appeared from correspondence enclosed with the complaint that the patient had had a photograph of the scarring taken; he had sent it to the doctor when he had complained to him. Yet there is no sign that the GMC asked to see a copy of the photograph. The complainant also said that he had taken the advice of another cosmetic surgeon, who was going to carry out

remedial surgery. Apparently, this surgeon had said that the original result had been poor as the result of the operation not being performed in a 'good enough sterile environment'. In his statement to the Inquiry, Dr Korlipara said that he closed the case because he considered it to be an unjustified and trivial complaint. How he came to form the view that it was either unjustified or trivial on the material before him is not clear. He added that he saw nothing in the earlier complaint that caused him to change his mind on the second one. However, it is clear from his comments on the earlier case that his understanding of the issues was very limited.

19.233 The two cases involving Dr KD 03 give rise to real concern in my mind about the attitude of the GMC towards complaints that are 'about (only) the cosmetic outcome/failure of cosmetic surgery'. I recognise the possibility that unjustified complaints might be made by patients with unrealistic hopes and expectations. However, that apart, it seems to me that there are good reasons to examine complaints about cosmetic surgery with particular care. Much cosmetic surgery and cosmetic treatment is carried out in the private sector. There is a real danger that the advertising material used by providers of such surgery and treatment may not always be accompanied by appropriate counselling about realistic expectations. It is, as I understand it, well known that some cosmetic surgery clinics are operated by doctors with no special training as plastic surgeons. Often, the patient will not have been referred to the clinic by a GP or other doctor; s/he might well have walked in 'off the street'. The local handling of complaints by some small private providers is likely to be less than ideal. Some patients who undergo plastic surgery may be emotionally vulnerable. In my view, complaints from patients who have undergone private cosmetic surgery should be scrutinised with particular care. They should certainly not be subject to virtually automatic closure, as has evidently been the case in the past.

Cases Dealt with under the Chapter XV Procedures

19.234 The Inquiry requested papers in the last five cases before 30th September 2003 where Dr Korlipara had dealt with the case under the Chapter XV procedures. These case files, when examined, showed, first, that the caseworkers concerned were expressing appropriate and tenable views about the cases in question. Four of Dr Korlipara's decisions seemed to me to be reasonable, at least so long as the allegation was considered in isolation; the allegation, standing alone, could not arguably have constituted SPM. In two of the four cases, the doctor had failed to explain his diagnosis and treatment to the patient; in each case, he was advised to do so in the future. In a third case, the doctor had failed to 'write up' the patient's need for pain relief; as a result, the patient was left in pain for some hours. The doctor was reminded of the guidance on making an adequate assessment of a patient's condition and the need to keep a careful record of treatment. In the fourth case, the doctor was advised to be more polite to patients.

19.235 However, because it has not been the GMC's practice to make local enquiries about any other complaints against or concerns about the doctor, there remains some uncertainty in my mind as to whether it was appropriate to close these four cases with a letter of advice. For example, in the fourth case, KF 04, the complainant had alleged that the doctor had changed his medication without explaining that he was doing so or why. The new

medication had given rise to a number of unpleasant side effects. Having read the medical notes, Dr Korlipara thought that the change in medication was not unreasonable and felt that a failure to give a sufficient explanation could not amount to SPM. Standing alone, that decision seems reasonable. However, it seems to me that, for the proper protection of patients, some enquiry should have been made of the PCT to ascertain whether there were any concerns about the doctor's practice. It is possible that the PCT would have been aware of other concerns which, taken with this one (of which it might well have been unaware), could have raised a question of SDP.

19.236 In one of these five cases, KF 03, I feel some concern about the fact that the case was closed. The complaint came from an employee of an insurance company. The insurance company had received a claim under a policy on the life of one of Dr KF 03's patients who had recently died. Because the deceased's family would not agree to the disclosure of the deceased patient's medical records, Dr KF 03 had been asked to provide a medical report to the insurance company. In his report, the doctor described the deceased's medical history, as taken from the records. The description included a reference to an admission to hospital in the late 1990s following a drug overdose, and reference to the deceased's addiction to diazepam which, it was said, had been heavy since a few years earlier when he had lost his job. It appears that either of these two references would have entitled the insurance company to avoid the policy. In respect of the drug overdose, Dr KF 03 was asked by the insurance company if he could say what drug had been taken. He replied that in fact this had been an **'overdose'** of alcohol. He apologised for his earlier **'error'** but did not explain why he had made that error or why he was now able to correct it. It is clear from his letter that he had spoken to members of the family about the circumstances of the **'overdose'** since providing his original report. The letter of correction did not explain what information he was now relying on. The doctor did not refer to the hospital discharge letter which would have been written very shortly after the overdose. One would expect such a letter to specify the nature of the substance taken. Some months later, the doctor wrote to the insurance company again, volunteering the information that there had been another mistake in his original report. The deceased had apparently not been heavily addicted to diazepam until a year later than the doctor had previously reported, when he lost his job. The doctor apologised again. Again, he did not explain how he had come to make the earlier error or why he was now able to correct it. He did not make any reference to the medical records. The insurance company took the view that the doctor had acted dishonestly (by seeking to support the relatives' claim under the policy) or, at the very least, had been very careless when writing his initial report.

19.237 When the GMC notified the doctor about the complaint, his medical defence organisation wrote denying any intent on the doctor's part to deceive. The GMC caseworker was concerned about the allegations of fraud, which, if proved, would plainly be serious. He pointed out to the medical screener that the GMC had been unable to examine the deceased patient's records. The caseworker noted a conflict between the allegation and the doctor's denial. Dr Korlipara took the view that it was not for the GMC to investigate the possibility of fraud; that was for the police. The insurance company had decided not to report the case to the police. It had decided to refuse to pay out under the policy. However, it appears that there were other grounds for the insurance company to take this course,

which did not depend on the truth of the doctor's 'corrections'. Dr Korlipara decided to deal with the case on the basis that there was no evidence of fraud and that the doctor should be advised to be more careful in future when writing such reports. I can see that there was no direct evidence of fraud but there was a real suspicion of it and that should have been a matter of concern to the GMC. Many organisations, not only insurance companies, have to rely on the probity of medical reports and the GMC claims that it takes allegations of dishonesty very seriously. In my view, the GMC should be concerned when presented with evidence of something as suspicious as this. It seems to me that the attitude of the GMC to such a case should be to discuss ways and means to investigate the truth of the matter. It is not sufficient in my view simply to say that the case should be closed. I think this case should have been sent to the PPC for discussion about how best to proceed. Legal advice would have been required as to the possibility of obtaining the medical records, which might well have disclosed the truth of the matter. This case – and others to which I refer – seems to me to demonstrate a lack of determination on the part of the GMC to get at the truth. In general, it seems to have had a preference for leaving others to investigate and, if there was no one else prepared to do so, was content to leave even a potentially serious case uninvestigated.

Dr Korlipara's Screening Decisions

19.238 The Inquiry asked for disclosure of the papers in the last ten cases closed by Dr Korlipara before 30th September 2003. None of these cases gave rise to serious concern. However, it seems to me that, in the interests of patient protection, enquiries should have been made locally in some of those cases, in order to ascertain whether there were any other concerns of a similar or related nature about the doctor's practice or performance. An example is the case of Dr KE 10.

Dr KE 10

19.239 In the case of Dr KE 10, to which I refer in Chapter 18, it was alleged that the doctor had failed to diagnose the patient's terminal condition and had failed to provide her with adequate pain relief. In particular, it was said that the doctor had relied too heavily on telephone consultations instead of visits. The complaint had been pursued locally and an IRP had made a number of criticisms of the doctor, none of which would have amounted to SPM. However, if there had been other complaints or concerns about this doctor, it is possible that an issue of SDP would have arisen. To find that out, it would have been necessary to make local enquiries. In any event, it would seem to me to be appropriate for the GMC to find out what, if anything, the local PCT was doing about the criticisms made in the IRP report. In cases like this, I think that the GMC should have taken a more active role in the protection of patients, instead of simply closing the case because, standing alone, the allegations did not, in its view, amount to SPM or SDP. The GMC's attitude was that there was no need to intervene because the PCT was under a duty to act upon the IRP report and the GMC was entitled to assume that that had happened. I do not think that the GMC could reasonably have had confidence that the PCT would have taken action. A telephone call from the GMC enquiring what was known about the doctor and what steps had been taken in the light of the IRP report would have had three beneficial effects. First,

it would have enabled the GMC to satisfy itself whether there was a history of complaints or concerns which might suggest SDP. Second, if the PCT had not done anything about the IRP report, the call from the GMC would probably have had a salutary effect. Third, if the PCT had taken appropriate steps, the GMC could have told the complainant that, although it was not going to take action itself, it had satisfied itself that the PCT had matters in hand. It does not enhance the public perception of the GMC if it takes no action at all in a case in which another body, such as an IRP, has found grounds for criticism.

Dr JA 40

19.240 In addition to the ten cases mentioned in which the papers had been supplied pursuant to a specific request, the Inquiry came across another case, that of Dr JA 40, in which Dr Korlipara had screened out a complaint. The Inquiry first saw papers relating to this doctor because he had been convicted of drugs offences in the early 1980s. At that time, his case was dealt with at the GMC by the PPC, which closed the matter with a warning letter recommending continued medical supervision. A complaint against Dr JA 40 was received in the late 1990s, relating to his alleged failure to appreciate the severity of the condition of a small baby and to admit him immediately to hospital. At the time, the doctor was working for a deputising service. In essence, the mother complained that the doctor had been called out and had examined the baby who, according to the mother, was obviously ill; his breathing was abnormal. The doctor had said that there was nothing seriously amiss, that the baby had a 'sniffle' and had advised taking the baby to the GP in the morning. The mother had insisted that the baby must go to hospital and, somewhat reluctantly, the doctor had agreed and arrangements had been made for his admission. The mother said that, because the doctor had been so reassuring, she had decided that she would take the baby to hospital after she had made arrangements for the care of her other child. When the baby was admitted to hospital, about two hours later, he was found to be very seriously ill. Fortunately, he made a full recovery.

19.241 The doctor gave a different account of the consultation. He said that, on first receiving notice of the mother's concern about the baby, he had advised that she should be told to take the child to the local Accident and Emergency Department. He claimed that he believed that that was to be done. (The mother completely denied that.) He said that he nonetheless went to the house and found that the mother had waited for his arrival. After examining the baby, he agreed with the mother that the baby should be admitted to hospital. He did not make a definite diagnosis but he did not think that there was any emergency. He arranged admission and offered the mother an ambulance but she said that she wished to make childcare arrangements and would take the baby to hospital herself. He claimed that the baby's condition did not deteriorate severely until later. The mother agreed that the baby's condition had deteriorated further after the doctor's departure.

19.242 Dr Korlipara decided that the case should be closed because, he said, the doctor had acted reasonably and competently. He said that it was clear that the baby's condition had deteriorated after the doctor had left. In evidence to the Inquiry, when it was put to him that he had gone beyond his real function as a screener and had resolved the dispute between the complainant and the doctor, he said that there was a sufficient basis of undisputed

evidence to exonerate the doctor from criticism. In my view, there was not. Quite apart from the dispute about whether the doctor did in fact advise that the mother should be told to take the child to hospital even before he had visited, there was a further dispute as to whether the doctor had realised that the child was ill. If he had not, and if the child was admitted to hospital only because the mother had insisted, that might well amount to a serious failure or error of judgement on the doctor's part. In my view, Dr Korlipara resolved the conflict of evidence in the doctor's favour. He ought to have asked himself whether the allegation, if true, might amount to SPM. The case should have gone through to the PPC. This is another example of a medical screener going beyond his/her proper remit.

19.243 In this case too, as in several others, the GMC should have made local enquiries. On the file, there is an indication (as there was in the case of Dr KE 03) that the deputising service was not prepared to continue to employ the doctor. It should have been asked why. It might have taken that view because it was seriously concerned about the doctor's handling of this particular case; it might have had more general concerns about him. In the interests of patient protection, the GMC should have found out.

The Lay Screeners

19.244 Before describing a further group of cases examined by the Inquiry, i.e. those involving lay screeners, it may be helpful if I say a little more about the lay screeners' role. Screening by lay members of the GMC was introduced in 1990. The November 2002 Screeners' Handbook described their role thus:

> **'Their role is to ensure that the medical screeners, in judging doctors' behaviour against the values and standards of the profession, do not accept a lower standard than would be acceptable to society at large. The profession, through the medical screeners, regulates itself, but needs the confirmation of the public – in the shape of the lay screeners – that appropriate and generally acceptable standards are being applied.'**

19.245 Lay screeners are not required to participate in the screening of every case. Instead, they are involved only in those cases where the medical screener has decided that the case should not proceed further. As I have explained at paragraph 19.31, lay members were also involved in the 'old' Chapter XV procedures which were in operation until 1999.

The Statutory Provision

19.246 By the General Medical Council Preliminary Proceedings Committee and Professional Conduct Committee (Procedure) (Amendment) Rules 1990, rule 10(2) of the 1988 Professional Conduct Rules was amended to read:

> **'Subject to the foregoing rules** (*including rule 6(3)*) **and to paragraph (4)** (*which related to notification of a complainant, an informant and the doctor*) **the President** (*i.e. the medical screener*) **may direct the Registrar to refer any case relating to conduct to the Preliminary Proceedings Committee ... Provided that the President shall not decide not to refer a complaint to**

the Preliminary Proceedings Committee except with the concurrence of the lay member appointed under rule 4(5) (*i.e. the lay screener*)**.'**

The Nature and Extent of the Involvement of Lay Screeners

19.247 The 1996 PSI Report described the involvement of the lay screeners. In a case where a medical screener had decided that the case need not proceed further, the papers in the case, including the medical screener's comments, were passed to the lay screener. As I have said, the medical screener's comments might have been confined to a single word, indicating agreement with the contents of the memorandum on the case written by the GMC staff. They might have been more extensive. The lay screener would then confirm the decision of the medical screener or indicate his/her disagreement with it. If the lay screener disagreed with a decision, there would usually be a discussion between the two screeners. The lay screener might accept the medical screener's views and agree that the case should be closed. He or she might ask for further information to be obtained before a final decision was taken. The lay screener might (prior to 1999) suggest that the 'old' Chapter XV procedures should be invoked, as an alternative to closing the case immediately. If, however, after discussion, the lay screener remained of the view that the case should be referred to the PPC, this would be done.

19.248 There were limitations on the involvement of lay screeners. They played no part in the screening of conviction cases. Nor did the Rules ever require lay screeners to be involved before a decision was taken to remit cases to a health screener as an alternative to referring it to the PPC. Decisions as to whether a case should proceed along the conduct route to the PPC or by means of the voluntary health procedures were very significant. It was true that referral to the voluntary health procedures meant that a case was not being closed by the GMC at that stage. However, the effect of such a referral was to remove the possibility of the doctor's name being erased from the register.

19.249 Moreover, lay screeners have never been involved in cases in which the medical screener or a member of the GMC staff had decided that a complainant should be advised to pursue his/her complaint by means of local complaints procedures. Until 1993, and after March 1999, such decisions were dealt with by GMC staff without the involvement of medical screeners. In Chapter 18, I expressed my view that that practice was not compliant with the provisions of rule 6 of the 1988 Professional Conduct Rules. Between 1993 and 1999, there was a change of policy, whereby cases which might previously have been identified by the GMC staff as suitable to be pursued by means of local complaints procedures were first referred to a medical screener. Even then, however, lay screeners were not involved in the decision to refer such cases back to complainants to be pursued through local procedures. Apparently, this was because such cases were deemed not to be 'closed', but merely to have been deferred with the possibility that they might at some point be referred back into the GMC procedures. Thus, the thinking must have been that the medical screener had not made a substantive decision not to refer the complaint to the PPC. To all intents and purposes, however, cases that were referred back to be pursued through local procedures were 'closed', since no steps were taken to follow up their progress. Only if the complainant or a NHS body chose to refer them back to the GMC

would they be reconsidered. It seems to me that the failure to seek the concurrence of the lay screener in such cases was probably a breach of rule 10(2).

The 2000 Policy Studies Institute Report

19.250 In 2000, Professor Allen and her colleagues analysed the data contained on 792 SDFs completed during the second six months of 1999. Lay screeners were required to state on the SDF whether they agreed with the medical screener's decision. If they did not, they were required to give their reasons. The PSI team found that lay screeners had agreed with the medical screener's decision in almost 98% of the 423 cases in which a lay screener had been involved. Lay screeners had disagreed with the medical screener in only ten cases. At the time, four lay screeners carried out most of the work. The interventions of one of the four had accounted for half of those ten cases.

19.251 In August 2000, when the screening test was changed (see paragraph 19.120), the amended rule made it clear that a medical screener must refer to the PPC every case submitted to him/her unless s/he decided (and the lay screener agreed) that a question as to whether the doctor's conduct constituted SPM did not arise. The exceptions to this general rule were when a complainant who was a private individual had failed to provide a statutory declaration, and where a case was referred by the medical screener into the health procedures. By that time, GMC staff (not screeners) were responsible for making the decision to advise complainants to refer cases to local complaints procedures.

A Change in the Statutory Provision

19.252 In November 2002, when the screening test was changed again, a new rule 6(3A), dealing with the role of the lay screener, was introduced into the 1988 Professional Conduct Rules:

> **'The medical screener shall seek the advice of a lay member appointed under rule 4(5) in relation to any case submitted to him under paragraph (1) which he does not propose to refer to the Preliminary Proceedings Committee, and he shall direct that no further action be taken in the case only if the lay member so consulted agrees.'**

The effect of this change appeared to be that there would be consultation before the decision was made, rather than the medical screener making the decision first and the lay screener agreeing or disagreeing with it. It seemed to imply that the medical screener would make direct contact with the lay screener when s/he was proposing to make a decision to close a case. However, as I shall explain below, that does not appear to have happened in all cases.

The Evidence of Dr Arun Midha

19.253 The Inquiry heard evidence from Dr Midha, who has been a member of the GMC since November 2000 and was a lay screener from July 2001. Dr Midha explained that he dealt with the screening of cases in his spare time, in the evenings and at weekends. He applied the same test as did the medical screeners. He said that his practice was not to discuss the case with the medical screener before making his decision; lay screeners were given

the opportunity to speak to medical screeners before making a decision, but he did not choose to do so. He first considered the memorandum written by the caseworker and he used that to guide him through the file. Having identified the principal allegations and issues and the relevant evidence, he would then read the medical screener's recommendations. He would then make his decision. If he required an expert opinion, he would request that a report be obtained. If he had doubts about whether a case should be referred to the PPC, he would err on the side of caution and refer it. If he disagreed with the recommendation of the medical screener, he would communicate this fact to the caseworker by telephone or email. He would also communicate with the medical screener by email or ask the caseworker to contact the medical screener to inform him/her that the case would have to go forward to the PPC. He would provide reasons for his decision. He would do this as a matter of courtesy. However, he would not discuss his decision with the medical screener. This practice is rather different from that observed by the PSI team and described in their 2000 Report. It is also rather different from that apparently envisaged by rule 6(3A) of the 1988 Professional Conduct Rules.

19.254 In his witness statement, Dr Midha said that the most usual reason for disagreement with the medical screener concerned differences in judgement on whether an allegation was sufficiently serious to reach the threshold of seriousness in the screening test for SPM or SDP. In the past, medical and lay screeners worked in teams, with the same medical and lay screeners adjudicating on the same cases. By December 2003, however, distribution to the lay screeners was random so Dr Midha saw cases from all the medical screeners. He said that he had observed a 'slight variance' in the way that different medical screeners perceived what was and was not 'serious'. However, he felt that it would be difficult to set identifiable thresholds of seriousness. He did, however, acknowledge that guidelines identifying features that would aggravate or mitigate seriousness might be of value.

19.255 Dr Midha felt that the screening process had its limitations. Under the old system, as it was in December 2003, screeners had limited information on which to make decisions in some cases. He thought that there needed to be 'much more opportunity to investigate, to get much more in-depth information'. He recognised that there could be 'opportunities missed' because of lack of investigation. He hoped that more investigation would be possible under the new FTP procedures.

An Analysis of Recent Screening Decisions

19.256 Mr Marshall, Head of the GMC's Screening Section, had carried out an analysis of screening decisions taken in the 12 months to 30th September 2003. During that time, conduct and performance cases involving 1300 doctors had been screened by the medical screeners. Of those, the cases involving 750 doctors had been referred to a lay screener with a recommendation that the case should be closed. The lay screeners disagreed with the medical screeners in the cases of 50 doctors (i.e. almost 7% of cases dealt with by lay screeners). That is a rather higher incidence of disagreement between medical and lay screeners than had occurred during the six-month period in 1999 that was analysed by the PSI team: see paragraph 19.250. It suggests that lay screeners were more willing to disagree with the views of medical screeners in the period from 2002 to 2003 than had been the case in 1999.

Cases Considered by the Inquiry

19.257 The Inquiry requested that the GMC provide the papers in the last five cases before 30th September 2003 in which a lay screener had disagreed with the decision of a medical screener. In the event, it became clear that the cases provided were not the last five in which that had occurred; they had all been dealt with some time previously. It may be that they were the last five cases where the lay screener had disagreed with the medical screener's decision and where the case had already been dealt with by the PPC.

19.258 The lay screener in four of the five cases was Dr Midha. Four of the five complaints related to allegations of poor treatment and/or substandard practice, which were said to have caused the patients' deaths. All four involved complex medical issues. The fifth case was an allegation of breach of confidentiality. Four cases were subsequently closed by the PPC; the fifth was referred by the PPC to the PCC but the referral was subsequently cancelled. However, in four of the five cases, the PPC was sufficiently concerned to send a letter of advice or a warning letter to at least one of the doctors concerned. It seems to me that, in each case, the lay screener had been right to intervene; there was a real issue for discussion and decision by the PPC. In one, which concerned an allegation against an anaesthetist, the medical screener, who was a GP, wished to close the case without obtaining any independent expert evidence on an issue of anaesthetic practice. He relied on the opinion expressed in the report of an investigation carried out by the hospital employing the anaesthetist. Dr Midha asked for an independent expert report, which expressed a different opinion from that of the hospital report. The case went to the PPC, which, in the event, closed the case. Dr Midha told the Inquiry that he thought it was useful for the PPC to discuss such cases. I agree with him and, in my view, the GMC would not have been doing its job properly if that case had been closed without obtaining an independent expert report and discussing the case fully. It appears to me that there is real value in the role of the lay screener. I have the impression, however, that it must sometimes be difficult for lay screeners to take issue with a medical screener, particularly as there are no standards or criteria by which to judge whether it is arguable that the conduct constitutes SPM.

Conclusions

19.259 As has been seen, the wording of the statutory test underlying the screening process has changed in recent years. However, in practice, the test has not really changed. Screening always was, or should have been, only a preliminary filter, designed to remove from the caseload those complaints which clearly could not give rise to disciplinary action. As I have said, for many years, the test appears to have been wrongly applied. Far more cases have been screened out than should have been. It is impossible to assess how many or what proportion of cases were closed by screeners which ought to have proceeded to the PPC. Of course, the fact that a case ought to have gone to the PPC does not necessarily mean that it should necessarily have gone through to the PCC; it would have been open to the PPC to close it. But screeners and the PPC had different functions and had different tests to apply. I shall consider the work of the PPC in Chapter 20. The point I make here is that there seems to have been an ethos of early closure, which was, in my view, indicative

of an unwillingness to give complaints against doctors the consideration that they deserved. The balance between protecting patients and being fair to doctors was weighted towards the interests of the doctors. In my view, so long as members of the GMC are elected by the profession, there will always be a danger that their 'judicial' decisions will be subconsciously biased towards the interests of their electorate.

19.260 I do not wish to suggest that individual screeners were not conscientious in carrying out their work. I think they were. The problem was that, for many years, they were left to use their own discretion as to how they approached the task. This was to a large extent because of the history of the way in which their role developed. For about 75 years, screening was the sole preserve of the leader of the profession, the President of the GMC. He decided what was and was not acceptable. Even in the 1970s, when the President ceased to hold all three key roles (i.e. medical screener, Chairman of the PeCC and Chairman of the DC), he nominated the screeners and chairmen of the various FTP committees and so could wield his influence vicariously. Until 2004, the President nominated the screeners and the GMC was obliged to appoint them. It seems to me that this association with the President may have inculcated in screeners the feeling that they were in a position to exercise discretion and to make decisions on the basis of their personal views to a far greater extent than the GMC Rules actually allowed them to do. When, as the result of judicial review, it was clear that the screeners had not been applying the Rules, the medical screeners (or some of them at least) were not willing to learn and to change their practice. Also, when the PSI and the GMC agreed on measures which would have produced greater consistency of results, the medical screeners (or some of them) sabotaged the new arrangements. It may be that there was some improvement in the quality and consistency of decision-making in the last year or two of the old FTP procedures. I cannot say. However, it seems to me fortunate that screening as such will disappear under the new procedures. The preliminary filtering process is to be carried out by case examiners, who will not be elected members of the GMC and, it is to be hoped, should not feel under any subconscious pressure to lean towards the protection of doctors. It is to be hoped that there will be a fresh start with clearly defined and commonly understood standards and criteria to be applied at each stage of the process.

19.261 I shall return to the issue of standards and criteria on more than one occasion in this Report. The absence of standards and criteria seems to me to underlie many of the problems faced by the GMC in the past. In each of the PSI Reports, Professor Allen and her colleagues recommended that standards and criteria should be developed, with a hierarchy of seriousness. Only when that was done, she said, would it be possible to achieve consistency and transparency of decision-making. I agree with her completely.

19.262 My other major concern, highlighted by this examination of the screening process, is the failure of the GMC to investigate cases thoroughly before the preliminary decisions are taken and, in particular, to make enquiries of the doctor's employer or PCT. I noted in Chapter 18 that Dr Korlipara expressed the view that it was not part of the GMC's function to try to make a case against the doctor. In my view, there is a world of difference between trying to make a case against a doctor and carrying out a thorough and impartial investigation.

CHAPTER TWENTY

The General Medical Council Conduct Procedures: the Preliminary Proceedings Committee

Introduction

20.1 From 1951, General Medical Council (GMC) Rules provided for a further filtering process, to take place after that carried out by the screeners, as described in the last Chapter. Under the old fitness to practise (FTP) procedures, all complaints and reports of convictions which survived the filtering processes carried out by the GMC staff and by the screeners had to pass through a third filtering process if they were to be referred for a public disciplinary hearing. Before 1951, this third filtering process was carried out informally. Between 1951 and August 1980, the Penal Cases Committee (PeCC) assumed responsibility for the third filtering process. In August 1980, the Preliminary Proceedings Committee (PPC) replaced the PeCC and carried out the same function. Until 1980, the GMC committee responsible for holding public hearings in disciplinary cases was the Disciplinary Committee (DC). In 1980, the Professional Conduct Committee (PCC) replaced the DC.

20.2 In this Chapter, I shall describe the powers and functions of the PPC. I shall discuss the test applied by the PPC when deciding whether it should or should not refer a case to the PCC, and the guidance that was available to members of the PPC to assist them when making such decisions. I shall consider the evidence about how the PPC operated in practice. In particular, I shall examine some decisions of the PPC which have been the subject of judicial review. I shall also examine the decisions in a number of cases dealt with by the PPC, in respect of which files have been obtained by the Inquiry. I shall consider the light shed on the operation of the PPC by the work undertaken by the Policy Studies Institute (PSI). No complaint relating to Shipman ever reached the PPC. However, the operation of the PPC over the last 24 years is an important indicator of how the GMC conducted its FTP procedures in the past and is, therefore, of relevance to the Inquiry's task of making recommendations for the protection of patients in the future. As in previous Chapters, I shall focus particularly on evidence relating to patient protection.

Witnesses

20.3 Dr Robin Steel was a medical member of the GMC from 1984, an additional medical screener from 1987 and the principal medical screener and Chairman of the PPC between June 1992 and November 1999, when he retired from the GMC. He provided a witness statement but was not well enough to attend to give oral evidence to the Inquiry. Mr Robert Nicholls, a lay member of the GMC and Chairman of the PPC from November 1999 until June 2003, provided a written statement and also gave oral evidence. In addition, the Inquiry heard oral evidence from other witnesses with knowledge of the PPC, including Professor Isobel Allen, Emeritus Professor of Health and Social Policy, University of Westminster PSI. In the course of her research into the conduct procedures, Professor Allen observed 11 meetings of the PPC between June 1999 and January 2000.

The Annual Reports of the Preliminary Proceedings Committee

20.4 From 1981, the PPC was required by GMC Standing Orders to present a report on its activities to the full Council of the GMC at least once a year. By convention, the Annual Reports also covered the activities of the screeners. For many years, the Reports contained information (sometimes very detailed) about the numbers and types of complaints received by the GMC and about the outcome of those complaints at the pre-screening, screening and PPC stages. The Annual Reports also gave information about recent changes in practice and procedure. They provide a very useful source of information about the early stages of the GMC conduct procedures during the 1980s and the early 1990s.

20.5 During the late 1990s, the form of the PPC's Annual Reports changed. They contained less information about practice, procedures and outcomes for specific types of case. Instead, they became more concerned with statistical information. After 2001, the Annual Report of the PPC was subsumed into a document containing statistics for the conduct, health and performance procedures (the annual FTP statistics). The same annual FTP statistics also contain data about performance against service standards.

20.6 The Annual Reports did not contain reference to, or discussion of, any standards, criteria or tests being applied by staff, screeners or the members of the PPC when making decisions about the disposal of a case.

The Composition of the Preliminary Proceedings Committee

20.7 The composition of the PPC was governed successively by the General Medical Council (Constitution of Fitness to Practise Committees) Rules Order of Council 1980, 1986 and 1996 (the Constitution Rules). Between 1980 and 1996, the PPC was composed of the Chairman, eight medical members and two lay members of the GMC (i.e. 11 members in all). With the exception of the President of the GMC, members were not permitted to sit concurrently on more than one of the GMC's FTP committees (i.e., at that time, the PPC, the PCC and the Health Committee (HC)).

20.8 Until 2000, the Constitution Rules provided that the President (or the medical member nominated by him and appointed by the Council to act as medical screener in his place) should chair the PPC. In practice, save for a period between 1984 and 1989, when the President acted as medical screener and chaired the PPC, the PPC was chaired by the medical screener appointed in the President's place. That medical screener came to be known as the 'principal' medical screener to distinguish him/her from the additional medical screeners who were appointed to assist in the screening process.

20.9 Other members of the PPC were elected by the Council annually. As more medical screeners (and, from 1990, lay screeners) were appointed, it was usual for at least some of them also to be members of the PPC. Medical and lay screeners who were not elected members of the PPC were nevertheless invited to attend meetings of the PPC as observers. Although they had no vote, they might be called upon to address the PPC in relation to cases that they had screened. The legal quorum of the PPC was five.

20.10 The medical member of the GMC appointed to screen cases which raised a question whether a doctor's fitness to practise was seriously impaired by reason of his/her physical or mental condition was known as the health screener. By 1984, it was established practice for the health screener, if s/he was not an elected member of the PPC, to attend PPC meetings in order to advise upon cases where the health of a doctor was in issue. In 1986, the Constitution Rules were amended to provide that the health screener should automatically become a member of the PPC unless s/he had already been elected as such.

20.11 In 1994, the Constitution Rules were further amended to provide for the situation where fewer than five members were available to attend a meeting of the PPC, so that a legal quorum could not be achieved. The President was given the power to appoint temporarily to the PPC any member of the GMC who would have been eligible to stand for election to the PPC. In 1996, membership of the PPC was reduced from 11 (including the Chairman) to seven, although the quorum remained five. Five members of the PPC were to be medical members and two were to be lay members. The Constitution Rules continued to provide that the PPC should be chaired by the President or, if he chose not to act in that capacity, by the medical screener appointed in his place. If the Chairman of the PPC was not available to chair a meeting, the President had the power to appoint another member of the PPC to act as Chairman.

20.12 From 1996, the Constitution Rules no longer obliged the health screener to be a member of the PPC. However, notes produced by the GMC in June 1997 for the use of new members of the PPC indicated that, in practice, the principal health screener was treated as an *ex officio* member of the PPC. The second health screener attended meetings as an observer. The legal quorum continued to be five, to include at least one lay member. As the workload of the PPC increased, further GMC members were co-opted to sit on the PPC, using the power which had been conferred on the President in 1994. In addition, 'observer' screeners were sometimes called upon to deputise for members of the PPC who were absent, so as to ensure that there was a legal quorum.

20.13 In November 1999, the GMC decided, in anticipation of the coming into force in October 2000 of the Human Rights Act 1998, that the functions of the screeners and of the PPC should be separated. From November 1999, screeners (medical, health and lay) were no longer eligible for election to the PPC. Medical and lay screeners no longer attended meetings as observers. The Chairman of the PPC was to be the President or, if he chose not to act in that capacity, some other GMC member appointed by him. Mr Nicholls, a former lay screener, became acting Chairman of the PPC in November 1999. His appointment was confirmed in January 2000. In August 2000, the Constitution Rules were amended to reflect the changes which had already been put in place. Although the health screeners were no longer eligible for election to the PPC, at least one of them continued to attend meetings of the PPC whenever possible, to offer advice in cases where the health of a doctor was in issue. The health screeners had no vote.

20.14 As I have explained in Chapter 15, in 2000, the GMC was given the power to co-opt non-GMC members, both medical and lay, to sit on its FTP committees. A pool of such persons, who were known first as 'adjudicators', then as 'associates', was soon recruited.

Also in 2000, the Constitution Rules were further amended to give the President power (subject to the approval of the Council) to appoint a member of the PPC as Deputy Chairman, to perform the duties of Chairman in the Chairman's absence. This power, together with the power to co-opt onto the PPC other members of the GMC and associates, made it possible for differently constituted panels of the PPC to sit far more frequently than would have been feasible when it had a small static membership. In November 2002, the quorum of the PPC was reduced to three, to include one medical and one lay member.

Meetings of the Preliminary Proceedings Committee

20.15 The PPC met in private and considered only documentary evidence and written submissions. Neither the complainant nor the doctor was invited to attend its meetings. An exception to that general rule existed between 1980 and 2000, during which period the PPC had the power to suspend or impose conditions on a doctor's registration pending his/her appearance before the PCC or the HC. In such cases, the doctor would be notified in advance if the PPC was considering making an interim order. He or she (and/or his/her representative) was then entitled to attend the meeting at which his/her case was considered and to make representations on whether or not an interim order should be made.

20.16 From its inception in 1980, the PPC was always advised during its meetings by a legal assessor, who was appointed by the GMC and had to be a barrister, advocate or solicitor of at least ten years' standing. In practice, the role was usually filled by a junior barrister with significantly more than ten years in practice, by a Queen's Counsel or by a retired judge. It was the duty of the legal assessor to advise on any questions of law which might be referred to him/her by the PPC. The legal assessor also had a duty to inform the PPC immediately of any irregularity in the conduct of proceedings before the PPC which might come to his/her knowledge and to advise the PPC on his/her own initiative where it appeared to him/her that, but for such advice, there was a possibility of a mistake of law being made. There was no requirement (as was the case with legal advice given by a legal assessor to the PCC) that that advice (and any refusal by the PPC to accept it) should be made known to the doctor or to a complainant. Until the early part of 2000 at least, one or more representatives of the GMC's solicitors also attended meetings of the PPC in an advisory capacity. However, it seems that their attendance was subsequently discontinued. Members of the GMC staff also attended meetings in order to provide secretarial and other administrative support.

The Functions and Powers of the Preliminary Proceedings Committee

20.17 Section 13(2) of the Medical Act 1978 (which came into force in August 1980) defined the functions of the PPC. It stated:

> **'It shall be the duty of the Committee to decide whether any case referred to them for consideration in which a practitioner is alleged to be liable to have his name erased ... or his registration suspended or made subject to conditions ... ought to be referred for inquiry by the Professional Conduct Committee or the Health Committee.'**

This subsection was reproduced in section 42(2) of the Medical Act 1983 and continued unchanged thereafter.

20.18 Rule 11(1) of the General Medical Council Preliminary Proceedings Committee and Professional Conduct Committee (Procedure) Rules Order of Council 1980 (the 1980 Professional Conduct Rules) provided:

> **'Where a case has been referred to the Preliminary Proceedings Committee ... that Committee shall consider the case and, subject to these rules, determine:**
>
> **(a) that the case be referred to the Professional Conduct Committee for inquiry, or**
>
> **(b) that the case shall be referred to the Health Committee for inquiry, or**
>
> **(c) that the case shall not be referred to either Committee.'**

20.19 The 1980 Professional Conduct Rules also gave the PPC the power to adjourn a case for further investigations to be made, or in order to obtain legal advice before making its determination. These provisions were reproduced in the General Medical Council Preliminary Proceedings Committee and Professional Conduct Committee (Procedure) Rules Order of Council 1988 (the 1988 Professional Conduct Rules) and remained virtually unchanged thereafter.

20.20 No criteria were ever stated in the Medical Acts or in the Rules for the guidance of the PPC when deciding whether a case **'ought to be referred'** to the PCC or the HC or to neither. It is to be noted that the wording of rule 6(3) of the 1980 Professional Conduct Rules (later rule 6(3) of the 1988 Professional Conduct Rules) which governed the decisions of screeners was very similar to that of section 13(2) of the Medical Act 1978, later section 42(2) of the Medical Act 1983. Rule 6(3) provided:

> **'Unless it appears to the President** (*i.e. the medical screener*) **that the matter need not proceed further he shall direct the Registrar to write to the practitioner ... stating the matters which appear to raise a question whether the practitioner has committed serious professional misconduct.'**

20.21 As I shall later explain, the similarity between the wording of rule 6(3) and section 42(2) led Professor Allen to conclude that there was no real difference between the two filtering processes carried out by the screeners and the PPC. One decided whether a matter **'need not proceed further'** and the other decided whether it **'ought to be referred'** to the PCC. The distinction appeared to be a fine one.

20.22 At the time of the introduction of the performance procedures in 1997, the PPC was not given the power to refer a case to the Committee on Professional Performance (CPP). Nor was it able to refer a doctor for a performance assessment or for consideration to be given by a medical screener to the possibility of directing such an assessment. That represented a significant gap in the powers of the PPC. Mr Nicholls said that the lack of such powers had 'caused quite a lot of heart searching in the PPC' during his time as Chairman.

The Possible Outcomes of the Consideration of a Case by the Preliminary Proceedings Committee

Referral to the Professional Conduct Committee

20.23 As I have said, the PPC had to decide whether a case **'ought to be referred'** to the PCC. Until 1988, once the PPC had decided that a case ought to be referred to the PCC, rule 11(2) of the 1980 Professional Conduct Rules applied. Rule 11(2) provided:

> **'When referring a case to the Professional Conduct Committee the Preliminary Proceedings Committee shall indicate the convictions, or the matters which in their opinion appear to raise a question whether the practitioner has committed serious professional misconduct, to be so referred.'**

The 1988 Professional Conduct Rules amended rule 11(2) to make clear that the **'convictions'** or **'matters'** indicated by the PPC were those which would form the basis of the charges which the doctor would have to answer at the hearing before the PCC.

Referral to the Health Committee

20.24 The 1980 Professional Conduct Rules provided that, if the PPC was considering referring a case to the HC, it could seek medical evidence about the doctor's condition before taking the decision whether to refer, and could adjourn the case pending receipt of such evidence. Alternatively, the PPC could refer the case to the HC and invite the doctor to undergo medical examination(s) before the case came before the HC. When referring a doctor to the HC, the PPC was required to indicate the nature of the physical or mental condition(s) that made it appear to the PPC that the doctor's fitness to practise might be seriously impaired.

20.25 If the PPC referred a case to the HC and the referral proved inappropriate for some reason (e.g. because, on examination, no health problem was identified), the HC had no jurisdiction to act, nor any power to send the case back to the PPC. In those circumstances, the GMC would be powerless to act. This was a *lacuna* in its powers which was never remedied. In practice, however – no doubt because members of the PPC were aware of the potential problem – very few cases were referred by the PPC direct to the HC. The Inquiry was told that, on the rare occasions when a case was referred to the HC, medical evidence would invariably have been obtained before the referral was made.

Adjournment for Further Investigation

The Use of the Power to Adjourn in Conduct and Conviction Cases

20.26 It does not appear that the PPC's power to adjourn for further investigations was used frequently for the purpose of instituting investigations about substantive issues relating to the conviction or conduct under consideration. This is surprising given that the amount of

evidence put before the PPC seems, in most cases, to have been the same evidence as was put before the screener. The amount of evidence required for the screening decision was said to be 'minimal'. I infer therefore that, in many cases, the amount of evidence put before the PPC will also have been minimal. The practice was that the PPC reached a decision to send a case to the PCC 'for inquiry' and formulated the charges that the doctor was to face on the basis of quite limited evidence. The file was then referred to the GMC's solicitors to be prepared for the hearing; this process would sometimes involve evidence gathering. As Mr Finlay Scott, Chief Executive of the GMC, told the Inquiry, this involved 'putting the cart before the horse'. The adverse consequences of late investigation are obvious. First, some cases were probably not referred to the PCC because their seriousness had not been fully appreciated and/or because the PPC had the impression that the evidence available would not be adequate. Second, it sometimes transpired that the evidence that was eventually gathered by the solicitors did not adequately support the charges that had already been formulated. This resulted in the dropping of some, or even all, of the charges against the doctor. On the other hand, the evidence collected might disclose that the allegations were rather more serious than had been thought and that the charges required amendment. Ideally, investigation should take place at an early stage. But, if it had not taken place at the very outset, it should, I would have thought, at least have taken place before the PPC reached its decision.

Adjournment in Health Cases

20.27 It was not uncommon for the PPC to adjourn a case in order to initiate investigations into a doctor's health. There was a good reason for this.

20.28 If, at the screening stage, the medical screener did not refer the doctor to the PPC, but instead remitted the case to the health screener, the doctor might then be invited to agree to undergo medical examinations. If, as a result of those examinations, it appeared appropriate to the health screener, the doctor could be invited to enter into voluntary undertakings as to his/her future conduct and as to any restrictions on his/her practice that the health screener might deem necessary. The process of dealing with doctors by means of voluntary undertakings became known as the 'voluntary health procedures'. I shall explain their operation in Chapter 22. Provided that the doctor complied with his/her undertakings (and that his/her health did not deteriorate), s/he would not be required to attend a formal hearing and would not be at risk of suspension, which was the most serious sanction available in a 'health case'.

20.29 By contrast, if a doctor was referred by the PPC to the HC, the voluntary health procedures were not available. The doctor would be subjected to a hearing before the HC that, although not held in public, was nevertheless formal in nature. He or she would, in theory at least, be at risk of suspension. Thus, a doctor who was referred by the PPC to the HC was in a disadvantaged position when compared with a doctor whose case had been remitted to the health screener by a medical screener. Recognising the potential unfairness of this, the PPC was concerned to prevent doctors from being disadvantaged in this way. Thus, in a case where it was considered that a doctor's fitness to practise might be impaired through ill health, the PPC would use its power to adjourn the case for further investigation. It would then remit the case to the health

screener. The health screener would arrange for the doctor to be medically examined and, depending on the contents of the examination reports, would assess the doctor's suitability to be dealt with by means of the voluntary health procedures. If the doctor was considered suitable to be dealt with under the voluntary health procedures, the PPC would adjourn the case *sine die* to allow this to be done. If the doctor proved for some reason unsuitable to be dealt with under the voluntary health procedures (perhaps because no health problem was found or because s/he refused to enter into voluntary undertakings), the health screener would refer the case back to the PPC. The PPC was then able to consider the case again and decide how to deal with it. The options of referring the case to the PCC or to the HC were still open to it. This facility – whereby a case could be referred by the PPC to the health screener who could, if necessary, pass it back to the PPC – made it preferable for the PPC (save in very rare cases) to use its power to adjourn for investigation rather than referring the case to the HC.

20.30 I have said that, when a case was remitted to the health screener and was dealt with by means of the voluntary health procedures, the PPC would adjourn the case *sine die*. The Annual Report of the PPC presented to the Council in November 1985 indicated that, rather than leaving an adjourned case 'in limbo', a practice had by that time been developed whereby, at some later stage, the PPC would receive medical evidence and, if it thought fit, would then close the case. Mr Nicholls told the Inquiry that, between September 1999 and May 2002, when he was on the PPC, it would receive regular reports on cases that had been adjourned *sine die* to the voluntary health procedures. This enabled cases to be formally closed by the PPC. In order to comply with the 1988 Professional Conduct Rules, formal closure by the PPC was necessary if a case was not to be referred to the PCC or the HC. However, Mr Nicholls said that, from May 2002, there was a period of about nine months when reports on cases which had been adjourned *sine die* were not made to the PPC. Although Mr Nicholls was confident that the 'loose ends' were being 'perfectly well tied up' by the Health Section during that time, the PPC did not know the outcome of the adjourned cases and Mr Nicholls said that this was something he regretted. The practice of regular reporting to the PPC was, he said, subsequently reintroduced.

Decision Not to Refer

20.31 If the PPC decided not to refer a doctor to the PCC or to the HC, the Registrar (or the GMC staff exercising his legal powers) was required to inform both the doctor and the complainant (if any) of the decision in such terms as the PPC might direct.

Warning Letters

20.32 This provision was used on occasion to send a warning letter to a doctor, advising him/her about his/her future conduct. Initially, warning letters were sent mainly in conviction cases, many of them drink driving cases. A few warning letters were sent in cases involving allegations of serious professional misconduct (SPM). They were not used in cases where the facts giving rise to the complaint were disputed. In such cases, there

would be no proven misconduct about which the doctor could be warned. Warning letters were used, therefore, only in cases where the doctor had admitted the allegations in whole or in part, or where the facts were proved or were beyond dispute. Over time, a hierarchy of different warning letters (termed 'mild', 'standard' and 'strong' or 'severe') developed. They were used extensively.

Cautionary Letters and Letters of Advice

20.33 In a case where the PPC had concerns about the doctor's conduct but did not feel it appropriate to refer the case to the PCC and where there was no proof or admission of misconduct, the practice grew up of sending a 'cautionary letter' or a 'letter of advice'. In the past, it appears that the two types of letter were rather different. A cautionary letter would inform the doctor that the papers relating to the complaint would be kept in the GMC's records and would be looked into if the doctor were to be the subject of a similar complaint in the future. It would also advise the doctor as to his/her future conduct. Letters of advice merely made recommendations to the doctor about his/her future conduct. They often contained references to the publication 'Good Medical Practice' (after 1995), or to other GMC guidance. The Inquiry was told that, in recent years, the sending of cautionary letters had been discontinued. However, the PPC continued to send letters of advice in a large number of cases. In 2002, the PPC considered the cases of 546 doctors; it sent 234 letters of warning or advice. In 2003, the PPC sent letters of warning or advice to 185 of the 418 doctors whose cases it considered.

20.34 Mr Nicholls said that the increase in the number of letters of advice sent by the PPC reflected a greater appreciation by the GMC of its overall duty to attempt to raise standards of care generally. Instead of confining itself to the narrow range of very serious cases in which a doctor's registration was in issue, there was a desire to take some action in less serious cases where there had been a departure from 'Good Medical Practice'. This in itself is a laudable aim. However, I am uncertain how much can be achieved by the sending of a letter of advice in a case where the allegation has not been investigated and the doctor has not admitted any shortcoming.

The Treatment of Further Convictions or Allegations of Misconduct

20.35 Rule 14 of the 1980 Professional Conduct Rules dealt with conviction cases in which the PPC had decided not to make a referral either to the PCC or to the HC, or in which the medical screener had decided not to refer the case to the PPC. If the GMC were subsequently to receive notice of another conviction or a complaint of misconduct concerning the same doctor, it was open to the President (or the medical screener appointed in his place) to direct that the earlier conviction should be referred to the PPC, together with the subsequent conviction or complaint. In that event, the earlier conviction would be dealt with afresh, as if the PPC or medical screener had not made the earlier decision, and the PPC might refer it to the PCC or to the HC. It was in the context of the forerunner of this rule that Shipman was warned in 1976 that any repetition of his misconduct was likely to result in the reconsideration of his convictions for drug-related offences.

20.36 In 1988, the rule was amended so as to apply also to cases where the original matter considered by the PPC or the medical screener had been a complaint about a doctor's conduct, rather than a conviction. However, in such cases (but not where the original matter had been a conviction), the rule applied only if the subsequent complaint was notified within two years of the PPC's or screener's decision in the earlier matter. In 2000, the rule was changed again so as to apply the two-year limit to convictions, as well as to conduct cases. It appears to me that the two-year limit on the power to resurrect a closed case might not have provided adequate protection for patients. If, for example, Shipman had been convicted of further drugs offences (or had been found to have been abusing drugs) three – or even five – years after the case against him had been closed with a warning, I do not think it would have been satisfactory for the GMC to have dealt with him without being able to take account of the fact that the later problem represented a relapse into old habits.

20.37 At one time, as I have explained, the letters sent by the PPC sometimes warned the doctor that, although the PPC had decided not to refer the complaint to the PCC on the occasion in question, the complaint might be resurrected if the GMC received a further complaint or report about the doctor within two years. Mr Nicholls said that this was 'very unpopular'. The view was that the two-year limit was in the Rules, so that there was no need to refer to it when writing to doctors and, in any event, nothing had been proved against the doctor concerned. Because of its unpopularity, the practice of including the 'resurrection clause' in letters was discontinued. Mr Nicholls told the Inquiry that the intention of a letter of advice was to tell the doctor to 'watch it'. He did not think that putting an 'artificial time' on the advice added anything. I can see that to put an 'artificial time' on the advice would not be sensible. However, the time was not artificial; it was a provision of the Rules. If, within a specified period, a doctor was at risk that a closed case might be resurrected, s/he ought to have been told not only of the risk but also of the period for which the risk would persist. It cannot be assumed that all doctors are familiar with the small print of the GMC's Rules. I would have thought that any doctor who was not warned of the risk that a closed case might be resurrected would have had an argument for opposing its resurrection.

Interim Orders

The Position before 2000

20.38 Section 13(3) of the Medical Act 1978 and rule 12 of the 1980 Professional Conduct Rules gave the PPC the power to make an interim order suspending a doctor's registration or making his/her registration conditional on his/her compliance with such requirements as the PPC thought fit to impose for the protection of members of the public or in the doctor's own interests. Such an order could be made only after the PPC had decided that a case should be referred to the PCC or to the HC. An interim order had to be imposed for a specified period not exceeding two months. The PPC was given no power to renew the order after that period. Notice had to be given to the doctor that the PPC was considering making such an order and s/he had to be given the opportunity to be heard. Between 1980 and 1996, very little use was made by the PPC of its interim powers. Only four interim orders were made. The small number of such orders made seems very surprising. One would have expected that, over a period of 16 years, there would have been quite a lot of

cases in which an interim order would have been needed for the protection of patients. I can see that the short period for which such an order could operate might have been less than satisfactory, but an order for two months would seem to be better than nothing. If an interim order had been made, the PCC could have been asked to expedite its hearing. However, it appears from the PPC's Annual Reports that the PPC saw little need to make interim orders.

20.39 In 1996, the maximum period for which an interim order could be imposed was increased to six months and the PPC was given power to renew the order for up to three months. Thereafter, the use made by the PPC of the power to impose interim orders increased markedly. Five interim orders for suspension were made (in respect of three doctors) in 1997. Nine new interim suspension orders were made in 1998, together with one order imposing interim conditions and several renewed orders. In 1999, the number of new interim suspensions rose to thirteen, with nine new orders imposing interim conditions being made.

20.40 In the period from January until August 2000, the PPC made 17 new orders for the suspension of doctors' registration, together with 15 new orders imposing interim conditions. In August 2000, the power to impose interim orders was removed from the PPC and given to the newly created Interim Orders Committee (IOC). After that, if it appeared to the PPC that the circumstances were such that the IOC might wish to make an interim order, whether for the suspension of registration or for the imposition of conditions on registration, the PPC was required to refer the case to the IOC.

The Circumstances Leading to the Creation of the Interim Orders Committee

20.41 The IOC was created as the direct result of the GMC's inability to suspend Shipman's registration when it was informed, in August 1998, by the Greater Manchester Police (GMP), that he was under investigation for murder.

20.42 The second (and successful) police investigation into the deaths of Shipman's patients began in late July 1998. The first death to be investigated was that of Mrs Kathleen Grundy. On 10th August 1998, the GMP learned for the first time that Shipman had convictions for offences involving controlled drugs. Four days later, enquiries were made of the GMC about Shipman. A member of the GMC staff confirmed that Shipman had previous convictions, but declined to give further details, save to say that the case had not proceeded to a disciplinary hearing. Later the same day, the results of the toxicological examination of the body of Mrs Grundy were received by the police. These revealed the presence of an opiate (possibly morphine) in her body tissues.

20.43 At that point, Detective Superintendent (Det Supt, later Detective Chief Superintendent) Bernard Postles, who was leading the police investigation, notified the GMC of the position by telephone and informed a member of staff of the concerns that he had about Shipman continuing in practice. Det Supt Postles was informed that the GMC could do nothing until Shipman had been convicted of a criminal offence. On 18th August 1998, Det Supt Postles wrote to the GMC, setting out details of the ongoing investigation into Mrs Grundy's death and inviting the GMC to take any action it considered appropriate. A member of the GMC staff responded by letter, requesting Det Supt Postles to keep the GMC informed of the

progress of the investigation. It was apparent that no action was to be taken by the GMC and, indeed, its Rules at the time did not permit it to take interim action to suspend a doctor unless and until the doctor had been convicted of a criminal offence or a decision had been taken by the PPC to refer his/her case to the PCC or the HC.

20.44 By this time, it had become clear that Shipman might have killed other patients besides Mrs Grundy. Shipman was still practising and Det Supt Postles was becoming increasingly concerned about the safety of his patients. He was in contact with the West Pennine Health Authority, which was exploring the possibility of taking steps through the NHS Tribunal to suspend Shipman. It was not possible to achieve his suspension quickly by that means. Accordingly, Det Supt Postles decided that the only way to protect Shipman's patients was to arrest him. This was done on 7th September 1998, earlier than Det Supt Postles would have otherwise chosen to act. Shipman was remanded in custody from that time. Eventually, he was suspended from practice by the NHS Tribunal on 15th October. The decision took effect on 29th October. I have recounted in Chapter 7 the sequence of events that led to Shipman's suspension.

20.45 Meanwhile, the police were compiling an antecedent history for Shipman, to be placed before the court. A telephone enquiry was made of the GMC as to whether any disciplinary action had been taken against Shipman as a consequence of his convictions in 1976. A member of the GMC staff replied that the GMC had no documentary record of Shipman's case, but that the most likely course of action would have been for Shipman to have been issued with a warning letter. In fact, as is evident from Chapter 16, the GMC did have a file containing documents relating to Shipman's case in 1976. In January 2000, shortly before Shipman's conviction and in response to a request by Mr Richard Henriques QC (now Mr Justice Henriques), Leading Counsel for the prosecution at Shipman's trial, the GMC provided details from its files about its handling of Shipman's conviction in 1976 and of complaints made to the GMC about Shipman in 1985 and 1994.

20.46 The inability of the GMC to take interim action in Shipman's case was the cause of considerable embarrassment, both to it and to the Government. In November 1998, the GMC's Fitness to Practise Policy Committee (FPPC) considered a paper relating to doctors charged with serious criminal offences. The paper made clear that the problem caused by the inability of the GMC to take interim measures in respect of such doctors was not a new one. The paper observed:

> **'We often become aware of criminal proceedings, involving a doctor, before the matter goes to trial. Typically, a Health Authority or Trust will phone when a doctor is charged. There is frequently an expectation that the doctor's registration will be suspended pending the outcome of the criminal case. We also become aware of cases from press cuttings, or direct from the doctor concerned ...**
>
> **We have to explain that the Medical Act 1983 gives no power to intervene unless and until the doctor has been convicted.'**

20.47 The paper acknowledged that it was impossible to make a reliable assessment of the number of cases in which this problem arose, since the GMC would not necessarily be

aware of all cases where doctors were facing serious criminal charges. It was reported that, at the time the FPPC considered the paper, the GMC was aware of six current cases of this type. Two doctors (one of them Shipman) had been charged with murder and were in custody. Two doctors were known to be on bail and practising; one was charged with multiple offences of indecency against female patients, one with multiple offences of rape and indecent assault. A third doctor, who had been charged with an offence involving an indecent assault on a patient, was on bail and believed to be seeking work. The fourth doctor was on bail and believed to be seeking work; he had been charged with offences of rape, causing grievous bodily harm and making threats to kill. The four doctors who were on bail must have presented a serious risk to patients. The majority of the six doctors were general practitioners (GPs), since primary care organisations (PCOs) experienced more difficulty than hospital trusts in preventing doctors from practising. However, even if a hospital trust suspended a doctor, the doctor could simply move and practise elsewhere.

20.48 The paper observed that the GMC's inability to suspend registration pending the trial of a doctor charged with serious offences:

> **'... is beginning to appear unsatisfactory, whether considered from the point of view of the GMC, the Trust or health authority or, most importantly, the public interest'**.

20.49 The paper referred to the **'risks'** of suspending a doctor in these circumstances. It pointed out that criminal proceedings could be protracted and that suspension might, therefore, last for up to a year or more. It might be thought **'inherently undesirable'** for a doctor to be deprived of the means of earning his/her livelihood for such a long period and it might appear to be a **'grave injustice'** if the doctor were eventually acquitted. The paper also mentioned that an order for interim suspension might be considered oppressive by the courts and could lay the GMC open to judicial review or to claims for compensation for loss of earnings and reputation. The paper did, however, note that the UK Central Council for Nursing, Midwifery and Health Visiting (the predecessor of the Nursing and Midwifery Council) had power to impose interim suspension where it appeared necessary to do so as an interim measure for the protection of the public, or in the practitioner's interests.

20.50 The paper noted that one option was to leave it to the courts to remand in custody doctors whom they considered a danger to the public. However, it was recognised that, even if a doctor were in custody, s/he could still enjoy some of the privileges of registration, such as prescribing. The paper suggested that, as a matter of principle, the GMC should not expect the courts to discharge its responsibility to protect the public interest. It therefore recommended that the FPPC should consider whether it was desirable to have wider powers of interim suspension.

20.51 This recommendation was adopted by the FPPC which resolved to seek legal advice on various related matters. That advice was received and there the matter appears to have rested until the end of 1999, when Shipman's trial was drawing to a close. At that stage, discussions were opened with the Department of Health about what was to be done. A letter from Miss Isabel Nisbet, Head of the GMC's Fitness to Practise Directorate, written

in December 1999, mentioned other problems arising from the limitation on the GMC's existing powers. She said:

> **'... we regard it as very unsatisfactory that we have no power of interim suspension via the performance procedures for doctors about whose professional performance there are very serious concerns and who may be a danger to patients'**.

20.52 She observed that the GMC was obliged to pursue such cases through the conduct procedures in order to enable the PPC to consider the question of interim suspension. Presumably, that would not be possible in some cases. In any event, it was plainly unsatisfactory, since there was no mechanism then to get cases back into the performance procedures. Miss Nisbet also drew attention to the lack of any power to make an initial interim order within the voluntary health procedures, despite the fact that a doctor posed an ongoing threat to the safety of patients. She pointed out that, even when interim measures could be taken, the time periods allowed by the Rules meant that it was very unusual for the GMC to be able to impose interim suspension earlier than six to eight weeks after the time when it first became aware of a concern.

20.53 Miss Nisbet suggested ways in which the necessary powers might be given to the GMC. This could be done by amendment of the Rules or by the creation of a new committee with power to impose interim suspension when it appeared to be necessary for the protection of the public. This latter solution would require both primary and secondary legislation and was the solution favoured by the GMC.

20.54 Mr Scott told the Inquiry that, on 1st February 2000, the day after Shipman's conviction, there was a 'heated discussion' with the then Secretary of State for Health (SoS), the Rt Hon Alan Milburn MP. Mr Scott said that 'it was being thought in some quarters that the GMC had an abhorrence of imposing interim suspension and that simply was not the case'. He said that the problem was that its powers were 'inoperable'. He said that, prior to 1998, the GMC had not fully understood the limitation in its powers in relation to doctors who were involved in criminal proceedings. The GMC's attention had instead been focussed on the problems caused by the period for which interim suspension could be imposed. As I have explained, until 1996, the maximum period was only two months. In 1996, this was increased to six months, with the opportunity to renew the order for up to three months thereafter. Mr Scott acknowledged that the GMC had not 'spotted the problem' of doctors who were subject to criminal investigation but had not yet been convicted. The result of the discussions with the SoS was the creation of the IOC in August 2000.

20.55 It seems to me surprising that, until 2000, the GMC did not take action to extend its powers to make interim orders so as to enable it to suspend the registration of a doctor under investigation for or charged with a serious criminal offence. The need for such a power should have been obvious as is demonstrated by the contents of the paper considered by the FPPC in November 1998 and in the snapshot of doctors facing serious criminal charges at that time. It is clear that, although the GMC was generally aware of the problem, it had not considered

it necessary to take steps to protect patients from such doctors. In addition, the GMC was aware that it did not have the power to order initial interim suspension of a doctor in the health procedures (before a decision had been taken to refer him/her to the HC) or of a doctor who was being dealt with in the performance procedures. The Rules relating to the making of interim orders in the conduct procedures were changed in 1996 and it might have been expected that the GMC would have taken that opportunity to seek adequate powers to make whatever interim orders were necessary for the protection of patients. However, as Mr Scott observed, there was no recognition of the problem until it was thrown into relief in Shipman's case.

20.56 Following Shipman's conviction, urgent steps were taken by the GMC to erase his name from the register. This was done by the PCC on 11th February 2000.

The Giving of Reasons for Decisions

20.57 Until 2000, the only record of a decision made by the PPC was a brief minute. The PPC did not formulate or record any considered reasons for its decisions. The minute would, therefore, contain, at most, only brief notes of points that had been made in discussion, in addition to a record of the decision. Minutes of the PPC were not made public.

20.58 Rule 16 of the 1980 Professional Conduct Rules provided that, where the PPC had decided not to refer a case to the PCC or the HC, no complainant, informant or practitioner was to have any right of access to any documents relating to the case submitted to the GMC by any other person. Nor was the PPC to be required by a complainant, informant or practitioner to state reasons for its decision. That rule was reproduced in the 1988 Professional Conduct Rules. Despite the rule, it became the practice from about 2000 for the complainant and the doctor concerned to receive a letter, outlining the reasons for the PPC's decision. Until that time, the reasons given in the letter had been based on the brief minute of the decision made in the course of the relevant meeting of the PPC. Since 2000, following a recommendation made by the PSI team, the practice was for members of the PPC to agree the key reasons for their decisions at the time those decisions were taken. Those reasons were recorded in writing by a member of the GMC staff. The recorded reasons were subsequently reviewed by the Chairman of the PPC and were authorised by him as an accurate report of the PPC's decision. They then formed the basis of the letters sent to the doctor and the complainant.

Review of Decisions

20.59 Decisions of the PPC whether or not to refer a case to the PCC or the HC were, as I have said, made in private. The only means of challenge available to a complainant or doctor who was dissatisfied with the decision was judicial review. As I have already observed in Chapter 19, this was an expensive and somewhat intimidating process which was little used until the late 1990s.

The Approach Adopted by the Preliminary Proceedings Committee in Some Specific Types of Case

Conviction Cases Generally

20.60 In June 1997, a Note was produced for the guidance of new members of the PPC. It set out the test that members of the PPC should apply when deciding whether to refer a conviction to the PCC. It stated:

> **'The PPC must decide whether to refer a conviction to the PCC if the conviction is serious enough to justify a public inquiry which might lead to removal or restriction of the doctor's registration.'**

Leaving aside the problems of syntax, this guidance cannot have been helpful to PPC members. It really amounts to no more than saying that 'the PCC ought to refer a conviction to the PCC if it thinks that it ought to do so'. No guidance was given as to how serious the conviction had to be **'to justify a public inquiry which might lead to removal or restriction of the doctor's registration'**. On reading this guidance, any new member of the PPC would surely have wished to know how serious the conviction had to be to justify such a public inquiry. In the absence of any guidance setting out criteria and standards and illustrating them by examples, members of the PPC would be left to take decisions on the basis of their differing personal perceptions as to when it would be appropriate to refer a conviction to the PCC.

Cases Involving Allegations of Potential Serious Professional Misconduct

20.61 As I have mentioned, the Annual Reports of the PPC did not discuss the standards and criteria which should be applied by the PPC when deciding whether a case **'ought to be referred'** to the PCC. In June 1997, the Note for new members of the PPC, to which I have referred previously, advised that the question for the PPC was not whether a doctor had committed SPM. Instead, it had to decide whether a *prima facie* question of SPM arose. If the PPC decided that a *prima facie* question of SPM did arise, it then had to decide whether all, or only some, of the allegations against the doctor should be referred to the PCC. The Note observed that there was **'no absolute definition'** of what constituted SPM. It quoted the definition given by the Judicial Committee of the Privy Council in the case of Doughty v General Dental Council[1], namely:

> **'... ''conduct connected with his profession in which the dentist** (*the Note substituted the word 'doctor'*) **concerned has fallen short, by omission or commission, of the standards of conduct expected among dentists** (*doctors*)**, and that such falling short as is established should be serious'' '**.

20.62 The Note went on:

> **'The following three questions are relevant to decisions about referral to the PCC: whether to refer all, or only some, of the allegations against the doctor; whether there is sufficient evidence for the allegations to be**

[1] [1988] AC 164.

proved – the GMC's Solicitor may be asked to advise; and whether to review referral if, after seeing the witnesses, the GMC's Solicitor advises that the evidence is insufficient to come up to proof. For example, allegations about incidents which are more than 3–4 years old might be difficult to prove for practical and/or legal reasons; the PCC does not receive the documents which go to the PPC – the allegations must be proved by the oral testimony of witnesses.'

20.63 The Note also gave examples of the circumstances in which the PPC might send a warning letter to a doctor, rather than referring his/her case to the PCC. One such example was:

> **'Where a Medical Service Committee case reveals failures which are admitted or regretted by the doctor but are not considered by the PPC as sufficiently serious to justify restricting or removing the doctor's registration, when seen in the context of the whole career.'**

That example implies that the PPC would not necessarily confine its consideration to the case before it, but would view the case in the context of the doctor's **'whole career'**. However, it is not clear what, if anything, the PPC would have known about the doctor's **'whole career'**.

20.64 The PPC would have had a limited amount of information about any previous involvement of the doctor in the GMC's FTP procedures. Legal advice received by the GMC in 1998 suggested that the PPC should have been informed of any previous complaint or report about the doctor to the GMC which had resulted in a sanction being imposed by the PCC, the HC or the CPP. It should also have been informed of a previous complaint which had resulted in the sending of a warning or cautionary letter by the PPC, or in the referral of the doctor's case by the PPC to the HC. It would not have been made aware of a doctor's previous involvement in the voluntary health procedures or performance procedures. The PPC would have had no information about cases that had resulted in an 'acquittal' before the PCC, even where the facts which formed the basis of the allegation(s) had been proved and the 'acquittal' resulted from a finding that, although unacceptable, the doctor's conduct did not amount to SPM. Nor would the PPC have had any information about a case where the PPC had decided to take no action, unless the earlier case had been 'revived' within the two-year period stipulated under the Rules. The PPC would have no access to any information about previous complaints relating to the doctor that had not been referred by the medical screener to the PPC, even where a Chapter XV letter had been sent to the doctor. The PPC was not entitled to information about any case that had previously been referred by the PPC to the PCC but had not yet been heard. Even such information as should have been available would have been put before the PPC only if the GMC data retrieval systems had enabled the relevant papers to be traced, if previous case papers had not been thrown away and if the doctor had been properly identified in any previous complaints about him/her. Even if the systems worked as they should, the information would not necessarily have provided a complete picture of the doctor's **'whole career'** in terms of any involvement which s/he had previously had with the GMC's FTP procedures.

20.65 In assessing the extent to which the PPC would have been able to consider the doctor's **'whole career'**, it is important also to consider how much the PPC would have known about any complaints made about the doctor in the locality in which s/he practised. When a doctor's employer or PCO referred to the GMC a case where there had been a medical service committee (MSC) or independent review panel (IRP) hearing or other disciplinary proceedings, the information given to the GMC by the employer or PCO sometimes included details of previous similar incidents involving the same doctor which had not been the subject of a previous referral to the GMC. The information might or might not contain details of previous complaints or concerns about the doctor which had not been the subject of a formal hearing. As I have explained in Chapter 18, it was not in the past the practice of the GMC, when a complaint was made by a private individual, to make specific enquiries of the doctor's employer or PCO about previous complaints or problems in relation to the doctor. Even if such enquiries had been made, an employer or a PCO would not necessarily have been aware of a MSC or IRP hearing or other disciplinary proceedings which had occurred while the doctor was working in another area, nor about previous complaints which had been made, or concerns which had been expressed about the doctor. There is no one source from which information about a doctor's **'whole career'** can be obtained.

20.66 It is difficult to see, therefore, how the GMC could have claimed that the PPC was able to view a case in the context of the doctor's **'whole career'**. If the PPC's view were to be based solely on information held by the GMC, it might well have been incomplete. It appears that it was the PPC's practice to receive testimonials and references submitted by the doctor. I must confess to feeling some concern at that. First, such background material was not relevant to a consideration of the question whether the evidence showed a *prima facie* question of SPM. Second, if background information was to be considered, it should have been balanced. That relating to past complaints or concerns should have been complete and information relating to the doctor's general attitude and ability should have been available from someone independent of him/her. Golden opinions from patients unconnected with the issues before the PPC should not have been received by it. They could have served only to obscure the question to be decided. Moreover, their only effect could have been to influence the PPC in the doctor's favour.

20.67 Later, the GMC produced a document entitled 'Frequently Asked Questions' for members of the PPC. The Inquiry has the version which was current in January 2002. The document addressed a number of practical and administrative questions. It also provided general information about the FTP procedures and about the courses of action open to the PPC when making its decisions. However, it contained little guidance which would have assisted in making these decisions. It described SPM in these terms:

> **'There is no statutory definition of serious professional misconduct but we describe it as behaviour which may raise issues about the doctor's registration and fitness to continue to practise.'**

The inadequecy of this guidance is obvious and accounts for much of the confusion and disagreement about SPM among members of the PPC which was observed by Professor Allen and her colleagues, to which I shall refer at paragraph 20.94.

The Workload of the Preliminary Proceedings Committee in the 1990s

20.68 During the early 1990s, the number of cases considered by the PPC rose gradually until, between 1994 and 1996, it was considering about 240 cases a year. During the period between 1994 and 1996, the PPC met about five times a year for up to a day each time. Occasional short extra meetings were necessary to consider urgent cases but there was rarely more than one such meeting a year. It is clear that the number of cases to be considered by the PPC at each of its meetings must have been very substantial.

20.69 After 1996, the increase in the use of its power to make interim orders had a significant effect on the PPC's workload. Doctors threatened with the making of an interim order often exercised their right to a hearing. Such hearings took longer than the usual consideration of a case on paper. It was not unusual for a hearing to take one or two hours or more. These factors, combined with the increased number of cases referred to the PPC generally (over 300 referred in 1998 and over 400 in 1999), resulted in a sharp rise in the number of meetings and in the amount of work to be transacted at those meetings. Mr Nicholls said that, when he joined the PPC in September 1999, there were meetings on about two days each month. Each day's meeting involved about a day to a day and a half's reading in preparation. A large number of cases were considered at each meeting.

The 2000 Policy Studies Institute Report

20.70 The PSI team carried out a detailed analysis of the numbers and types of cases dealt with by the PPC during the years 1997, 1998 and 1999. The results were set out in its 2000 Report. It also examined the outcomes of those cases. Its primary purpose in carrying out this exercise was to discover whether there was any difference between the treatment of cases involving doctors who had qualified overseas and the treatment of those involving UK and Irish (for convenience, I shall refer to both as 'UK') qualifiers. However, its findings had much wider implications.

Unexplained Differences in the Referral Rates of UK and Overseas Qualifiers

20.71 In 1997, 30% of the cases considered by the PPC were referred on by the PPC to the PCC. By 1999, this figure had risen to 40%. Throughout the period 1997 to 1999, consistently higher proportions of doctors who had qualified overseas compared to those who had qualified in the UK were referred by the PPC to the PCC. In 1999, 33% of the UK qualifiers whose cases came before the PPC were referred to the PCC, whereas 54% of overseas qualifiers were referred. The overall pattern of referrals gave rise, therefore, to the possibility that overseas qualifiers were being treated unfairly.

20.72 Of the doctors whose cases were considered by the PPC in 1997, 39% received a cautionary letter or a letter of advice. In 1998 and 1999, the proportions were 49% and 41%, respectively. In 1998 and 1999 (but not 1997), UK qualifiers were more likely than their overseas counterparts to receive a letter of caution or advice, rather than being referred to the PCC. In addition, UK qualifiers were significantly more likely than overseas qualifiers to be referred into the voluntary health procedures. Part of the explanation for this was the fact that many convictions dealt with by the PPC were for drink driving

offences and UK qualifiers were twice as likely as overseas qualifiers to have been convicted of such offences. However, that could not account entirely for the disparity. These disparities again raised the possibility that overseas qualifiers were being discriminated against by the PPC.

20.73 There was no obvious explanation for the disparities. During the course of the same study, the PSI team had discovered similar disparities in the decisions made by screeners. However, it had found a possible explanation for the higher proportion of overseas qualifiers referred to the PPC by screeners. It could be explained by the fact that cases referred to the GMC by public bodies (in which overseas qualifiers were twice as likely as UK qualifiers to be the subject of complaint) were in general more likely to be referred by screeners to the PPC than were cases originating from private individuals. Thus, it could have been the fact that a case had been referred by a public body (rather than the fact that it concerned an overseas qualifier) that accounted for its referral by the screeners to the PPC.

20.74 The same explanation could not account for the marked disparities in outcome once a case reached the PPC. Like the screeners, the PPC was more likely to refer on to the PCC cases originating from public bodies than cases from private individuals. However, among cases originating from public bodies, the PPC sent a significantly higher proportion of cases involving overseas qualifiers (55% of such cases considered by the PPC in 1999) than of those involving UK qualifiers (36% in 1999). Even among cases originating from private individuals, there was a difference in the proportion of cases referred by the PPC to the PCC when overseas and UK qualifiers were compared. Similar differences were seen in the way the PPC dealt with every category of complaint (e.g. complaints about dishonesty or criminality and about poor treatment or substandard clinical practice, etc.). Since, at that time, the PPC gave no reasons for its decisions, it was impossible for the PSI team to say why these differences were occurring.

Unexplained Differences in the Treatment of UK and Overseas Qualifiers Convicted of Criminal Offences

20.75 The PSI team examined the pattern of referral for convictions. This was important because greater uniformity of treatment might have been expected when the PPC was dealing with doctors who had been convicted of criminal offences, as opposed to doctors who had been accused of a variety of other types of misconduct. In the period from 1997 to 1999, between 17% and 23% of all the cases dealt with by the PPC were conviction cases. A substantial proportion of those convictions were for offences of drink driving. UK qualifiers represented a higher proportion of conviction cases than their overseas counterparts in all three years, both for drink driving and for other offences.

20.76 In 1997, 13% of conviction cases were sent by the PPC to the PCC. The figures for 1998 and 1999 were 16% and 29%, respectively. If drink driving cases were left out of the calculation, the proportion of conviction cases referred by the PPC to the PCC rose to 35% of cases considered by the PPC in 1997, 28% in 1998 and 58% in 1999. With or without drink driving cases, a significantly higher proportion of overseas qualifiers with convictions were referred by the PPC to the PCC than of their UK counterparts. In 1999,

the proportion of UK qualifiers with convictions (other than for drink driving) referred by the PPC to the PCC was 38%; for overseas qualifiers, the proportion was 85%. This represented a marked disparity between the treatment of UK and overseas qualifiers.

20.77 In 1997, 41% of conviction cases dealt with by the PPC were referred into the voluntary health procedures. In 1998 and 1999, the proportions were 15% and 24%. There was a change of procedure for drink driving cases in 1998. The effect of that was that some doctors who would previously have been referred by the PPC into the voluntary health procedures were instead referred into those procedures at an earlier stage, so that their cases never reached the PPC. When drink driving cases were left out of account, the proportions of conviction cases referred into the voluntary health procedures were 22% in 1997, 19% in 1998 and 19% in 1999. Significantly higher proportions of UK qualifiers than of overseas qualifiers were referred to the voluntary health procedures in all years.

20.78 In 1997, 35% of conviction cases resulted in a cautionary letter or letter of advice. In 1998 and 1999, the figures were 63% and 45%. When drink driving cases were excluded, the figures were 22%, 44% and 19%. Significantly higher proportions of UK qualifiers than of overseas qualifiers were sent letters of advice or cautionary letters in all years. Again, these results gave rise to the possibility of unequal treatment of UK and overseas qualifiers.

20.79 The PSI team acknowledged that it was possible that the offences for which overseas qualifiers had been convicted might have been more serious than the offences committed by UK qualifiers. This would explain the apparent disparities in treatment between the two groups. However, since the PPC did not give reasons for its decisions, it was impossible to confirm this. Nor was it possible to rule out the possibility that racial bias had caused the disparities. The presence of racial bias, on the evidence available, could not be proved or disproved. The PSI team observed that a detailed analysis of individual cases would be necessary in order to discover why convictions which, from the brief description that appeared on the GMC's database, sounded similar had nevertheless been treated differently. So far as the Inquiry is aware, no such analysis has been undertaken.

The Treatment of Conviction Cases Generally

20.80 The PSI team had concerns about the way in which the PPC dealt generally with conviction cases, quite apart from the unexplained disparities between the treatment of UK qualifiers and that of their overseas counterparts. In its 2001 Report, the PSI team drew attention to the variation in the pattern of outcomes in conviction cases from year to year. In 1997, as I have said, 35% of all convictions (excluding drink driving convictions) considered by the PPC had been referred to the PCC; in 1999, the proportion was 58%. This represented a considerable variation for which there was no apparent explanation. The PSI team suggested that a detailed analysis of the type mentioned above might assist in explaining why such variations were occurring.

20.81 The PSI team was concerned that its own analysis demonstrated a general lack of consistency in dealing with convictions. The 2000 PSI Report observed that, for the sake of consistency, as well as to prevent bias, it was essential that no discretion should be applied in deciding whether a conviction should be referred to the PCC. The Report

therefore recommended that all convictions referred to the PPC, other than drink driving convictions, should automatically be referred on to the PCC. It observed that there was a need to ensure efficiency and speed in dealing with convictions, since such cases might be considered automatically to call into question a doctor's registration.

20.82 Professor Allen, who led the PSI team, told the Inquiry that she and her colleagues were very concerned about the number of convictions that were not being referred by the PPC to the PCC. There were anomalies for which they could find no explanation, either from the statistics or from their observations of the PPC at work. Professor Allen said that her personal opinion was that any conviction, save for a minor road traffic offence or a drink driving conviction, had implications for a doctor's fitness to practise. She also expressed the view that, if a policy were adopted of referring all conviction cases to the PCC, that would prevent the need to justify minutely why one conviction should be sent to the PCC and another not.

The Need for the Preliminary Proceedings Committee to Give Reasons

20.83 Professor Allen and her colleagues concluded the relevant section of their 2000 Report by saying that there was an urgent need for the PPC to make explicit its reasons for referring cases to the PCC and for other decisions. In the absence of explicit reasons, there were **'unexplained differences'** between the outcomes for UK and overseas qualifiers at this stage of the conduct procedures. This recommendation was implemented shortly afterwards, when the PPC adopted the practice of agreeing the key reasons for its decisions at the time those decisions were made. So far as the Inquiry is aware, there has been no subsequent analysis of the PPC's decisions, by reference to those reasons.

Analysis of the Conduct of Meetings of the Preliminary Proceedings Committee

The Observations

20.84 During the period between June 1999 and January 2000, Professor Allen and her colleagues observed 11 meetings of the PPC. In November 1999, as I have explained, there were significant changes to the composition of the PPC. Prior to that time, the PPC had been chaired by Dr Steel, the principal medical screener. Three other screeners (two medical screeners and one lay screener) were members of the PPC. Other screeners were invited to attend meetings of the PPC as observers and might be called upon to comment on cases that they had screened. Screeners who were not members of the PPC did not necessarily attend all its meetings, so that it was a matter of chance whether a screener was present to comment on his/her own screening decision. 'Observer' screeners were sometimes called upon to deputise for members of the PPC who were absent and thus to ensure that there was a quorum, which was then five. If that was not possible, other members of the GMC were called upon to deputise on an *ad hoc* basis.

20.85 From November 1999, screeners were no longer eligible for election to the PPC and no longer attended its meetings. The new Chairman of the PPC was Mr Nicholls, a lay member of the GMC and a former lay screener. None of the other members of the newly constituted PPC had any experience of screening.

20.86 Professor Allen and her colleagues noted that the papers in cases coming to the PPC frequently ran to hundreds of pages, including medical records and reports of previous hearings by NHS and other bodies. No summary of the case was provided, save for the letter to the doctor outlining the allegations against him/her. Nor did PPC members receive the screening decision form or the memorandum prepared by a caseworker for the screeners' assistance. The PPC would usually have the doctor's response to the complaint, often in the form of a letter from the doctor's medical defence organisation or solicitors. Other documents would sometimes be enclosed with the response. It was not unusual for the responses submitted by doctors to be received only shortly before the PPC meeting. Members of the PPC would often have to read a batch of such responses (together with any other material supplied) on the day of the meeting. Professor Allen told the Inquiry that this could often be an 'enormous amount' of further evidence and information. It must have been very difficult for members to absorb the new material and to place it in the context of each individual case. At that time, a complainant (whether a public body or a private individual) had no right to see or comment on the doctor's response to the complaint. Thus, there was no opportunity for a complainant to correct any inaccuracies in the doctor's account or to deal with any additional questions raised by him/her.

20.87 Professor Allen and a colleague attended six meetings of the PPC before November 1999 and five meetings thereafter. They did not see the same combination of members and co-opted members sitting on the PPC more than once. They analysed the meeting papers in advance and recorded *verbatim* accounts of the discussions. They then analysed various features of the discussions at the meetings. They interviewed the Chairman and eight members or co-opted members of the PPC as it was constituted before November 1999.

Consistency, Transparency and Fairness

20.88 In carrying out their analyses, Professor Allen and her colleagues looked to see whether the PPC was applying the principles of good decision-making and was achieving its objectives of consistency, transparency and fairness. In May 1996, the GMC had publicly committed itself to these principles. It had said:

> **'We are committed to a system of self-regulation which is open and accountable; and to developing procedures and processes that are fair, objective, transparent and free from discrimination.'**

20.89 The principles were:

> **'*consistency*:**
>
> - **there should be agreement on the criteria to be applied in reaching a decision**
> - **the criteria used in considering each case should always be the same**
> - **they should be applied within each meeting by each member for each case in the same way**

- **they should be applied across meetings in the same way**

***transparency*:**

- **it should be clear how the criteria have been applied in reaching a decision**
- **the reasons for each decision should be clearly stated**

***fairness*:**

- **each case should be treated by giving due consideration to all pieces of evidence**
- **each case should be assessed on its merits**
- **it should be made clear what weight has been applied to the different pieces of evidence.'**

20.90 The analyses carried out by the PSI team related both to the process of decision-making and to the content of the PPC's deliberations.

The Conduct of Meetings

20.91 Professor Allen and her colleagues observed that, before the significant changes to its constitution in November 1999, the PPC usually dealt with between 30 and 50 cases at each meeting. Half of the cases were dealt with in three minutes or less; 76% of cases were concluded in five minutes or less. Only 10% took ten minutes or more. After November 1999, only 13% of cases were concluded in three minutes or less and 29% in five minutes or less; 47% of cases occupied ten minutes or more. These timings did not include hearings relating to interim orders, which could take far longer, as I have explained above.

20.92 At least part of the explanation for the increase in the time taken over each case after November 1999 lay in the way in which the discussions about individual cases were conducted. The 2000 PSI Report noted that, before November 1999, participation in a discussion about an individual case was limited to the Chairman (who would introduce each case) and only one or two others. Some members were invited to participate in discussions to a greater extent than others. After November 1999, meetings were run in a more structured way that encouraged much greater and more equal participation from all members of the PPC. In general, every member was asked for his/her view in relation to every case under consideration. Inevitably, this increased the length of time spent on cases but it did mean that the opinions of all members were canvassed. Before November 1999, decisions would often be made without taking a vote, even when there was dissent about what the outcome of a case should be. It was more common for the Chairman to put forward a proposed outcome, leaving it to the dissenters to voice their disagreement if they chose. After November 1999, votes were taken more frequently.

20.93 The observations and analyses of the PSI team demonstrated that few discussions within the PPC, whether they took place before or after November 1999, adhered to the principles of good decision-making to which the GMC had previously committed itself. There was an absence of commonly agreed and applied criteria. It was often impossible

to tell why some cases were referred to the PCC and others were not. This was particularly so in cases of poor treatment and substandard clinical practice, but it was also true of convictions and other cases involving dishonesty and dysfunctional personal behaviour which had been designated 'SPM by definition' for screening purposes. Many of those cases were not referred by the PPC to the PCC.

Serious Professional Misconduct

20.94 The PSI team observed confusion and disagreement about what constituted SPM and what the threshold for SPM should be. It was suggested by some members of the PPC that **'For spm there has to be some evidence of recklessness and the action should be unreasonable ...'**. There were widely differing views of what was and was not **'unreasonable'**. Members of the PPC brought to the discussions their own views about the standards to be expected of a 'reasonable doctor' and individual members clearly applied different standards. There was also divergence of opinion about accepted margins of error. There was a tendency to speculate about why someone might have done something. Characteristics or behaviour were attributed to a doctor for which there was no evidence. Members of the PPC would speculate on how certain situations might have arisen when there was no evidence upon which to base such speculations.

20.95 One recurrent point of disagreement was whether the fact that a doctor's conduct had led to a poor outcome for a patient was relevant to the issue of whether that conduct amounted to SPM. The 2000 PSI Report quoted one exchange on this topic:

> **'Member 1: ''The outcome is totally irrelevant. Get rid of the idea that it is more serious if the patient dies than if he didn't.''**
>
> **Member 2: ''It does matter to the patient if the outcome is death. It is the duty of a doctor to sort out the urgent and important.'' '**

20.96 Considerable difficulty was experienced in dealing with expert opinion. Sometimes, the papers in a case contained expert reports obtained in the course of investigation of the complaint by another body; sometimes, the doctor produced expert evidence in support of his/her defence. In other cases, the screeners had called for an expert opinion. The experts were sometimes GMC members and sometimes not. On occasion, the experts disagreed with each other. Professor Allen and her colleagues observed real difficulty on the part of members of the PPC in knowing what weight to give to the views of the experts and how to approach a conflict in the expert evidence. Sometimes, the PPC would decide in accordance with one expert view, rather than another, without it being clear why one view had prevailed. The position became even more complicated when there was a practitioner in the relevant field at the meeting. It was a matter of chance whether there was such a practitioner present at a meeting. In any event, the weight that was given to a practitioner member's expertise varied between meetings.

Lack of Understanding of the Processes

20.97 Members of the PPC often expressed uncertainty over GMC procedures and processes. Sometimes, members did not appear to appreciate that it was not open to them to refer a

case into the performance procedures. There was a lack of understanding, on the part of some, of the difference between the voluntary health procedures and the HC. There was also uncertainty about the circumstances in which a doctor should be offered the opportunity of voluntary erasure of his/her name from the register. There were other areas of uncertainty among members which contributed to the difficulty in decision-making.

20.98 The possible existence of mitigating circumstances (e.g. systems failures, poor management, practice in a deprived area, a large patient list) were mentioned frequently in discussions. The fact that a doctor had apologised or acknowledged some fault was frequently mentioned. The PSI team noted:

> **'... it was clear that members were often looking for explanations of a doctor's behaviour. These could be directly related to the circumstances of the doctors themselves or could be related to the circumstances in which they found themselves working. They were certainly taken into account when differences of opinion occurred within a committee, particularly in relation to treatment/sub-standard clinical practice cases.'**

Considering the Strength of the Evidence

20.99 One theme which, according to Professor Allen and her colleagues, was **'never far beneath the surface'** in many of the PPC's discussions was the issue of whether the extent and nature of the evidence was such that the case would 'run' at the PCC. They observed lengthy discussions about the amount of evidence needed to send a case to the PCC. Sometimes, during these discussions, there were disagreements between members of the PPC and the legal assessor. The latter would advise that it was the PPC's function only to ensure that there was a *prima facie* case and that the PPC should not attempt to resolve differences or conflicts of evidence during the course of its deliberations on whether a case should be referred to the PCC or not. Members were unhappy about this. Despite the legal advice, members tended to discuss the sufficiency of, and conflicts in, the evidence. Later in this Chapter, I shall refer to the judicial review case of R v General Medical Council ex parte Richards[2], which illustrates the problem described by Professor Allen. In that case, the PPC had plainly discussed the conflicts of evidence and had resolved them in the doctor's favour, in circumstances in which the decision should have been to refer the case to the PCC.

20.100 Professor Allen told the Inquiry that she had been surprised at the extent to which the PPC discussed the likely prospects of success at the PCC. In particular, she was concerned about the emphasis on evidence. As I have explained, it was not at that time the GMC's practice to collect evidence (save for the response of a doctor and any evidence s/he might care to volunteer) relating to a complaint unless and until the case had been referred by the PPC to the PCC. Once a case had been referred to the PCC, there was an opportunity for the GMC's solicitors to gather more evidence in preparation for the hearing. Professor Allen said that she was concerned that the PPC was sometimes looking at cases on the basis of very limited information, and was making decisions about the

[2] [2001] Lloyd's Rep Med 47.

adequacy of the evidence at a time when it was in no position to know whether it would be possible to collect further evidence in the future.

Analysis of Outcomes and Conclusions

20.101 The analysis by the PSI team of the outcomes of PPC meetings showed that there was a marked difference between the outcomes of those that took place before and those that took place after November 1999. In the period from June to November 1999, 35% of cases considered by the PPC were referred to the PCC. Between November 1999 and January 2000, 47% were referred. The reason for this appeared to be that the post-November 1999 PPC operated a lower threshold for referring cases to the PCC. However, the 2000 PSI Report observed that it was unclear, in respect of either period, what that threshold was. The PPC, as constituted after November 1999, was more likely than its predecessor to refer cases to the PCC if there was an unresolved conflict of evidence or if the case was thought to raise an issue of SPM, even where the evidence did not appear substantial. It was less likely than the earlier PPC to decide that there was insufficient evidence to refer a case to the PCC. Otherwise, the same problems and uncertainties continued to characterise discussions of the PPC, even after November 1999. The 2000 PSI Report commented that, **'even with the greater length of discussions and the more structured approach of the new committee, there are still large areas of obscurity in the decision-making process of the PPC'**.

20.102 The 2000 PSI Report observed that the main question left unanswered was why such a small proportion of cases considered by the PPC was referred to the PCC. The Report posed this question:

> **'If a screener considers that a case raises an issue of serious professional misconduct, what is it that happens at the PPC to result in two thirds of cases considered before November 1999 and over half the cases considered after November 1999 being reassessed as not raising an issue of serious professional misconduct?'**

20.103 It is clear, as I observed in paragraph 20.21, that Professor Allen was of the view that the test to be applied by the screeners was virtually the same as that to be applied by the PPC.

20.104 The 2000 PSI Report went on to refer to the absence of any agreed standards against which a decision could be made whether or not conduct amounted to SPM. It observed:

> **'The problem which arose time and again in PPC discussions was that there was no consensus on what these standards were, particularly in relation to matters of clinical practice, and there was no agreement on the threshold of seriousness. There is clearly a need for guidelines to be established so that consistency, transparency and fairness can be demonstrated at all stages of the GMC conduct procedures.'**

20.105 The PSI team questioned whether the PPC was an appropriate forum for discussing whether poor treatment or substandard clinical practice cases raised issues of SPM. It pointed to the lack of consistency, both in the composition of the PPC (with different

combinations of people attending every meeting) and in the availability of expertise among its members.

20.106 Finally, the 2000 PSI Report recommended that the GMC should clarify the differences between the role and function of the PPC and the role and function of screeners. It observed that the roles and functions of both appeared to be very similar. It was suggested that, if the PPC was intended to apply different tests and criteria for onward referral of cases from those applied by the screeners, those tests and criteria should be defined and guidance should be given on how they should be applied. Indeed, it was suggested that the GMC should consider whether it needed to maintain the separate functions of screeners and the PPC at all. I mentioned earlier that it would be usual for the screeners and the PPC to have the same amount of information before them. In the past, there had been one significant difference: the PPC would have the doctor's explanation whereas the screener would not. That difference was removed in 1997. It may have been envisaged originally that the PPC would use its power to adjourn for investigations to be made so as to put itself in a better position than the screeners. In practice, however, this was almost never done.

Comment

20.107 The descriptions of what happened at meetings of the PPC and the discussions described by Professor Allen are strongly reminiscent of some of the evidence heard at the Inquiry. Some of the witnesses, when asked to explain a decision in a particular case, would speculate about why the doctor concerned might have acted as s/he had, often seeking to find an acceptable explanation for what had happened. It was clear that, if there had been a *lacuna* in the evidence available (as there often was in cases considered by the PPC, because so little evidence was gathered at the preliminary stages of the process), the decision-maker would fill the gap with assumptions, which were invariably favourable to the doctor against whom the allegation was made. Doctors asked by the Inquiry to express an opinion – about, for example, Shipman's conduct in the case of Mrs Renate Overton – would give a view based, in part, on speculation about what might have happened or why Shipman might have acted as he did. These were not speculations about how serious the implications of his conduct might be; they were attempts to proffer an explanation of his conduct that would render it acceptable or, at any rate, less serious. The Inquiry was told about similar tendencies which had surfaced in debates at meetings of the Medical Advisory Committee, as I described in Chapter 6. To a lawyer, the inclusion of such irrelevant material in the consideration of a case is obviously wrong. Yet it appears that, to many doctors, this is not obvious.

20.108 More generally, the analysis carried out by the PSI team into the operation of the PPC presents a depressing picture of inconsistency and lack of transparency. For important decisions such as those made by the PPC to be made on incomplete information by people who acted upon their personal views, without the benefit of any kind of framework of standards or criteria – or even a collection of old cases from which to see how decisions had been made in the past – seems to me to be a recipe for unfairness of outcome. It is plain that the GMC was not, at this time, achieving its objectives of consistency, transparency and fairness in decision-making. It may be that, on some occasions, the

inconsistency resulted in unfairness to doctors. However, on some occasions, it must have resulted in a failure to protect patients.

The Differing Roles of the Preliminary Proceedings Committee and the Screeners: the Case of Toth

20.109 The roles of the PPC and the screeners were discussed by Mr Justice Lightman in his judgement in the case of R v General Medical Council ex parte Toth[3]. That judgement was delivered in June 2000. I outlined the facts of that case in Chapter 19. The dispute in Toth related to two decisions of a medical screener. The case never reached the PPC. However, the Judge took the opportunity to give guidance on the respective roles of the screeners and the PPC.

20.110 The Judge observed that there was a difference in language between rule 6(3) of the 1988 Professional Conduct Rules, which governed the role of screeners, and section 42(2) of the Medical Act 1983, which governed the role of the PPC. He confirmed that it was an **'obvious fact'** that the roles of the screener and the PPC could not be intended to duplicate each other and that **'decisions are not intended to be made by the screener which the PPC (if necessary, after invoking their powers to investigate further) may be better equipped to make'**. The screener could filter out only those cases that it appeared to him/her **'need not proceed further'**. The only conclusion on the merits of the complaint which was required of the screener before s/he allowed a complaint to proceed was that the matters stated **'appear to raise a question'** whether the doctor had committed SPM. However, the PPC had the task of deciding whether the complaint **'ought to proceed further'**. Although the Judge regarded it as obvious that the roles of the screener and the PPC could not be the same, Professor Allen had understood that there was no real difference between them and, to be fair to her, the wording of both tests was so general that her point of view was understandable.

20.111 The Judge went on to draw attention to two particular features of the GMC's conduct procedures. First, he noted that the complainant had no right to see the doctor's comments on the complaint or to see any other material that was put before the PPC. Second, he observed that the **'central feature'** of the procedures was the investigation of complaints by the PCC. Only before the PCC, he noted, was there full disclosure of documents and evidence and a form of hearing whereby the complainant and the public could see, and be reassured by seeing, the proper examination of the merits of the complaint. He went on:

> **'The PPC may examine whether the complaint has any real prospect of being established, and may itself conduct an investigation into its prospects, and may refuse to refer if satisfied that the real prospect is not present, but it must do so with the utmost caution bearing in mind the one-sided nature of its procedures under the Rules which provide that, whilst the practitioner is afforded access to the complaint and able to respond to it, the complainant has no right of access to or to make an**

[3] [2000] 1 WLR 2209.

informed reply to that response, and the limited material likely to be available before the PPC compared to that available before the PCC. It is not its role to resolve conflicts of evidence. There may be circumstances which entitle it to hold that the complaint should not proceed for other reasons, but the PPC must bear in mind its limited (filtering) role and must balance regard for the interests of the practitioner against the interests of the complainant and the public and the complainant and bear in mind the need for the reassurance of the complainant and the public that complaints are fully and properly investigated and that there is no cover-up. In the case of the PPC (as in case of the screener) any doubt should be resolved in favour of the investigation proceeding.'

20.112 The Judge observed that both the screener and the PPC should be particularly slow in halting a complaint against a doctor who continued to practise, as opposed to one who had since retired. The paramount consideration must, he said, be the protection of the public in respect of those continuing to practise.

After the 2000 Policy Studies Institute Report and the Case of Toth

20.113 Mr Nicholls told the Inquiry that, as a result of the recommendations contained in the 2000 PSI Report, various changes were made to the procedures of the PPC. Most important was the change to which I have already referred, whereby members of the PPC agreed the key reasons for their decisions, which were then minuted by a member of staff. In addition, a system was introduced whereby all cases referred to the PPC were accompanied by a screener memorandum setting out the reasons for the referral. Another change was that, from July 2000, the GMC's policy was that the doctor's response to a complaint should be disclosed to the complainant, who was invited to provide comments before the case was screened. If the complainant provided comments, they were disclosed to the doctor for his/her further observations.

20.114 In his evidence to the Inquiry, Mr Nicholls said that he could understand how the suggestion that the PPC placed too much emphasis on the question of whether there was sufficient evidence for the case to 'run' at the PPC, contained in the 2000 PSI Report, came to be made. However, he suggested that the PPC's approach was, to some extent at least, vindicated by the view expressed by Lightman J in Toth, namely that the PPC was entitled to examine whether the complaint had any real prospect of success. It is clear, however, from the case of Richards, which I shall discuss below and which concerned a decision of the PPC made in March 2000, that the PPC was going far beyond its remit in the way it considered the evidence in a case.

20.115 Mr Nicholls believed that the decision in Toth caused the PPC to adjourn more often for further investigations to be made. He felt that, before then, the PPC had not adjourned enough for that purpose. It is impossible to tell from the statistics whether this was the case.

The Case of Richards

20.116 The case of Richards was decided by Mr Justice Sullivan on 18th December 2000. It concerned an application for judicial review of a decision of the PPC not to refer to the PCC a complaint made by Ms Joanne Richards.

The Complaint

20.117 The complaint related to the treatment of Ms Richards' sister, Miss Jane Wetherell, by a GP, Dr S K Pathak. Miss Wetherell had died of a pulmonary embolism on 19th January 1995, at the age of 36. She had had a number of risk factors for pulmonary embolism, including the fact that she was severely overweight, she was a smoker and she was taking the contraceptive pill. The complaint centred on a consultation with Dr Pathak which had taken place eight days before Miss Wetherell's death. The issue was whether Miss Wetherell had complained or showed signs of breathlessness or breathing problems at that consultation. Ms Richards said that Miss Wetherell had told her that she had mentioned such symptoms to Dr Pathak. A colleague of Miss Wetherell said that Miss Wetherell had made an emergency appointment on the day of the consultation specifically to discuss her breathing problems. The colleague said that she had been present at the time the appointment was made and had heard Miss Wetherell complain to the receptionist that she could not breathe properly.

20.118 Dr Pathak gave evidence at the inquest into Miss Wetherell's death. He denied that she had complained or shown evidence of breathing problems at the consultation. He said that she was complaining, not of breathlessness, but of nausea and 'strong urine'. He had referred Miss Wetherell to hospital for an endocrinology report. It is clear that the report was to be preceded by tests. His medical note recorded that she had attended him for a **'pill check'**.

20.119 In his summing-up to the jury, the Coroner observed that, had the patient complained to the doctor of breathlessness, the contraceptive pill should have been stopped. He commented on the inadequacy of Dr Pathak's notes. At the judicial review, the Judge did not say what the outcome of the inquest had been. Following the inquest, Ms Richards complained to the local Family Health Services Authority (FHSA). The MSC rejected her complaint; it is not clear if there was a hearing at that stage but it seems unlikely. Ms Richards appealed. Her appeal was heard by an appeal panel, probably convened by the Family Health Services Appeal Authority (FHSAA). Dr Pathak again gave evidence, denying that there had been any mention of breathing problems at the consultation. During his evidence, he conceded that, in fact, Miss Wetherell had not attended him for a **'pill check'**, as his note had stated. Rather, he said that she had attended a Well Woman Clinic run by his practice nurse. The nurse had referred Miss Wetherell to him, he said, because of the nausea she was suffering and because she was unable to lose weight.

20.120 Miss Wetherell's sister had by this time obtained the hospital records, including the endocrinology report. On it were the letters **'SOB'**, a common medical abbreviation for 'shortness of breath'. A hospital witness said that it was highly probable that **'SOB'** had formed part of the clinical details written by Dr Pathak on the form requesting that endocrinological tests should be carried out. Dr Pathak responded by saying that, at the time of the relevant consultation, he had had before him details of a consultation which Miss Wetherell had had with his wife (a partner in his general practice) in December 1994, when shortness of breath had been mentioned. It was probable, he said, that he had written **'SOB'** on the request form as part of the past clinical history. He remained adamant that it had not been mentioned at the relevant consultation. The original request form was

no longer available, having been destroyed by the hospital in accordance with normal procedure.

20.121 The appeal panel convened by the FHSAA, comprising a legally qualified chairman and two medically qualified members, heard evidence from 11 witnesses over four days. Dr Pathak was represented by counsel. The complainant was also represented. The appeal panel found that Miss Wetherell had made an emergency appointment and that she was significantly short of breath at the consultation. It also found that Dr Pathak's clinical note was written after Miss Wetherell's death when there had been a complaint, or when he believed that a complaint was likely to be made. The appeal panel found that Dr Pathak had been in breach of his terms of service in not referring Miss Wetherell to a consultant, although it considered this breach was **'a minor one'**. The **'most serious'** aspect of the case, it found, was the attempt by Dr Pathak to cover up the breach. The appeal panel's decision was given in June 1998, three and a half years after the death.

20.122 It appears that, as a result of the appeal panel's findings, the FHSA then referred Dr Pathak's case to the GMC. In addition, Ms Richards made complaints to the GMC about both Dr Pathak and his wife who, it was alleged, had been complicit in the falsifying of records. I shall deal only with the complaint against Dr S K Pathak.

The First Decision of the Preliminary Proceedings Committee

20.123 The complaint went to the medical screener, who referred it to the PPC. The PPC considered it in June 1999. It may be that Professor Allen was present at the meeting at which the case was discussed. Following that meeting, a letter of decision was sent to Ms Richards. The letter pointed out that the appeal panel had made its judgement on the balance of probabilities, whereas the standard of proof at PCC hearings was **'beyond reasonable doubt'**. The PPC had concluded that there was insufficient available evidence (and no likelihood of obtaining the necessary evidence) to give a reasonable prospect of proving the charge that the doctors had made alterations to the records and had misled, or sought to mislead, subsequent inquiries into the death.

20.124 The letter went on to express the concern of members of the PPC at Dr Pathak's conduct in failing to refer Miss Wetherell to hospital; they took the view that he should have done this, whatever the way in which she had explained her symptoms to him. They also considered that his notes fell short of the standards they expected to see. However, the letter indicated that the PPC did not **'consider that the circumstances were such as to warrant a public inquiry on the right of either doctor** (*i.e. Dr Pathak or his wife*) **to retain unrestricted registration as a doctor'**. Instead, the PCC had directed that Dr Pathak should be sent a letter advising him of the PPC's concerns and warning him about his future conduct. In passing, I observe that this letter simply echoed the form of words used in the Note containing guidance for new members of the PPC which had been issued in June 1997; it would not have helped the complainant to understand why the case had been closed.

20.125 In July 1999, solicitors instructed by the complainant wrote to the GMC, contending that the decision of the PPC was not reasonable and setting out reasons. They invited the PPC to reverse its decision, failing which they said that an application would be made for

judicial review. The GMC obtained legal advice which suggested that the decision of the PPC had been flawed. The GMC then agreed to a consent order, quashing the decision of the PPC. That order was approved by the Court in 1999. A statement of reasons was attached to the order, in which the parties (i.e. Ms Richards and the GMC) agreed that there were three reasons for quashing the decision. First, the PPC had applied the wrong test, in considering what was **'the likelihood'** of obtaining sufficient evidence. Second, the way in which the PPC had assessed the evidence did not support the ultimate conclusion reached; the PPC must be inferred to have accepted the findings of the appeal panel and this was enough to **'raise a question'** whether there had been SPM. Third, it was agreed that the PPC had misdirected itself on the evidence. There was some evidence that Dr Pathak had lied at the inquest, that he had fabricated Miss Wetherell's medical notes to protect himself and that, contrary to his denials, Miss Wetherell had complained of shortness of breath at the relevant consultation. It was agreed that this evidence should have been sufficient to persuade the PPC that the complaint **'raised a question of'** SPM. However, the PPC had failed to appreciate its relevance and importance. Anyone reading that statement of reasons would have inferred that the GMC had understood that the test the PPC should have been applying was whether the complaint **'raised a question of'** SPM.

The Second Decision of the Preliminary Proceedings Committee

20.126 The complaint was then remitted to a differently constituted panel of the PPC which was not told about the background of the case. In fact, since the previous PPC panel had considered the complaint, there had been a change of Chairman and of the membership of the PPC, as I have described at paragraph 20.13. The Chairman of the panel on the second occasion was Mr Nicholls.

20.127 Further submissions on behalf of both Ms Richards and Dr Pathak were made to the PPC; neither saw each other's submissions before the PPC made its decision. The PPC panel met in March 2000. A decision letter was sent to the parties in April 2000. Briefly, the PPC concluded that, even if Miss Wetherell had complained of shortness of breath at the relevant consultation, that would not have been the key to diagnosis and outcome. It would have been possible for the condition to have been undetectable, regardless of any shortness of breath. The PPC considered Dr Pathak's notes of the consultation to be genuine and adequate. (The appeal panel had, as I have said, concluded that the notes had been written after Miss Wetherell's death, at a time when Dr Pathak knew that a complaint had been made or was likely to be made.)

20.128 In accordance with the recent changes of practice, the decision letter on this occasion was much fuller. It mentioned Ms Richards' statement that Miss Wetherell had told her that she had complained of breathlessness at her consultation with Dr Pathak. It said that the statement was hearsay evidence and would, therefore, be inadmissible before the PCC. If it were admitted (the PCC had discretion to admit hearsay evidence if satisfied that its **'duty of making due inquiry into'** the case made its reception **'desirable'**), it would probably not, the decision letter observed, be **'given great weight'**. The letter said that, because of this, the PPC would not have expected the evidence of Ms Richards to make any difference to the overall outcome. In relation to the appearance of the letters **'SOB'** on

the endocrinology report, the decision letter said that members of the PPC had observed that, in their experience, it was very common for information to find its way into such reports by means other than the referring doctor writing it on the request form. The PPC did not, therefore, accept that the inclusion of **'SOB'** on the report form in Miss Wetherell's case meant that Dr Pathak had been aware of the symptoms of breathlessness at the time of the consultation. In view of the fact that the original request form was missing, and of the time that had elapsed since the relevant events, the PPC considered that there was no practical way of pursuing that issue further.

20.129 The decision letter indicated that the PPC did not accept that Dr Pathak had deliberately falsified Miss Wetherell's medical notes and had misled subsequent inquiries into the events leading to the death. The letter observed that there was nothing to falsify. Moreover, in the absence of signs of shortness of breath at the consultation, no referral for specialist treatment was demanded. The PPC did not think it right to criticise Dr Pathak for his failure to make such a referral.

20.130 The decision letter stated that the PPC disagreed with the findings of the appeal panel. As I have said, that panel had sat for four days and heard evidence from 11 witnesses, including Dr Pathak himself. The letter concluded by stating that the material before the PPC:

> **'... did not appear to raise a question whether the serious professional misconduct had been committed, taking into account (amongst other things) the criminal standard of proof to be applied by the PCC'**.

20.131 Before going further, I draw the reader's attention to the way in which this second PPC panel had resolved every issue in favour of the doctor, even in the face of conclusions reached by the appeal panel after a four-day hearing. Also, any uncertainty in the mind of the PPC (e.g. about the appearance of **'SOB'** on the endocrinology report) was resolved by the drawing of an inference favourable to the doctor.

The Judicial Review

20.132 That decision was the subject of an application for judicial review. In his judgement, Sullivan J referred to Lightman J's decision in Toth, which had been given six months earlier.

20.133 In argument before Sullivan J, the GMC attacked the decision in Toth, arguing that the PPC had a much wider discretion to consider whether a complaint **'ought to be referred for inquiry'** by the PCC than had been suggested by Lightman J. It was submitted that the PPC **'had to get its sleeves rolled up'**, and had to look at the evidence and assess its weight in order to see if a complaint was properly arguable. In doing so, the PPC was entitled, so it was contended, to resolve conflicts of evidence, especially if the evidence was largely documentary and there was little prospect of its being supplemented by admissible oral evidence at a PCC hearing. In any event, it was argued, the second decision letter of the PPC complied with the guidance given by Lightman J in Toth.

20.134 Mr Nicholls provided a witness statement for use at the judicial review hearing. In it, he detailed his experience on the PPC. He had been a member of the PPC since September

1999 and had become its Chairman, as I have said, in November 1999, just over a year before the judicial review hearing. He said that, since becoming Chairman, he had chaired 13 meetings, over a total of 28 days, at which 314 decisions had been made. In addition, he had been involved in a further 89 decisions prior to becoming Chairman. Mr Nicholls also described the expertise and experience of the medical members of the PPC who had been present at the relevant meeting. He expanded on the reasons set out in the PPC's decision letter. He explained that the question of whether Miss Wetherell had complained of, or presented with, shortness of breath at the consultation was a **'secondary issue'** once the PPC had decided that **'it was not in the least unreasonable'** for a pulmonary embolism not to have been detected or diagnosed. Even if she had been short of breath, it was said, there were not enough symptoms to make it reasonable to expect a referral to a specialist. The decision of members of the PPC (both medical and lay) had been unanimous.

20.135 Sullivan J agreed that the PPC should adopt the approach suggested by Lightman J in Toth, subject to two comments. First, Lightman J had said that the PPC should exercise **'the utmost caution'** in deciding not to refer a complaint to the PCC on the basis that it had no real prospect of being established, having itself conducted a preliminary investigation into its prospects on the documents alone. Sullivan J suggested that, while caution was required, the need for **'the utmost caution'** in every case might be debatable. However, he suggested that **'the utmost caution'** *was* necessary in a case such as Richards, where the PPC was disagreeing with the conclusion of another body with medical expertise, a conclusion that had been reached after a public hearing where oral evidence had been presented. Second, Sullivan J did not interpret Lightman J's observation that it was not the PPC's role to resolve conflicts of evidence as meaning that the PPC must never under any circumstances resolve any conflict of evidence. Sullivan J preferred to say that the PPC **'should not normally seek to resolve substantial conflicts of evidence'**. To do so, he said, would be to go beyond its screening role and to usurp the function of the PCC.

20.136 Sullivan J observed that there was a public interest in having complaints of SPM thoroughly and openly investigated by the PCC at a public hearing. Meetings (such as those of the PPC) to consider documents in private might, he said, serve to maintain standards, but would not **'ensure public confidence in the process'**. He drew attention to the number of cases dealt with at PPC meetings, which had been given by Mr Nicholls. The Judge accepted that the PPC's decision in the Richards case had received particular care and attention. Nevertheless, he said that such a throughput of cases gave some indication of the level of scrutiny that the PPC was able to give to an individual complaint. This was in contrast to the four days of oral hearing before the appeal panel.

20.137 Sullivan J found that the PPC's decision letter showed that the PPC had sought to resolve substantial conflicts of evidence. The PPC had concluded that the issue of whether Miss Wetherell was suffering from shortness of breath was not significant. That finding conflicted with the views of the Coroner, with Dr Pathak's own evidence (which was that, if there had been a complaint of shortness of breath, he would have recorded it in his notes), with the conclusion of the appeal panel and (although the second PPC panel was not aware of it) with the view of the first PPC panel. He observed that he found it:

> **'... impossible to understand how it** (*i.e. the PPC*) **could reasonably have concluded not merely that it disagreed with these conclusions of the Coroner and the Health Authority** (*by which he must have meant the appeal panel*)**, but that the existence of these very different conclusions did not appear to raise a question for the PCC'**.

20.138 Sullivan J found the PPC's conclusion that the records of the consultation were **'both genuine and accurate'** even more difficult to understand. The Coroner had concluded that the notes were inadequate. The appeal panel had concluded that the notes did not record shortness of breath which was present at the time of the consultation. Dr Pathak had accepted that the note that Miss Wetherell had attended for a **'pill check'** was inaccurate. The Judge said that he could not understand how any reasonable committee could have been so persuaded of the accuracy of the notes as to conclude that no question for the PCC was raised.

20.139 The appeal panel had also concluded (albeit on a balance of probabilities) that Miss Wetherell was significantly short of breath at her consultation with Dr Pathak. The PPC had disagreed with that conclusion. It had considered Ms Richards' evidence and excluded it as hearsay. Sullivan J found that, although the evidence would have been inadmissible in law, the PCC could have chosen to use the discretion given to it under the Rules to receive the evidence. He observed:

> **'... in exercising that discretion the PCC would no doubt bear in mind not merely the interests of the individual complainant and doctor, but also the public interest in having complaints thoroughly investigated. The PCC is not in precisely the same position as a criminal court. It has an important investigatory and regulatory role in the public interest ... Would the reception of this evidence be ''desirable'' in the interests of ''making due inquiry''? In circumstances where firsthand evidence is not available because the patient has died and it is claimed that this is due to the doctor's serious professional misconduct, it might well be in the interests of making due inquiry to admit hearsay evidence of what the patient is said to have told the doctor. The weight to be attributed to such evidence will of course depend upon all the circumstances, including the extent to which the evidence is contradicted or supported by other admissible evidence.'**

20.140 In relation to the appearance of the letters **'SOB'** on the endocrinology report, Sullivan J observed that the PPC had taken it upon itself to draw inferences (albeit on an incomplete review of the evidence) and to resolve a critical area of dispute. He noted that further information (which tended to undermine the PPC's finding) had been obtained from the hospital since the PPC's decision, and observed that this illustrated:

> **'... the dangers of reaching final conclusions on highly contentious aspects of a complaint at a private meeting where neither party is present, and without making further investigation ...'**.

20.141 The Judge observed that it was perhaps because of the PPC's expertise that it had **'set out to answer the matters in dispute rather than decide whether there was a question for the PCC to answer'**. He concluded:

'I understand the basis on which the members of the PPC reached their own (unanimous) conclusions as to clinical care and as to whether Miss Wetherell had told Dr S K Pathak about or displayed breathing difficulties. However, in the light of all of the evidence I do not understand how a body with a screening function, even one as expert as this PPC, could possibly have formed the opinion that the material before them under these two heads did not even ''raise a question whether serious professional misconduct had been committed''.'

20.142 Sullivan J quashed the decision and remitted the case to a third PPC panel. Its consideration was to be conducted in the light of all the information then available, including information about the previous two decisions of the PPC.

Comment on the Case of Richards

20.143 These two decisions of the PPC (one taken before the change of Chairmanship and one after) illustrate many of the problems of which Professor Allen and her colleagues wrote in the 2000 PSI Report and of which she spoke when giving evidence to the Inquiry. They demonstrate what happens when decisions are taken by a committee that has no clear understanding of its functions or of the limitations on its powers. They demonstrate what happens when decisions are taken in an unstructured way and without the benefit of objective standards and criteria which can be consistently applied. They illustrate what Professor Allen described and what I have observed to be a tendency to look for acceptable explanations for the doctor's actions. When these two decisions are considered in conjunction with the 2000 PSI Report, the evidence of Professor Allen and other PPC cases examined by the Inquiry, it seems clear to me that the decisions in Richards were not just unfortunate – but isolated – errors. It is evident that decision-making in the PPC must have been defective for years, if not always.

20.144 There are a number of particular causes for concern. One is that a decision to close a case was sometimes taken on the basis that the evidence was hearsay and was therefore unlikely to be admitted by the PCC. As Sullivan J pointed out, the PCC had a discretion to admit hearsay evidence, even though, in general, it applied the rules of evidence applicable in a criminal trial. Whether it is appropriate for a disciplinary body charged with the protection of patients and the public to operate under the rules of criminal procedure is a different question to be dealt with later in this Report. However, it is worrying that the PPC should base a decision, even in part, on the assumption that the PCC would take little or no heed of hearsay evidence which it could have admitted had it thought fit.

20.145 Another particular cause for concern is that, in Richards, the GMC argued that it was appropriate that the PPC should **'get its sleeves rolled up'** when considering cases. I infer from this that the GMC thought that the PPC should have a general role in resolving disputed evidence in FTP cases. As a screening body, it should not have done this usually and should never have done it where there was evidence, capable of belief, in support of the allegation. It is astonishing that the PPC should have thought it appropriate to do so in a case in which that exercise involved disagreeing with the conclusions of a medically qualified panel which had heard evidence over a period of four days.

After the Case of Richards

20.146 Mr Nicholls told the Inquiry that he remembered 'some despair' after the decision in Richards. I can understand why. To make one fundamental error of approach in dealing with an individual case would give rise to some embarrassment, but to make two in respect of the same case – in which there was such an abundance of good quality information – must indeed have created a sense of despair. Mr Nicholls recalled that there was another judicial review at about the same time. That would have been the case of Holmes, with which I shall deal later in this Chapter. The claimants in that case were granted permission to apply for judicial review shortly before the judgement was delivered in the case of Richards.

The *Aide Memoire*

20.147 In the light of the case of Richards, the GMC sought advice from counsel as to how the PPC should proceed in future. Counsel produced an *aide memoire* for the use of the PPC when making its decisions. The first version was available in January 2001. This reads as follows:

> **'1. In conduct cases the PPC's task is to decide whether, in its opinion, there is a real prospect of serious professional misconduct being established before the PCC. Serious professional misconduct may be considered in the context of conduct so grave as potentially to call into question a practitioner's registration whether indefinitely, temporarily or conditionally.**
>
> **2. The ''real prospect'' test applies to both the factual allegations and the question whether, if established, the facts would amount to serious professional misconduct. It reflects not a probability but rather a genuine (not remote or fanciful) possibility. It is in no-one's interest for cases to be referred to the PCC when they are bound to fail, and the PPC may properly decline to refer such cases. On the other hand, cases which raise a genuine issue of serious professional misconduct are for the PCC to decide.**
>
> **3. The following does not purport to be an exhaustive list, but in performing its task the PPC:**
>
> > **(1) should bear in mind that the standard of proof before the PCC will be the criminal standard (beyond a reasonable doubt);**
> >
> > **(2) is entitled to assess the weight of the evidence;**
> >
> > **(3) should not, however, normally seek to resolve substantial conflicts of evidence;**
> >
> > **(4) should proceed with caution (given that, among other considerations, it is working from documents alone and does not generally have the benefit of the complainant's response to any**

reply to the complaint submitted on behalf of the practitioner); (*in fact, as I have said, GMC policy from July 2000 was that the complainant's response should be obtained and put before the screeners*)

(5) should proceed with particular caution in reaching a decision to halt a complaint when the decision may be perceived as inconsistent with a decision made by another public body with medical personnel or input (for example, an NHS body, a Coroner or an Ombudsman) in relation to the same or substantially the same facts and, if it does reach such a decision, should give reasons for any apparent inconsistency;

(6) should be slower to halt a complaint against a practitioner who continues to practise than against one who does not;

(7) if in doubt, should consider invoking Rule 13 of the Procedure Rules (*i.e. the power to cause further investigations to be made before reaching a decision*) **and in any event should lean in favour of allowing the complainant to proceed to the PCC; and**

(8) should bear in mind that, whilst there is a public interest in medical practitioners not being harassed by unfounded complaints, there is also a public interest in the ventilation before the PCC in public of complaints which do have a real prospect of establishing serious professional misconduct.'

20.148 In March 2001, the *aide memoire* was amended slightly (and re-numbered) to include the following paragraph:

> **'(8) before referring to the Health Committee, should consider any causal connection between the alleged misconduct and some potential serious mental or physical impairment and should be mindful of the PCC's own power to refer; ...'**.

20.149 This first version of the *aide memoire* was approved by Mr Justice Burton in the later case of Woods v General Medical Council[4], with a minor change in paragraph (4) to reflect the fact that there might not be a complainant in every case.

20.150 Mr Nicholls told the Inquiry that he had found the definition of SPM contained in the 1997 Note (see paragraph 20.61), which had constituted the guidance to the PPC up to this time, 'rather circular'. The difficulty centred on the word 'serious', the meaning of which was not clear. He said that, to a complainant, 'serious' might be the outcome of a case (i.e. whether the patient had died or suffered serious harm as a result of the doctor's conduct). However, to the medical profession, 'serious' meant whether the doctor's registration was going to be brought into question. He said that there were arguments in his early days on the PPC 'about serious – serious for whom and for what?' The *aide memoire* had settled those arguments. It was then clear, he said, that 'serious' meant 'sufficiently bad,

[4] [2002] EWHC 1484 (Admin).

sufficiently below the standard you expect, sufficiently poor conduct to call the doctor's registration into question'.

20.151 I can see that the *aide memoire* might have solved the particular problem that had concerned Mr Nicholls and some of his colleagues on the PPC but it did not tackle the other difficulty, namely knowing how serious a doctor's misconduct or deficient performance has to be before it calls registration into question.

20.152 When asked what conduct he would regard as calling a doctor's registration into question, Mr Nicholls said that he would look at 'Good Medical Practice', he would look at the occurrence, at the frequency of the conduct, at whether the incident was a 'one-off' or whether there was a pattern in the conduct. He would consider whether the conduct was so far below the standard expected of a doctor at that level as to raise questions about the doctor's registration.

20.153 Mr Nicholls told the Inquiry that, after the introduction of the *aide memoire* in January 2001, he felt that the PPC did achieve greater consistency than the 2000 PSI Report had suggested was the case in 1999 and early 2000. However, he said that, under the GMC's new FTP procedures, he would like to see 'much more criteria-based decision processes' which could then be monitored and quality assured. I understood him to be saying that he believed that the PPC had applied more consistent criteria since the *aide memoire* was introduced, but that this could not be demonstrated adequately. He welcomed the idea of guidelines to assist decision-makers but emphasised that there should be room for individual judgement within the process. He feared that, if there were not, the process would become 'too mechanistic'. He felt that a return to a list of published criteria setting out the types of conduct which would lead the GMC to act against a doctor's registration would be counter-productive and at odds with the GMC's other functions of raising the overall standard of practice and of educating doctors for the future. He conceded that the disparities highlighted in the PSI research could not be explained even at the time when he gave evidence to the Inquiry in December 2003, because the GMC did not have the necessary data.

20.154 Mr Nicholls said that, following the production of the *aide memoire*, the PPC 'hardly ever' made a decision in conflict with that of an IRP which had received medical advice or with that of a coroner's inquest. If it did, it had to show very clearly why it had done so.

The Workload of the Preliminary Proceedings Committee from 2000 to 2003

20.155 It is clear from Mr Nicholls' evidence in the case of Richards that the workload of the PPC in 2000 was very heavy indeed. He sat on 314 cases between November 1999 and the time when he made his witness statement for the hearing, which took place in December 2000. A large number of interim orders were made by the PPC in the period up to August 2000, at which time responsibility for making interim orders passed to the IOC. In 2000, the PPC considered 423 cases. In 2001, the number of cases considered by the PPC rose to 571 and the PPC sat for 35 days. In 2002, the PPC dealt with 610 cases over 35 days. Mr Nicholls said that the target set for the PPC was to deal with 20 cases at each meeting. The outcome for some of those cases would be very obvious and that would assist the PPC

in achieving its target. However, the PPC missed its target quite often, as a result of which backlogs of cases built up. During this time, different panels of the PPC sat with different chairmen; use was made of co-opted GMC and associate members.

20.156 Mr Nicholls said that, at the time when he first joined the PPC, the time allowed for discussion of cases at meetings was too short to give proper consideration and judgement to some cases and, in particular, to the very difficult issue of whether a doctor's conduct was sufficiently serious to call his/her registration into question. This view accords with the observations of Professor Allen and her colleagues contained in the 2000 PSI Report. Mr Nicholls said that the increase in the number of days' sitting was, in part, to allow more time for the more difficult cases. In addition, the system for ordering the papers which were given to members of the PPC improved as a result of the recommendations of the PSI team. A system of indexing the papers was adopted, which made it easier for members to find their way round what might be a large file of papers. From July 2000, the screener's memorandum, setting out the screener's reasons for referring the case, was included in the papers. However, even with these improvements, Mr Nicholls said that it still took him between one and one and a half days to prepare for a day's sitting.

20.157 That Mr Nicholls should mention that there was insufficient time for discussion of the difficult question of whether the conduct amounted to SPM suggests that the PPC was asking itself the wrong question. If, on seriousness, it had confined itself to considering whether the PCC might conclude that the conduct amounted to SPM, that would have reduced the need for long arguments. It seems to me that a useful convention for a committee such as the PPC may be that, if one member thinks that the conduct (if proved) could amount to SPM, the rest should accept that view and act upon it. A similar convention guides the Court of Appeal (Criminal Division), when considering oral applications for permission to appeal against conviction or sentence. If one member of the Court thinks that leave should be granted, the others immediately acquiesce.

Two More Cases of Judicial Review

The Case of McNicholas

20.158 In March 2001, Mr Justice Sullivan, who had heard the case of Richards, heard a renewed application for permission to apply for judicial review of a decision of the PPC in the case of R v General Medical Council ex parte McNicholas[5]. The case concerned complaints made against three doctors. I do not intend to describe the case in any detail because it did not establish any new principles. I mention it partly lest it be thought that I have focussed too closely on cases in which the GMC was found wanting and have not noticed those in which the GMC's approach was found by the Court to be correct. The other reason for mentioning it is that the Judge affirmed that which I do not think has ever been in doubt, namely that the GMC is the arbiter of what does and does not amount to SPM. In short, the Judge refused permission to seek judicial review on the ground that the PPC's decision had been taken lawfully. He found that it had not, as was alleged, resolved major conflicts of evidence; nor had it reached factual conclusions that were contrary to the findings of

[5] 13th March 2001 (unreported).

the Health Service Commissioner (and possibly an IRP) who had investigated the case. The Judge said that the case was to be distinguished from that of Richards because there was really no issue that the doctors had fallen short of the standard of care that a conscientious doctor would have provided in the circumstances. The remaining question was, he said, **'very much a matter for the professional judgment of the committee: was it arguable that their failures were so serious as to amount to serious professional misconduct'**.

20.159 The Judge pointed out that **'not every error by a medical man'** amounted to SPM. The other bodies who had looked at the case had identified, at least in the case of two of the doctors, **'particular and isolated errors rather than a course of conduct'**. The other bodies had been considering whether the standard of care given by the doctors fell short of the standard to be expected of a conscientious GP. It would have been perfectly possible to answer that question in the affirmative and yet at the same time to conclude that the failure was not such as to amount to SPM. That, the Judge said, was the reason for the PPC's conclusion. He accepted that a differently constituted PPC might have taken a different view. That was not to say that it was not open to **'this very expert committee'** to take the view that it did. He therefore refused permission to apply for judicial review.

The Case of Woods

20.160 I mention also the case of Woods, to which I referred at some length in Chapter 19. That case concerned several doctors whose conduct was the subject of criticism in the report of the Royal Liverpool Children's Hospital Inquiry (the Alder Hey Inquiry). Mr Nicholls provided a witness statement in respect of the nine doctors whose cases had been considered and closed by the PPC. He referred to the *aide memoire* and asserted that the PPC had acted in accordance with its guidance. The Judge approved the advice given in the *aide memoire* and accepted that the PPC had indeed followed its guidance. In respect of all the decisions of the PPC, the application for judicial review failed.

The Case of Holmes

20.161 In Chapter 19, I outlined the circumstances of the case of R v General Medical Council ex parte Holmes and others[6], which was decided by Mr Justice Ouseley in April 2001. It concerned applications for judicial review challenging, *inter alia*, decisions of the medical and lay screeners in respect of a complaint against Dr M M Rahman and a decision of the PPC relating to a complaint against Dr S Sengupta. The Judge quashed all the decisions. I discussed the decision in Dr Rahman's case in Chapter 19. I shall now consider the Judge's decision in Dr Sengupta's case. This case was also considered by the Court of Appeal in October 2002[7].

The Complaints

20.162 The case concerned complaints by the partner, Ms Caryl Nancy Holmes, and the parents (I shall refer to the three of them as 'the claimants') of Mr Derrick Marcus Dean, who died

[6] [2001] EWHC 321 (Admin).
[7] [2002] EWCA CIV 1838.

on 26th July 1995, aged 34, from a colloid cyst on the brain. The complaints related to the standard of care given to Mr Dean by his GP, Dr Rahman, and by a deputising doctor, Dr Sengupta. Mr Dean had seen Dr Rahman at his surgery two days before his death. On the evening before he died, he had been seen at his home by Dr Sengupta. He had subsequently been admitted to hospital where he died. The precise nature of the failure of the standard of care alleged by the claimants is not clear from the judgement. It seems likely that the claimants alleged failure by both doctors to appreciate the seriousness of Mr Dean's condition.

20.163 Following Mr Dean's death, Ms Holmes complained to the local FHSA about both doctors. In March 1996, a MSC concluded that Dr Sengupta had breached his terms of service but Dr Rahman had not. Ms Holmes appealed to the SoS for Wales against the decision in respect of Dr Rahman. The appeal was allowed and, in June or July 1998, the SoS for Wales directed that the complaint against Dr Rahman should be referred to the GMC. In July 1998, the claimants made a complaint to the GMC against Dr Sengupta. Some time in early 1999, the principal medical screener, Dr Steel, and another medical screener, Professor Hilary Thomas, decided that the complaints against both Dr Sengupta and Dr Rahman should not be referred to the PPC; a lay screener agreed in the case of Dr Rahman. His case was closed and, as I explained in Chapter 19, that decision was later quashed on judicial review. However, in Dr Sengupta's case, the lay screener disagreed with the medical screeners' view and Dr Sengupta's case was therefore referred to the PPC.

The Decision of the Preliminary Proceedings Committee

20.164 The PPC considered the complaint against Dr Sengupta on 9th September 1999. The meeting was chaired by Dr Steel. This must have been one of the last cases where a PPC panel was chaired by the person who had also been responsible for screening the complaint. Until November 1999, this was a very frequent occurrence but, to modern eyes, was obviously unsatisfactory. A person in that position could hardly be expected to approach the case with an open mind and the chance that s/he would change his/her mind and support the referral of the case to the PCC must have been remote. Professor Allen had observed at this time that there was very little discussion of a case after the Chairman had introduced it. Not surprisingly, the PPC decided not to refer Dr Sengupta's case to the PCC but, instead, to send Dr Sengupta a warning letter. The minute recording the PPC's decision stated:

> **'W/L** (*i.e. a warning letter*) **on the basis that this is a single case, patient had been seen very recently in hospital, doctor offered review in 12 hours and condition difficult for GP to diagnose. But Ctte did not accept he'd carried out an adequate examination and also were critical of the fact that his assessment was not documented. Letter should also say Ctte reinforced decision of MSC.'**

20.165 Subsequently, the GMC wrote to the claimants' solicitors and to Dr Sengupta, informing them of the decision of the PPC. The letter to the claimants' solicitors, written by a caseworker, stated that the PPC had decided that it would not be necessary to refer the case to the PCC for further consideration of the doctor's fitness to practise. It went on:

> **'The Committee concurred with the view of the original Medical Service Committee which found that Dr Sengupta had not placed himself in an adequate position to make a clinical judgement and that the record keeping of the consultation with Mr Dean was poor.**
>
> **They felt that Dr Sengupta did not give due regard to Mr Dean's prior medical history and that his actions were inadequate in the circumstances.**
>
> **However, the Committee took into account that this was a single case and that Mr Dean had recently been seen in hospital. They noted that Dr Sengupta had offered to review Mr Dean's condition in 12 hours and the condition which Mr Dean had was, of itself difficult to diagnose.**
>
> **The Committee felt having regard to all these circumstances that this matter did not reach the threshold of serious professional misconduct.'**

20.166 The letter went on to say that the Committee had asked the author of the letter to explain that the Committee had a duty to examine the doctor's individual actions and that an error or omission (even where this had had serious consequences) might not **'justify the revocation of a doctor's license** (*sic*) **to practise permanently'**. The letter stated that Dr Sengupta had been reminded of his professional obligations and had been warned that the matter might be reconsidered should the GMC receive any further information about his practice in the next three years. The reference to three years suggests that it was contemplated that it might be taken into account in future performance (rather than conduct) proceedings. As I have explained, a two-year limit operated for the revival of conduct matters, but it seems that the GMC operated an unofficial cut-off of 3 years for performance allegations.

The Judicial Review Process

20.167 The claimants issued judicial review proceedings, challenging the GMC's decisions in relation to both doctors. The doctors were joined in the proceedings as interested parties. Grounds of opposition were filed by the GMC and the doctors. In December 2000, the claimants were granted permission to apply for judicial review. That was about six months after the decision in Toth and 13 days before the decision in Richards, which was delivered on 18th December 2000. Very shortly after, the GMC informed the doctors' solicitors that it was minded to concede the claim because of doubts as to the lawfulness of the decisions of the screeners (in Dr Rahman's case) and of the PPC (in that of Dr Sengupta). Subsequently, the GMC decided to consent to the quashing of the two decisions on the ground that, in reaching those decisions, the wrong legal tests had been applied. A consent order was agreed between the GMC and the claimants. The doctors opposed the application at a hearing before Ouseley J. As I have said previously, this gave rise to an unusual form of hearing.

20.168 The reasons why the GMC agreed that the decision in Dr Sengupta's case was unsustainable were set out in a witness statement provided by a representative of the GMC's solicitors. He said that the letter to the claimants' solicitors and the doctor was in

'PCC language'. It echoed the test of the PCC and did not appear to be consistent with the test to be applied by the PPC. It indicated that the PPC had reached conclusions or findings as to the errors that Dr Sengupta had made. The witness statement continued:

> **'It suggests that they** (*i.e. the PPC*) **then reached a conclusion that these errors did not reach the level of serious professional misconduct. They did not ask themselves whether there was a ''question'' of whether that level was reached, or whether it was arguable that it might have been reached. They reached a definitive conclusion.'**

20.169 The witness statement went on to cite the reference in the GMC's letter to the power to revoke a doctor's licence to practise **'permanently'**. It observed:

> **'This is troubling since it does not appear that the PPC has considered the power to affect the right to practise temporarily or conditionally or the power to impose a lesser sanction (such as a reprimand).'**

20.170 Ouseley J noted that he had received no evidence from the GMC about the tests which had been applied by the screeners or the PPC. He observed:

> **'... if there had been clear evidence of a test being consistently applied with the relevant distinctions between the roles of the various bodies being routinely observed, I would have had it, even if the individual case itself could not be remembered. I attach weight, but not determinative weight, to the position of the GMC, knowing its decision makers and the language which is used by them, being unable to support the decisions in this case as positively showing that the correct approach had been adopted.'**

20.171 It was clear from the position taken by the GMC that it had recognised that its decision-makers had not adopted the correct approach. I refer back to the observations of Professor Allen and her colleagues that GMC decision-makers appeared to have no clear idea of their role or of the tests that they should be applying.

20.172 Ouseley J said that he was not persuaded that the part of the letter which I have quoted at paragraph 20.165, taken in isolation, evidenced an error of law. Nor was there any impermissible finding of fact, since the PPC had taken the case against the doctor at its highest. However, that left the **'seriously troubling'** matter of the use of the word **'permanently'**. He said:

> **'... I do consider that the language shows that the range of conduct capable of constituting serious professional misconduct was unduly narrowed because other and lesser penalties exist for serious professional misconduct which are relevant to the judgment of the quality of conduct as capable of constituting serious professional misconduct.'**

20.173 As a result, Ouseley J concluded that there had been an error of law and quashed the PPC's decision. Dr Sengupta applied to the Court of Appeal for permission to appeal

against the Judge's decision. Permission was initially refused but was subsequently granted at an oral hearing.

The Court of Appeal Hearing

20.174 Before the hearing of the appeal, the GMC filed a Respondent's Notice contending, as an additional reason for upholding the Judge's decision (which had, of course, been to quash the decision of the PPC), that the statement in the GMC's letter that the PPC **'felt that having regard to all the circumstances that this matter did not reach the threshold of serious professional misconduct'** set the threshold too high. Ouseley J had rejected that contention. The GMC also conceded that the entirety of the letter was couched in terms of decision-making on the merits of the case. In my view, it is greatly to the credit of the GMC and its legal team that it adopted this approach in the Court of Appeal. The GMC was in effect inviting the Court to hold that the PPC had been wrong in two respects and not only in the one respect found by the Judge.

20.175 Giving judgement in the Court of Appeal, Lord Justice Parker said:

> **'... the terms of that** (*i.e. the GMC's*) **letter, read as a whole, are consistent only with the PPC having applied the wrong legal test in reaching its decision, in that (a) it regarded itself as having a fact-finding role, and (b) it treated the range of ''serious professional misconduct'' as being restricted to conduct which would attract ''permanent'' erasure from the register of practitioners, and in doing so left out of account conduct which would justify a lesser penalty'**.

He accepted the GMC's submission that the Judge had been in error in not concluding that the PPC had assumed a fact-finding role. Also, in his view, the use of the word **'permanently'** was consistent only with the PPC having misdirected itself as to its true role. The other members of the Court of Appeal agreed with Parker LJ and Dr Sengupta's appeal was dismissed. The mistakes made by the PPC in the case of Holmes were of a fundamental nature. The errors revealed in the case of Richards had not been isolated.

Later Developments

The 2003 Policy Studies Institute Paper

20.176 Professor Allen and her colleagues analysed the outcomes of cases referred to the PPC during the period from 1999 to 2001. The results were published in their 2003 Paper.

20.177 The proportion of all doctors whose cases were referred by the PPC to the PCC had increased markedly, from 30% of all cases considered by the PPC in 1997 and 31% in 1998, to 41% in 1999 and 2000. The proportion dropped again to 34% in 2001. The proportion of UK qualifiers sent by the PPC to the PCC was much lower than the proportion of overseas qualifiers in all five years.

20.178 Over the years 1999, 2000 and 2001, the PPC had sent fewer than half of the doctors who had been convicted of criminal offences (other than drink driving) to the PCC. In all three years 1999, 2000 and 2001, the proportion of overseas qualifiers with convictions referred

by the PPC to the PCC was considerably higher than that of UK qualifiers. This was puzzling since one might have expected the PPC to adopt a consistent approach when dealing with doctors who had committed criminal offences. Once again, a greater proportion of UK qualifiers than of overseas qualifiers was referred to the health procedures, raising the possibility that overseas qualifiers were being treated unfairly as compared with those who had qualified in the UK.

20.179 On this occasion, the PSI team had been commissioned by the GMC to carry out a purely quantitative analysis. Professor Allen and her colleagues did not carry out any qualitative analysis, such as an analysis of the reasons given by the PPC for its decisions. They were unable to find any explanation for the anomalies. The continuing disproportionate referral rates of overseas qualifiers who had been convicted of criminal offences were particularly difficult to explain. In its 2003 Paper, the PSI team warned that, until there were some objective measures, which could demonstrate that the disproportionate referral rates had occurred for good reason and were fair and reasonable, the GMC remained open to accusations of bias. The 2003 Paper reiterated the need for commonly agreed criteria and thresholds to be applied when reaching judgements about the seriousness of cases and about how they should be dealt with.

20.180 Mr Nicholls told the Inquiry that the contents of the 2003 PSI Paper were very disappointing for the GMC. There was still no explanation for the disparities revealed by the analysis carried out by the PSI team. This was, of course, not surprising since, on this occasion, the PSI team had been commissioned to carry out only a statistical analysis of the cases dealt with during the relevant period. It had conducted no further research into the decision-making processes. Nor had the GMC itself carried out any such research. And, despite all the changes, the people making decisions on behalf of the GMC – of whom there were by this time hundreds – still had no standards and criteria to use in the process. What the analysis showed was that there was a continuing problem which needed addressing. The difference in treatment of convictions in particular needed an explanation. Mr Nicholls said that the PPC's view was that research should be undertaken in order to explore the reasons for the apparent disparities. Now that the PPC recorded reasons for its decisions, he said that it would be possible to carry out a retrospective study. In addition to that, there was a need for continuing monitoring and audit.

Changes in the Treatment of Convictions

20.181 On the face of it, the proportion of conviction cases referred by the PPC to the PCC seems remarkably low. As I have also explained, the PSI research highlighted a disparity between UK and overseas qualifiers in the treatment of cases where doctors had been convicted of criminal offences. The PSI team was concerned about both sets of findings.

20.182 It is true that the numbers of convictions (other than drink driving cases) referred to the PPC were small (23 in 1997, 32 in 1998 and 31 in 1999). The GMC's procedures permitted more minor convictions to be filtered out by GMC staff (in the case of minor motoring offences) and (in the case of other minor offences) by the medical screeners, so that they would not have reached the PPC. As I have said in Chapter 19, the medical screeners had for many years been authorised to use their discretion in deciding whether to refer cases

relating to offences committed more than five years before notification to the GMC. The medical screeners had also been given discretion not to refer convictions for minor offences not ostensibly related to a doctor's professional practice, nor involving a degree of dishonesty such as to bring disrepute upon the medical profession. In addition, the 'conviction' cases considered by the PPC did not include cases in which an absolute or conditional discharge had been imposed by the courts. Given that the PPC would not be called upon to adjudicate on the types of case described above, it must follow that the conviction cases which the PPC was deciding not to refer to the PCC were for offences of a higher degree of seriousness.

20.183 Mr Nicholls said that there were some minor convictions (he described them as 'one-offs') where the Court had imposed a very low sentence and where the PPC might take the view that a warning letter was sufficient. A document describing the GMC's conduct procedures, published in July 2000, suggested that first convictions for 'shoplifting' would be dealt with by way of a warning letter or a letter of advice. This was presumably the type of case to which Mr Nicholls was referring.

20.184 I interpose to say that it does appear that, in the past, the GMC has tended to assess the gravity of a doctor's conduct by reference to the penalty imposed by the court. When sitting as a judge (and, before that, when appearing in court as counsel), I have heard pleas in mitigation made on behalf of doctors convicted of criminal offences, in which the court has been urged to treat the doctor leniently because his/her career – or even life – is said to be in ruins as a result of the action that will inevitably be taken by the GMC as a result of his/her conviction. The implication is that the doctor will lose his/her livelihood and will face professional disgrace. Faced with that kind of plea in mitigation, it is not surprising if a court feels constrained to impose a more lenient sentence than might otherwise be thought appropriate. The court would no doubt be surprised to learn that the GMC had later taken a lenient view of the case because the judge had imposed a lenient sentence. It seems to me that the sentence passed by the criminal court is of very limited relevance to the seriousness of the doctor's conduct from the GMC's point of view. What should matter to the GMC is the doctor's fitness to practise as a doctor and whether s/he represents a risk to patients. Those are not the issues on which the Court will have focussed. I will return to this subject later in this Report.

20.185 As I have said, the PSI team had recommended that all convictions (save those for drink driving) should be referred directly to the PCC without the intervention of the screeners or the PPC. This recommendation was not adopted. Instead, a far more limited rule was brought into force. In November 2002, the 1988 Professional Conduct Rules were amended so as to permit all convictions where an immediate (i.e. not suspended) custodial sentence had been imposed to be referred by the Registrar direct to the PCC unless he was of the opinion that such a direct referral would not be in the public interest.

20.186 Mr Scott explained that the GMC had not moved immediately to a full implementation of the PSI team's recommendation because of resistance from some members of the Council. Their belief was that there should be an opportunity for the exercise of discretion (presumably by the PPC and, to a lesser extent, by the medical screeners), even in cases where doctors had been convicted of criminal offences. Mr Scott said that, in the light of

this opposition, it had been possible to make progress only in stages, rather than in one leap. He told the Inquiry that his personal view was that the GMC should move as rapidly as possible to a position whereby all save the most minor convictions were referred to the PCC (or, in the future, to a FTP panel). However, the decision was not for him but for elected members. Mr Scott said that he had no doubt that the GMC would 'continue to shift the boundaries' and would in time implement the recommendation of the PSI team. Meanwhile, in addressing the question of why all convictions had not previously been referred routinely to the PCC, Mr Scott said:

> **'... I do not think I can honestly explain that except in the terms that decision makers exercised a discretion they were entitled to exercise and they made decisions that others might not have done'**.

Comment

20.187 If the PPC had had a good track record for exercising its discretion consistently and in a way that was appropriate in the public interest, I might have been able to understand why the GMC did not wish to move to the position recommended by the PSI team. I can see why it might be felt that not every single case in which a doctor had been convicted should go to the PCC. However, this was not so. The GMC could see from the statistics produced by the PSI team that a substantial proportion of the more serious conviction cases were not being referred to the PCC. In other words, it was clear that the PPC was not referring a lot of cases that should have been referred. Rather than allowing this state of affairs to continue, the GMC should, in my view, have laid down some clear rules as to which convictions should be referred and which need not be. As it was, the GMC allowed the *status quo* to continue and did not even provide any guidance or criteria for the PPC, let alone a clear rule. Two problems resulted from this. First, there was a real potential for unfairness as between doctors. Second (as examination of the cases reveals), cases which, in the interests of the public, of the honour of the medical profession and of the reputation of the GMC, ought to have had public hearings did not.

20.188 It was clear to me, from an examination of some of the case files produced to the Inquiry, why the PPC failed to refer conviction cases that ought to have been referred. The PPC had a tendency to focus on the circumstances of the doctor rather than on the seriousness of the offence. Of course, the circumstances of the doctor should be taken into account by the PCC when deciding upon a penalty, but not by the PPC. Take, for example, a case in which a doctor has stolen money while working in a hospital. Instead of focussing on the facts underlying the conviction and deciding whether the conduct was serious enough to warrant referral, the PPC tended to focus on aspects of mitigation. It might have taken into account the fact that the doctor was under stress, was over-worked or had personal problems. It might have received testimonials as to the doctor's clinical abilities. On those grounds, the PPC might well have decided not to refer the case. In fact, the correct approach would have been to examine the conduct which had given rise to the conviction, decide whether it warranted referral and leave issues of mitigation to the PCC. Not only would such an approach have been correct in law, but it would also have ensured that the public (or that section of the public that was aware of the case) would have known how the GMC had dealt with the doctor and why it had dealt with him/her as it had. The difficulty

for the PPC was that they had no standards to apply when considering whether the case ought to be referred.

20.189 Under the new FTP procedures, it appears that some discretion will be exercised by the office staff, case examiners and, possibly, the Investigation Committee (IC), in relation to some types of conviction. They will be able to decide, in some instances, whether or not a conviction case should go forward to a public hearing before a FTP panel. I shall describe the proposals for the treatment of convictions under the new FTP procedures in Chapter 25.

The Recent Statistics

20.190 In its 2000 Report, the PSI team had asked why such a high proportion of cases (two thirds during its observations of meetings before November 1999 and over half after November 1999) which had been referred by screeners to the PPC were not referred to the PCC. The GMC's annual FTP statistics show that only 35% of those doctors who were dealt with by the PPC in 2002 were referred to the PCC. In 2003, the percentage of doctors referred by the PPC to the PCC was 30%.

20.191 Mr Nicholls said that he did not find the proportion of cases sent to the PCC surprising. The screeners were operating a low threshold, particularly after the judicial reviews (presumably those in the cases of Toth and Holmes), when there was 'more nervousness' about their 'limited powers'. The PPC, on the other hand, was looking at whether there was a realistic prospect of proving SPM. Mr Nicholls pointed out that, in many cases which were not referred to the PCC, the PPC took 'some action in the interests of the public against the doctor' by sending a warning letter or a letter of advice. In 2002, 43% of doctors dealt with by the PPC were sent a warning letter or a letter of advice. In 2003, the figure was 44%. In 2002, 61% of conviction cases were dealt with by way of a warning letter or a letter of advice. In 2003, the total was 65%. Some of these would be drink driving cases, but it seems that other convictions were also dealt with in this way. Warning letters and letters of advice must also have been sent in conduct cases where some or all of the facts had been proved or admitted by the doctor concerned or were beyond dispute. It seems to me that the explanation for the high proportion of cases not sent through to the PCC probably lay in the continued unwillingness of the PPC to confine itself to an assessment of the appropriate issues and in its tendency to take mitigating factors into account.

20.192 In evidence, Mr Nicholls was asked about the fact that, in 2002, the PPC had referred to the PCC only 23 (28%) of the 82 cases of sexual assault and indecency that had been referred to it by screeners. These were not cases where there had been a conviction, since convictions were listed separately in the annual FTP statistics. Mr Nicholls thought that the most likely reason for a decision not to refer was the difficulty of establishing the allegations to the criminal standard of proof required by the PCC. However, he pointed out that warning letters had been sent in 21 of the sexual assault or indecency cases. Since warning letters are sent only in cases where the allegation has been proved or admitted or is beyond dispute, it is difficult to see how evidential difficulties could account for the fact that those cases were not referred. Revised figures recently produced by the GMC (based on the number of doctors about whom allegations had been received, rather than

on the number of individual allegations) show that 33% of the 51 doctors against whom allegations of sexual assault or indecency had been made were referred to the PCC in 2002. The figure for 2003 was 30%. Letters of warning or advice were sent to 45% of doctors against whom allegations of sexual assault or indecency had been made in 2002 and to 39% of such doctors in 2003.

20.193 Mr Nicholls was also asked about the fact that, on the basis of the figures available at the time, it seems that, in 2002, the PPC had referred only 38 (55%) of the 69 dishonesty cases (again non-convictions) to the PCC. In 15 such cases (22%), a warning letter had been sent and, in eight cases, a letter of advice. Again, Mr Nicholls suggested that, since there had been no conviction in these cases, there might have been evidential problems in satisfying the criminal standard of proof. However, this could not account for cases in which a warning letter had been sent. Mr Nicholls said that there would be some 'very minor' offences in the dishonesty category. The revised figures show that 45% of doctors who faced allegations of dishonesty in 2002 were referred by the PPC to the PCC in 2002 and that 35% were referred in 2003. In 2002, 43% of such doctors were dealt with by way of a warning letter or a letter of advice. In 2003, that figure was 57%.

The Cancellation by the Preliminary Proceedings Committee of Hearings before the Professional Conduct Committee

20.194 Rule 19 of the 1980 Professional Conduct Rules provided:

> **'(1) Where, after a complaint or information has been referred to the Committee** (*i.e. the PCC*) **for inquiry, it appears to the President that the inquiry should not be held, he may after consultation with the members of the Preliminary Proceedings Committee who made the determination to hold the inquiry and in accordance with the opinion of those members or the majority of their opinions (including his own opinion) direct that the inquiry shall not be held ... Provided that in any case where there is a complainant the President shall, before he consults with members of the Preliminary Proceedings Committee as aforesaid, communicate or endeavour to communicate with the complainant with a view to obtaining the observations of the complainant as to whether the inquiry should be held.**
>
> **(2) Where the opinions of the members of the Committee are equally divided the question shall be deemed to have been resolved in favour of the practitioner, and the President shall direct that the inquiry shall not be held.**
>
> **(3) As soon as may be after the giving of any such direction the Solicitor** (*appointed by the GMC*) **shall give notice thereof to the practitioner and to the complainant (if any).'**

In this connection, the function of the President could be exercised by the member appointed to act as medical screener in his stead.

20.195 In the 1988 Professional Conduct Rules, rule 19 was changed. From that time, the function of the President could be exercised by the member appointed to act as medical screener in the President's place only if s/he had also been appointed Chairman of the PPC. The President (or the Chairman of the PPC) had to consult the PPC about a cancellation. However, the PPC was not required to meet for the purpose of this consultation. If the PPC agreed, the President (or the Chairman of the PPC) had the power to direct that the hearing by the PCC should not take place. In the event of the votes being equally divided, the President or Chairman of the PPC would have had an additional casting vote. The obligation to consult the complainant was preserved. In practice, however, this was done only if the complainant was a private individual. If the doctor had been referred to the GMC by a public body such as a NHS trust, that body would not have been consulted.

20.196 In 2000, the power to initiate the procedure for cancellation of a PCC hearing was given to the Chairman of the PPC. In November 2002, as I have said at paragraph 20.185, the 1988 Professional Conduct Rules were amended so as to permit all convictions where an immediate custodial sentence had been imposed to be referred by the Registrar direct to the PCC unless he was of the opinion that such a direct referral would not be in the public interest. At the same time, a new rule 19(3) was added:

> **'Where, after the Registrar has referred a conviction to the Committee for inquiry, it appears to him that the inquiry should not be held, he may direct that the inquiry shall not be held.'**

20.197 So far as the Inquiry is aware, no guidance was given or criteria set down as to the circumstances in which the Registrar or the GMC staff exercising his legal powers should use this power to cancel a PCC hearing in a conviction case which had been referred directly to the PCC by the Registrar or staff. I can see that it may be appropriate for a hearing by the PCC to be cancelled if a doctor's appeal against a criminal conviction is allowed, or if the doctor dies or is found to be terminally ill. However, it is not clear whether it was intended that the power should be exercised in any other circumstances.

20.198 Nor does there appear to have been any indication of the criteria which the PPC should apply when deciding whether to cancel a hearing by the PCC in a conduct case. Such decisions were taken in private and did not need to be taken at a meeting although, in practice, it appears that cancellations were considered at, and recorded in the minutes of, meetings of the PPC.

20.199 For most years, no figures showing the number of cancelled PCC hearings appear in the GMC's annual FTP statistics. At the Inquiry's request, the GMC provided information about the number of cases where an initial referral by the PPC of a case for hearing by the PCC was subsequently cancelled under the provisions of rule 19. That information shows that the hearings in 13% of the cases referred by the PPC to the PCC in 2000 were subsequently cancelled. The subsequent figures are 15% of the cases referred to the PCC in 2001, 20% of those referred to the PCC in 2002 and (as at the beginning of August 2004) 11% of the case referred to the PCC in 2003.

20.200 The GMC provided a breakdown of the reasons for the cancellation of hearings as recorded in the relevant files. The most common reasons were said to be

'unwilling/unreliable complainant or witness' and **'other evidential difficulties'**. In a significant proportion of cases, it was said that the expert reports which had been obtained did not support the case. In a few cases, the reason given was **'new information'**, and in two cases criminal appeals had succeeded. One doctor had died. There was one case (cancelled in 2000) where the reason given was **'unlikely to reach the threshold of SPM'**. The information provided by the GMC showed that doctors sometimes requested that the hearing in their cases should be cancelled for evidential or other reasons. If a first request was refused, the doctor might renew his/her request at a later stage.

Comment

20.201 These statistics seem to me to require further consideration by the Council. It may be that a changed approach by the PPC (with less emphasis upon consideration of whether the evidence was likely to stand up before the PCC) resulted in the PPC passing through some cases which, on further examination by the GMC's solicitors, were found to have serious evidential difficulties. If so, that would be reasonable although, if that were the case, it would underline the need for improved evidence gathering at an earlier stage of the process. However, 20% is a very high proportion of cases to be cancelled. The figures were not usually reported to the Council in the annual FTP statistics.

20.202 As many as 30 cases cancelled in 2002 were said to involve an unwilling complainant or witnesses. This might have been because of delay, because the complainant or witnesses had previously given evidence at another hearing, or because s/he felt intimidated in some way. One would have thought that the GMC would have been concerned that cases were being 'lost' because of unwilling complainants and witnesses and would have wanted to know what was behind this. It is possible that such witnesses might be assisted in the future by the vulnerable witnesses provisions which are proposed in the new FTP procedures. Better investigation earlier might also eliminate some cases which have no prospects of success. However, there is cause for concern because the proposals for cancelling cases are much more lax under the new FTP procedures. In my view, the full statistics should be published annually, showing clearly the percentage of cases referred which have subsequently been cancelled. The reasons for the cancellation, as well as the statistics, should be readily available. Research should be conducted into the reasons why cases are failing at this stage and steps should be taken to reduce such cases to a minimum.

The Inquiry's Examination of Cases

20.203 The Inquiry requested the disclosure of the files relating to certain classes of case considered by the PPC. The request related to three particular issues which the Inquiry had to address. First, the Inquiry wished to discover how, over the years, the GMC had handled the cases of doctors who had been convicted of controlled drugs offences (such as those of which Shipman had been convicted in 1976) and of those whose misconduct was thought to involve the abuse of controlled drugs. Many such cases were referred to the PPC. Second, the Inquiry wished to know how the GMC (and, in particular, the PPC)

had handled cases of alleged substandard clinical treatment during the 1990s, when Shipman was reported to the GMC following two adverse findings by a MSC. In addition, the Inquiry was interested to discover how the PPC would have dealt with a complaint, if one had been made, arising out of the case of Mrs Renate Overton, which I described in Chapter 10. The following discussion does not deal with all the case files disclosed. It focusses on those cases which have some similarity to the circumstances of Shipman's referrals, or which raise an issue of patient protection of concern to the Inquiry.

Cases Involving Controlled Drugs

20.204 As will be seen, the general theme underlying all the cases involving the abuse of controlled drugs is that the PPC would refer the doctor into the voluntary health procedures, even if s/he had been guilty of quite serious misconduct affecting patient safety or welfare. One recent case, that of Dr JO 09, which is typical of the way in which the PPC dealt with drug abusing doctors, is described in Chapter 23.

Dr JO 04

20.205 In most cases in which the PPC referred a doctor into the voluntary health procedures, there was some evidence of addiction or dependence such as would justify that referral. However, in the case of Dr JO 04, there was no evidence of addiction and no evidence which, to my eyes at least, could justify a referral into the voluntary health procedures. Yet that was the outcome. While working as a senior house officer at Hospital A, Dr JO 04's conduct gave rise to a suspicion that he was stealing fentanyl and injecting himself. No action was taken at the time. The doctor left that hospital and started work at Hospital B. Some time later, a member of staff at Hospital A informed Hospital B of the concerns and suspicions that had arisen. A few months later, the doctor was confronted with these suspicions in an interview attended by a member of staff from each hospital. He admitted that he had abused fentanyl in the past although, he claimed, this had never compromised his care of patients. He refused to give a hair sample for testing, claiming that he had taken cannabis at a party four days earlier. He was suspended or sent on sick leave and reported to the GMC.

20.206 After initial consideration, the case was referred to a medical screener, who recommended that the case be referred to the PPC and the IOC. He observed that there were concerns about SPM and about patient safety. At the hearing before the IOC, counsel for the doctor said that the doctor had retracted his admission that he had abused fentanyl. His case was that he had once taken the drug on the tongue (not by injection) while at Hospital A, but any suggestion that he had used it over a period would be strongly denied. The IOC imposed conditions on the doctor's registration for the protection of patients. It considered that there was **'cogent and credible prima facie evidence of substance misuse'**. It is clear that there were in existence letters from witnesses from Hospital A where the drug abuse had occurred.

20.207 Later that week, the case came before the PPC, which adjourned the case for medical reports. The first medical report was a remarkable document in which the examiner went well beyond the giving of a medical opinion. First, he noted, quite properly, that the

allegation of the abuse of fentanyl had been denied by Dr JO 04 and that no drugs had been detected on a recent hair test. However, the examiner then went on to discuss the strength of the evidence in relation to Dr JO 04's past abuse of drugs. He mentioned the witness evidence from Hospital A and the fact that Dr JO 04 had avoided taking a hair test at Hospital B when offered the chance to demonstrate that he was drug-free. The examiner then went on to say that the evidence was **'finely balanced'** but concluded, on the balance of probabilities and in the light of the doctor's retraction of his admission, that the evidence was not sufficient to suggest that Dr JO 04 had a present or past problem with the misuse of drugs that would affect his ability to practise. However, Dr JO 04 had admitted to using cocaine in the past and the examiner considered that he should be kept under observation to ensure that he was not using substances illicitly.

20.208 Another medical report said that the examiner found it difficult to draw firm conclusions about Dr JO 04's drug abuse. However, because of the high risk to patients that would arise if he were to abuse drugs, he recommended that the doctor should remain suspended until a full hearing could assess the evidence. A third report recommended medical supervision.

20.209 The minutes of the resumed consideration of this case by the PPC give rise to concern. First, there appears to have been discussion about the propriety of the conduct of the staff at Hospital A. It appears that they had been aware of concerns some time before Dr JO 04 had left Hospital A, but had nevertheless sanctioned his promotion within the hospital. The concerns had not been raised properly until Dr JO 04 had moved on to Hospital B. On the face of it, that did not appear satisfactory, but it was wholly irrelevant to the issue of whether Dr JO 04 had been abusing drugs and, if so, what should happen to him. The PPC then discussed the fact that there was not much evidence of drug abuse now that the admissions had been withdrawn. They noted that the admissions had been made without the benefit of legal advice. All the other evidence was said to be hearsay. The prospect of proving the allegations at the PCC was felt to be poor. The PPC noted that the medical examiners had recommended supervision. In fact, they had not. Only one had done so. Apparently, Dr JO 04 was willing to undergo supervision. One is bound to wonder why he should have done that, if he did not have and had never had a drug problem. The PPC's decision was to adjourn *sine die* to enable the doctor to be dealt with under the voluntary health procedures.

20.210 When giving evidence about this case, Mr Nicholls was asked to explain why the PPC had thought that the only evidence of drug abuse was (and presumably could only ever be) hearsay. He said that the PPC thought that the prospects of the case being proved at the PCC were very poor. There had been delay and no local investigation. When it was suggested that evidence would have been available about the circumstances in which the doctor had made his admission and the terms of his admission, Mr Nicholls said that he thought it would be a 'hard struggle' to obtain further evidence about the admission. He agreed that the effect of the PPC's decision was that the issue of whether the doctor had been abusing drugs had never been resolved. He also accepted that there was no medical evidence that the doctor had any medical or psychiatric problem such as would justify referral into the voluntary health procedures. Mr Nicholls explained the PPC's decision on the basis that there was a possibility that the doctor had been abusing drugs,

so that it was preferable, in the interests of patient safety, that he should be made subject to some voluntary supervision than that the case against him should fail completely at the PCC.

20.211 I can see that the PPC's solution must have appeared to be a pragmatic way of dealing with an evidential problem which, I am sure, it regarded as insuperable. However, this case shows the PPC misdirecting itself in several respects. First, the discussion about the conduct of the staff at Hospital A was quite irrelevant to the issues before the PPC. Second, its assessment of the availability and cogency of the evidence available was wrong. It was, incidentally, quite different from the assessment that had been made of the same evidence by the IOC. It is no personal criticism of Mr Nicholls or of any member of the PPC if I say that it appears to me that they did not understand the hearsay rule; they are not lawyers. But the trouble is that they made decisions based on their misunderstanding of that rule. The PPC should not have based its decisions on the strength or availability of evidence save in the most obvious and straightforward circumstances.

Dr JO 10

20.212 Another case which gives rise to some concern was that of Dr JO 10. The doctor was an anaesthetist who was found to have been abusing a variety of anaesthetic drugs. Initially, he took drugs left over from the clinical procedures in which he had taken part. He would order larger ampoules than were needed for the patients. Later, he took to drawing off part of the contents of an open ampoule and replacing what he had taken with water. Thus, the patients received less than they should have had. When eventually confronted about these matters, he admitted them. The case was referred to the GMC. The Medical Director of the hospital at which Dr JO 10 worked considered that patients had been put at risk not only because they had not received appropriate medication but also because the doctor had been under the influence of drugs while on duty.

20.213 No conviction had been recorded against the doctor. The case went to the medical screener as one of 'SPM by definition'. The screener, very properly, referred it to the IOC and the PPC. The IOC imposed a series of interim conditions. When the case came for consideration by the PPC, there was a psychiatric report which said that the doctor had been self-administering drugs for over a year and was using between 10 and 15 injections per day; the size was not specified. However, the report said that the doctor was not suffering from any physical or any discernible psychiatric disorder. The prognosis was said to be good. The PPC referred the case into the voluntary health procedures. The Inquiry does not know what the reasons were for this decision. The doctor entered into voluntary undertakings as to the conditions under which he practised and the interim conditions imposed by the IOC were later revoked.

20.214 When giving evidence about this case, Mr Nicholls, who chaired the PPC panel which decided the case, said that he felt 'uncomfortable' about this decision. He now felt that it should have been referred to the PCC. He agreed that there was clear evidence of SPM and no evidential difficulties. In my view, he is right; the case should have been referred to the PCC. This doctor did not, on the evidence, have a health problem. His dishonesty

was never addressed. Nor was his willingness to involve patients in his drug taking activities and to endanger patients while working under the influence of drugs. The PCC might or might not have thought it appropriate to impose conditions that would have required the doctor to undergo medical supervision. But the matter would have been considered openly and thoroughly in the presence of the doctor, instead of in a private procedure which is, by its nature, far less thorough and transparent.

Dr JO 06

20.215 Dr JO 06 stole prescription forms from the surgery at which he worked as a locum. He issued prescriptions for diazepam, in the names of fictitious patients, forging the signature of the GP from whom the prescriptions had been stolen. He was not prosecuted. It is not clear why not; it seems to have been suggested that there was no direct evidence but, in fact, the forged prescriptions were eventually recovered. Moreover, Dr JO 06 wrote to the doctor from whom he had stolen the prescriptions, admitting what he had done and apologising. In any event, the case was reported to the GMC and the medical screener, Dr Krishna Korlipara, referred the case to the PPC. On the first occasion on which the PPC considered the case, it received a psychiatric report, which said that the doctor was doing well. However, the PPC decided to obtain two more psychiatric reports. When these were available, the PPC reconsidered the case. The doctor had admitted to both psychiatrists that he had been addicted to benzodiazepines for about five years and had stolen prescription forms and forged another doctor's signature in order to obtain supplies. Both psychiatrists were of the view that the doctor was fit to practise subject to medical supervision. The minute of the PPC's decision records, first, that the doctor did not appear to pose a threat to patient safety but that it was in his own interests to continue medical supervision under the voluntary health procedures. It then recorded that, after taking into account the mitigating circumstances and the letters of support submitted on behalf of the doctor, it would be appropriate to send the doctor a warning letter and adjourn *sine die* to enable him to be dealt with under the voluntary health procedures, where he was to be supervised by the psychiatrist who had provided the original report. That is what happened.

20.216 The case gives rise to concern because the PPC seems to have lost sight of its primary function. This was a bad case of dishonesty, which clearly amounted to SPM. Yet the PPC minute does not mention that. Instead, it seems to have focussed on the medical aspects and the mitigation submitted, including letters of support. Mr Nicholls did not chair the PPC panel on this occasion. However, he sought to assist the Inquiry by explaining what was likely to have been in the PPC's mind. He said that the PPC would have considered the doctor's dishonesty to be a symptom of his ill health. The PPC would have noted that his actions had had no adverse effect on patients and that he had displayed insight and was responding well to treatment. Mr Nicholls thought there might well have been evidential difficulties; he was under the impression that the prescriptions had been destroyed. It might be that one forged prescription had been destroyed but, certainly, there were three within the GMC files. It seems to me that this was a case in which there really could be no proper course of action for the PPC other than referral to the PCC. This was a clear case of SPM with no evidential difficulties. In disposing of the case, the PPC usurped the functions of the PCC.

Dr JO 05

20.217 The case of Dr JO 05 was quite similar although, in this case, the doctor was convicted of forging another doctor's signature on a prescription in an attempt to obtain a supply of dihydrocodeine, to which she was addicted. The case was reported to the GMC and referred to the PPC. There was psychiatric evidence that the doctor had been addicted to the drug for many years. The medical evidence was that the doctor was fit to practise with the proviso that she could not prescribe. The PPC adjourned the case *sine die* to enable it to be dealt with under the voluntary health procedures. The minute of its decision does not make reference to the question of whether the conduct might amount to SPM. The determinative factor was that there was evidence of a health problem.

20.218 The approach in these last two cases seems to have been that, although the facts clearly amounted to SPM and there were no evidential problems, in the PPC's view there was a better way of dealing with them. This approach may have seemed sensible and humane. I do not doubt that the PPC thought that it was taking proper account of patient safety. But, the PPC was using an unofficial procedure not sanctioned by the Rules. Also, before taking its decisions, the PPC had no evidence about whether, and if so to what extent, the doctors' conduct had affected their clinical practice or had had any impact on their patients.

Cases Concerning Clinical Errors

20.219 I propose to discuss only two cases under this heading, both of which involved errors in the prescribing or administration of drugs. These cases are of interest to the Inquiry because of the possibility that Shipman might have been reported to the GMC in the mid-1990s with an allegation that he had administered to Mrs Overton a wholly inappropriate dose of morphine which had resulted in her suffering brain damage and remaining in a persistent vegetative state until her death 14 months later.

Dr JK 07

20.220 Dr JK 07, a locum consultant surgeon, administered an excessive dose of 2% lignocaine to a patient as a local anaesthetic prior to an operation. The patient died. The post-mortem examination did not include any toxicological tests. The death was attributed to the deceased's longstanding condition of muscular dystrophy. The hospital trust was concerned about the death and undertook an internal investigation. It became apparent that there was a serious discrepancy between the amount of the drug that the nurses said had been given (13.5ml) and that which the doctor had recorded in the notes (5ml). The appropriate dose would have depended on the patient's body weight. Yet it was clear that the doctor had made no attempt to have the patient weighed. Informally, the hospital trust sought expert advice. When available, this suggested that the dosage administered was excessive and might have caused the death. The local Coroner appeared reluctant to open an inquest so the trust reported the case to the GMC.

20.221 The GMC obtained an expert opinion from an eminent professor of paediatric anaesthesia, who was also a member of the GMC. He agreed with the conclusions of the

experts consulted by the trust. He said that, if 13.5ml had been administered, that would be a gross overdose bearing in mind the deceased's weight (which, it appears from the file, had been estimated by the parents at 4.5 stone, i.e. about 28kg). The expert expressed surprise at the doctor's failure to weigh the patient, whose muscular dystrophy had resulted in reduced muscle mass. If only 5ml lignocaine had been administered, that would have been just above the maximum recommended dose for a person of the deceased's weight. If 13.5ml had been given, that would have been wholly excessive and would have amounted to SPM.

20.222 The doctor was warned that the case was to be referred to the PPC. Three allegations were to be considered: the failure to weigh the patient; the administration of 13.5ml, which was excessive, and the making of a false entry in the clinical records to the effect that only 5ml had been given. Solicitors for Dr JK 07 replied to the GMC on their client's behalf, saying that the doctor had made a genuine error in recording that he had given only 5ml; in fact he had given 10ml. He admitted that more than 10ml had been expended from the syringe but some had been wasted. I interpose to say that the nurses said that the doctor had been handed a syringe containing 10ml and had injected it all. They said that, a while later, he had asked for more; he had been given another 10ml and, when he had finished injecting, there was 6.5ml left. The doctor's account was different. He claimed that, based on his estimate of the patient's weight, he believed he could safely use up to 10ml of 2% lignocaine. He took a syringe containing 10ml and injected 5ml. During this procedure, some lignocaine was spilled; only 3.5ml was left. After a pause while the drug took effect, the operation began. It was obvious that the patient was in pain and the doctor then injected the remaining 3.5ml. The patient then appeared to be free of pain and the operation began again. Part way through the procedure, the patient again complained of pain and the doctor asked for more lignocaine. He was handed a syringe containing 10ml. On this occasion, the doctor was able to inject only about 0.5ml successfully and lost about 1.5ml through spillage. The operation recommenced. Once again, the patient complained and the doctor administered a further 1ml with further spillage of 0.5ml. The overall effect of the doctor's account was that the patient had received 10ml and 3.5ml had been spilled.

20.223 It was said on the doctor's behalf that, when making his note, the doctor had totalled the various small amounts injected but had forgotten about the first 5ml he had injected. He had recorded 5ml as the total amount injected when he should have put 10ml. When asked to write a report on the incident a few days later (for the purposes of the internal investigation), he had had his note before him and he had perpetuated his mistake. There had been no intention to mislead.

20.224 The case was considered by the PPC before the time when a minute was routinely made of the reasons for its decisions. Incredibly, as it seems to me, the PPC decided not to refer the case to the PCC, but to close it with a warning. The deceased's family was outraged at the decision and asked for full reasons. The GMC's reply explained that the caseworker had spoken to the Chairman of the PPC who had explained the decision on the basis that the PPC did not think the doctor's errors were such as to justify the GMC in restricting or stopping his medical practice.

20.225 Dr Steel, who was Chairman of the PPC at the time of this decision, explained in a witness statement to the Inquiry that, in his view, this was a borderline case. He considered that the doctor had provided a satisfactory reason for having made an error in the medical notes. He had **'admitted'** that he had given 10ml and that 13.5ml had been expended from the syringe (as the nurses claimed). The doctor had also acknowledged that he should have weighed the patient but he had made a **'genuine assessment'** that the patient's weight had been between 40 and 50kg. Dr Steel said that, in the circumstances, the PPC would have concluded that it was doubtful if the administration of 10ml was irresponsible.

20.226 Dr Joan Trowell, Chairman of the Fitness to Practise Committee, commented on this case in her written evidence to the Inquiry. She accepted that the case should have gone to the PCC for full investigation. She said that 10ml lignocaine would have been an excessive dose. However, she did not think that there was any real conflict of evidence between the doctor and the nurses; it was quite possible, she said, to lose as much as one third of the liquid during injection. I must observe that that may well be so, but it was not for members of the PPC to reach a judgement on that kind of issue without hearing the evidence. If, having heard the nurses and the doctor, the PCC had been unsure about the evidence of spillage, it would have been quite appropriate for it to take into account its knowledge of what could happen; but it was not appropriate for it to do so when there had been no examination of the evidence.

20.227 Sir Donald Irvine, President of the GMC from 1995 until 2002, also commented on this case and said that it was clear to him that the case should have been referred to the PCC. It seems to me a pity that the family did not take proceedings for judicial review. Had they done so, the application must, I think, have succeeded. The PPC had clearly gone beyond its function of considering whether the conduct complained of, if proved, might amount to SPM. On the basis of his so-called 'admission', the doctor had administered 10ml, which, according to the expert instructed by the GMC, would still have been double the maximum recommended dose. The expert had not been asked for his view on how serious an error the administration of 10ml would have been. It seems to me that the case clearly raised a question of SPM and that evidence was available to support the allegation that 13.5ml had been given, although it conflicted with what was being advanced on the doctor's behalf. In any event, it was not for the PPC, but for the PCC, to decide whether the doctor's 'admission' was in fact true. There was evidence from the nurses that he had administered 13.5ml and no one had investigated what the nurses would say about the claim that 3.5ml had been spilled and that the drug had been administered in several small amounts. Further, it was for the PCC, not the PPC, to decide whether to accept that the entry in the notes had been a genuine mistake or a deliberately false entry. Some might suggest that the doctor's claim that he had forgotten about the first 5ml ampoule sounds rather implausible. After all, it must be a fairly unusual experience in the professional life of an individual surgeon that a patient dies on the operating table; the doctor must have had plenty of time to think over his actions, in the aftermath of the death. Yet he did not advance his explanation until he was facing the possibility of proceedings at the GMC. It is not for me to make a judgement about whether the entry in the notes was a genuine error. However, nor was it for the PPC to do so.

20.228 For the sake of completeness, I shall recount the further history of this case. In the light of the PPC's decision, the family put further pressure on the Coroner to hold an inquest. The

Coroner asked to see the GMC's papers. Solicitors acting for the GMC suggested that the Deputy Coroner should obtain the relevant papers from the hospital trust. The solicitors disclosed the existence of Dr JK 07's response and said that the GMC would seek the doctor's consent to its disclosure. The GMC did not disclose the existence of the expert report but mentioned that it had been assisted by advice from its members. This was inappropriate, as the Deputy Coroner had made it clear that she was not minded at that time to accept the family's assertion that the GMC had had evidence before it of clinical incompetence. In the event, the Coroner was persuaded to hold an inquest and the verdict was misadventure. The police investigated and, in due course, Dr JK 07 was charged with manslaughter. His defence was that, although he had been negligent, he had not been grossly so. He was acquitted of manslaughter but the trial Judge refused an order for costs, a decision which implies that the Judge's view was that the defendant had brought the prosecution upon himself.

Dr JK 09

20.229 The complaint in the case of Dr JK 09 comprised an allegation that the doctor, a consultant urologist, had prescribed an excessive dose of an alpha-blocker, terazosin (Hytrin), as a result of which the patient died. The patient was admitted to hospital in the mid-1990s with a three-week history of breathlessness and problems with micturition. He subsequently developed an unproductive cough and breathlessness. A diagnosis was made of hypertensive heart failure for which he was prescribed medication. Six days later, his blood pressure and heart failure were better controlled but he was still complaining of difficulty in voiding urine. His medication was adjusted and he was referred to Dr JK 09. Nine days after the patient's admission to hospital, Dr JK 09 reviewed him and prescribed 5mg Hytrin. The manufacturers recommend that the initial dose of this drug should not exceed 1mg and that the drug should be taken **'before bedtime'**. When the pharmacist saw the prescription, she telephoned the ward to say that this was rather a high dose and that close monitoring of the patient's blood pressure would be required following administration. The drug was not available until the next day. At 11am the following day, the patient was found collapsed. He had not been given any Hytrin and was not due to take it until 'bedtime'. His heart rate was fast and irregular. Blood pressure was stable at 130/80. Treatment was commenced with digoxin. The patient appeared to recover. At 10.05pm, Hytrin was administered in accordance with the instructions of Dr JK 09. Within a short time, the patient's blood pressure had fallen to dangerously low levels. He died a week later and the cause of death was found to be hypoxic organ damage due to drug induced hypotension. The coroner's inquest recorded a verdict of misadventure and that the death was a consequence of the deceased having been prescribed a dose of Hytrin in excess of the recommended dose.

20.230 The deceased's daughter made a complaint to the GMC and submitted the British National Formulary data sheet for Hytrin. Dr JK 09 was asked for his explanation and submitted a sworn affidavit in which he agreed that he had prescribed a dose in excess of the recommended dose but said that he had done so on the basis of a discussion he had had with the local representative of a drug company which supplied or manufactured it. He said he had been advised that this larger dose was being prescribed by doctors and

that 'serious side effects were rare'. He said that he could not substantiate this conversation but he would never have gone against the data sheet advice without having received guidance. He claimed that he had treated other patients with a 5mg dose without adverse effect. He also said that, subsequently, he had attended a conference of urologists, where a paper had been presented which reported on a study of 30 elderly men who had been treated with 5mg Hytrin daily. Two had experienced dizziness but, otherwise, there were no severe side effects. He had tried to contact the urologists who had presented the paper without success. Nor had he been able to obtain a copy of their paper. He produced an abstract of the paper from a British journal, but this did not mention the dosage used in the trial. Dr JK 09 also added that he had not been told about the collapse during the morning of the day it occurred. Had he been told, he would have said that the Hytrin should not be given, as it was only for the relief of urinary tract symptoms. He was also critical of the way in which the emergency following the administration of the drug had been handled. He was of the view that the patient should have been admitted to intensive care, whereas he had been treated by junior staff on the ward.

20.231 The case came before the PPC, which decided not to refer it to the PCC. The letter of explanation sent to the complainant explained the decision on the basis that the doctor **'had acted in good faith in what he thought at the time would be** (*the patient's*) **best interests, however,** (*the doctor*) **has been warned that the Committee would take a serious view if further complaints of a similar nature were to be received'**.

20.232 In his statement to the Inquiry, Dr Steel said that this was a **'borderline decision'**. He said that, after careful consideration, the PPC would have decided, on balance, that this isolated example of clinical misjudgement, for which the doctor had expressed regret, was not an appropriate case for referral to the PCC. The PPC would have used the clinical expertise of its own members when arriving at the decision.

20.233 Dr Trowell was of the view that the case should have been referred onwards. The GMC solicitors would then have had the opportunity to investigate further the various claims made by the doctor in his response. She expressed the view that, had this case come to the PPC after the case of Toth, rather than before, it would have been handled differently. She was also confident that, under the new FTP procedures, a case such as this would be fully investigated at an early stage before any decisions were taken.

20.234 It is clear, as Dr Trowell recognised, that, in this case, the PPC again exceeded its powers. It should have referred this case on so that the doctor's various claims could be investigated. As it was, the PPC accepted them all as true and then formed a judgement about how the case should be dealt with. It should have considered whether the prescribing of a dose five times that which was recommended might amount to SPM. If it might (and, plainly, it could), the case should have been referred. The basic facts were admitted. It was for the PCC, not the PPC, to decide upon the truth of the doctor's explanation and whether the doctor's conduct did in fact amount to SPM.

Conclusions

20.235 The two cases of judicial review (Holmes and Richards), to which I have referred, demonstrate clearly that, in those cases, the PPC exceeded its powers by reaching a

concluded judgement on whether the matters alleged might amount to SPM and that, in the case of Holmes, it also misdirected itself as to the meaning of SPM. In the case of Holmes, the GMC plainly accepted the criticisms of the Court; indeed it actively sought them. However, in the evidence of its witnesses and its submission to the Inquiry, its stance was that the cases of judicial review were not representative of the general standard of PPC decisions. In any event, it was said that, after the *aide memoire* was produced for the guidance of PPC members, any problems there might have been had been resolved. I can see that it should not be said that the PPC habitually misdirected itself just because it was found to have done so in two cases of judicial review. But the problems in those cases were very fundamental. Three separate decisions were involved. In the nature of things, very few cases go to judicial review; the remedy was not used at all against the GMC until the late 1990s. It seems to me likely that the errors disclosed in the judicial review cases were typical of the PPC's approach.

20.236 However, the cases of judicial review are not the only evidence available as to the quality of PPC decisions. Professor Allen and her team observed the operation of the PPC in a large number of cases and expressed their concern that members of the PPC did not appear to understand their role or the test they were to apply. The cases examined by the Inquiry also throw light on the operation of the PPC. PPC panels sat in private and there was no means of monitoring or auditing their outcomes. The judicial reviews and the few cases the Inquiry has looked at are the only glimpses afforded to the public of what happened there. The observations of the PSI team, the cases of judicial review and the Inquiry's own evidence all present a similar picture. Together, these different sources of evidence lead me to the conclusion that, in making decisions, the PPC often exceeded its powers and applied the wrong legal test. Of course, I am not saying that the PPC was always wrong when it declined to refer a case on to the PCC. However, I am driven to the conclusion that it was wrong in a significant number of cases and that those cases give rise to a real cause for concern that the PPC has been far too much influenced by its desire to be 'fair to doctors' and far too little concerned about the protection of patients and the public.

20.237 Of particular concern to the Inquiry is the statistical evidence showing that many conviction cases (apparently of a quite serious nature) were closed by the PPC. The Inquiry has not examined these cases in detail but the figures are worrying and give rise to a fear that, in this respect also, the GMC has been failing to protect patients.

20.238 I am also concerned about the way in which some cases were referred by the PPC into the voluntary health procedures despite the fact that there was plainly evidence of conduct capable of amounting to SPM and no real evidence of ill health. I accept, of course, that referral into the voluntary health procedures may be a proper way – even the best way – of protecting patients and the public in some cases. However, in the case of Dr JO 04, that cannot be said. The truth about the doctor's allegedly dishonest and unethical conduct was never established and there was no medical evidence that he was driven to obtain drugs by dishonest means as the result of an addiction. After a while under the voluntary health procedures, that doctor will doubtless have been free to practise without restriction and yet, for all anyone knows, he might be thoroughly dishonest.

20.239 It seems to me that there were several underlying causes for the failures of the PPC. First, the Committee's statutory powers and duties were not clearly spelled out in the legislation. The PPC had to decide whether any case **'ought to be referred for inquiry'** by the PCC. The Rules provided only that, when referring a case to the PCC, it should indicate the matters which, in its opinion, **'appear to raise a question whether the practitioner has committed serious professional misconduct'**. In Chapter 17, I described the difficulty that had been experienced over a period of many years in defining and explaining SPM. It seems to me obvious that, for the purposes of ensuring consistency and fairness, the GMC, as a body, should have given careful consideration to the proper function of the PPC, when compared with the functions of the screeners and the PCC, and should have developed clear guidelines for its operation. It appears that, until 2001, when the *aide memoire* was produced, it was thought that no guidance was needed because members of the PPC were well-respected professionals and lay Council members who carried out their duties in a conscientious fashion. I do not doubt their conscientiousness but it is clear that their understanding of the nature of their function was flawed, probably because many of them acted at times as screeners, and at other times as members of the PCC, and confused their various roles. Moreover, the lack of guidance left individuals to form their own views on a wide range of topics, including, for example, the threshold for SPM and the role of hearsay evidence in GMC hearings.

20.240 Another serious underlying problem has been the absence of proper criteria for decision making. There has never been a concerted attempt to define thresholds for SPM, applicable for various forms of misconduct. At times, examples of what might or might not be regarded as SPM were given, but these were never more than a miscellaneous collection drawn from a wide variety of different types of conduct. There has never been what Professor Allen described as a 'hierarchy' of examples of misconduct from which thresholds could be established. Although the *aide memoire* no doubt assisted in directing the PPC's mind to the sorts of questions it should have been asking (and in dissuading it from taking irrelevant considerations into account), it provided no assistance at all in deciding whether a case did or did not reach the required threshold for referral to the PCC. Until this problem is tackled, there will be difficulties with any decision-making person or body within the GMC.

20.241 Very shortly, the PPC will no longer exist. It may be said that, for that reason, there has been little point in examining its operation, since its past failures are of only historical interest. I do not accept that, for three reasons. In future, the PPC's filtering functions will be performed mainly by case examiners, who will not be Council members but will be contracted to the GMC to undertake the work and will be directed and managed by Council members and staff. In theory, that seems a good idea; how it will work in practice remains to be seen. However, whenever case examiners disagree on whether a case should be referred to a FTP panel for a hearing, the IC will have to decide what should happen. To that extent, it will be the successor to the PPC. Second, until recently, members of PPC panels have always been members of the GMC. Examination of the ethos of the PPC is of relevance to my assessment of the ethos of the GMC as a whole and to my recommendations as to whether the GMC is willing to and capable of providing adequate protection for patients in the way it regulates doctors in the future. Third, in 1996, the GMC

committed itself to the development of procedures and processes that would be fair, objective and transparent. Those were fine and appropriate words. It has been important to examine the actual decisions of the PPC, to discover how they have measured up to the GMC's aspirations. The result of that examination suggests to me that there is a gulf between the aspiration and reality.

CHAPTER TWENTY ONE

The General Medical Council Conduct Procedures: the Professional Conduct Committee

Introduction

21.1 As I have explained, under the old fitness to practise (FTP) procedures, the Professional Conduct Committee (PCC) was the disciplinary committee of the General Medical Council (GMC). In this Chapter, I shall describe the function and powers of the PCC and will examine its procedures and the sanctions available to it. I shall consider some of the PCC's decisions on sanction, particularly as they relate to issues of interest and concern to the Inquiry. I shall consider the review of the PCC procedures and decisions undertaken by a Working Group in 1999. I shall consider the impact of decisions of the Judicial Committee of the Privy Council (and more recently of the High Court) upon the operation of the PCC. I shall also examine other recent developments, including changes to the arrangements for restoration to the register. In conclusion, I shall discuss some of the major difficulties which have been encountered by the PCC in the past and how those difficulties might be dealt with in the future.

Evidence

21.2 Professor Sir Graeme Catto (President of the GMC), Mr Finlay Scott (Chief Executive) and Sir Donald Irvine (immediate past President) all gave evidence in relation to some of the issues under discussion in this Chapter. Dr Krishna Korlipara, who has been a member of the GMC since 1984 and was a member of the PCC at various times between 1984 and 1997, also gave evidence. Dr Joan Trowell, Chairman of the Fitness to Practise Committee, provided a witness statement. Professor Isobel Allen, Emeritus Professor of Health and Social Policy, University of Westminster Policy Studies Institute (PSI), and her team undertook an analysis of outcomes of PCC cases, the results of which appeared in their 1996 and 2000 Reports and in their 2003 Paper. In writing this Chapter, I have drawn upon their work and also upon many documents disclosed by the GMC. Among these documents were the Report of the PCC Working Group produced in May 1999 and the Indicative Sanctions Guidance (ISG), first published in 2001 and updated in 2003 and again in 2004. This guidance was designed to assist members of the PCC in reaching consistent decisions on sanction and is intended to provide similar assistance to members of FTP panels under the new procedures.

The Composition of the Professional Conduct Committee

21.3 From its inception in 1980, the composition of the PCC was governed successively by the General Medical Council (Constitution of Fitness to Practise Committees) Rules Order of Council (the Constitution Rules) 1980, 1986 and 1996. Between 1980 and 1986, the PCC

was composed of the Chairman, Deputy Chairman, 16 medical members and two lay members of the GMC (i.e. 20 members in all). The legal quorum of the PCC was five. The Constitution Rules provided that no more than ten members of the PCC should be invited to sit on panels for the hearing of cases. Those invited to attend a panel hearing had to include either the Chairman or the Deputy Chairman or both, eight medical members and one lay member of the PCC. Subject to those requirements, panel members were to be chosen, so far as was practicable, in rotation from all the members of the PCC.

21.4 From 1980, the Constitution Rules permitted the President to choose whether to sit as Chairman of the PCC. If the President chose not to do so, he was required to appoint another member of the GMC as Chairman. Between 1980 and 1996, the Constitution Rules also required the President to appoint one member of the GMC as Deputy Chairman of the PCC. From 1980, any appointments to the Chairmanship and Deputy Chairmanship of the PCC were subject to the approval of the full Council. Members of the PCC (except for the Chairman and Deputy Chairman) were elected annually.

21.5 In 1986, 1987 and 1994, the Constitution Rules were amended to permit increases in the membership of the PCC. By 1994, the PCC had 34 members, comprising 26 medical members (including the Chairman and Deputy Chairman) and eight lay members. The number of members invited to sit on a hearing was reduced to eight. Two of those eight had to be lay members of the PCC. The legal quorum for a PCC panel was five, to include at least one lay member.

21.6 In 1994, the Constitution Rules were further amended to provide for the situation where insufficient members were available to achieve a quorum. The President was given the power to appoint temporarily to the PCC any member of the GMC who would have been eligible to stand for election to the PCC. In 1996, the Constitution Rules were again amended to reduce the membership of the PCC to 30. From that time, the President was required to appoint two members of the GMC as Deputy Chairmen, who would chair hearings in the absence of the Chairman. There had been a significant increase in the number of cases referred to the PCC during the mid-1990s and the appointment of an additional Deputy Chairman allowed a greater number of hearings to be conducted by differently constituted panels of the PCC. From 1996, the total membership of the PCC comprised 23 medical and seven lay members.

21.7 In 2000, the Constitution Rules were amended to reduce the legal quorum of a PCC panel to three, including at least one medical and one lay member. I have already explained that, also in 2000, the GMC was given the power to co-opt non-members or 'associates', both medically qualified and lay, to sit on its FTP committees. At that time, the PCC had a large backlog of cases and there were serious delays in bringing cases to the hearing stage. The appointment of a large number of associates made it possible for multiple panels of the PCC to sit simultaneously. In 2000, PCC panels sat for a total of 129 days. In 2001, that rose to 242 days and, in 2002, to 631 days. In 2003, the figure dropped slightly to 595 days. Since July 2003, when the number of Council members was reduced to 35, members have not sat on PCC panels unless it has proved impossible to find an adequate number of associates to do so.

The Function and Powers of the Professional Conduct Committee

21.8 The function of the PCC was to adjudicate on disciplinary cases.

Conviction and Conduct Cases

21.9 Section 7(1) of the Medical Act 1978 (which came into force in August 1980) set out the powers of the PCC. It provided:

> **'Where a fully registered person –**
>
> **(a) is found by the Professional Conduct Committee to have been convicted (whether while so registered or not) in the United Kingdom or any of the Channel Islands or the Isle of Man of a criminal offence; or**
>
> **(b) is judged by the Professional Conduct Committee to have been (whether while so registered or not) guilty of serious professional misconduct;**
>
> **the Committee may, if they think fit, direct –**
>
> **(i) that his name shall be erased from the register;**
>
> **(ii) that his registration in the register shall be suspended (that is to say, shall not have effect) during such period not exceeding twelve months as may be specified in the directions; or**
>
> **(iii) that his registration shall be conditional on his compliance, during such period not exceeding three years as may be specified in the direction, with such requirements so specified as the Committee think fit to impose for the protection of members of the public or in his interests.'**

These powers were reproduced in section 36(1) of the Medical Act 1983 (the 1983 Act) and remained essentially unchanged. Thus, it was the function of the PCC to determine first whether a doctor referred to it had been guilty of serious professional misconduct (SPM) or had been convicted of a criminal offence. If so, it had to go on to consider what, if any, sanction was appropriate.

The Procedure at a Hearing before the Professional Conduct Committee

21.10 The procedure to be adopted by the PCC at the hearing of a case was set out in Schedule 4 to the 1983 Act (formerly Schedule 4 to the Medical Act 1978) and in the General Medical Council Preliminary Proceedings Committee and Professional Conduct Committee (Procedure) Rules Order of Council 1988 (the 1988 Professional Conduct Rules). The 1988 Professional Conduct Rules largely reproduced the provisions which had previously been contained in the General Medical Council Preliminary Proceedings Committee and Professional Conduct Committee (Procedure) Rules Order of Council 1980. I shall summarise the procedure as it was at the time of the Inquiry's hearings in November and December 2003.

A Public Hearing

21.11 The 1988 Professional Conduct Rules required that, save in exceptional circumstances, the proceedings of the PCC should be held in public. Panel members could, however, deliberate (i.e. discuss their findings and their decisions on sanction, together with any other matters that arose in the course of the hearing) in private.

The Role of the Legal Assessor

21.12 I referred in Chapter 20 to the role and duties of the legal assessor. Members of PCC panels were advised at hearings by a legal assessor. Any advice given to the PCC panel by the legal assessor had to be tendered in the presence of the parties attending the hearing or their representatives. The legal assessor was permitted to accompany members of the PCC panel while they deliberated in private and to give advice as appropriate. However, the legal assessor was required to inform the parties or their representatives publicly of any advice given (and of any question which had given rise to that advice) as soon as possible after the advice had been provided. The advice given to the parties by the legal assessor had to be recorded and a copy of the record given to every party or representative. If members of a PCC panel did not accept the advice of the legal assessor, a record had to be made of the question referred to him/her, the advice given and the refusal to accept the advice, together with the reasons for refusing it. A copy of that record had to be given to every party, or person representing a party, at the hearing.

The Quasi-Criminal Proceedings

21.13 The procedures of a PCC panel resembled those of a criminal court. The hearing was adversarial rather than inquisitorial. In other words, the two sides competed, each side seeking to persuade the panel of the truth of its evidence and the soundness of its contentions. The 'prosecution case' (whether a complaint or a conviction) was usually presented by a solicitor or counsel instructed by the GMC. Under the old procedures (and in a conduct case only), it was open to a complainant, whether personally or through a legal representative, to conduct his/her own case. This was sometimes done, but it was more usual, where the complainant was a private individual, for the GMC to 'take over' the complaint and to conduct the case at the hearing before the PCC panel. Doctors appearing before a PCC panel were usually legally represented, in general through their medical defence organisations.

Evidence

21.14 Witnesses could be subpoenaed and evidence was given on oath. Rule 50 of the 1988 Professional Conduct Rules provided that the PCC could receive oral, documentary or other evidence of any fact or matter which appeared to it relevant to its inquiry into the case before it. Rule 50 was subject to the proviso that, where any evidence was tendered that would not be admissible in criminal proceedings in England, it should not be received unless, after consultation with the legal assessor, the PCC was satisfied that its duty of making due inquiry into the case before it made the reception of that evidence desirable. I referred in Chapter 20 to the observations of Mr Justice Sullivan in the case of R v General

Medical Council ex parte Richards[1] about the way in which he would have expected the PCC to exercise its discretion in admitting evidence which would otherwise have been inadmissible. Sullivan J pointed out that the PCC is not in precisely the same position as a criminal court. It has an important investigatory and regulatory role in the public interest and must, therefore, take into account the public interest in having complaints thoroughly investigated. However, it seems to me, from an examination of the case of Richards and of other cases I have looked at, that, whatever the PCC's attitude to inadmissible evidence, the view of those making decisions at the earlier stages of the FTP procedures was that, if evidence was hearsay, it was unlikely to be received by the PCC or, if received, it would be accorded little weight. It is possible that some had experienced this approach when sitting on the PCC in the past.

21.15 Rule 50(4) of the 1988 Professional Conduct Rules gave the PCC power to cause any person to be called as a witness in any proceedings before it, whether or not the parties consented. The PCC also had power to put questions to any witness itself or through the legal assessor. The doctor was entitled to give oral evidence but was under no obligation to do so.

Conviction Cases

21.16 In a conviction case, once the conviction had been proved (usually by production of the certificate of conviction), the facts giving rise to it did not have to be proved at the hearing. The 1988 Professional Conduct Rules permitted the GMC's representative to adduce evidence about the circumstances leading up to the conviction and about the character and previous history of the doctor.

21.17 The words 'previous history' were a reference to the doctor's FTP history, i.e. any previous sanction imposed on the doctor by the PCC, the Health Committee (HC) or the Committee on Professional Performance (CPP). The PCC would, of course, have no information relating to such matters as past complaints to the GMC about the doctor which had been closed by the GMC staff, or which had been closed by the screeners or rejected by the Preliminary Proceedings Committee (PPC). Nor would the PCC have any information about past complaints to, or disciplinary action by, any NHS body, unless the complaint or action had been directly connected with the subject matter of the conviction or complaint with which the PCC was currently dealing. The result was that the PCC might well have an incomplete picture of the doctor's past history.

21.18 The doctor or his/her representative was then entitled to address the PCC by way of mitigation and to adduce his/her own evidence about the circumstances leading up to the conviction and about his/her character and previous history. The doctor might give evidence him/herself but was not obliged to do so and, in practice, often did not do so. It was usual for the doctor to submit testimonials from patients and/or colleagues. The ISG, which, as I said, was first produced in 2001, contained a warning that care should be taken when drawing inferences from such testimonials. It warned, in particular, that some testimonials were written by persons who believed that the doctor concerned was not guilty of the misconduct alleged; the validity of such an opinion was plainly questionable

[1] [2001] Lloyd's Rep Med 47.

if the doctor had since been found guilty. Also, the ISG warned that there might be cultural reasons for the absence of testimonials. Panel members should not assume that testimonials would not be available if requested.

21.19 The PCC panel would then proceed to consider the question of sanction. I shall return to the imposition of sanctions later in this Chapter.

Conduct Cases

21.20 In a conduct case, the doctor would face a charge, or series of charges, each containing one or more factual allegations. Some allegations or whole charges might be admitted and others denied. All might be admitted or all denied.

The 'Prosecution Case'

21.21 The GMC's representative (or the complainant) would adduce evidence of the facts alleged which had not been admitted by the doctor.

Submission of No Case

21.22 As in a criminal trial, at the close of the 'prosecution case', it was open to the doctor to submit that no sufficient evidence had been adduced in respect of any or all of the facts which were in dispute, so that the PCC panel could not find those facts proved. The doctor might also submit that, in respect of any charge, the facts about which evidence had been adduced or which had been admitted were insufficient to support a finding of SPM. The GMC's representative (or the complainant) then had an opportunity of answering the submission and the doctor had an opportunity to reply. The PCC panel would then determine whether the doctor's submission should be upheld. If the submission was upheld, the finding of the PCC panel would be that the doctor was not guilty of SPM in respect of the matters to which the relevant charge related.

The 'Defence Case'

21.23 If the doctor made no submission (or if s/he made a submission but it was unsuccessful), s/he (usually through his/her representative) then had the opportunity to address the PCC panel concerning any charge which remained outstanding and could at that stage adduce evidence, whether oral or documentary, in his/her defence. As I have said, it was open to the doctor to give evidence him/herself.

Further Evidence and Submissions

21.24 At the close of the evidence called by or on behalf of the doctor, the GMC's representative (or the complainant) could, with the permission of the PCC panel, adduce evidence to rebut any evidence that had been adduced by the doctor. The GMC's representative (or the complainant) was then permitted to address the PCC panel. The doctor (or his/her representative) had the final word. At this stage, the parties' submissions would be directed at persuading the PCC panel what findings it should make in relation to the facts

which formed the basis of the allegations against the doctor and in relation to whether those facts which the PCC panel might find proved or were admitted would be insufficient to support a finding of SPM. Those were the two issues which the PCC panel was required to resolve at this stage of the proceedings.

The Panel's Decision on the Facts and on Insufficiency

21.25 Those two issues were identified in rule 27(2) of the 1988 Professional Conduct Rules, which required the PCC to consider and determine, in respect of each charge:

> **'(i) which, if any, of the remaining facts alleged in the charge and not admitted by the practitioner have been proved to their satisfaction, and**
>
> **(ii) whether such facts as have been so found proved or admitted would be insufficient to support a finding of serious professional misconduct ...'**.

21.26 The PCC panel was first required to reach a decision on the facts. Although the Rules did not specify the standard of proof to be applied, in practice the GMC has always taken the view that factual allegations must be proved to the criminal standard of proof, i.e. that members of the PCC panel should be satisfied so that they are sure that the facts are as alleged. There is Privy Council authority to support the view that the criminal standard of proof is appropriate in disciplinary cases. In Bhandari v Advocates Committee[2], the Privy Council held that the criminal standard of proof was appropriate in proceedings against an advocate who was alleged to have deliberately deceived and misled the Court. Again, in the case of McAllister v General Medical Council[3], the Privy Council drew a distinction between cases in which the allegation being considered by the disciplinary body amounted to a serious criminal charge (in which case the standard of proof should be that of a criminal trial) and one where it did not. In the latter case, it was **'neither necessary nor desirable'** that the charge should be proved according to the standards and procedures of a criminal trial. What mattered was that the proceedings should be fair to the doctor in all respects.

21.27 Rule 52(3) of the 1988 Professional Conduct Rules set out the system of voting. A bare majority of the PCC panel was sufficient for a decision. If the votes were equal, the rule provided that the question must be deemed to have been resolved in favour of the doctor. If the PCC panel found that none of the facts alleged in the charge had been proved to the required standard, a finding of 'not guilty' would be made.

21.28 It should be noted that there is not and never has been any requirement for the PCC to give reasons for its findings of fact. Reasons are now required for conclusions but not for the findings of primary fact.

21.29 Sub-paragraph (ii) of rule 27(2) required that the PCC panel should then consider and determine, not whether the facts which had been proved or admitted amounted to SPM, but whether they were **'insufficient to support a finding'** of SPM. At this stage, the PCC

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[2] [1956] 3 All ER 742.
[3] [1993] AC 388.

panel was asked to make a decision (the insufficiency decision) on the basis of the available evidence and, if it decided that the facts proved would be insufficient to support a finding of SPM, the proceedings were at an end. If the PCC panel decided that the facts would not be insufficient to support a finding of SPM, the case would continue. However, there would not yet have been a decision by the PCC panel that the facts which it had found proved or which were admitted did amount to SPM.

21.30 This insufficiency decision was taken in the absence of any information about the doctor's past FTP history. It was possible that a PCC panel might have found, for example, that a doctor had failed to attend a patient who was in need of treatment but that the facts were **'insufficient to support a finding'** of SPM. That would be unfortunate if, in fact, the doctor had previously been warned about a similar failure. A repetition of such misconduct would have been more serious than an isolated occurrence. It seems to me that this process of making a preliminary decision as to whether the facts were **'insufficient to support a finding'** of SPM required a very careful direction by the legal assessor. The direction should have been that the PCC panel should not find the facts **'insufficient to support a finding'** of SPM unless it was satisfied that, even if relevant information were later to be presented which was seriously adverse to the doctor, it would still not find that the facts proved or admitted amounted to SPM. In other words, the insufficiency decision should have been taken on the assumption that, when set in context, the doctor's conduct might appear far more serious than it did at the time the decision was being made. I am pleased to see that, under the new procedures, a FTP panel will not be required to make this preliminary insufficiency decision, which, to my mind, was both difficult and rather artificial and was likely to lead to cases being dismissed when they should not have been. In my view, it is doubtful whether panel members understood and applied the legal assessor's direction correctly. Also, I cannot see why there was any need for the insufficiency decision. It seems to me that it merely provided another hurdle for the prosecution and another bite at the cherry for the defence.

Evidence and Findings on the Issue of Serious Professional Misconduct

21.31 Rule 28 of the 1988 Professional Conduct Rules provided that, where a PCC panel found the facts, or some of the facts, alleged in a charge proved or admitted (and, presumably, that they were not insufficient to support a finding of SPM), it should then invite the GMC's representative (or the complainant) to address it:

> **'... as to the circumstances leading to those facts, the extent to which such facts are indicative of serious professional misconduct on the part of the practitioner, and as to the character and previous history of the practitioner. The Solicitor or the complainant may adduce oral or documentary evidence to support an address under this rule.'**

21.32 The doctor (or his/her representative) was then invited to address the PCC panel in mitigation and to adduce evidence in support if desired. After that, the PCC panel would deliberate again. It would consider whether the facts proved did amount to SPM and, if so, what sanction should be imposed. In my view, these were both matters of judgement for the PCC panel, rather than a matter of proof. However, there are indications in the GMC

documents that some people were of the view that SPM must be proved **'beyond reasonable doubt'**. For example, in a document entitled 'Establishing the appropriate standard of proof for GMC hearings into conduct, performance and health: key issues for consideration', produced by the King's Fund in October 2000, which was designed to form a framework for discussion about the appropriate standard of proof to be applied at FTP hearings, it was said that the standard of proof might be applied at any of three stages: when making findings of fact, when assessing whether the facts amounted to SPM and when deciding the penalty if SPM was proved. In my view, only the facts were a matter for 'proof'; the other issues were matters of judgement. In a Consultation Paper in March 2001, the GMC said that opinions differed on whether the criminal standard of proof should apply to the decision whether the facts found proved amounted to SPM and to sanction. I understand that the GMC now takes the view that only the facts need be proved to the criminal standard, and that whether the facts which have been found proved amount to SPM is a matter of judgement.

21.33 Having found the facts (or some of them) proved, the PCC panel might have come to the conclusion that the doctor's behaviour amounted to professional misconduct of a nature which was unacceptable, but not so unacceptable as to amount to SPM. In that event, the panel could take no action. It could not itself issue a warning. It could not remit the case to the PPC with a view to a warning letter or letter of advice being issued. In those circumstances, the PCC panel (and, therefore, the GMC) was, to all intents and purposes, powerless to act. It was pointed out in the report of the PCC Working Group in 1999 that, pursuant to rule 34, a PCC panel could, if it wished, comment on the doctor's conduct, even if it had found that the conduct did not amount to SPM. Of course, that was right; the panel could comment. However, such a comment did not amount to an official warning or reprimand and would not form part of the doctor's FTP history. I note that, under the new procedures, a FTP panel will have the power to issue a warning in cases in which it finds that a doctor's fitness to practise is not impaired.

The Effect of Mitigation

21.34 The practice, as permitted by rule 28 of the 1988 Professional Conduct Rules, of receiving evidence about the doctor's background at the stage before the PCC panel decided whether the doctor's conduct amounted to SPM caused me considerable concern. It seems to me highly likely to have led to the PCC panel, when deciding whether the doctor was guilty of SPM, taking into account material which was, as a matter of logic and principle, irrelevant to that issue. Any evidence (including, of course, evidence in mitigation) which affected the seriousness of the conduct under consideration was relevant to the question of whether that conduct amounted to SPM. It is right also that, in making a judgement about whether the doctor's actions amounted to SPM, those actions had to be viewed in context. Evidence of context would usually have been introduced during the first stage of the evidence. After the decisions on the facts and on insufficiency had been made, evidence relating to other matters might well have been introduced. For example, following a finding that the doctor had breached a patient's confidentiality, it would have been appropriate for the PCC panel to hear evidence that, on a previous occasion, the doctor had been found guilty by a PCC of similar misconduct. That would

have made the breach of confidence under consideration more serious. However, evidence that the doctor had been found guilty by the PCC of misconduct arising from a serious prescribing error would not have been relevant to the seriousness of the breach of confidence under consideration. It would have made it neither more nor less serious. Nor would the fact that the doctor had not been the subject of any previous complaint to the GMC have made the breach of confidence more or less serious.

21.35 Similarly, some forms of evidence in mitigation were relevant to the seriousness of the misconduct in question and others were not. For example, the fact that a doctor had apologised to the patient immediately after the breach of confidence occurred would have been relevant to the seriousness of the misconduct. But the fact that many of the doctor's patients found him/her to be attentive, caring and sympathetic would not. Such evidence about the doctor's character would have been relevant only to sanction. Rule 28, however, permitted the doctor to put before the PCC panel, not only any mitigation relating to the offence that s/he had not advanced earlier, but also purely personal mitigation, which might well have been quite irrelevant to the issue of SPM. For example, it was very common for the doctor to produce testimonials from patients and colleagues about his/her general abilities and character. Those matters might well have been relevant to sanction but they were quite irrelevant to the question of whether the doctor was guilty of SPM. Taking such material into account could have resulted in a finding that the same conduct amounted to SPM in the case of one doctor and not in another. When considering whether the conduct which had been proved amounted to SPM, the PCC panel should, as a matter of principle, have focussed only upon the seriousness of the conduct. Yet I have seen decisions in which it is apparent that, in deciding whether the doctor was guilty of SPM, the PCC panel took into account purely personal mitigation from testimonials.

21.36 A case in point was Kissen, which was decided by a PCC panel early in 2004. The PCC panel found that, over a period of months, the doctor (a general practitioner (GP)) had failed adequately to examine his patient and had failed to heed the complaints of symptoms made by the patient herself and by members of her family. He had attributed the patient's condition (which was, in fact, lung cancer, with symptoms of significant weight loss and the coughing of blood) to rhinitis, aggravated by psychosomatic factors. He admitted that his conduct had been inappropriate, not in the patient's best interests and below the standard of care to be expected of a registered medical practitioner. He denied that his conduct had been irresponsible but the PCC panel found that it had been. However, notwithstanding that finding, the PCC panel found that the conduct did not amount to SPM. In reaching that conclusion, the PCC panel took into account (in addition to some relevant mitigating factors relating to the misconduct itself) some factors amounting to no more than purely personal mitigation. These included a number of testimonials saying that the doctor was a good and caring practitioner. It mentioned the doctor's insight into his failings and the fact that he had taken steps to remedy his deficiencies. All of these matters would have been relevant to the issue of sanction, but were quite irrelevant to the issue of whether the conduct had amounted to SPM.

21.37 I do not criticise PCC panellists who took such material into account. Rule 28 permitted such material to be put before them and it was natural that they would be influenced by it. They were not lawyers. Moreover, the practice of taking irrelevant personal mitigation into

account when deciding whether conduct amounted to SPM was encouraged by some decisions of the Privy Council. In the case of Rao v General Medical Council[4], a PCC panel had imposed conditions on the doctor's registration following a finding of SPM. The doctor had failed to visit a patient in circumstances when he should have done so; he had questioned the patient's wife over the telephone, had concluded that there was nothing seriously wrong, and had offered reassurance. In fact, the patient's wife had reported symptoms of cyanosis and the patient was very ill and died during the night. The PCC panel found that the doctor had made a **'fundamental error'** which was not compatible with good medical practice; in its view, that error amounted to SPM. The doctor appealed to the Privy Council, alleging that the PCC panel had been wrong to find him guilty of SPM. He admitted that he had acted negligently but contended that his negligence was not such as could amount to SPM. He contended that the advice given to the panel by the legal assessor had been misleading as to what might constitute SPM in the context of the case. The Privy Council considered, first, the role of the legal assessor and, then, what was required for a finding of SPM in the context of a case of negligent treatment. In that context, two passages were cited from the Privy Council case of Preiss v General Dental Council[5]. The first was the passage at paragraph 28 of the judgement in that case, which stated:

> **'It is settled that serious professional misconduct does not require moral turpitude. Gross professional negligence can fall within it. Something more is required than a degree of negligence enough to give rise to civil liability but not calling for the opprobrium that inevitably attaches to the disciplinary offence.'**

21.38 In the judgement in Rao, this citation from paragraph 28 of Preiss was followed immediately by a passage taken from paragraph 29 of the judgement in Preiss as follows:

> **'That for every professional man whose career spans, as this appellant's has many years and many clients, there is likely to be at least one case in which for reasons good and bad everything goes wrong – and that this was his, with no suggestion that it was in any way representative of his otherwise unblemished record'**.

In Rao, this passage was cited as if it were part of the judgement of the Court. In fact it was not; it was a quotation from the submission of Counsel for Mr Preiss, in which the Privy Council thought that **'there was some force'**. The citation in Rao of that extract from paragraph 29 of Preiss immediately after the passage from paragraph 28 of Preiss, which deals with the seriousness of negligence which might amount to SPM, seems to suggest that the Privy Council in Preiss was saying that an unblemished record was relevant to the issue of whether the conduct in question amounted to SPM. In fact, the Privy Council was saying no such thing. However, there was no discussion of that issue at that point in Rao, and the judgement moved on to consider whether the advice given by the legal assessor was confusing or wrong. The finding was that the advice was ambiguous and misleading and may have undermined the validity of the PCC panel's decision.

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[4] [2003] Lloyd's Rep Med 62.
[5] [2001] 1 WLR 1926.

21.39 The Privy Council in Rao then listed the factors which the PCC panel should have taken into account in deciding whether the conduct amounted to SPM. It was said that the PCC panel should have started from the premise that this was a borderline case of SPM based upon a single incident. The decision continued:

> **'There was undoubted negligence but something more was required to constitute serious professional misconduct and to attach the stigma of such a finding to a doctor of some 25 years standing with a hitherto unblemished career.'**

21.40 In the event, their Lordships were not convinced that, if the legal advice had been correct, the PCC panel would inevitably have decided that the conduct amounted to SPM. They considered that the PCC panel's finding of SPM should be set aside. The words that I have quoted above seem to imply that it would be proper for the PCC, in deciding whether the misconduct amounted to SPM, to take into account the doctor's 25 years' standing with an unblemished record. In my view, if the Privy Council was suggesting that personal mitigation was relevant to the issue of whether conduct amounted to SPM, that would be contrary to general principle. As I have said, personal mitigation is relevant to sanction but should not, as a matter of principle, affect whether the conduct proved in a particular case amounts to SPM.

21.41 The decision in the case of Rao does not clearly say that an **'unblemished career'** should be taken into account when considering whether or not conduct amounts to SPM, although it does imply it. I thought it necessary to draw attention to this point because, four months after Rao, in Silver v General Medical Council[6], the Privy Council explicitly stated that a past good record should be taken into account when considering whether misconduct amounted to SPM. In the case of Silver, the PCC panel found the doctor guilty of SPM and imposed conditions for a period of 12 months. The allegation, which the PCC panel found proved, was that the doctor had persistently failed, over a period of nine days, to visit an elderly patient who was in need of care and, eventually, of referral to hospital. The doctor was a sole practitioner. It was found that the failure to visit arose from serious managerial, organisational and communications failures within the practice. In short, despite several requests to the practice for a visit – not only from the patient's family but also from other healthcare professionals – Dr Silver never received the message and never attended the patient. The PCC panel found that, as a sole practitioner with responsibility for management of the practice, he was responsible for these failures and that they amounted to SPM.

21.42 The doctor appealed on several grounds, most of which need not be mentioned as they were not successful. The ground which succeeded, and which is relevant to the point under present discussion, was that the conduct found proved did not amount to SPM and that the PCC panel's approach had been **'heavy handed and unfair'**. It was said that the conduct was an isolated lapse and that there was no allegation against the doctor of a broad-ranging nature. It appears from its decision that the PCC panel had considered the seriousness of the conduct, had concluded that it amounted to SPM and had then gone on to consider various matters in mitigation. The first was that the doctor worked in a

[6] [2003] Lloyd's Rep Med 333.

deprived area where it was difficult to get staff. That mitigation was clearly relevant to the gravity of the misconduct. Second, the PCC panel mentioned that the doctor had a large list of patients whom he had served for 40 years as a sole practitioner. It may be that the size of the doctor's list could be a factor to be taken into account in mitigation of the offence if he was under-staffed and over-stretched. However, it is clear that the fact that he had been a sole practitioner in the area for 40 years was purely personal mitigation. Third, the PCC panel mentioned that this was the first complaint recorded against the doctor and that he had produced a large number of testimonials. That was purely personal mitigation. Despite the mitigation, however, the PCC panel found the doctor guilty of SPM.

21.43 Far from criticising the PCC panel for taking personal mitigation into account at this stage, the Privy Council held that the PCC panel had paid insufficient attention to the personal mitigation in deciding whether the misconduct amounted to SPM. In giving the judgement of the Judicial Committee, Sir Philip Otton said that it was **'axiomatic'** that, once the findings of fact had been made, all the relevant circumstances must be considered *before* a finding of SPM could be made. That of course was right. However, their Lordships went on to say that, in their view, all the mitigation was relevant to the decision on SPM.

21.44 In support of this proposition, their Lordships cited a passage from the case of Roylance v General Medical Council[7], which discussed the constituent elements of SPM and referred back to the case of Doughty v General Dental Council[8], which I cited in Chapter 17. The passage from Roylance says nothing about mitigating factors. Their Lordships then cited the same passage from paragraph 28 of the judgement in Preiss and ran it together with the same extract from Counsel's submission quoted in paragraph 29, which I have quoted above. Once again, as in Rao, by running these two passages together, the Privy Council implied that Preiss was authority for the proposition that evidence of good past record was relevant to the question of whether certain conduct amounted to SPM. However, examination of the report of Preiss shows that the Privy Council was not saying that. At paragraph 28 of that case, Lord Cooke of Thorndon said, as I have cited, that SPM does not require moral turpitude, that gross negligence can amount to SPM and that something more is required than the degree of negligence that can give rise to civil liability. That is indisputably right. However, in paragraph 29, Lord Cooke turned to the question of sanction and it was in that context that he observed that Counsel's submission (about the man of many years' standing who has one case where everything goes wrong) had **'some force'**. It is clear that he was saying that evidence of long and blameless service was relevant to sanction. That is plainly right. However, it appears to me that, in both Rao and Silver, the citation from Preiss was taken out of context and was misunderstood. In my view, when asking the question whether an incident or specific course of conduct amounts to SPM, the fact that the doctor had been otherwise blameless for 10, 20 or 40 years was irrelevant. It was, however, highly relevant to what sanction should be applied if it was decided the conduct did amount to SPM.

21.45 Finally, in the case of Silver the Privy Council cited its own decision in Rao. However, as I have just said, that decision too was based upon a misreading or misinterpretation of what Lord Cooke had said in Preiss. In neither Rao nor Silver did the Judicial Committee

[7] [1999] Lloyd's Rep Med 139.
[8] [1988] AC 164.

expressly rely on the GMC Rules as permitting a practice that would otherwise be contrary to principle; it either implied (in Rao) or stated (in Silver) that personal mitigation was relevant to whether conduct amounted to SPM. With great respect to the eminent members of the Judicial Committee, I must say that, in my judgement, the decisions (insofar as they relate to that issue) in Silver and Rao are wrong.

21.46 Under the old FTP procedures, PCC panels received all sorts of material in mitigation before they decided whether the doctor's conduct amounted to SPM. Taking into account material which was irrelevant to the issue 'muddied the waters' and inevitably resulted in cases of serious misconduct being excused because the doctor had a good past record. This must have resulted in some doctors who were in fact guilty of SPM avoiding a finding to that effect, with obvious implications for patient safety. It must also have caused great distress to patients and families who will have had the impression that the misconduct which had been demonstrated was somehow acceptable to the GMC. Such poor decisions reduce public confidence in the GMC and lead to allegations that it is 'too soft on doctors'.

21.47 This problem of taking irrelevant mitigation into account should not arise under the new procedures, where the question for the FTP panel will not be whether the conduct found proved was serious enough to amount to SPM but whether, in all the circumstances, the doctor's fitness to practise is impaired and, if it is, whether the impairment is sufficient to justify action on registration. Thus the panel must take a view 'in the round' of the doctor's fitness to practise and all mitigation is relevant.

Cases in Which the Health of the Doctor Was in Issue

21.48 Schedule 4, paragraph 4 to the Medical Act 1983 reproduced the provisions of Schedule 4, paragraph 4 to the Medical Act 1978. It dealt with the situation where, during the course of a PCC hearing, a question arose as to whether a doctor's fitness to practise might be seriously impaired by reason of his/her physical or mental condition. When such a question arose, the PCC panel had power to refer the question to the HC for determination. The doctor would be medically examined and the HC, having considered the results of the examination, would form a judgement about whether the doctor's fitness to practise was seriously impaired. If, in the HC's judgement, there was no serious impairment, it was required to certify its opinion to the PCC. The PCC panel would then resume its consideration of the case and dispose of it. If, on the other hand, the HC's judgement was that the doctor's fitness to practise was seriously impaired by reason of his/her condition, the HC was required to certify its opinion to the PCC and then to proceed to dispose of the case. The PCC would then cease to exercise its functions in relation to the case. By referring a case to the HC for its opinion, therefore, the PCC did not necessarily lose its jurisdiction over a case. If no serious impairment of fitness to practise was found, the PCC could proceed to deal with the case. The PCC had no power to refer a case to a health screener to be dealt with by means of the voluntary health procedures.

21.49 The relationship between the PCC and the HC is well illustrated by the Privy Council case of Crabbie v General Medical Council[9]. A PCC panel decided to erase Dr Crabbie's name

[9] [2002] 1 WLR 3104.

from the register following her conviction for offences of causing death by dangerous driving and drink driving, for which she had been sentenced to five years' imprisonment. Before the PCC panel, evidence was adduced that Dr Crabbie's fitness to practise was seriously impaired by reason of ill health, namely alcohol dependency. It was contended on her behalf that the PCC panel should refer her case to the HC. The PCC panel declined to do so, saying that the convictions were so serious that the sanctions available to the HC were not adequate to protect the public; the case was so serious that only erasure was appropriate. The doctor appealed to the Privy Council, contending that the PCC panel had erred in refusing to refer the case to the HC and that, in any event, the sanction of erasure was wrong in principle and manifestly too severe. It was said that the case should have been dealt with by the imposition of conditions that would have ensured that the doctor could not resume medical practice until she was fit to do so. The Privy Council advised that the appeal should be dismissed. The PCC panel's reasoning disclosed no error of law and its conclusion was plainly open to it. The Privy Council expressed the view that, as the HC had no power to direct erasure, the PCC should not refer a case to the HC if erasure was **'a serious possibility'**, notwithstanding the fact that there was good evidence that the doctor's fitness to practise was impaired by reason of ill health.

Cases in Which the Performance of the Doctor Was in Issue

21.50 It should be noted also that, on the introduction of the performance procedures in 1997, the PCC was given no power to refer a case to the CPP. Nor was it given any specific power to direct that a doctor should undergo a performance assessment. In practice, this was sometimes achieved by making the undergoing of a performance assessment a condition of continued registration. If the assessment revealed that the doctor's performance was seriously deficient, the PCC panel could not direct that the doctor should be monitored by the CPP or by a performance case co-ordinator under a voluntary statement of requirements. However, the assessment could be of value in that it might have assisted the PCC panel in forming a view about any conditions that should be attached to the doctor's registration when s/he was brought back before the panel. However, the lack of a power to refer the case to the CPP (in the way that it could refer a doctor to the HC) was a *lacuna* in the powers of the PCC. This will be remedied under the new procedures where a FTP panel will be able to direct a performance assessment and act upon it.

Postponement of Determination

21.51 Once a PCC panel had decided that a doctor was guilty of SPM, or that the fact of a conviction had been admitted or proved, it would go on to consider, first, whether it was necessary and appropriate to postpone its determination on whether to impose a sanction. It could, if its members thought fit, postpone its determination to some future date in order to obtain and consider further evidence about the doctor's conduct. It is not clear to me how frequently this power was used. Such documents as I have seen suggest that it was very rarely used in the late 1990s. Where a decision was postponed, the PCC panel might invite the doctor to provide the names of professional colleagues and **'other persons of standing'** to whom the GMC could apply for confidential information as to their knowledge of the doctor's conduct since the time of the original hearing. If the PCC panel

decided that no postponement was necessary, it would then go on to consider whether a sanction was appropriate.

Conclusion of the Case without Sanction

21.52 If the PCC panel decided that no postponement was necessary, it then had to go on to consider whether it was sufficient to make no direction and to conclude the case. If it decided that question in the affirmative, it might decide to issue a reprimand. A reprimand was not a **'direction'** but, in some GMC documents, it was described as a **'sanction'**.

Issuing a Reprimand

21.53 Until recently, the term used was an 'admonishment' but, in 1999, the term was changed to a 'reprimand', as the word 'admonishment' was considered somewhat old-fashioned. The power to admonish was contained in rule 34 of the 1988 Professional Conduct Rules, which provided:

> **'The Chairman shall announce any finding, determination, direction, or revocation of the Committee under these rules in such terms as the Committee may approve and, where the announcement is one that a conviction has been proved or that the practitioner has been judged guilty of serious professional misconduct but the Committee do not propose to make any direction, may, without prejudice to the terms in which any other announcement may be made, include any expression of the Committee's admonition in respect of the practitioner's behaviour giving rise to the charge or charges in question.'**

21.54 A reprimand did not affect a doctor's registration. However, having been given at a public hearing, the reprimand was in the public domain and, if a specific enquiry was made about a doctor's FTP history, the fact that the doctor had been reprimanded should have been disclosed by the GMC.

21.55 The status of a reprimand was not entirely clear. It could not sensibly be regarded as 'action on registration'. The PPC's *aide memoire*, which I described in Chapter 20, advised members of the PPC that SPM might be considered in the context of conduct **'so grave as potentially to call into question a practitioner's registration whether indefinitely, temporarily or conditionally'**. That raised the question whether, when the PPC was considering whether or not to send a case through to the PCC, it should have had in mind that, while no restriction of the doctor's registration was likely to be contemplated by the PCC panel, the panel might well have considered that a reprimand would have been appropriate. If so, should the case have been referred to the PCC? Mr Robert Nicholls, former Chairman of the PPC, said that, for the PPC, the test was whether the relevant conduct had the potential to warrant conditional registration, suspension or erasure. Although it was recognised that a reprimand might be the outcome of a referral to the PCC, that possibility was not in the minds of members of the PPC when deciding whether to refer the case on. It appears that, if the PPC thought that a reprimand would suffice, it would issue a warning letter itself. Such a course avoided the risk, in borderline cases, that the

doctor might be found 'not guilty' of SPM, with the result that the PCC would then be unable to issue a warning or reprimand. I can see the logic of that approach in conduct cases. However, in conviction cases, the PCC would definitely have jurisdiction to impose a sanction, if it thought it appropriate to do so, and it should, in my view, have been for the PCC, rather than for the PPC, to decide on sanction. In any event, the conviction would already have been in the public domain and the public had a legitimate interest in knowing how doctors convicted of criminal offences were dealt with by the GMC and why.

21.56 The 2003 ISG, which, as I have said, was produced for the assistance of PCC panellists, advised that a reprimand might be considered where most of the following factors were present:

> '• **Evidence that behaviour would not have caused direct or indirect patient harm.**
>
> • **Insight into failings.**
>
> • **Isolated incident which was not deliberate.**
>
> • **Genuine expression of regret/apologies.**
>
> • **Action under duress.**
>
> • **Previous good history.**
>
> • **No repetition of behaviour since incident.**
>
> • **Rehabilitative/corrective steps taken.**
>
> • **Relevant and appropriate references and testimonials.'**

The 2003 ISG emphasised that the list of factors was not exhaustive. In my view, all these factors were undoubtedly relevant to the issue of sanction. However, it was safe to take such matters into account only where there was a reasonable evidential basis for them. It might well have been unsafe for a PCC panel to accept, without corroborative evidence, that, for example, the incident was an isolated lapse or that there had been no repetition of the conduct since the incident. In the past, it seemed to be assumed that these things were so in the absence of evidence to the contrary. There was rarely any investigation and there was rarely, if ever, any evidence about them. They usually depended upon the assertion of counsel – made, no doubt, in good faith. It appears to me, from the cases that I have read, that assumptions were readily made in the doctor's favour, without any satisfactory evidential basis.

21.57 In considering how the GMC might have treated Shipman if his conduct in the case of Mrs Renate Overton had been reported to the GMC (see Chapter 10), the Inquiry examined a number of other cases which had been reported to the GMC in the mid-1990s and in which a drug overdose had been given with serious or fatal consequences. One such was the case of Dr JM 03, who was given a **'severe'** reprimand at the conclusion of the PCC hearing.

Dr JM 03

21.58 The doctor was a specialist registrar in anaesthesia. Late one evening, she was called upon to provide post-operative analgesia using a device known as an Abbott Provider. The doctor was unfamiliar with the equipment and re-set it wrongly (and unnecessarily) so that the patient received ten times the appropriate dose of the drug, which was fentanyl. The effect was fatal. The case was reported to the GMC but could not progress for some time because other proceedings were current. The police investigated the death but decided not to prosecute the doctor. The Coroner's inquest concluded with a verdict of unlawful killing. The Health and Safety Executive successfully prosecuted the hospital trust under the Health and Safety at Work Act 1974 for its failure to provide the doctor with adequate training in the use of the Abbott Provider. The trust was not able to discipline the doctor because, by the time the prosecution was over, she had left its employment.

21.59 In due course, the case was referred for hearing by the PCC. The allegations were that the doctor had embarked on the use of the Abbott Provider although she was unfamiliar with it; she did not seek the advice of a senior or more experienced colleague; nor did she obtain the instruction manual; she re-set the Provider when there was no need for her to do so. When she checked its operation, she failed to realise that she had miscalculated the dosage. She knew (or should have known) that to re-set the device incorrectly created a risk that the patient would receive a fatal dose. The facts of the case and the various criticisms were all admitted. The doctor expressly admitted that her actions had been reckless and irresponsible. The PCC panel found her guilty of SPM. In mitigation, it took account of the frankness of the doctor's admissions. A number of testimonials had been produced and the PCC panel found that the doctor was a **'caring and conscientious doctor held in high regard'**. The PCC panel also took into account the failure of the trust to provide the doctor with adequate training in the use of the Abbott Provider, as evidenced by its conviction. The PCC panel also expressed the view that a confusing method of describing the contents of solutions of drugs might have contributed to the doctor's error. The PCC panel said that the doctor had learned a great deal from the incident, which represented a single mistake in an otherwise unblemished career. In the particular circumstances, this decision seems to me to have been an acceptable use of the power of reprimand, although some might argue that a period of conditional registration with a requirement to undergo an educational programme might have been more appropriate.

Sanctions

21.60 If a PCC panel decided that it would not be sufficient to conclude a case without any sanction being imposed on the doctor, it then had to consider which of the available sanctions to impose.

Sanctions: Their Purpose

21.61 The GMC states that the purpose of the sanctions is not to be punitive. Rather, their purpose is to protect the public interest although, in fulfilling this purpose, they may have an incidental punitive effect. The 'public interest' includes not only the protection of

patients, but also the maintenance of public confidence in the medical profession and the declaring and upholding of proper standards of conduct.

21.62 The 2003 ISG stated that the **'public interest'** might also include **'the doctor's return to work if he or she possesses certain skills, competencies, or knowledge, for example expertise in a particular area, or language skills'**. The 2003 ISG also advised that, in deciding what sanctions to impose, the PCC panel should apply the **'principle of proportionality'**, weighing the interests of the public against those of the doctor, which latter interests include **'returning immediately to unrestricted practice or after a period of retraining'**. In addition, the 2003 ISG advised that the PCC panel would need to consider any mitigation in relation to the seriousness of the behaviour in question.

Sanctions: the Order in Which They Were Considered

21.63 Rule 31 of the 1988 Professional Conduct Rules stated that a PCC panel should first consider and determine whether it was sufficient to direct that the doctor's registration should be conditional on his/her compliance, for a maximum period of three years, with such requirements as the PCC panel might think fit to impose for the protection of the public or in his/her own interests. This sanction is usually known as 'conditional registration'. If the PCC panel decided that it was not sufficient to impose conditions on the doctor's registration, it had next to consider and determine whether it was sufficient to direct that the doctor's registration should be suspended for a maximum period not exceeding 12 months. If the PCC panel did not consider suspension to be sufficient, it then had to direct erasure of the doctor's name from the register. A PCC panel was, therefore, required to consider the available sanctions in reverse order of severity. The first it would consider was conditional registration.

The Sanction of Conditional Registration

21.64 As I have said, a PCC panel might make a doctor's registration conditional on his/her compliance with stated requirements for a period not exceeding three years in the first instance, renewable for periods of up to 12 months thereafter. The purpose of conditional registration is to enable a doctor to remedy any deficiencies in his/her practice while, in the meantime, protecting the public or the doctor from harm. The 2003 ISG stated that conditional registration would be appropriate **'where there is evidence of incompetence or significant shortcomings in the doctor's practice but where the Committee can be satisfied that there is potential for the doctor to respond positively to retraining'**. This guidance seemed to suggest that the imposition of conditions on a doctor's registration was appropriate in cases in which the proven misconduct was tantamount to seriously deficient performance (SDP). It seems to me that the PCC panels must sometimes have had difficulty in distinguishing between professional misconduct and deficient performance. However, the evidence on which a PCC panel acted was not an assessment of the doctor's overall performance, but an account of one – or at most a few – specific incident(s). The PCC panel was unlikely to have a full picture of the doctor's competence or shortcomings. In the future, the use of a performance assessment (possibly an abridged version of the present lengthy and expensive assessment) will be a useful tool for a FTP panel at this stage of the process.

21.65 The 2003 ISG advised that conditional registration might be an appropriate sanction when most or all of the following factors were apparent:

> '• **No evidence of harmful deep-seated personality or attitudinal problems.**
>
> • **Identifiable areas of doctor's practice in need of assessment or retraining.**
>
> • **No evidence of general incompetence.**
>
> • **Potential and willingness to respond positively to retraining.**
>
> • **Patients will not be put in danger either directly or indirectly as a result of conditional registration itself.**
>
> • **The conditions will protect patients during the period they are in force.**
>
> • **It is possible to formulate appropriate and practical conditions to impose on registration.'**

The 2003 ISG made clear that the list of factors was not exhaustive.

21.66 Conditions may impose exacting and far-reaching restrictions on a doctor's practice (e.g. s/he may not be permitted to practise, save under the supervision of another registered doctor) or may be far less onerous (e.g. s/he may have to take and follow guidance about a particular aspect of his/her practice).

Resumed Hearings

21.67 In a case where a PCC panel had imposed conditions on a doctor's registration, it was open to it, when announcing its decision, to announce also that it would resume consideration of the case at a hearing to be held before the expiration of the period of conditional registration. At the resumed hearing, the PCC panel could decide to revoke the conditions previously made, to vary them, or to impose a further period of conditional registration not exceeding 12 months. A resumed hearing would have afforded an opportunity to 'take stock' of the progress made by the doctor during the period since the conditions had been imposed and of considering whether the doctor had reached the stage of being fit to practise unrestricted.

21.68 The 2001 ISG made no mention of holding a resumed hearing in a case where conditions had been imposed on a doctor's registration. It might be that resumed hearings were not held, or were not held often in cases where conditional registration had been imposed. Resumed hearings were mentioned in the 2001 ISG only in connection with suspension. However, the 2003 ISG mentioned a resumed hearing as a possibility in a case where conditions had been imposed on registration, although the emphasis was still on resumed hearings in cases of suspension.

21.69 If no resumed hearing was held, it appears that, at the conclusion of the period of conditional registration, the conditions simply lapsed and the doctor returned to

unrestricted practice without more ado. I appreciate that to convene a resumed hearing would have been an additional drain on resources. However, I do think that it would have been of value to hold a resumed hearing. It would have focussed the mind of the doctor on what s/he would be expected to have achieved by the time of the resumed hearing. It would also have given the PCC panel some insight into the practical operation of the sanction it had imposed. In that way, PCC panels would have learned what worked well or less well as remediation for particular kinds of problem.

21.70 If the PCC panel did not announce that it intended to resume consideration of a case in which conditions had been imposed on a doctor's registration, the 1988 Professional Conduct Rules nevertheless permitted the case to be referred back to the PCC panel if information came to light about the conduct or conviction of the doctor since the original hearing or if it appeared that the doctor was not complying with the original conditions. The PCC panel could then consider whether the period of conditional registration should be extended, or the conditions varied or revoked, or whether the doctor's registration should be suspended or his/her name erased from the register. If an intimation had been given at the original hearing that the hearing would be resumed, the case could be brought back earlier than intended if relevant information was received.

Comment

21.71 It is clear that there are advantages in imposing conditions on a doctor's registration. They are the only means of enforcing remedial action with the prospect of achieving a result that is beneficial both to the doctor and, in the longer term, to the public. The disadvantages are that allowing a doctor to practise under conditions may expose the public to a potential risk. First, the doctor is usually allowed to practise while undergoing part-time re-education. The public may be at risk while that process is underway. It can be difficult for the GMC to monitor the doctor's compliance with conditions. Second, unless the doctor is assessed at the end of the period, there is no certainty that the exercise has been effective. Full-time remedial training for a concentrated period with assessment at the end would, in some cases, be a much more effective process – but very expensive. Third, it seems to me that the GMC should make it plain, in words and by its actions, that, if the doctor cannot demonstrate that the objectives underlying the conditions have been satisfactorily achieved, erasure will follow.

Cases Where Conditions Were Imposed on the Doctor's Registration

21.72 While examining cases that were relevant to the case of Mrs Overton, the Inquiry came across some examples of cases in which conditions had been imposed.

Dr JC 02

21.73 One such was the case of Dr JC 02, who was brought before the PCC in the early 1990s following two incidents in which he had (negligently) administered an overdose of diamorphine. Both patients had died. The Coroner had returned verdicts of misadventure in both cases and, on the second occasion, a medical service committee (MSC) had found the doctor in breach of his terms of service. The PCC found SPM proved but the

sanction was the imposition of conditions for eight months with a requirement that the doctor should undergo retraining in the use of **'therapeutics'** and should not prescribe or possess diamorphine. At the end of the period, there was to be a resumed hearing at which the doctor was to produce certificates and references to demonstrate that he had undergone retraining. At the resumed hearing, the doctor was referred to the Health Committee.

Dr JG 03

21.74 In another case, that of Dr JG 03, which was heard in the mid-1990s and to which I referred in Chapter 10, the PCC panel imposed a period of conditional registration following the doctor's conviction for perverting the course of justice and a finding of SPM. The events had taken place three years earlier. The doctor had been consulted by a patient who suffered from asthma. At the time, her asthma was not troubling her but she had been experiencing palpitations. The doctor prescribed propranolol, a drug which is contraindicated for asthmatics. The following day, the patient suffered a very severe attack of breathlessness and died. The doctor was told what had happened. He then made a number of changes in the computerised medical records, removing several references to the patient's history of asthma. In the course of the investigation that followed and when giving evidence at the inquest, he claimed that he had been unaware that the patient suffered from asthma. He claimed that he had had access only to the handwritten records on the day in question; he had not been able to read his partner's writing and had not recognised any reference to asthma. Later, it was found that he had falsified the computer records; he was prosecuted, convicted and sentenced to six months' imprisonment.

21.75 During the course of the investigation, evidence emerged that the doctor had falsified medical records on another occasion, in order to cover up an error that had been the subject of a separate complaint to the local MSC. However, the GMC did not take proceedings in respect of the earlier occasion; it considered only the prescribing error resulting in the death of the asthmatic patient and the conviction for perverting the course of justice. The PCC panel found that the doctor's care of the patient had fallen deplorably short of a reasonable standard and amounted to SPM. Because of the period of imprisonment served and other factors regarded as mitigating the severity of the offence, it decided to impose conditions on the doctor's registration for one year. The doctor was required to consult with his Regional Adviser in General Practice, to undergo an assessment of his consultation skills, history taking and physical examination and to follow the advice of the Regional Adviser about remedying any deficiencies in knowledge and history taking and about keeping accurate and contemporaneous records.

21.76 Dr Korlipara told the Inquiry that, although he had sat on the PCC panel which heard this case, he had no recollection of it. He was surprised that the PCC panel had imposed conditions and said that it would have been more usual to direct erasure or at the very least a long period of suspension. I interpose to say that the longest period of suspension available is a year. Dr Korlipara agreed that dishonesty could not be rectified by retraining. The PCC panel reviewed this case at a resumed hearing 11 months after the first hearing.

It received correspondence from the regional adviser who said that the doctor had made satisfactory progress. The doctor was then allowed to practise unrestricted.

21.77 As a footnote to this case, about seven years later, the GMC became aware of a further complaint about Dr JG 03, who was said to have failed to diagnose meningitis in a young baby. The case was closed by the office staff because the local complaints procedures had not yet been completed. There is no indication on the file that any steps were taken to monitor or follow up the progress of the local complaint. Dr Korlipara agreed that the GMC ought to pursue such complaints proactively in the case of a doctor with a serious disciplinary history such as Dr JG 03.

21.78 In my view, the imposition of conditions in the case of Dr JG 03 was inappropriate. I find it hard to accept that the PCC panel members could have had at the forefront of their minds the need to protect the public. There were serious concerns about the doctor's honesty. I believe that many members of the public would consider that dishonesty of this kind demonstrates an unfitness to practise because the doctor cannot be trusted. I recognise that attitudes might have hardened since it was discovered that Shipman habitually falsified medical records. But, even without that, I think that the public feels that it should be able to trust doctors – not always to avoid making mistakes but at least, when one is made, not to lie about it. Sir Donald Irvine told the Inquiry that, in his view, the GMC should seek to reach consensus with the public about appropriate sanctions. It seems to me that that would be a sensible course in respect of all sanctions but especially in respect of cases of dishonesty. Dr Korlipara agreed that a dialogue with the public about such issues would be helpful.

Dr JM 04

21.79 The case of Dr JM 04 also involved a serious prescribing error but, in his case, there was no attempt to 'cover up'. The doctor was called out to see a patient who was suffering from severe pain. The doctor diagnosed renal colic and, despite the fact that the patient said that his pain had subsided, administered 75mg Voltarol and 30mg diamorphine intramuscularly. This was a gross overdose and the patient died about an hour later, owing to morphine toxicity. The police investigated the death. They were unable to find either a prescription for 30mg diamorphine or an entry in the practice controlled drugs register. In the doctor's bag at his home, they found three 30mg ampoules and one 10mg ampoule of diamorphine, as well as other drugs and a copy of the British National Formulary. It would appear therefore that the doctor kept a supply of diamorphine and had used some from his stock on the patient who had died. He had not complied with the statutory requirements governing its use. The doctor was charged and convicted of manslaughter and was sentenced to 12 months' imprisonment, suspended for two years.

21.80 Shortly after the GMC was notified about the conviction, it was discovered that Dr JM 04 had been the subject of another complaint, which had been handled locally. This incident had occurred only a few weeks after the prescribing error. He had failed to attend a patient who was ill and complaining of sweating; the patient had died of pneumonia shortly afterwards. The local health authority (HA) had taken disciplinary proceedings, at which the mother of the deceased patient had given evidence. The doctor had been found in

breach of his terms of service. The mother was willing to sign a statement for the GMC but said that she would find it too distressing to repeat her oral evidence at a PCC hearing. The decision was taken at the GMC that it would be inappropriate to issue a *subpoena* to compel her attendance and that no action should be taken on the second complaint. I interpose to say that it does not appear that any attempt was made to visit the mother or even to speak to her on the telephone to explain to her the importance of her presence before the PCC and the consequences of her refusal to give oral evidence. In any event, the GMC could have applied to the PCC panel for her evidence to be admitted in written form; the PCC panel could have accepted it. Rule 50(1) of the Preliminary Proceedings Committee and Professional Conduct Committee Rules 1988 provided that the PCC might receive oral, documentary or other evidence of any fact which appeared to them to be relevant to its inquiry into the case before it. Further, insofar as any evidence was tendered which would not have been admissible in criminal proceedings in England (and written statements of evidence are not usually admissible), the PCC could not receive it unless, after consideration, it was satisfied that its duty of making due inquiry made reception of that evidence desirable. Thus, rule 50 could have been used to found an application to introduce the written evidence of the mother of the deceased patient in this case. As it was, the panel considered only the allegation relating to the administration of diamorphine.

21.81 The PCC panel found that the doctor's actions in administering 30mg diamorphine had been highly irresponsible. The doctor's explanation, advanced through counsel, was that he had qualified abroad, in a country where diamorphine was not generally used; therefore he was unfamiliar with its properties. He had been very anxious to relieve the patient's pain and had thought that the dose he gave was appropriate. Many testimonials were produced and the panel found that the doctor was a **'caring GP who had made a tragic error'**. It was, of course, quite unaware of the findings of the local MSC in respect of the second incident. The PCC panel imposed conditions on the doctor's registration for a period of 12 months. These were conditions of general supervision, of notification of where he would be practising and of providing reports on his performance to the GMC. There was no specific condition with regard to his right to prescribe controlled drugs or to any retraining in their use.

21.82 Dr Korlipara said that the PCC panel's decision in this case had been 'sympathetic' and that erasure or a 'long' period of suspension would have been more usual. He sought to justify the PCC panel's decision on the basis that this was believed to be an isolated error in the career of a good doctor. (The GMC knew that it was not but the PCC panel was not told.) Dr Korlipara mentioned that the error of dosage would never have happened had it not been that the doctor was so caring and so anxious to relieve the patient's pain. The PCC panel had sought to protect the public by arranging supervision. He did not think it would have been necessary or appropriate for the GMC to investigate any possible concerns about the doctor's practice of keeping diamorphine in his bag (although apparently not being accustomed to using it) and about his non-compliance with the statutory requirements. That, he said, was a matter for the local NHS bodies.

21.83 Soon after the PCC panel's decision was announced, the GMC received a letter from a colleague of Dr JM 04. He was able to impart information about the circumstances surrounding the administration of diamorphine that had led to the conviction and also cast

doubt on the accuracy of some of the matters advanced in mitigation. If this information was true, it would have put a different complexion on the case and the outcome might well have been different. As I have said, it has not been the GMC's practice to contact employers or colleagues as part of its investigation.

21.84 I wish to make three observations. First, there appears to be a real possibility that the PCC panel dealt with this case on the basis of incomplete information about the circumstances of the misconduct underlying the conviction and unjustifiably favourable mitigation. The result may well have been the imposition of a sanction that did not adequately protect the public or the doctor's future patients. Second, it seems to me that it would be sensible, especially in conviction cases, for the GMC to make enquiries of the partners or colleagues of the doctor and of his/her employer or primary care trust. Otherwise, the GMC cannot set the facts of the conviction in context. Nor is it in a position to check the veracity of matters advanced in mitigation by counsel on instructions. Third, in my view, it would be preferable for a PCC panel, when considering the imposition of conditional registration, to invite the doctor to give evidence. I do not see how a panel can adequately assess the doctor's attitude towards his/her misconduct and his/her commitment to retraining on the basis of an address by an advocate.

The Case of Ghosh

21.85 The importance of hearing evidence from a doctor during PCC hearings was recognised by the GMC in the case of Ghosh v General Medical Council[10]. Dr Ghosh was found guilty of SPM in April 1998 on charges of failure to visit patients when necessary. The PCC panel imposed conditions for two years. Excellent arrangements were made for Dr Ghosh's re-education under the supervision of the Associate Dean of Postgraduate GP education. She was placed in a practice where the partners were willing to supervise her. However, there were soon signs that Dr Ghosh did not accept the need for supervision or for any change in her attitude and, in due course, it became apparent that she was not complying with the conditions imposed. Moreover a serious complaint was received in July 1999 that the doctor had not attended a patient whom she had promised to attend and who was in urgent need of attention. Soon afterwards, Dr Ghosh went abroad for two and a half months without warning the practice. Both the practice and the Associate Dean abandoned their attempts to supervise her. The Associate Dean wrote to the GMC urging it to bring the case back for review earlier than the date originally envisaged for the resumed hearing. In October 1999, the HA by which Dr Ghosh had been employed during her period of supervision dismissed her for gross misconduct in respect of the incident in July 1999. Dr Ghosh then asked the GMC for permission to work in various settings and complained that the Associate Dean would not help her **'because she was ill'**. She repeatedly failed to provide the GMC with information about her activities.

21.86 In October 2000, Dr Ghosh came back before a PCC panel. She appeared by counsel and did not give evidence. It was claimed on her behalf that she had taken appropriate steps to re-educate herself. By way of example, she produced a letter from a doctor who said that she had attended antenatal clinics as an observer during August, September and

[10] [2001] 1 WLR 1915.

October 1999. When it was pointed out that, for much of that time, she had been abroad, it was said on her behalf that the doctor who had written the letter had made a mistake about the dates; however, she had begun attending the clinic on her return to this country and was still doing so. The PCC panel asked counsel what evidence there was of this attendance and counsel said that she was relying upon her instructions. The PCC panel indicated that that was not evidence and there followed some discussion about whether Dr Ghosh would testify. She did not do so. It is clear from the reasons given by the PCC panel for its decision that this failure on her part was a significant factor in its decision to reject Dr Ghosh's claims and to erase her name from the register. Dr Ghosh appealed against the erasure to the Privy Council, without success.

21.87 It is, I think, generally recognised that conditions requiring retraining are likely to succeed only if the doctor is genuinely committed to them. I repeat that, in my view, the PCC panel (and, indeed, other committees or panels empowered to impose conditions) should have required a doctor to answer its questions personally before deciding to impose conditions. I suspect that, in the case of Dr Ghosh, it would have been clear that she was not minded to co-operate. In such a case, if immediate erasure were thought inappropriate and conditions were the only possible course, it would surely have been preferable to arrange an early review of the case rather than leave matters for as long as two years. There is no evidence that Dr Ghosh practised in breach of her conditions but there must have been a risk that she would do so after the arrangements for supervision had broken down.

Dr JF 02

21.88 Finally in this section dealing with conditional registration, I must mention the case of Dr JF 02. The GMC received two complaints about this doctor in the early 1990s. One alleged an inappropriate internal examination, for which no chaperone was offered; the other alleged the administration of a gross overdose of diamorphine (100mg) shortly before the patient was despatched to hospital in an ambulance. The patient went into respiratory arrest but was resuscitated on arrival at hospital. Both matters were referred to a medical screener who requested immediate and urgent action in the case of the overdose and directed that the female complainant in the case of inappropriate examination should be asked to provide a statutory declaration. A letter of request was sent but no reply was received and, apart from a reference to the fact that the doctor disputed the allegation, there is no further record of this complaint in the file. In the light of subsequent events, the seriousness of the consequence of not following up that complaint will be understood.

21.89 The diamorphine complaint was referred to the PPC and the doctor was informed. His solicitors submitted his explanation, which was that he needed strong pain relief for the patient; he went to the pharmacy and asked for morphine or something similar. He was provided with diamorphine, which he had never used before. He checked the drug information leaflet and must have misread it, as he gave too much. The PPC sent the case to the PCC. Five months after the complaint had been recorded by the GMC, the doctor was found guilty of SPM and was placed on conditional registration for a period of six months, during which time he was to pursue a structured programme of retraining in the

use of controlled drugs. At the end of the period of conditional registration, the doctor was free to practise without restriction, having apparently completed his retraining.

21.90 Only two months later, the GMC received a complaint that Dr JF 02 had carried out an inappropriate internal examination on an elderly female patient. However, the GMC decided to take no action because it considered that the main issue was whether the doctor had obtained valid consent before examining the patient. The GMC wrote to the HA which had reported the matter, suggesting that the patient should take civil action through the courts and that, if it were established that the doctor had not obtained consent, it would be open to the patient to renew her complaint to the GMC. Pausing in the history there, that seems to me a wholly inappropriate response to such a complaint. The GMC should have investigated the allegation even if it had stood alone; the need to do so was even greater in view of the earlier allegation of an inappropriate examination received the previous year. The GMC now had two potential allegations of sexual misconduct, from apparently unrelated sources, and neither was investigated.

21.91 About two years later, the HA in whose area the doctor practised wrote expressing concern about a number of matters relating to Dr JF 02. His prescribing was said to show a **'seriously deficient pattern of performance'**. He had been prescribing methadone inappropriately for addicts and was also prescribing benzodiazepines to young patients over long periods. A GMC memorandum noted that these concerns might amount to SPM. However, three other complaints forwarded by the HA were thought not to raise questions of SPM and were screened out. These related to rudeness, excessive physical contact with a patient, performing an examination in an aggressive way and refusing to give assistance to a girl involved in a car accident. The HA wrote expressing its disappointment at the decisions to screen these complaints out, said that it was concerned about the welfare of patients and gave details of another specific concern. This related to a female patient, with whom it was alleged that Dr JF 02 was having a **'non-professional relationship'**; he was supplying her with prescriptions for large amounts of benzodiazepines and opiate analgesics including Oramorph solution. The PPC referred to the PCC the allegations of irresponsible prescribing of methadone. At the same time, the HA informed the GMC that Dr JF 02 had been charged with nine counts of indecent assault and 30 counts of obtaining drugs by deception. Soon afterwards, the doctor was suspended from the HA's list by the NHS Tribunal on an interim basis.

21.92 The PCC hearing was deferred pending the outcome of the criminal proceedings, which were concluded ten months later. The doctor was found guilty of one count of indecent assault and then pleaded guilty to five counts of theft of drugs. He was sentenced to eight months' imprisonment for indecent assault and four months' imprisonment for theft, both sentences to be suspended for two years. All remaining charges were 'left on the file'. That meant that they would not proceed further unless, because of some exceptional and unforeseen circumstance, the court decided that they should proceed. There was, of course, no bar on the GMC hearing evidence in relation to them and, in particular, in relation to the allegations of indecent assault, each of which must have raised a question of SPM. However, the GMC did not do so.

21.93 Shortly after the doctor's conviction, the HA intimated that further complaints about him were to be forwarded and expressed concern about the delay that had already occurred

and about the length of time it might take to bring all these matters to the PCC. It urged the GMC to take immediate action. Mr Scott, Chief Executive of the GMC, admitted in a letter to the HA that the GMC **'could have done better'** and promised that the case would be considered at the next meeting of the PPC. The following month, the HA sent details of the additional concerns. These included an allegation that the police had found pornographic material at the doctor's home and surgery. The PPC considered the issue of interim suspension at its next meeting (this was before the Interim Orders Committee (IOC) was established) but did not make an order. The case did not come before the PCC until five months later. Then, the only matters before the PCC panel were the convictions and the allegation of irresponsible prescribing of methadone to addicts. On this latter charge, a PCC panel found SPM proved. The sanction imposed in respect of the convictions and the finding of SPM was suspension for 12 months.

21.94 I must make two observations. First, even on the basis of the material before the PCC panel, this decision seems unduly lenient. The doctor was dealt with for indecency, dishonesty and irresponsible prescribing of controlled drugs. I would have thought that only erasure could provide adequate protection for the public. I think that, if such a decision were to be made today, the Council for the Regulation of Healthcare Professionals (now known as the Council for Healthcare Regulatory Excellence (CRHP/CHRE)) would refer the case to the High Court as being unduly lenient. However, the CRHP/CHRE did not exist at that time. Second, the GMC had made no attempt to resolve all the other complaints made and concerns expressed about this doctor. Several complaints had been screened out because, standing alone, they could not amount to SPM. Others, such as the allegations of indecent assault, which had not been tried at court, were simply not dealt with. It may be – I cannot say – that, if the evidence of all the other matters had been put to the PCC panel, the doctor might have been acquitted on all of them, in which case he was dealt with on a proper basis. However, in the light of subsequent events, it seems very likely that, if further charges had been put, there would have been further findings amounting to SPM. It seems to me that the GMC knowingly dealt with this doctor on the basis of incomplete information. The process by which complaints were considered in isolation, and were screened out if they could not, of themselves, amount to SPM, did not provide adequate protection to patients. A doctor who behaves unacceptably on three occasions (as for example by being rude or aggressive to a patient) may not be guilty of SPM on each individual occasion but, when all three allegations are considered together, his/her misconduct must surely be viewed in a much more serious light.

21.95 A PCC panel reviewed the case at a resumed hearing a year later and declared that it was not satisfied that it would be safe to allow the doctor to return to unrestricted practice. It imposed conditions on his registration for 12 months. The doctor was permitted to practise only under the general supervision of another doctor and was not to prescribe drugs of addiction or their substitutes to patients he knew or suspected to be drug addicts.

21.96 A year later, the NHS Tribunal made a final order, removing the doctor from all NHS lists. The Tribunal considered a wide variety of allegations, including sexual assaults, sexually inappropriate behaviour, keeping obscene videos in his surgery, rudeness and arrogance, dishonesty and clinical incompetence, both generally and specifically with

regard to the treatment of drug dependency. The NHS Tribunal found that Dr JF 02 was an **'irremediably bad doctor'** who should not be allowed to treat NHS patients. It should be noted that most of the allegations considered by the NHS Tribunal had been reported to the GMC. I have read the decision of the NHS Tribunal. It is clear that it heard a great deal of evidence and approached each allegation with care. Its findings are clearly explained and appear to me to be fully justified on the evidence. More importantly, because of its willingness to hear all the matters together, the Tribunal was able to gain a holistic view of the doctor's conduct, practice and character. By dealing with allegations in a piecemeal fashion, the GMC had not been able to do that. Following the decision of the NHS Tribunal, the doctor remained free to practise in the private sector.

21.97 Subsequently, the PCC panel resumed its consideration of Dr JF 02's case. It found that the doctor had been unable to practise in the NHS owing to the ruling of the Tribunal. He was not in breach of the conditions previously imposed by the PCC panel. He was placed on conditional registration for a further 12 months. It appears that, the following year, the doctor obtained work in a cosmetic surgery clinic in the private sector. Subsequently, the clinic reported concerns about him to the National Care Standards Commission. These concerns related to the doctor's poor standards of hygiene and inappropriate sexual behaviour. The substance of these concerns was brought to the attention of the PCC panel when it reconsidered Dr JF 02's case at the expiration of his period of conditional registration. Nonetheless, the PCC panel decided to renew the conditional registration for another year, during which the doctor was to undergo an assessment of his performance. He remained free to practise in the private sector.

21.98 In a witness statement made for the Inquiry, Sir Donald Irvine described this as **'an appalling case in which the GMC has failed and continues to fail to protect the public properly'**. I agree. I am pleased to report that, subsequently, the PCC granted Dr JF 02's application for voluntary erasure from the register. I would not envisage that any application for restoration would succeed.

The Sanction of Suspension

21.99 As I have explained, if it did not consider that the imposition of conditions on a doctor's registration was sufficient, a PCC panel had next to consider whether it would be sufficient to direct that the doctor's registration should be suspended for a period not exceeding 12 months.

21.100 Suspension normally took effect 28 days after the date of the PCC's order, unless the doctor exercised his/her right of appeal to the High Court (until 2003, the Privy Council). However, if a PCC panel decided to impose a period of suspension or to erase the doctor's registration and if it appeared to the PCC panel that there might be reasons (either in the public interest or in the interest of the doctor) for imposing immediate suspension, it had the power to do this, provided that it invited representations on the question before making its decision.

21.101 The 2003 ISG advised that suspension could be used to **'send out a signal'** to the doctor, to the profession and to the public about what was regarded as unacceptable behaviour. The 2003 ISG pointed out that suspension had a punitive effect, in that it prevented the

doctor from practising and, therefore, from earning a living as a doctor during the period of suspension. The 2003 ISG continued:

> **'It is likely to be appropriate for misconduct that is serious, but not so serious as to justify erasure (for example where there may have been acknowledgement of fault and where the Committee is satisfied that the behaviour or incident is unlikely to be repeated). The length of the suspension may be up to 12 months and is a matter for the Committee's discretion, depending on the gravity of the particular case.'**

As a signal, suspension may be effective, but as a sanction it may be counter-productive. Unless the doctor has undergone a programme of re-education or has otherwise used the time productively, s/he will emerge from suspension de-skilled, demoralised and probably a less effective doctor than s/he was when originally suspended.

21.102 The 2003 ISG advised that suspension might be appropriate when some or all of the following factors were apparent:

> **'A serious incident of misconduct but where a lesser sanction is not sufficient.**
>
> **Not fundamentally incompatible with continuing to be a registered doctor.**
>
> **No evidence of harmful deep-seated personality or attitudinal problems.**
>
> **No evidence of repetition of behaviour since incident.**
>
> **Committee satisfied that doctor has insight and does not pose a significant risk of repeated behaviour.'**

The 2003 ISG made clear that the list of factors was not exhaustive.

Resumed Hearings

21.103 As with conditional registration, when a PCC panel suspended a doctor, it could state, when announcing its decision, that it would resume consideration of the case before the end of the period of suspension. The 2003 ISG did not envisage that a resumed hearing would be necessary in every case. It stated:

> **'In some cases, it may be self-evident that following the period of suspension, there will be no value in seeing the doctor again. However in most cases where a period of suspension is imposed, the Committee may need to be reassured that the doctor has a continuing commitment to practise as a doctor; has fully appreciated the gravity of the offence; has not re-offended, and has maintained his or her skills and knowledge.'**

21.104 I would have thought that it would have been a rare case of suspension in which it was not appropriate to review the position at the end of the period of suspension. I also think it appropriate that any disciplinary panel should have the opportunity to question the doctor

personally, in addition to receiving any written reports. Of course, doctors cannot be compelled to give evidence but there should be an expectation that they will submit to questioning and that adverse inferences might be drawn from a refusal to do so.

21.105 At the resumed hearing, a PCC panel had the power to direct that the period of suspension should be extended for a further period, not exceeding a period of 12 months, from the time when it would otherwise expire. It was also open to the PCC panel to impose a period (not exceeding three years) of conditional registration or, if it did not regard either of the previous alternatives as sufficient, to direct that the doctor's name should be erased from the register. Cases could be brought back to the PCC panel where no intimation of a resumed hearing had been given, or in advance of the intended date for the resumed hearing, in circumstances similar to those which applied to conditional registration.

21.106 The 2003 ISG advised that there might be cases where a PCC panel might wish to impose a period of suspension and, at the same time, to direct a resumed hearing and to recommend the type of educational programme the doctor might undergo, or the action s/he might wish to take, during the period of his/her suspension. This could be a potentially useful tool if the objectives were made clear at the start and if, at the resumed hearing, there were to be proper evidence about what had been achieved. However, the wording of the 2003 ISG, which suggested that the PCC panel might recommend an educational programme that the doctor **'might undergo'** or an action that the doctor **'might wish to undertake'**, does not sound as if it was intended that there should be a clear objective which the doctor was expected to achieve or that the consequences of failure might be serious.

Cases Where the Doctor's Registration Was Suspended

21.107 I have said that the Inquiry had an interest in cases in which doctors were found to have been dishonest. The Inquiry also had a particular interest in cases in which doctors had fabricated medical records to cover up misconduct. Shipman did this on many occasions. The Inquiry examined some such cases and found that the sanction imposed was sometimes a period of suspension.

Dr JF 04 and Dr JF 03

21.108 The linked cases of Dr JF 04 and Dr JF 03 are an example of this. Dr JF 04 and Dr JF 03 were husband and wife and were in practice together. In the early 1990s, a complaint was made to the local Family Health Services Authority (FHSA) that Dr JF 04 (the husband) had, a short time earlier, failed properly to examine patient A and had failed to refer her for specialist investigation. Also, he had allegedly been rude to the patient. Later that year, when the complaint was under investigation, Dr JF 04 produced to the FHSA patient records that had been falsified by both Dr JF 04 and Dr JF 03 for the purpose of misleading the FHSA in its investigation. Shortly after receipt of the first complaint, another complaint was received by the FHSA on behalf of patient B, who alleged that both doctors had failed to examine the patient properly, had failed to ascertain the cause of his symptoms and had failed to refer him for specialist investigation when his condition required such referral. Later that year, when the complaint was being investigated by the FHSA, the doctors

produced records that had been falsified by them both for the purpose of misleading the FHSA.

21.109 Both doctors were referred by the PPC to the PCC and their cases were heard over two years after they had first been referred to the GMC. Some of the allegations (including the falsification of records) were admitted and others were found proved. Some allegations were found not proved. A PCC panel found both doctors guilty of SPM. After the receipt of material in mitigation (which included a large number of testimonial letters from patients), both doctors were suspended from practice for three months. Pausing there, I think that this decision would strike many members of the public as unduly lenient. Indeed, in her statement to the Inquiry, Dr Trowell expressed the view that these doctors' names should have been erased from the register. She felt that the PCC panel must have been very impressed by the mitigation advanced since it imposed only three months' suspension. As we shall see, the mitigation was not all that it seemed to be.

21.110 As I have explained, suspension normally took effect 28 days after the date of the order, unless the doctor exercised his/her right of appeal to the High Court (then the Privy Council). The wife did not appeal and 'served' her period of suspension. The husband appealed to the Privy Council, thereby deferring his suspension. The appeal was withdrawn in the month in which his wife's period of suspension expired and the withdrawal was accepted by the Privy Council in July. It is clear that this was a tactical appeal, designed to ensure that the two partners were suspended at different times.

21.111 A few weeks after the PCC hearing, the GMC received information that some of the testimonial letters presented to the PCC panel had been obtained in dubious circumstances. In one case, there was evidence that the wife had asked a patient to write a letter at her dictation, without explaining why it was needed. When the patient returned to the surgery to express concern about this, the husband told her that it would not be used. In fact it was. There were six other cases in which different complaints were made. In one, the patient complained that the wife had composed the letter and the patient had felt **'pushed'** into writing it; in another, the patient had agreed to write a letter of support, at the wife's request, but was not told why it was wanted. These complaints came before the PPC three months after the expiration of the wife's suspension. Presumably the screener must have thought that they raised a question of SPM. The husband admitted the allegation against him and apologised that he had not heeded the request of the patient who had asked to withdraw her letter. So far as I can see from the file, the wife did not reply to the letter informing her of the allegations.

21.112 The PPC panel decided not to refer the new complaints to the PCC. Instead, it directed that a letter of warning should be sent to the wife and a cautionary letter should be sent to the husband. In his Inquiry statement, Dr Robin Steel, who was Chairman of the PPC at the time, said that the PPC would not have sent the complaints on to the PCC because it would have thought it most unlikely that the PCC would wish to take any additional action on registration, bearing in mind that it had already imposed a three-month suspension. He also stated that all the testimonials submitted by the doctors had been **'investigated'** and only a small proportion turned out to have been obtained in dubious circumstances. This case leaves me with the impression that these two dishonest doctors ran rings around the GMC.

Dr JP 01

21.113 Another case in which a PCC panel imposed a period of suspension upon a doctor found guilty of substandard practice and dishonesty was that of Dr JP 01. The doctor had failed to carry out an adequate examination of a patient in 2000. The patient was subsequently admitted to hospital and died. The doctor failed to make a contemporaneous note of his examination and later made false entries in the records in relation to that occasion and to a previous consultation some 16 months earlier. At the hearing in 2003, the PCC panel found that the doctor's actions were irresponsible, dishonest and intended to mislead. He was found guilty of SPM and suspended from practice for six months. Here again, I think the public would feel that this sanction was unduly lenient. My own view is that the public needs protection from this kind of doctor who cannot be trusted. In any event, I believe that there is a need for the public to be consulted about the appropriate sanctions for misconduct, particularly those involving dishonesty.

The Sanction of Erasure

21.114 The most serious sanction available to the PCC is erasure of a doctor's name from the medical register. The 2003 ISG advised that erasure from the register was appropriate where this was the only means of protecting patients and maintaining public confidence in the medical profession. It advised that erasure was likely to be appropriate when the behaviour in question was **'fundamentally incompatible with being a doctor'** and involved any of the following:

> **'• Serious departure from the relevant professional standards as set out in Good Medical Practice.**
>
> **• Doing serious harm to others (patients or otherwise), either deliberately or through incompetence and particularly where there is a continuing risk to patients.**
>
> **• Abuse of position/trust (particularly involving vulnerable patients) or violation of the rights of patients.**
>
> **• Dishonesty (especially where persistent and covered up).**
>
> **• Persistent lack of insight into seriousness of actions or consequences.'**

Once again, the 2003 ISG emphasised that the list of factors was not exhaustive.

Cases Where the Doctor's Name Was Erased from the Register

21.115 I wish to discuss a few cases in which a PCC panel directed erasure from the medical register. Some of these cases were appealed to the Privy Council – some successfully, some not. These cases have been selected because they deal with issues that are of particular interest to the Inquiry in view of similarities to some aspects of Shipman's behaviour. I stress that the Inquiry has not undertaken a systematic review of PCC decisions. With that *caveat*, however, I must observe that it is difficult to detect any

consistent thread of seriousness or mitigating factors that explain why one case was dealt with by erasure while another resulted in suspension or the imposition of conditions. The impression is one of inconsistency. This was recognised by the PCC Working Group in its report of 1999.

Dr JM 08

21.116 I mentioned earlier that, because of the case of Mrs Overton, the Inquiry was particularly interested in cases in which a doctor had administered an overdose of an opiate drug. One case brought to the Inquiry's attention in this context was that of Dr JM 08. While working for a deputising service in 2000, Dr JM 08 had been called to see a patient suffering from lung cancer and bronchopneumonia. He administered 45mg morphine to the patient, who had never previously been given that drug. This was a grossly excessive dose. The patient died two hours later and the autopsy found that morphine poisoning was one of the causes of death. The police investigated the death but decided not to prosecute; they reported the case to the GMC. The PPC referred the case to the PCC and also to the IOC. About three months later, the IOC made an order imposing interim conditions on the doctor's practice. These included requirements not to work as a locum or in a single-handed practice and not to undertake out of hours work. The intention was obviously to ensure a degree of supervision of the doctor's work. He was to inform any employer of the conditions. At a review hearing three months later, the doctor claimed that he had not worked at all since the interim order was made. In fact, as it emerged at the next review hearing three months later, that was untrue. He had done locum work at a single-handed practice and had performed out of hours work. Rather surprisingly, the IOC did not impose interim suspension but allowed the doctor to continue working, subject to conditions as before.

21.117 At the substantive hearing by a PCC panel, which took place about 19 months after the case had been referred to the PCC by the PPC, the doctor was found guilty of SPM and his name was erased from the register. It is clear from the decision that a major factor in the PCC panel's reasoning was the doctor's contempt for the order made by the IOC and his willingness to mislead the GMC.

The Case of Manzur

21.118 Some of the cases where PCC panels directed erasure of a doctor's name from the register were cases involving allegations of dishonesty. One such was the case of Manzur v General Medical Council[11]. In that case, the doctor had pleaded guilty in the Magistrates' Court in May 2000 to five charges of false accounting and asked for five more to be taken into consideration. He had dishonestly obtained money from the local HA. He was fined £7500. At the GMC, his case was referred to the PCC. The PCC panel took a serious view of this misconduct and, after taking account of the mitigation advanced, decided to erase the doctor's name from the register. He appealed to the Privy Council on the ground that the sanction was too severe, particularly in the light of his long unblemished record and the many positive aspects of his career. Importantly, the Privy Council was told that there

[11] [2002] 64 BMLR 68.

had been no criticism of his treatment of patients or apparent doubts about his ability. The Privy Council allowed the appeal and substituted a period of suspension for three months.

The Case of Dey

21.119 The facts of the case of Dey v General Medical Council[12] were not unlike those of Manzur, although there was an additional feature, in that patient records had been falsified. In Dey, the doctor had been convicted in the Magistrates' Court of multiple charges of false accounting and two charges of obtaining money by deception. He had submitted to the HA applications for payment for health screening tests which he claimed to have carried out but had not. He was paid £7.10 for each test. Apparently, he had done this on over a thousand occasions. He had also made entries in patients' records, presumably recording health screening tests that had not taken place. A PCC panel erased his name from the register and the doctor appealed to the Privy Council, contending that the PCC had failed to have proper regard to the purpose of disciplinary proceedings, which was to protect the public and to maintain standards in the profession. It was claimed that it was wrong for the GMC to impose a further penalty when he had already been punished by the Court. The appeal failed. The Privy Council held that the PCC panel had been entitled to take the view that the doctor's conduct had undermined the confidence of the HA in the integrity of practitioners and that this reflected on the standards and reputation of the profession as a whole. Moreover, the falsification of records had placed patients at risk. The sanction was not excessive.

The Case of Gulati

21.120 In the case of Gulati v General Medical Council[13], the doctor had pleaded guilty to two charges involving the production of false medical reports for use in making fraudulent accident claims against insurance companies. A PCC panel erased him from the register and he appealed. In dismissing the appeal, the Privy Council said that the order of erasure was required in the public interest.

The Case of Bijl

21.121 The Inquiry also looked at some cases involving poor clinical practice where the PCC panel made an order for erasure. In the case of Bijl v General Medical Council[14], the Privy Council overturned the decision of a PCC panel to erase the doctor's name from the register. The doctor, a consultant urologist, had carried out 'keyhole' surgery to remove a kidney stone. The operation proved more difficult than expected and the patient lost a lot of blood. Transfusions were given and the anaesthetist gave advice about the abandonment of the operation. Eventually, the operation was abandoned because the patient was in a very poor state. Despite the patient's poor condition, the surgeon left the hospital and went home. Shortly afterwards, the patient suffered a severe haemorrhage. The surgeon could not be contacted. Another surgeon was found and he clamped the site

[12] [2002] Lloyd's Rep Med 68.
[13] [2001] 61 BMLR 146.
[14] [2001] Lloyd's Rep Med 60.

of the bleeding so that the patient's condition was stabilised. However, the patient died two days later.

21.122 The first surgeon appeared before a PCC panel, charged with two offences: failing to abandon the operation at an appropriate time and leaving the patient while she was in an unstable condition. The PCC panel found that the surgeon was guilty of SPM and directed erasure. It took the view that the surgeon's decision to leave the hospital was **'seriously irresponsible and a grave neglect of proper professional standards'**. It also considered that he lacked insight, which the Privy Council understood to relate to his attitude that it was his job to remove the kidney stone and the anaesthetist's job to keep the patient alive. It appears that there was also concern about the surgeon's failure to communicate adequately with other members of the team. Pausing there, it seems to me that the decision to erase was reasonable.

21.123 Indeed, the Privy Council did not say that it was not. However, after reminding its members of the traditional circumspection with which their jurisdiction to overrule the PCC in matters of judgement had usually been exercised, it nevertheless allowed the appeal. It did so because it felt that it was not **'necessary'** to erase the doctor's name in this particular case. It said that the PCC was **'rightly concerned with public confidence in the profession and its procedures for dealing with doctors who lapse from professional standards'**. But, it continued, **'this should not be carried to the extent of feeling it necessary to sacrifice the career of an otherwise competent and useful doctor who presents no danger to the public in order to satisfy a demand for blame and punishment'**. It cited a passage from 'A Commitment to Quality, A Quest for Excellence', which was a statement made on behalf of the Government, the medical profession and the NHS, in which it was said that:

> **'The Government, the medical profession and the NHS pledge ... without lessening commitment to safety and public accountability of services, to recognise that honest failure should not be responded to primarily by blame and retribution but by learning and by a drive to reduce risks for future patients.'**

21.124 No doubt all that is relevant and wise, but I cannot see that there was any evidence in the case of Bijl that the PCC panel had acted in order to **'satisfy a demand for blame and punishment'**. It is not for me to say who was right about Mr Bijl and who was wrong. Decisions of this kind are based upon the collective judgement of the individual members of the PCC panel or the constituent members of the Judicial Committee of the Privy Council. However, it is clear that differently constituted panels of the PCC will reach different conclusions about similar facts and, it appears, so will different constitutions of the Privy Council. At present, there is, in my view, far too much room for the exercise of discretion. Too much depends on impression and the differing attitudes of individual groups of decision-makers. In my view, there is an urgent need for more structured guidance in the way such decisions are taken.

The Work of the Policy Studies Institute

21.125 In previous Chapters I have explained the background of the work of the PSI team and some aspects of its work. This work included an analysis of cases dealt with by the PCC.

However, this was quantitative only. The PSI team did not carry out any observation of the PCC in action, as it did with the PPC. Nor did it undertake any analysis of the quality of decision-making of PCC panels.

The 1996 Report

21.126 In the research undertaken for the 1996 PSI Report, Professor Allen, who led the PSI team, and her colleagues found that, at the PCC, doctors who had qualified overseas were more likely than their UK counterparts to be found guilty of SPM. However, once found guilty, overseas qualifiers were more likely than UK qualifiers to be admonished or made the subject of conditional registration. The figures for suspension for both groups were very similar. Overseas qualifiers were only half as likely as UK qualifiers to be erased from the register.

21.127 The PSI team suggested a possible reason for the fact that more lenient treatment was apparently given by the PCC to overseas qualifiers found guilty of SPM. This was that the threshold of misconduct which a UK qualifier had to cross before his/her case was referred to the PCC might be higher than the threshold applicable to an overseas qualifier. If that were so, the complaints against UK qualifiers which reached the PCC (or some of those complaints) would be more serious than the complaints against overseas qualifiers and would thus be deserving of more serious sanctions. The PSI team observed that its findings would be consistent with that suggestion.

21.128 The PSI team advocated that a **'rigorous analysis'** should be undertaken of cases where findings of SPM had been made by the PCC in recent years. It was hoped that such an analysis would assist in the development of clear guidelines about what constituted SPM, both in general and in particular instances.

The 2000 Report

21.129 An analysis of the outcomes of PCC cases undertaken for the 2000 PSI Report showed that, if convictions were left out of account, the proportion of cases heard by the PCC where the doctor was found guilty of SPM was 79% in 1997. This proportion rose to 85% in 1998 and fell to 78% in 1999. In 1997, a higher proportion of doctors who had qualified in the UK than of overseas qualifiers were found guilty of SPM; in 1998 and 1999, a significantly higher proportion of overseas qualifiers were found guilty. In 1998, 71% of UK qualifiers were found guilty of SPM in comparison with 100% of overseas qualifiers. In 1999, the proportions were 70% and 87%, respectively.

21.130 So far as sanctions were concerned, the PSI team found that, in 1997, complaints against UK and overseas qualifiers had fairly similar outcomes at the PCC. In 1998, similar proportions of UK and overseas qualifiers had their names erased from the register. In 1999, however, overseas qualifiers were in general penalised more severely. The PSI team observed that the pattern of outcomes was complex. It emphasised that the outcomes might well be related to the seriousness of the cases against the doctors concerned, rather than to any bias on the part of the PCC. However, it was impossible, without qualitative analysis, to be certain of this.

21.131 The PSI team noted that doctors in conviction cases were much more likely than those in conduct cases to have their names erased from the register. Since overseas qualifiers accounted for higher proportions of conviction cases at the PCC, this increased their representation among those doctors who were erased. The 2000 Report observed that, since the PCC appeared to regard convictions so seriously, the question arose of why more convictions were not referred by the PPC to the PCC.

21.132 The Report went on to say that the PCC represented a **'much more transparent'** stage of the GMC procedures than the earlier stages. Nevertheless, it was still not always clear from the PCC's deliberations why it considered that SPM was made out in some cases and not in others. The PSI team advocated a more **'structured approach'** to the recording of reasons by PCC panels. The PSI research had shown **'marked differences in outcome'** from year to year, which were difficult to explain in the absence of any statement of the criteria on which each case was judged. The PSI team pointed out that the composition of the PCC was different on most occasions when a PCC panel sat. Moreover, the composition was likely to be susceptible to even greater change in the near future, as the GMC recruited people from outside the membership of the GMC (i.e. associates) in an attempt to reduce the backlog of cases. The 2000 Report suggested that the GMC might wish to consider whether greater consistency would be introduced by restricting membership of the PCC to a small number of permanent, highly trained individuals.

21.133 The PSI team also identified the need for a close examination of the definition of SPM. It reiterated the need for a common understanding of what did and did not constitute SPM and for clear guidelines on the factors to be taken into account, and the standards to be applied, when making decisions. It stressed the importance of consistency at the level of the PCC, so that the criteria and standards applied at the final stages of the conduct procedures could be fed back through the earlier stages.

The 2003 Paper

21.134 In its 2003 Paper, the PSI team analysed the complaints considered by the PCC during the years 1999, 2000 and 2001. In 2000, the number of doctors who appeared before the PCC (excluding resumed cases and applications for restoration) rose to 101. There was a further rise in 2001 to 122.

21.135 The PSI team found that, in all three years, overseas qualifiers were more likely than UK qualifiers to be found guilty of SPM. In its previous work, it had found that the overall proportion of doctors whose names were erased from the register by the PCC rose from 25% in 1997 to 47% in 1998. It was said that a likely contributory factor to this rise was the increase in the number of conviction cases. The proportion of doctors erased had then fallen slightly (to 43% or 45%) in 1999. In the later analysis, a further fall was observed. In 2000, the proportion was 34%; in 2001, it was 26%. In 1999, erasure was directed in a significantly greater proportion of cases involving overseas qualifiers than of UK qualifiers. In 2000, the differential was less and, in 2001, a slightly greater proportion of UK qualifiers had their names erased. In all three years, UK qualifiers were more likely than overseas qualifiers to be admonished or reprimanded, while overseas qualifiers were more likely to be suspended or to have conditions put on their registration.

21.136 Doctors in conviction cases were more likely to have their names erased than those in other types of case. The proportion of convictions dealt with by erasure was usually over 80% (73% in 1999). However, in 2001, erasure was imposed in only half the conviction cases dealt with.

21.137 The analysis found continuing differences between the outcomes of cases involving UK qualifiers and those of overseas qualifiers at the PCC. The factors causing this could not be determined without a detailed analysis of the reasons for the decisions made by the PCC.

The Professional Conduct Committee Working Group

21.138 In May 1999, the PCC Working Group, which had been established by the Fitness to Practise Policy Committee, reported on the powers and practice of the PCC. The background to its work was concern within the GMC about public and media criticism of PCC decisions as being inappropriate or inconsistent with previous decisions. One of the tasks of the Working Group was to ascertain whether there was or appeared to be inconsistency in the way sanctions were applied by the PCC.

21.139 The Working Group reviewed all decisions on sanction made by the PCC over the period from 1988 to 1997. The report said that the decisions reviewed were cases where **'SPM was found proved'**. It is possible that they also included convictions. The most common sanction (imposed in 37% of cases) was erasure of the doctor's name from the register. The Working Group expressed surprise, however, that 20% of cases were concluded with an admonishment. Members of the Working Group believed that a finding of SPM should usually lead to the imposition of a sanction unless there were **'strong mitigating factors'**.

21.140 The Working Group looked in particular at cases involving sexual misconduct (excluding consensual sexual relationships) and inadequate or inappropriate clinical care. It found that two thirds of proven sexual offences had resulted in erasure. In the remaining third, a very wide range of sanctions had been imposed by the PCC, including (in 7% of cases) an admonishment. In the case of clinical treatment, sanctions were very evenly distributed, with 26% resulting in erasure and 20% in admonishment.

21.141 The Working Group observed that the **'bare statistics'** could not show why individual decisions had been made. Neither had members of the Working Group found the official minutes of the cases, made at the time, of much help. It was not at that time the practice to include in the determination at the end of a case any more than a very brief explanation of why a particular sanction had been imposed. The report observed:

> **'There is therefore no sure way of knowing whether certain decisions which appear unexpected or inconsistent (such as merely admonishing a doctor for indecent behaviour with a patient) were genuinely aberrant, or whether there was some overwhelming mitigating factor which was not made explicit in the determination. So, while we have found no clear evidence of a pattern of inconsistent or inappropriate decision making, there is no doubt that the appearance of inconsistency and inappropriateness has sometimes been given.'**

21.142 The report rejected as unworkable the idea of using sentencing tariffs. The Working Group thought that this approach was inappropriate because, in contrast to the criminal courts, the PCC was dealing, not with a number of clearly defined offences for which a 'tariff' could be specified, but with a single offence of SPM. Furthermore, the Working Group considered that a tariff approach would **'place an undesirable restriction on the Committee's discretion'**. Instead, the Working Group recommended the development of a statement about the purpose of the sanctions generally and of each sanction in particular. It suggested that this would be a useful training aid. It was this suggestion that led, two years later, in 2001, to the production of the first version of the ISG.

21.143 Also, in a further attempt to promote consistency of decision-making, the Working Group recommended the circulation of the minutes of every meeting of a PCC panel to all PCC members. It also recommended regular meetings of legal assessors, committee chairmen and members of committees. It recommended that screeners and members of the PPC and the PCC should also meet regularly. It suggested the preparation of a training handbook and mentioned *aides memoire*.

21.144 The Working Group also advised that the PCC should give a fuller explanation of its reasons. It observed that that would enable all those with an interest in the decision – the doctor, the complainant, the public and the profession – to know why the decision had been made. It would also enable a panel which might need to consider the doctor's conduct in the future to have a fuller appreciation of the earlier panel's thinking. The Working Group did not suggest that the PCC should give reasons for its findings of fact.

Comment

21.145 The views expressed by the Working Group are similar to those I expressed earlier, namely that there was an appearance of inconsistency between decisions of the PCC. It is plainly desirable that something should be done about this. It does not seem to me that intervention by the Privy Council (which, in later years, showed less deference to the judgements of the PCC than had formerly been the case) was able to help; it did not hear enough cases to establish a framework of sanctions. The same is likely to be true of the High Court, to which appeals are now directed. The development of the ISG has obviously been a step forward in the drive for consistency. However, the ISG focusses on what type of sanction is appropriate in what type of case and does not seek to provide specific examples of what has been thought appropriate in particular cases in the past. The Working Group report said that it would not be feasible to **'make systematic use of precedents'** when reaching decisions on sanctions. The reasoning was that, because SPM covers so wide a range of possible forms of misconduct, it was not possible to categorise cases and to specify which sanctions were appropriate for which category of case.

21.146 I do not agree. The Court of Appeal (Criminal Division) is able to do so, when it lays down sentencing guidelines. True, it does so in the context of specific criminal offences. The position of a PCC panel is different from that of a judge imposing a sentence. A PCC panel has to impose sanctions in a wide variety of cases all amounting to SPM. However, the difference is more apparent than real. It appears to me that there are types of SPM which

recur time and time again. Of course, the precise circumstances vary but there are a few underlying themes. It would, in my view, be quite possible to develop sanctions guidance that relates to specific types of misconduct. Of course, such guidance must not restrict the right of a panel to exercise its discretion on the facts of the individual case, any more than the Court of Appeal seeks to inhibit the right of a judge or recorder to take individual circumstances into account when sentencing.

Recent Developments

21.147 During late 2003 and 2004, there were two developments in the way in which the GMC sought to provide guidance for its decision-makers.

The Determination Audit Sub Group

21.148 The first of these developments was the formation of the Determination Audit Sub Group (DASG). Its function was to monitor the decisions of FTP committees, to identify learning points to be fed into training sessions, to advise the President of issues arising from FTP decisions (including concerns about inappropriate decisions) and to report to the Fitness to Practise Committee at regular intervals. At its inception, the DASG comprised three experienced Council members, one of whom was a legally qualified lay member. I am unsure of the present constitution; the legally qualified lay member has recently become a judge and has left the GMC. In any event, it seems to me that the formation of the DASG was a most welcome development. There had hitherto been no systematic analysis of FTP committee decisions (save for the 'one-off' review by the PCC Working Group) and no attempt to correct or learn from decisions or practices that were unsatisfactory.

21.149 The early fruits of the DASG's labours were reported in the first edition of a new GMC publication, the Fitness to Practise Bulletin, published in May 2004. The Bulletin contains other information besides the DASG report. It will be published three or four times a year and is targeted at FTP panellists. This too is a welcome development. It is clear that the process of monitoring has led to the recognition of a number of the same problems with FTP decisions as I have noticed in the cases I have read, some of which I have mentioned in this Report. For example, the DASG reported that in some cases in which the outcome had 'appeared surprising', the reasons given by PCC panels were inadequate and did not explain the conclusions reached. It advised that adequate and legally justifiable reasons must be given. Another example was a reference to the tendency of some PCC panels to assume that, if they had not been told that a doctor had an adverse FTP history, s/he must have had a **'previously unblemished career'**. The DASG report advised that this must not be assumed, as the GMC does not have access to full information.

21.150 The main thrust of the DASG report, however, was to advise that panels hearing FTP cases must ensure that their decisions (both on what amounted to SPM or SDP and on sanctions) conform to GMC standards and policy. It said:

> **'Although panels exercise their judgment in making decisions they must do so within the framework set out by the Council. The determination of policy and the setting of standards is a matter for the Council; when**

reaching decisions on serious professional misconduct, panels must have regard to the Council's policy/standards.'

21.151 So far so good. I am delighted to see this recognition by the GMC that a framework of standards must be adhered to. The DASG report then went on to explain where this guidance was to be found. The primary source was the GMC publication 'Good Medical Practice'. In addition, it was said, the GMC had provided guidance on a number of other discrete topics, such as consent, confidentiality, research, the use of slimming drugs, intimate examinations, serious communicable diseases and several more. Lawyers presenting the GMC's case at hearings have been instructed to draw the panel's attention to any guidance relevant to the issues before the panel.

21.152 That is all very well so far as it goes. However, it does not go far enough. The GMC did not publish any material by which either doctors or FTP panellists could recognise a case of SPM or SDP when they saw one. In other words, there was no guidance on thresholds, and nothing by which anyone could tell where the line should be drawn. In Chapter 17, I described how 'Good Medical Practice' came to be written and how it superseded the old 'Blue Books'. The Blue Books used to give a few examples of the kind of conduct that would result in disciplinary action. However, these were limited in scope. I also explained that the purpose of 'Good Medical Practice' was to be 'positive' and to encourage good practice; it was to avoid focussing in a negative way on bad practice. It had at one stage been suggested that both booklets should be published but, in the event, the Blue Books were discontinued because the GMC wished to focus on its positive message. I mentioned the opinions of some senior GMC staff who said that, although they understood why these changes had been made, they felt that some clarity had been lost about the kind of circumstances in which a doctor might be disciplined. I quoted the opinion of Professor Allen, who said that 'Good Medical Practice' was 'absolutely fine' for the purposes for which it had been written but of no real assistance when it came to defining or recognising SPM.

21.153 Recent editions of 'Good Medical Practice' give this warning to doctors: **'serious or persistent failures to meet the standards in this booklet may put your registration at risk'**. But that is all that is said. Nor is the other guidance I have mentioned any more explicit. Some sources make no reference at all to disciplinary matters. Others give a general warning that certain conduct, for example giving treatment without consent, may result in a challenge in the courts or a complaint to an employer or the GMC. The strongest advice is given in connection with the trading of human organs, where it is said that involvement in such practice will render the doctor **'liable to disciplinary proceedings'**. It is true that some of the medical Royal Colleges have published more specialised guidance which applies the principles of 'Good Medical Practice' to the specialty concerned. The Royal College of General Practitioners has done so and has included a number of examples of excellent practice and, by way of contrast, of unacceptable practice. But it is not the function of the Royal Colleges to advise about misconduct and deficient performance or fitness to practise. It is for the GMC, as the regulatory body responsible for the FTP procedures, to do this. As I have said, there was nothing from which anyone could gauge whether what a doctor had done was likely to be categorised

as SPM or SDP or whether, in the future, it will be found that his/her fitness to practise is impaired. This problem must be tackled.

The Publication of Case Studies

21.154 I had thought that the GMC had recognised the need for much more specific guidance about the threshold for SPM and SDP. At the Inquiry hearings, Sir Donald Irvine said that, at the time when the performance procedures were being set up, when he was President, the idea of publishing case studies had been discussed. The idea would have been to illustrate by example the kinds of conduct that would and would not amount to SPM. He thought this was a good idea and regretted that it had not been done at that time. He mentioned how useful he had found the anonymised case summaries that are published periodically by the medical defence organisations and also said that, on occasion, when he had had to look at a law report, he had found that being able to read the detail had 'brought the case alive'. He thought such summaries would be very helpful for members of GMC committees who had to decide whether conduct amounted to SPM.

21.155 In evidence, Sir Graeme Catto echoed Sir Donald's view and expressed enthusiasm for the idea of publishing a series of case reports. On that subject he said:

> **'It is, I think, a deficiency on our part that we talk about being a learning organisation and helping to get the public and the profession to be aware of the problems arising in medical practice and yet we have been pretty deficient in doing that. I know that Sir Donald was keen to do that. I am absolutely determined that it will happen.'**

21.156 In December 2003, Mr Scott told the Inquiry that the case studies (or at least the first set of them) would be published in February 2004. As I understood it, these were to be summaries of cases in which the decision taken by a PCC panel was regarded as good and was an example to be followed. I hoped that these would provide useful examples of the kind of conduct which did or did not amount to SPM and also guidance on appropriate sanctions. I thought that they would enable those sitting on PCC panels to 'get their eye in' as to what, in the past, had been regarded as a good decision and why. On sanction, I hoped that the studies would not only help on issues of proportionality but would also illustrate the weight that had been attached to various mitigating factors. I hoped that their production would mark a real advance towards consistency in decision-making.

21.157 The first group of 'case studies' was published in September 2004. I regret to say that they are a great disappointment. First, there are only five of them and they are very limited in range. Two relate to a failure to obtain consent, two involve dishonesty and the other was a case of breach of confidentiality. The 'studies' are so brief as to be almost useless. For example, in one of the two cases of dishonesty, the doctor was convicted of nine counts of obtaining money by deception by making **'repeated fraudulent insurance claims'** and was sentenced to nine months' imprisonment. Her name was erased from the register. We are not told the nature of any dishonest misrepresentations made or whether the claims were connected with the doctor's professional practice. We do not even know the total sum involved – it might have been enormous. Nor do we know the period over which the offences were committed. We are given some unimportant information about the doctor's

failure to answer to police bail. In deciding to erase the doctor's name, the PCC panel said that **'there can be no place in the medical profession for dishonest doctors, especially where the deceit is repeated'**.

21.158 If the message to be conveyed to the reader of these 'studies' is that persistent dishonesty involving substantial sums of money will result in erasure, the reader is likely to be puzzled by the outcome of the other case of dishonesty described, in which the doctor was not erased but was suspended for a year. In that case, the doctor, a GP, dishonestly obtained nearly £36,000. He received a 'notional' rent from his HA for a flat within his surgery premises. He also let the flat to a tenant and kept the rental, so receiving two rents from one flat. It appears that he was not prosecuted but we do not know whether this was because his conduct was not reported to the police or whether it was because they took the view that his conduct was not criminal. The conduct might have been criminal; one cannot tell. In any event, it was obviously dishonest conduct and disgraceful for a doctor. Apparently, the PCC panel took the view that his behaviour had been **'dishonest, misleading and a contravention of the NHS General Medical Services statement of fees and allowances'**. I do not see how anyone reading these case studies is to understand why it was appropriate for the doctor in one case to be struck off and in the other to be suspended. If the reasoning in the first case were correct, there would have been **'no place in the medical profession'** for the doctor in the second case. I assume that there are good reasons for the difference, apart from the fact that one doctor was prosecuted and one was not. Otherwise, both could not have been advanced as examples of appropriate sanctions.

21.159 I am puzzled as to why it should have taken so long to produce these case studies and why they should have been so inadequate when they arrived. In December 2003, the President had plainly recognised the need for them and his enthusiasm was manifest. In Chapter 27, I have suggested how case studies should be prepared. The essentials are that the facts found should be summarised so that the reader can understand why the panel found that they amounted to SPM. The mitigation should be summarised so that the reader can understand why the panel decided as it did on sanction. This work still needs to be done, despite the advent of the new procedures. The new FTP panels will have to consider whether the doctor's fitness to practise is impaired and whether the impairment is of such a degree as to justify action on registration. The wording of the test is changing but the kind of behaviour that panels will have to consider will not change. The old cases will still serve as a useful guide on impairment and sanction. The process of collecting case studies should then continue under the new procedures.

Restoration to the Medical Register

21.160 Contrary to public perception, erasure does not necessarily mean the termination of a doctor's professional practice for all time. The PCC has no power to impose permanent erasure or fixed terms of erasure. A direction that a doctor's name should be erased from the register is always subject to a future application by the doctor for restoration to the register. Until August 2000, an application for restoration to the register could be made at any time after the expiration of ten months from the date of erasure. If an application was made and was unsuccessful, a further application for restoration could be made after a

further ten months had elapsed. Applications for restoration could be renewed every ten months thereafter.

21.161 In 1999, the GMC recognised that there was considerable public concern that doctors were being restored to the register too soon and too easily. In the light of the concern about the issue of restoration, the PCC Working Group undertook a review of the outcomes of applications for restoration which had been dealt with by the PCC between 1988 and 1997. During that period, 131 doctors had been erased. In the same period, 35 doctors had been restored to the register out of 80 doctors who had applied. The Working Group undertook an analysis of the types of conduct or conviction that had led to the erasure of those doctors who had subsequently been restored. Ten of those doctors had originally been erased by reason of SPM arising from clinical treatment; four each had been erased for clinical fraud, improper relationships and sexual assault. Three doctors had been erased for drugs offences and a further three for fraud (other than clinical fraud). Two doctors had been erased for false claims to qualifications and two for soliciting money; one doctor had been erased for violence, one for abusive behaviour and one for theft.

21.162 The Working Group observed:

> **'There is no question that, on the face of it, the decisions to restore some doctors appeared surprising. We felt generally that there was an appearance of inconsistency. To take just two examples, while the overwhelming majority of applicants erased for sexual assaults or indecent behaviour were not restored, four doctors guilty of behaviour of apparently similar gravity were restored. All four doctors erased for research fraud in the period were restored.'**

21.163 The Working Group pointed out that any inferences from a review of this kind must be drawn very cautiously. There was no sure way of knowing why decisions were taken or what factors, other than the nature of the offence, might (quite properly) have been taken into account. This was because it had not been the PCC's practice to provide any explanation at all about restoration decisions. The Working Group report observed that, as a result:

> **'Unfortunately, we, and more importantly the doctor, complainant and public at the time, cannot know why. In this as in other areas, it is important that the Committee explain their reasoning whether they have decided to restore, or not to restore, the doctor.'**

The Working Group recommended that PCC panels should provide an explanation of their decisions on all restoration applications, regardless of outcome. It appears that this is now done.

21.164 The review also showed that 17 out of 35 (i.e. almost half) of the doctors restored to the register had been restored within three years of erasure (seven had been restored within 17 months). Two thirds of doctors restored had been restored within three and a half years of erasure. The Working Group considered the case for recommending an extension of the minimum period of erasure before an application to restore could be made to, say, two years, but decided not to do so.

21.165 The Working Group went on to observe that a **'perennial problem'** for the PCC had been the difficulty of establishing whether a doctor applying to be restored was fit to practise and, in particular, if his/her skills, knowledge and attitudes were satisfactory. Its members discussed the view held by some that the appropriate way to address that problem was to give the PCC the power to impose conditions on the registration of a doctor who was restored. Those conditions would be lifted only if and when the doctor had demonstrated that s/he was suitable to resume unrestricted practice. In the event, the Working Group decided not to recommend that the PCC should be given such a power. Its unanimous view was that, if the power were available, there would be a real risk that doctors might be restored who were not fit to practise. The report said:

> **'There is a danger that a panel might pay insufficient regard to the gravity of the original offence by concentrating on the rehabilitation of the doctor rather than on the overriding public interest. If there is any reasonable doubt about a doctor's fitness to practise, he or she should simply not be restored. We see this as a fundamentally important point.'**

The Working Group therefore recommended that restoration should continue to be **'all or nothing'**. However, it observed that an alternative way forward was to consider whether the GMC might employ the assessment methods which had been developed for the performance procedures in order to assess the skills, knowledge and attitudes of a doctor wishing to be restored. The Working Group recommended that further work should be done to explore the viability of that proposal.

21.166 In August 2000, the Medical Act 1983 was amended to provide that no application for restoration to the register could be made before the expiration of five years from the date of erasure or within 12 months of an unsuccessful application for restoration. Following a second unsuccessful application for restoration during the same period of erasure, the PCC was given power to direct that the right to make further applications should be suspended indefinitely. Such an order could be reviewed on a three-yearly basis. It seems to me that the case for a performance assessment including a knowledge test is even stronger now than it was in 1999. The competence of any doctor who has been away from practice for five years must be questionable.

21.167 Also in 2000, a new three-stage procedure for determination of applications for restoration to the register was introduced. The first stage required the PCC panel to decide (having regard to the reasons why the doctor's name was erased from the register, to the application itself, to the doctor's conduct since erasure and to any representations made to the PCC panel) whether the doctor's name should be restored to the register, subject to his/her satisfying the PCC panel as to his/her good character, professional competence and health.

21.168 If the panel decided that question in the doctor's favour, the second stage was for the PCC to decide what assessment the doctor should undergo for the purpose of satisfying the PCC panel as to his/her good character, professional competence and health and to order that the appropriate assessment should be carried out. The third stage of the process was for the PCC panel to consider the assessment report and to decide whether the doctor's name should be restored to the register. This new procedure seems to me to be a very

good idea. I do not know how it is working. Because all erasures since 2000 must operate for at least five years, it may be that relatively few applications for restoration are being made at the present time.

Comment

21.169 Until 2000, the minimum period of erasure was extraordinarily short. What sounded like a severe sanction might amount, in effect, to no more than a year's 'suspension'. It was certainly not the draconian punishment that the public believed it to be. The new minimum period of five years is, I believe, much more in line with what the public expects when a doctor's name is erased. However, there must be a possibility, now that erasure means at least five years off the register, that FTP panels will be reluctant to impose it save in the most serious cases.

21.170 The Working Group drew attention to inconsistencies between the approach of different panels to the question of restoration. Panels need standards and criteria if they are to achieve consistency in decision-making. It should be possible to develop such criteria from actual decisions now that reasons are given for decisions. Again, the process should be to weed out inappropriate decisions and ones with inadequate reasons. The remainder should be collated and examined and could form the basis for the preparation of a set of standards and criteria. Reports or summaries of appropriate decisions would also help panel members to 'get their eye in'.

21.171 The new three-stage procedure for restoration seems an excellent idea. I hope that an assessment will be ordered in all cases. I cannot imagine any case in which it would be appropriate to allow a doctor to return to practice after five years' absence without requiring him/her to undergo an objective assessment. I can understand why the Working Group advised that restoration must be **'all or nothing'** and set its face against any period of conditional registration. I wonder whether the same objection would be raised to the proposal that, on restoration to the register, a doctor must have a supervisor or mentor, approved by the GMC, who would be required to give an undertaking to bring to the GMC's attention any concerns s/he has about the newly restored doctor's practice, conduct, performance or health. I think that would be a good idea and I would hope that the knowledge that that would happen would not cause FTP panels to lower the threshold for restoration too far.

Appeals and Referrals

Appeals by a Doctor

21.172 Appeals from decisions of the PCC were governed by section 40 of the 1983 Act. Until April 2003, a doctor who was the subject of a finding of SPM or a direction for erasure, for suspension or for conditional registration (or variation of the conditions imposed by a direction for conditional registration) had a right of appeal to the Judicial Committee of the Privy Council. After April 2003, any appeal lay to the High Court.

21.173 In the past, the process of appeal to the Privy Council resulted in the provision of helpful statements of principle and approach but did not lead to the development of a

jurisprudence on the determination of issues relating to SPM or sanction. Until about 2000, it was the policy of the Privy Council to show a great degree of deference to the professional expertise and experience of the PCC. That deference appeared to lessen in later years, possibly because of the coming into force in October 2000 of the Human Rights Act 1998. The number of appeals heard since that time has not permitted the development of a coherent framework of principles. Nor, as yet, has the process of appeals to the High Court. It is very early days.

Referrals by the Council for the Regulation of Healthcare Professionals

21.174 Under the provisions of section 29 of the National Health Service Reform and Health Care Professions Act 2002, the CRHP/CHRE had, from April 2003, the power to refer to the High Court a **'relevant decision'** of the PCC. Section 29(4) provides that the Council could do this if it considered that:

> **'(a) a relevant decision falling within subsection (1) has been unduly lenient, whether as to any finding of professional misconduct or fitness to practise on the part of the practitioner concerned (or lack of such a finding), or as to any penalty imposed, or both, or**
>
> **(b) a relevant decision falling within subsection (2) should not have been made,**
>
> **and that it would be desirable for the protection of members of the public for the Council to take action under this section...'**.

21.175 Section 29(1)(a) to (h) lists the directions and determinations made by the various disciplinary bodies to which the section applies. At (c) and (d) it includes directions made by the PCC and CPP of the GMC. They are therefore 'relevant decisions'. Section 29(2)(a) provides that section 29 also applies to:

> **'a final decision of the relevant committee not to take any disciplinary measure under the provision referred to in whichever of paragraphs (a) to (h) of subsection (1) applies'**.

The expression **'disciplinary measure'** is not defined by the Act. The Act provides that, if a case is referred for hearing by the High Court, it is to be treated as an appeal by the CRHP/CHRE.

Appeals against an Unduly Lenient Sanction

21.176 At the time of writing, only a few appeals have been heard. However, two cases, that of Council for the Regulation of Healthcare Professionals v General Medical Council and Solanke[15] and Council for the Regulation of Healthcare Professionals v Nursing and Midwifery Council and Truscott[16] show how the Court is likely to approach its task in appeals against sanction. In both, the CRHP/CHRE appealed on the basis that the sanction imposed by the regulatory body was unduly lenient. In both cases, the Court

[15] [2004] EWHC 944 (Admin).
[16] [2004] EWHC 585 (Admin).

made plain that, when considering whether a decision had been unduly lenient, it would apply the same test as is applied by the Court of Appeal (Criminal Division) when considering, on the application of the Attorney General, whether a sentence passed by a criminal court is too lenient. The test is whether the sanction imposed is outside the range of sanctions which the tribunal, applying its mind to all the factors relevant to its jurisdiction, could reasonably consider appropriate. The Court will also require to be satisfied that intervention is **'desirable for protection of members of the public'**. However, as Collins J observed in the case of Truscott, that will usually follow if the sanction is found to be unduly lenient.

21.177 In Solanke, the GMC had found the doctor guilty of SPM. He had become involved in a sexual relationship with a patient; moreover the patient suffered from depression and was rather vulnerable. The matter came to light some time after the relationship was apparently over, when the woman told another GP about it. The doctor admitted the truth of the allegation. The woman did not wish to be involved in disciplinary proceedings and the GMC had no information about when or how the relationship had begun. The doctor was also guilty of another form of misconduct. He had falsified his own birth certificate and, during his medical career, had used a *curriculum vitae* which represented that he was six years younger than he really was.

21.178 At the PCC hearing, the doctor gave evidence but was not asked any questions about how the improper sexual relationship had started. He said only that it had started and finished by mutual consent. It had lasted about six months. At the time, he said, his marriage had broken down and his wife was denying him access to his children. He acknowledged that his relationship with the patient had been wrong and said that he had taken counselling subsequently. The PCC found SPM proved and imposed a period of suspension of three months. It said that it took into account the fact that the doctor had not worked for six months as he had been suspended by the practice where he had worked.

21.179 On appeal by the CRHP/CHRE, Leveson J first established the test that should be applied and then concluded that, on the material available, he regarded the sanction imposed as lenient. His impression was that he could not say that it was unduly lenient. However, in the course of the judgement, Leveson J was critical of the GMC for the paucity of the information it had collected about the circumstances relating to this misconduct. He pointed out that it was difficult to make a reliable estimate of the risk that the doctor might repeat this kind of conduct without having some insight into the detailed circumstances in which the relationship had started and finished. The fact that the woman had been unwilling to provide information did not excuse the GMC from its duty to investigate the case properly. Although its options were limited by her refusal, it did have the opportunity to question the doctor when he gave evidence. Neither counsel for the GMC nor the members of the PCC panel had asked him about these important patient protection issues and the PCC panel had not put itself in a position to make a judgement about them. Leveson J considered whether the information available was so inadequate that he was unable to say whether the sanction had been unduly lenient, in which case he would allow the appeal and send the case back for re-hearing. He recognised that there would be no obligation on the doctor to submit to questioning for a second time. He decided that, in

the circumstances, he would not send the case back for further investigation. He found that the sanction was not unduly lenient and dismissed the appeal.

21.180 Leveson J also discussed the origin and purpose of the ISG and expressed the view that this was very useful. He made clear that, if the point arose, the ISG would not be binding on the Court. Nor did he think that it would be appropriate for the Court to suggest modifications of the ISG. However, he did think that the CRHP/CHRE was in an admirable position to take part in the process of revising the ISG.

21.181 The events giving rise to the disciplinary proceedings against Mr Truscott, a paediatric nurse, took place when he was working on a ward devoted to the care of adolescent patients of both sexes. While on night duty, he 'surfed' the internet on six separate occasions and accessed a number of sites providing pornographic material. He was dismissed from his position and reported to the Nursing and Midwifery Council (NMC). The police decided not to prosecute, apparently because it could not be shown that the material he had accessed was 'child pornography' or whether the photographs were in fact of adults who were made to look like children. Some of the material appeared to show naked children but they were not engaged in sexual acts. Another difficulty was that it was not clear how many sites the nurse had deliberately accessed and how many had been opened to him by the 'cascading' effect. In any event, whether the pornography showed adults or children, Mr Truscott's conduct clearly amounted to misconduct and the NMC found it to be so. It decided to caution him for his behaviour. The CRHP/CHRE appealed on the ground that this was unduly lenient and that only erasure could provide sufficient protection for the public. The principles underlying the approach of Collins J were the same as those to be expounded by Leveson J a few weeks later in Solanke. Collins J held that it was not clear that Mr Truscott had broken the law; nor was it clear which sites he had deliberately accessed. In those circumstances, he considered that the sanction imposed was lenient but not unduly so.

21.182 The CRHP/CHRE appealed this decision. Their concern was that, regardless of whether or not Mr Truscott had deliberately accessed the sites which showed or appeared to show naked children, the fact that he had an unhealthy interest in pornography and was prepared to view it while working on an adolescent ward gave rise to concern about patient safety. The Court of Appeal dismissed the appeal. It approved the test applied by Collins J and said that this was a case in which it was right to show some deference to the views of the Committee of the disciplinary body, which had not made any error of principle.

21.183 I can understand why the CRHP/CHRE felt that this sanction was unduly lenient. The problem was that the case had never been put against Mr Truscott on the basis that his interest in pornographic pictures of people who looked like children even if they were adult meant that he presented a risk to his adolescent patients. A great deal of emphasis was laid on the question of whether or not he had broken the law. This is also the emphasis in the GMC's recent amendment to the ISG. This makes it plain that PCC panels should consider erasure for doctors found guilty of child pornography offences. I can see why the guidance has been drafted in that way; usually a concern about accessing pornography will arise as a result of a prosecution. However, as in Mr Truscott's case, there was no prosecution. Should that be determinative of the outcome of disciplinary proceedings?

From the point of view of a disciplinary body whose duty is to protect the public, the fact that the doctor has or has not been convicted is surely not the main question. The main question must be whether the healthcare professional's conduct shows that s/he is a risk to patients.

The Right to Appeal against an Acquittal

21.184 The position relating to the right of the CRHP/CHRE to appeal against an acquittal of a doctor on a charge of SPM has proved to be rather more problematical. In the case of Council for the Regulation of Healthcare Professionals v General Medical Council and Ruscillo[17], the doctor was charged with SPM. He admitted that he had been involved in an emotional and sexual relationship with a patient.The particulars of the charge had included an allegation that the patient had **'significant psychiatric problems'** and was therefore **'particularly vulnerable'**. It was further alleged that the doctor was aware of the patient's history. However, at the hearing, the GMC applied to amend the charge so that it was limited to a history of **'psychiatric problems'**, rather than **'significant psychiatric problems'**, and to omit the references to the patient being **'particularly vulnerable'** and to the doctor's knowledge of the history. The head of charge was duly amended and then admitted by the doctor. The only head of charge that remained in dispute was that the doctor's actions had been **'inappropriate'**, **'an abuse of the doctor-patient relationship'**, **'not in the best interests'** of the patient and had been **'likely to bring the medical profession into disrepute'**. The GMC called no witnesses and the doctor chose not to give evidence. The PCC panel found that the disputed head of charge was **'not proved in its entirety'** in that none of the allegations was made out. In announcing the panel's decision, the Chairman of the PCC made reference to a lack of evidence in the case. The panel found that the facts that had been admitted were insufficient to support a finding of SPM. The case against the doctor was, therefore, concluded. It emerged after the PCC hearing that medical records could have been made available which would have supplied the evidence necessary to prove the additional aspects of the charge and that the doctor's partners had been willing and available to give evidence before the PCC panel but had not been called. In other words, there was a concern that the case had been under-prosecuted. The CRHP/CHRE appealed to the High Court. On behalf of the doctor, a preliminary issue was raised; it was contended that section 29 did not provide for an appeal against a decision to find a doctor not guilty of SPM. The CRHP contended that it did. On the hearing of this preliminary issue, Leveson J held that a **'relevant decision'** within section 29 was not restricted to a decision as to the appropriate sanction, but included a decision to acquit a doctor of SPM.

21.185 The appeals in the cases of Ruscillo and Truscott[18] were heard together and the judgements were handed down in October 2004. The Court of Appeal held that, under section 29, the Council had the power to refer to the Court a decision of the PCC to acquit the doctor of SPM. However, the Court construed the words **'decision of the relevant Committee not to take any disciplinary measure'** in s29(2)(a) as meaning a decision not to impose a penalty or sanction. Thus, the scope of the section was, the Court said,

[17] [2004] EWHC 527 (Admin).
[18] [2004] EWCA Civ 1356.

limited to those cases in which a relevant decision has been unduly lenient whether because the findings of professional misconduct are inadequate or because the penalty does not adequately reflect the findings of professional misconduct that have been made, or both. In short, the Council will have the power to refer an acquittal to the Court only if the 'findings of professional misconduct are inadequate'. So, in the case of Ruscillo, where the Council took the view that the case had been under-prosecuted, there was the power of referral.

21.186 For the sake of completeness, I mention the most recent decision under section 29 of the 2002 Act. This was Council for the Regulation of Healthcare Professionals v General Medical Council and Leeper[19]. The Court held that the sanction imposed (the imposition of conditions on the doctor's registration) was unduly lenient and that the doctor should have been suspended. The doctor had admitted that his conduct in involving himself in an inappropriate sexual relationship with a patient had amounted to SPM. The case is of interest in that the Judge, Mr Justice Collins, made some observations about the extent of disclosure which must be given to the CRHP/CHRE in cases where the evidence has been presented to the PCC as an agreed statement of facts. That had been done in this case. The CRHP/CHRE wanted to satisfy itself that the agreed statement of facts adequately reflected the gravity of the doctor's misconduct – in other words, it wanted to be sure that the case had not been under-prosecuted. The GMC had been reluctant to disclose the original statements of the principal witnesses for reasons of confidentiality. The Judge said that the GMC must disclose them. In the event, once they had been examined, it was not alleged that the case had been under-prosecuted; the agreed statement of facts was fair to both sides. The point is that the CRHP/CHRE must be able to check that that is so.

Comment

21.187 The institution of the process of appeals under section 29 is to be welcomed. It will provide a mechanism for over-ruling decisions on sanction that are outside the band of what was reasonable in the circumstances. Although the Court of Appeal has stated in Ruscillo that section 29 gives the CRHP/CHRE the power to refer an acquittal to the Court, it observed that the section had not been well drafted. It is apparent from the judgement that the construction of the section gave rise to real difficulty. It seems to me that, when the opportunity arises, section 29 should be amended to make plain beyond argument that the CRHP/CHRE has the power to refer to the Court any decision of a disciplinary committee or panel that it considers to be wrong and in respect of which it considers that it ought to take action, in the interest of patient protection.

Discussion

21.188 It seems to me that there were a number of problems with the old procedures of the PCC. Some of these will or may be rectified under the new procedures. However, others may be perpetuated. I shall mention what appear to me to have been the major difficulties in the past.

[19] [2004] EWHC 1850 (Admin).

Criminal Procedure

21.189 It has long been established that the PCC conducts its proceedings in the style of a criminal trial. The justification for this is that, because there is a possibility that the doctor will be erased from the register, proper safeguards must be provided so as to ensure fairness to the doctor. That is understandable. However, there is another important factor to be taken into account: the protection of the public. In some respects and on some occasions, these two factors are in conflict.

The Discretion to Receive 'Inadmissible' Evidence

21.190 In the past, the PCC usually insisted that any facts that the doctor did not admit should be proved by oral evidence. That was so even where the witness had given evidence and been cross-examined by or on behalf of the doctor on another occasion. It was so even though the PCC had a discretion to admit evidence that would not otherwise have been admissible, if satisfied that its **'duty of making due inquiry into'** the case **'makes its reception desirable'**. In the case of Dr JM 04, to which I referred earlier at paragraphs 21.79–21.84, the conflict of these two interests was resolved in favour of the doctor and against the interest of protecting patients. Dr JM 04 was facing charges before the PCC in respect of the administration of a gross overdose of diamorphine which had resulted in the patient's death. He was convicted of manslaughter. Before the PCC hearing, the GMC discovered that the doctor had been the subject of another quite serious complaint, which had been dealt with locally, resulting in a finding of breach of terms of service. The allegation plainly gave rise to a question of SPM. As I have explained, the GMC decided not to take proceedings in respect of the second complaint because the main witness was unwilling to go through her evidence orally for a second time. She had already given evidence once and had been cross-examined during the local procedures. The GMC could have issued a *subpoena* but decided that it would have been insensitive to do so; it could have sought to persuade the witness to change her mind; it could have invited the PCC panel to receive a record of what had been said at the MSC hearing. It might be that, in the absence of oral evidence, the PCC panel would not have found that the doctor's conduct was to be criticised in respect of the second incident. So be it. The point is that the GMC did not try; it simply decided not to proceed on the second matter.

21.191 Under the new procedures, FTP panels will have a similar discretion to admit evidence which would not strictly be admissible at a criminal trial. It remains to be seen whether, in future, the GMC will be more ready than it has been in the past to invite panels to use these powers. It seems to me that what is needed is a greater determination to prosecute each case fully, bringing all the facts before the panel and not just those for which oral evidence is readily available.

Standard of Proof

21.192 During the hearings, I expressed my concern that the PCC always applied the criminal standard of proof when reaching conclusions on the facts. I was concerned that this high standard of proof might not be appropriate in a jurisdiction which had, as its primary purpose, the protection of the public from doctors who are not fit to practise. I had not at

that stage noticed (as I have done since) that decisions of the PCC could be taken upon a bare majority of the panel. I had noticed that Miss Jean Ritchie QC, who conducted an Inquiry into the conduct of Rodney Ledward, had recommended that the civil standard of proof should be applied at PCC hearings. Ledward was a gynaecologist who, over the years, carried out a large number of 'botched' operations and caused his patients a great deal of harm. He was eventually erased from the medical register in September 1998. As I understand it, Miss Ritchie's concern was that the public might not be adequately protected by a disciplinary body that could act only if the facts were proved to a very high standard of certainty. I share that concern.

21.193 In the light of Miss Ritchie's recommendation, in 2000, the GMC held a conference to discuss the advisability of applying a 'sliding civil standard' of proof. That would mean that the PCC panel would have had to have been satisfied to a degree of probability that was appropriate to the gravity of the allegations under consideration and the seriousness of the likely sanction. In cases where the allegation amounted to a serious criminal offence, a higher standard of proof would be required than in one where the allegation was one of, say, gross negligence. The conference decided that the PCC should continue to apply the criminal standard of proof in all cases. It was thought that it would not be fair to deprive a doctor of his/her livelihood save on evidence that reached this high standard of proof. Thus, on the face of it, the concept of being fair to the doctor was to be allowed to override the need to protect the public.

21.194 However, the problem is not exactly as I had thought it to be. I had thought that there must have been many cases in which an allegation of SPM failed because the PCC was not satisfied that the facts had been proved to the criminal standard. However, in the course of his evidence to the Inquiry, Sir Donald Irvine said that, in his years on the PCC, he had found that the difficulties and disagreements arose, not over whether the facts were proved to the required standard, but over whether those proven facts constituted SPM. He also said that there was often disagreement on sanction. I found this most surprising. My experience as a judge presiding over jury trials leads me to believe that, when a group of people have to be satisfied of facts to a high standard of proof, there are often difficulties and disagreements. It seems to me that there are three possible explanations for the apparent absence of difficulty as reported by Sir Donald. One is that only cases where the evidence was very clear ever reached the PCC. Another is that the PCC panel was not actually applying the high standard of proof, but a lower standard. Another possibility, which is quite speculative, is that the high standard was being applied but that decisions were sometimes reached, not unanimously, but by a majority; under the GMC's Rules a bare majority will suffice. As for this last possibility, the fact that a bare majority is enough is, in my view, not inappropriate in a 'protective jurisdiction'. However, it is strange that the GMC should be so concerned about maintaining the high standard of proof in order to be fair to the doctor, when a finding can be made on the basis of a bare majority. Dealing only with the findings of fact, I would have thought there would have been greater protection for the doctor in requiring all members of the panel to be satisfied to the civil standard as to what the doctor has actually done than in permitting a decision to be made where (assuming a panel of five) three members of the panel were satisfied about a set of facts to the criminal standard but the other two might even think that the doctor had done nothing wrong at all.

21.195 It seems to me that the GMC should reopen its internal discussion about the application of standards of proof and should also consider the question of majority decisions. Good decision-making should, if possible, be unanimous. An attempt should always be made to reach unanimity, and only if it proves impossible should a majority decision be acceptable. In general, in a protective jurisdiction, the civil standard of proof will be appropriate. However, it is certainly arguable that it would be appropriate to retain the criminal standard of proof where the allegation amounts to a serious criminal offence.

A Legally Qualified Chairman

21.196 In her report into the Ledward case, Miss Ritchie recommended that PCC panels should be chaired by a circuit judge or an experienced recorder of the Crown Court. Her thinking was that this would ensure that the proceedings were carried out fairly and independently. It appears to me also that having an experienced lawyer as chairman of the panel would bring greater legal rigour to the determinations than does the advice of a legal assessor. For example, such a chairman would be able to ensure that the panel did not take irrelevant considerations into account and would be able to guide them more closely on such issues as the standard of proof.

21.197 Another advantage of a legally qualified chairman would be that s/he would have many years' experience of the forensic process and would be far better able to respond appropriately to unexpected occurrences, which do sometimes happen. I have observed from some of the material used to assist PCC panellists and chairmen when sitting that it cannot be assumed that they will have any idea of what should be said or done in certain situations. They are provided with forms of words to use at the various stages of the process. There would be a real advantage, it seems to me, in having chairmen who know, from long experience, what to do and what sort of thing to say at each stage of the process. In future, FTP panels may have to consider a mixed bag of allegations, some relating to misconduct and some relating to deficient performance or even impairment of health. FTP panel hearings may be more complex in future. I fear that FTP panels may find it difficult to sort out what evidence is relevant to what issues and, as they may well have to do, to apply different standards of proof to different aspects of the case. The guidance of a legally qualified chairman would, I think, be invaluable.

21.198 I note that, as recently as May 2003, the GMC was considering the possibility of using a legally qualified chairman in the more complex cases, although this idea now seems to have been abandoned. It seems to me that that would be an eminently sensible way of proceeding. It may be found that the advantages are such that the practice could be extended to all but the most straightforward cases.

The General Medical Council's Past Inability to Take a Holistic View

21.199 In the past, the GMC was prevented by its own procedures from taking a holistic view of doctors' problems. A case had to be assigned to either the conduct, health or performance procedures. As the GMC well understands, the human condition does not lend itself to such compartmentalisation and many doctors present with a variety of

different problems. I shall not dwell upon this past difficulty because I am optimistic that it will be resolved when the new procedures come into operation very shortly.

The Lack of Standards and Criteria

21.200 I cannot take the same optimistic view for the future as I return to discuss further the need for standards, criteria and thresholds for the operation of the FTP procedures. That they have been needed in the past is clear. Professor Allen advised about this in each of the PSI Reports. Her main concern was that there was no generally agreed perception of what amounted to SPM. In his evidence to the Inquiry, Sir Donald Irvine spoke about the differences of views among professionals on SPM. The same problem existed in relation to the concept of SDP. I have also referred to the view of the PCC Working Group that there was a need for greater consistency in the application of sanctions. Consistency of decision-making is necessary: first, in order to provide an appropriate degree of protection for patients, second, in order to be fair to doctors and third, to enable the GMC to command the confidence of the public and to uphold the reputation of the medical profession.

21.201 In its submission to the Inquiry, the GMC suggested that established standards, criteria and thresholds were neither appropriate nor necessary. They have not been necessary, it says, because the decision-makers of the past were experienced and well-respected members of the medical profession and were all members of the GMC. In essence, it is said, their judgement could be trusted. The GMC also suggests that the panellists of the present and future are and will be selected on merit and trained for the task. All that may be true but they are and will be all individuals and, however conscientious they are, they will reach inconsistent decisions unless guided by established standards, criteria and thresholds. The GMC has also suggested that established standards, criteria and thresholds are not appropriate because they inhibit the freedom of the decision-maker to take account of the individual circumstances of the doctor and the case. That is simply not so. No one is suggesting a mechanistic assessment which will result in cases being put into a specific pigeonhole. What is needed is a framework within which individual circumstances can be taken into account without producing unreasonable decisions. It appears from the DASG report in the first edition of the Fitness to Practice Bulletin, to which I referred in paragraph 21.150, that some members of the GMC are beginning to recognise this.

21.202 I am firmly of the view that established standards, criteria and thresholds have been needed in the past and will be needed every bit as much in the future, possibly even more so, because, as I shall explain in Chapter 25, the tests to be applied under the new procedures are, if anything, more open to personal interpretation than those applied under the old ones. I am also firmly of the view that, if the GMC is to gain the trust and confidence of the public, members of the public and patients' representatives must be actively involved in the setting of the standards, criteria and thresholds.

21.203 So far as sanctions are concerned, the ISG is clearly helpful and the publication of appropriately detailed case studies would also be useful. However, I do not think that such measures will be sufficient to restore public confidence in the GMC's willingness and

ability to apply appropriate sanctions to erring doctors. I recognise that, in formulating the ISG (and in developing new guidance on specific topics), the GMC does, to some extent, consult with patients' representative bodies. However, in my view, what is needed is a consensus between the GMC and the public about the range of appropriate sanctions in the types of case that regularly recur. As a model for reaching consensus, I would urge the GMC to examine the operation of the Sentencing Advisory Panel, which provides advice to the Court of Appeal (Criminal Division) about particular types of case. The Panel comprises members from a wide range of backgrounds: judges, barristers, magistrates, academics and lay people. The Panel also consults more widely when it embarks on the consideration of each new topic. The Panel's reports advance an agreed view which, by reason of its origin, commands the respect of the Court of Appeal (Criminal Division) which is, in effect, the standard-setting body for the decision-makers at first instance, the judiciary and magistracy. Such views should also command public confidence. The exercise of consultation enables the criminal justice professionals to understand the public viewpoint and *vice versa*. It seems to me that this kind of process could easily be adapted so as to provide guidance to the GMC. It may be that a consultative council could be set up under the auspices of the CRHP/CHRE.

CHAPTER TWENTY TWO

The General Medical Council's Health Procedures

Introduction

22.1 I have already explained how, in the 1960s and early 1970s, there was increasing concern about the ability of the existing regulatory system to deal adequately with the problem of doctors whose fitness to practise was impaired by ill health. The General Medical Council (GMC) had no power to deal with a doctor who was sick, unless s/he had been convicted of a criminal offence or was guilty of conduct that would amount to serious professional misconduct (SPM). Patients were not adequately protected against, for example, the chronic alcoholic who had not been convicted of a criminal offence and who, despite presenting an obvious risk to patients, had not been guilty of any misconduct which would have been considered by the GMC as falling within the definition of SPM.

22.2 The other problem was that, in cases where it was possible to use the GMC's disciplinary procedures to deal with a sick doctor, those procedures were punitive in nature and offered no mechanism for supervising a doctor, for supporting his/her attempts to rehabilitate or for placing restrictions on his/her practice during the rehabilitation process. Disciplinary hearings were conducted in public and afforded the doctor no medical confidentiality. Many people felt that this type of public hearing was an inappropriate – even inhumane – way of dealing with doctors who were suffering from a physical or mental illness. There was reluctance on the part of doctors to report colleagues who were known to be a risk to patients by reason of their illness. This reluctance was attributed, in part at least, to the inadequate means available for dealing with sick doctors.

22.3 In its Report, published in 1975, the Committee of Inquiry into the Regulation of the Medical Profession, chaired by Dr (later Sir) Alec Merrison (the Merrison Committee), recommended the establishment of the arrangements that were to become known as the GMC's 'health procedures'. The health procedures were introduced in the Medical Act 1978 (the 1978 Act) and came into operation in August 1980. The relevant provisions were later set out in the Medical Act 1983 (the 1983 Act). Over the period for which they were in force, they changed little. In this Chapter, I shall describe the procedures as they operated in December 2003, at the time of the relevant Inquiry hearings. Where there had been significant changes between the introduction of the procedures and December 2003, I shall describe those changes.

The Procedures in Outline

22.4 Health cases were handled by the GMC's Health Section. The health procedures included two distinct processes for dealing with doctors whose fitness to practise was, or might be, seriously impaired by reason of a physical or mental condition. The first process was commonly known as the 'voluntary' health procedures. The purpose of the voluntary health procedures was to protect the public from doctors whose fitness to practise was seriously impaired on health grounds and to help the doctors concerned to follow a programme of medical supervision and rehabilitation.

22.5 Under the voluntary health procedures, the GMC received medical evidence on the condition of the doctor under consideration. If the evidence revealed that the doctor was suffering from a serious impairment of health, as a result of which s/he was not fit to practise or was fit to practise only subject to medical supervision, limitations on his/her practice and/or other conditions, the doctor might then be invited to give undertakings based on any recommendations made by the medical examiners who had provided the medical evidence. The undertakings would relate to such matters as the acceptance of medical supervision, abstention from alcohol or drugs (if appropriate) and any limitations on the doctor's professional practice that were deemed necessary. If the doctor agreed to the proposed undertakings, and complied with them, his/her case would be managed, supervised and reviewed regularly without the need for a formal hearing. If the doctor made a good recovery from the impairing condition, s/he would be released in due course from his/her undertakings and would be free to resume practice unsupervised and without restriction.

22.6 The second process occurred if a doctor decided to challenge the need for a medical examination or if s/he refused to accept medical supervision or any proposed limitations on his/her practice or if his/her health deteriorated or if s/he breached any undertakings previously given. In that event, his/her case would be referred to the Health Committee (HC), which had the power to suspend, or impose conditions on, the doctor's registration. The HC had no power to erase a doctor's registration but could, in certain circumstances, suspend a doctor's registration indefinitely.

22.7 At the time of the Merrison Report, it was thought that the largest category of case likely to be dealt with under the new health procedures was that arising from the abuse of alcohol and other drugs. That indeed proved to be correct and, for many years after their introduction, the number of cases referred to the health procedures that fell within this category was as high as 75% to 80%. Sometimes, the alcohol or drug abuse was combined with some other psychiatric condition. Dr Sheila Mann, a consultant psychiatrist, who was a member of the GMC from 1996 until July 2003 and was a health screener from 1996 until 2004, told the Inquiry that her impression was that about half the cases dealt with by the Health Section involved substance misuse in one way or another. Few cases involving purely physical impairment were referred to the GMC. A doctor suffering from such a condition is likely to have insight into the effect of his/her condition on his/her fitness to practise and to cease voluntarily to practise if s/he realises that this is appropriate. By contrast, a doctor suffering from a psychiatric illness, or abusing alcohol or drugs, may continue to practise when unfit to do so.

22.8 The Inquiry was interested in the health procedures for a number of reasons. First, the Inquiry was concerned to see how the GMC had handled cases involving the abuse of drugs or alcohol, especially those involving an element of misconduct, such as dishonesty. It was necessary for the Inquiry to consider how Shipman would have been dealt with if the health procedures had been in operation when his case was considered by the GMC. I wished to see what happened to such cases in practice. I wished to assess whether the health procedures have afforded sufficient protection for patients. I shall also look at some of the changes currently proposed for the treatment of cases with a health element under the new fitness to practise (FTP) procedures.

Evidence

22.9 As well as receiving oral evidence from Dr Mann, the Inquiry heard from Mr Alan Howes, who was employed by the GMC between 1977 and 2002 and was Head of the Health Section from August 1985 until October 1986 and from 1997 until April 2001, and from Miss Jackie Smith, who has been employed by the GMC since 1998 and was a senior caseworker in the Health Section from January to September 1998 and Head of the Health Section from April 2002 until May 2003. Evidence about the health procedures was also given by Mr Finlay Scott, Chief Executive of the GMC, by Professor Sir Graeme Catto, the current President, and by Sir Donald Irvine, the immediate past President.

22.10 From 1981, the health screener and the HC were required by GMC Standing Orders to present Reports on their activities to the full Council at least once a year. For many years, these Annual Reports contained a great deal of information about the cases dealt with in the Health Section, about problems that had been encountered and about changes in practice and procedure. They provided very useful information about the development and operation of the health procedures during the 1980s and 1990s. More recently, the Annual Reports have been subsumed into the GMC's annual FTP statistics and are less informative.

22.11 Between 1998 and 1999, a team from the Department of Public Health Science, King's College London, and the Nuffield Institute for Health, University of Leeds (the King's College team), carried out an evaluation of the GMC's health procedures. The results of the evaluation were reported to the GMC in November 1999. I shall refer to this report as the 1999 Evaluation Report. The evaluation had been commissioned as part of an initiative by the then President, Sir Donald Irvine, to subject the GMC's FTP procedures to independent review. The evaluation involved a retrospective review of the GMC's management of health cases. The review was based on case notes relating to doctors who had been referred to the Health Section between 1980 and 1996. The King's College team carried out a quantitative study of the 771 cases for which case notes were available. The team also examined a random sample of reports submitted to the GMC by medical supervisors in the cases of 40 doctors who had been placed under medical supervision in the period 1989 to 1996 and whose cases had been concluded. The 1999 Evaluation Report provided a useful insight into the operation of the health procedures during the late 1990s and I shall refer to its contents in the course of this Chapter.

22.12 The first formal internal GMC guidance document dealing with the health procedures was entitled 'Health Screening: Guidance for Screeners and Health Section Staff'. It was produced in November 1999. I shall refer to it as 'the 1999 Guidance'. It was prepared at a time when the findings of the King's College team would have been known to the GMC. It no doubt reflected changes in practice introduced as a result of those findings. The 1999 Guidance (although out of date in some respects) was still in use in December 2003, when the Inquiry heard oral evidence about the operation of the health procedures.

Local Procedures for Dealing with Concerns about Doctors' Health

22.13 If a doctor is ill and his/her employers or colleagues become aware that his/her illness is or may be affecting his/her fitness to practise, there will usually be some attempt to deal

with the matter locally. A hospital trust may use its own occupational health facilities to arrange a medical examination and may then place any necessary restrictions on the doctor's practice. For a general practitioner (GP) working as an independent contractor, however, the management of a health problem can be more difficult. Until recently, NHS primary care organisations (PCOs) had very limited powers to deal with sick doctors. Their recently acquired list management powers, however, mean that a primary care trust (PCT) is now able to remove or suspend a doctor from its list or to impose conditions on his/her continued inclusion on the list. This should make it possible for the PCT, in an appropriate case, to exert pressure on a doctor to accept medical advice and treatment and to restrict his/her practice as necessary.

22.14 Often, however, a GP's illness may not be known to his/her PCT. It may be evident only to the other doctors in his/her practice (if any) and/or to his/her treating doctor (if any). Not all doctors have an established relationship with a GP. Some treat themselves. In those circumstances, the problem may not have been recognised at all or, if it has been, there may be attempts to contain the problem privately, without the knowledge or intervention of the PCT. There are various support groups in existence that offer assistance to doctors with health problems, in particular those who are abusing alcohol and drugs.

22.15 In many cases, health problems can be resolved locally, without the involvement of the GMC. There are cases, however, where the doctor lacks insight into his/her condition and/or persists in practising when unfit to do so, thereby putting patients at risk. This is the type of case in which action is required by the GMC. In some cases, a PCT or NHS trust may act in concert with the GMC.

Sources of Reports about a Doctor's Ill Health

22.16 The fact that a doctor is, or may be, suffering from a physical or mental condition serious enough to impair his/her fitness to practise may be brought to the attention of the GMC in one of a number of ways. It may be reported by a professional colleague of the doctor, by his/her employer or PCT or by a pharmacist, a patient or a member of the public. It might come from the National Clinical Assessment Authority (NCAA) as the result of its undertaking a performance assessment. On occasion, the report may come from the doctor him/herself or from a member of his/her family or his/her treating doctor. Often, the initial information will amount, not to a report, but to an enquiry about whether a report is appropriate. Sometimes, the information will be received by way of notification from the police that the doctor has been convicted of a criminal offence which might indicate the presence of an underlying health problem. The most common examples are drink driving convictions and convictions for drug-related offences. The fact that a doctor is, or may be, unwell may also come to light in the course of consideration of a doctor's case under the GMC's conduct or performance procedures.

22.17 The GMC becomes aware of only those cases which are referred to it. It has no means of knowing how many doctors with health problems are being managed locally and with what degree of success. The Inquiry was told that, in recent years, there had seemed to be a much higher level of awareness among members of the medical profession of their duty to report sick colleagues. As a consequence, there has been an increase in referrals to

the GMC, together with an increase in enquiries about whether or not a referral should be made.

22.18 Dr Mann said that the usual point of contact for the GMC was the doctor's partners (if the doctor was a GP) or his/her own GP or treating psychiatrist. There would sometimes be contact with the relevant local medical committee (LMC). It was less usual for a GP's PCT to get in touch with the GMC. However, she said that medical directors of PCTs had become more involved recently. Dr Mann had had experience of two PCTs using their powers of list management to impose conditions on the inclusion on their lists of doctors who were suffering from health problems. She thought that this was an encouraging development. However, she had some concerns about the capacity of very small, isolated PCTs to deal with doctors' health problems.

The Initial Process for Dealing with Reports about Health

22.19 The health procedures were governed successively by the General Medical Council Health Committee (Procedure) Rules Order of Council 1980 (the 1980 Health Rules) and the General Medical Council Health Committee (Procedure) Rules Order of Council 1987 (the 1987 Health Rules).

The Health Screeners

22.20 Rule 5(2) of the 1987 Health Rules required the GMC to appoint either the President or some other member of the GMC to screen cases which raised a question about a doctor's health. If the President proposed to sit on the HC, or if for any other reason he did not wish to act as health screener, he was required to nominate another member of the GMC for appointment to the post. The 1987 Health Rules gave the President power to nominate a second member of the GMC to assist in the screening of health cases when, for any reason, the President or the health screener appointed in his stead was unable to act. In fact, an additional health screener had been appointed to assist the President since 1984.

22.21 In 1980, Professor Sir Denis Hill was appointed as screener, both for conduct and health cases. After Sir Denis' death in May 1982, Dr Philip Connell took over responsibility for screening health (but not conduct) cases. In November 1984, the then President, Sir John (later Lord) Walton, became screener for both conduct and health cases. Sir John was the last President to act as a screener. He was assisted, in relation to health cases, by Dr Connell. In November 1987, Professor Neil Kessel was appointed to give further assistance with the screening of health cases. In February 1989, after the end of Sir John's Presidency, Dr Connell became the health screener and Professor Kessel was appointed as additional health screener. In 1991, Dr Connell retired as health screener and was replaced by Professor Kessel. Dr Thomas Bewley was appointed as additional health screener. Professor Kessel retired in February 1995 and Dr Bewley took over, with Professor Andrew Sims as additional health screener. On Dr Bewley's retirement in July 1996, Professor Sims succeeded him, and Dr Mann, then a new member of the GMC, was appointed as additional health screener. In 1999, Professor Sims retired as health screener and Dr Mann succeeded him. Dr Michael Wilson, a GP, was also appointed a health screener at that time. Dr Mann and Dr Wilson remained in post until some time in

2004. In the past, most of the health screeners were consultant psychiatrists. This reflected the fact that most of the doctors dealt with in the health procedures were suffering from psychiatric problems.

22.22 As will now be apparent, there had been relatively few people involved in the screening of health cases from the inception of the health procedures. The system was that the knowledge and experience of each successive health screener was passed to his/her more junior colleague. When Dr Mann was first appointed, she had no formal training for the role. She read the GMC's literature about the health procedures and received advice from Professor Sims. At first, she assumed responsibility for the cases of doctors who were already in the voluntary health procedures and were under supervision, while Professor Sims dealt with new cases and with those to be referred to the HC. In that fashion, Dr Mann learned what the job of health screener entailed.

22.23 The role of the health screener was to direct action in new cases up to the point when the doctor was placed under medical supervision. The health screeners were then responsible for monitoring the doctor's progress under supervision. They also directed the preparations for hearings before the HC and for resumed hearings. All decisions that had any bearing on how a health case should be handled were, in the past, taken by a health screener, although the administrative arrangements were undertaken by GMC staff. Under the new FTP procedures, it seems likely that the staff of the Health Section will assume a far greater degree of responsibility for decision-making in health and potential health cases. It seems that the responsibility for many of the decisions on the handling of cases will pass from medically qualified GMC members to staff who, although possibly very experienced, will not be medically qualified. I shall refer to these changes further in Chapter 25.

Referral of a Case to the Health Screeners

Referral by the Office Staff

22.24 Rule 6(1) of the 1987 Health Rules provided that:

> **'Where information in writing or a complaint in writing is received by the Registrar about any practitioner which raises a question whether the fitness to practise of the practitioner is seriously impaired by reason of his physical or mental condition, the Registrar shall submit the information to the President.'**

The functions of the Registrar were, in practice, undertaken by the GMC staff, and those of the President by the health screeners.

22.25 Where the information or complaint (I shall refer to both as 'information' for brevity) received by the GMC plainly raised a health issue, it was dealt with by the Health Section. It might be received direct by the Health Section or it might be passed to the Health Section from the Conduct Screening Section. From April 2003, a triage system was in operation, whereby a casework manager would consider any written information received and make an initial assessment. He or she would then make a recommendation as to the appropriate action to be taken and would delegate responsibility for the day-to-day

conduct of the case to a caseworker. The casework manager would consider whether the case might warrant the attention of the health screener with a view to referral to the Interim Orders Committee (IOC). He or she would also consider whether the case was a 'clear cut' health case or whether it had elements of conduct and/or performance, in which case it might have been appropriate for it to be referred in the first instance to a medical screener for conduct and performance cases. If neither of these courses of action appeared appropriate, the caseworker would prepare the case for submission to a health screener. The health screener would then decide whether the evidence raised a question of possible serious impairment of fitness to practise.

Referral by a Medical Screener

22.26 So far, I have dealt with cases which were immediately identified by the GMC staff as potential health cases. Some cases, however, came to the health screener via a medical screener. If, for example, a doctor had been convicted of a criminal offence, the General Medical Preliminary Proceedings Committee and Professional Conduct Committee (Procedure) Rules Order of Council 1988 as amended (the 1988 Professional Conduct Rules) required that the conviction (unless it was a minor motoring conviction) should be referred to a medical screener appointed to deal with conduct cases. Such a conviction might have a 'health element'. In a case where there had been no conviction but where there was an allegation of misconduct, it might not be recognised immediately that there was, or might be, a health element in the case. There might be a number of elements to the case, of which health was only one. In all those circumstances, members of the GMC staff would first refer the case to the medical screener, who would then decide how the case should be dealt with.

22.27 Rule 7 of the 1988 Professional Conduct Rules gave the medical screener two options for dealing with a case in which it appeared to him/her that the fitness to practise of a doctor might be seriously impaired by reason of his/her physical or mental condition. The first option was to direct the staff to inform the doctor of the medical screener's view about the possible impairment of fitness to practise through ill health and to invite the doctor to provide medical evidence for consideration by the Preliminary Proceedings Committee (PPC). Dr Mann said that, in practice, such a case would be referred to the health screener, who would arrange for the doctor to be examined by medical examiners from the GMC's list. (I shall refer to the role and function of such medical examiners later in this Chapter.) It would then be open to the PPC, having considered the medical evidence and received the advice of the health screener, to refer the case to the Professional Conduct Committee (PCC) for a disciplinary hearing, or to the health screener for action under the voluntary health procedures or to the HC.

22.28 The second option open to the medical screener was to remit the case to the health screener for action under the 1987 Health Rules as an alternative to referring the case to the PPC. Dr Mann said that this would be done when it appeared to the medical screener preferable that action should be taken under the health, rather than the conduct, procedures. According to the 1999 Guidance, a medical screener could refer a case into the voluntary health procedures without the concurrence of a lay screener, provided that no question of SPM arose. If a question of SPM arose but the medical screener was of the

view that it was nevertheless in the public interest that the case should be transferred into the health procedures, this could be done, but only with the concurrence of a lay screener. There was no requirement for the lay screener to agree in a conviction case.

22.29 Dr Mann said that only 'a very few' cases reached the health screener by way of the medical screener. She said that, as well as receiving formal referrals, she would sometimes receive informal requests for advice from medical screeners as to whether the doctor's fitness to practise might be seriously impaired because of health and whether it would be appropriate to obtain a medical report before a case was referred to the PPC.

Referral by the Preliminary Proceedings Committee

22.30 As I have explained in Chapter 20, it was common for a health screener to be present at PPC meetings at which conduct cases with a potential health element were considered. Usually, the health screener would advise whether a medical examination of the doctor appeared appropriate. If s/he advised that it did, and if the PPC decided to adopt that course, the health screener would arrange for the doctor to be invited to submit to medical examination and the PPC would adjourn consideration of the case for that purpose. Provided that the doctor agreed, the examination would take place and, if appropriate, the doctor would be invited to give voluntary undertakings. If the doctor agreed to do so, the health screener would report back to the PPC, which would then close the case under the conduct procedures. Referral to the voluntary health procedures formally occurred at the point when the doctor agreed the undertakings. If a doctor failed to co-operate with the examination, or refused to agree undertakings, the case would return to the PPC which would then consider what further action was necessary. The PPC might then refer the case to the PCC or to the HC.

Convictions for Drink Driving Offences

22.31 Until 1995, the PPC did not routinely request that doctors convicted of drink driving offences should be medically examined with a view to ascertaining whether their convictions resulted from addiction to alcohol. Instead, it would request the health screener to arrange a medical examination only in cases where the doctor's alcohol level had been at least two and a half times in excess of the legal limit or where s/he had a previous drink driving conviction. By 1995, however, there was concern that there might be cases which did not fulfil either of these criteria but where the doctor might nevertheless be suffering from a health problem which would benefit from early intervention. Accordingly, from that time, the PPC adjourned the cases of all doctors who had been convicted of an offence of drink driving so that they could be medically examined. The results of those examinations revealed that some doctors who had been convicted of only one offence of drink driving and whose alcohol levels had been less than two and a half times the legal limit were nevertheless suffering from a seriously impairing condition.

22.32 In 1998, there was a change of procedure whereby the health screener would arrange for a medical examination before the case was considered by the PPC. It seems likely that, if it was clear from the report that the doctor had a health problem, the health screener would invite the doctor to give voluntary undertakings. If the position was not clear, or if the doctor

was not willing to give undertakings, the case would be referred back to the PPC for decision.

22.33 Dr Mann said that the majority of doctors convicted of offences of drink driving were found to be fit to practise without restriction. However, about one third were found to have a health problem. Some of these were placed under supervision in the voluntary health procedures.

The Power of the Health Screener to Investigate

22.34 Under rule 6(3) of the 1987 Health Rules, once a case had been referred to him/her, the health screener had power to cause such inquiries to be made as s/he might think fit. Dr Mann said that she would sometimes suggest people whom the staff might contact to obtain information. She might even suggest writing to the doctor him/herself at that stage.

Consideration of a Case by the Health Screener

The Sufficiency of the Evidence

22.35 Dr Mann told the Inquiry that the first question the health screener had to consider was whether there was sufficient evidence that the doctor's fitness to practise might be seriously impaired. She emphasised that there must be sufficient firsthand evidence.

22.36 Sometimes, the person (usually a doctor) who had originally reported the concern to the GMC was unwilling to supply evidence on which GMC action could be based. The relevant information had to be put in writing. In addition, until November 2002, in a case where information about a doctor's health was received from a private individual, that information would not be submitted to a health screener unless and until a statutory declaration (i.e. a statement confirming the truth of the information, sworn in front of a solicitor or a member of certain other limited classes of person) had been provided. The rule applied even when the information came from a colleague of the doctor or from his/her treating doctor. In November 2002, as I have previously explained, the requirement for a statutory declaration was removed. Dr Mann said that this requirement had caused problems and was 'quite troublesome' for some members of the public. She said that she was 'very glad' that it had been removed.

22.37 Throughout the 1980s and early 1990s, considerable concern was expressed in the Annual Reports of the health screener about the fact that some doctors were reluctant to co-operate by providing the information required by the GMC in the correct form. It seems likely that part of the problem was the requirement for a statutory declaration. The unwillingness of the GMC to carry out its own investigations and to gather evidence itself was no doubt also a factor. However, there seems also to have been a feeling on the part of some doctors that, once they had expressed their concerns to the GMC, they had 'done their bit' and they had no obligation to do more. In the 1991 Annual Report of the health screener, this attitude was condemned as **'a failure of duty both to patients and to the sick doctor'**. Over the years, a significant number of cases were closed because of insufficient evidence.

22.38 The 1999 Evaluation Report revealed that, between 1981 and 1996, 10% of the 771 cases examined by the King's College team had been closed because the GMC had considered that it had insufficient evidence to warrant instigating the health procedures. Examples were cases where there was no firsthand (as opposed to hearsay) evidence that patient safety was being compromised or where firsthand information was available, but it was not in the correct form. The Report showed that a significantly lower percentage of cases was closed for this reason during the period from 1989 to 1996 than in the earlier period from 1980 to 1988; 14% were closed during the period from 1980 to 1988, compared with 7% in the later period.

22.39 The King's College team noted that, overall, one third of cases that had been closed owing to insufficient evidence subsequently returned to the GMC with a second health-related referral. The figure for such cases from the period 1989 to 1996 was almost 40%.

22.40 The 1999 Evaluation Report recommended that, once contact had been made by a person concerned about a doctor's health, the GMC should be more proactive in following up the information (regularly if necessary) until it was sure that the doctor was not a risk to patients. The Report suggested that caseworkers might be sent out to talk to potential referrers about their concerns. It also recommended that more assistance and advice should be made available to potential referrers.

22.41 From the contents of the 1999 Guidance, it seems that the GMC took some steps to implement those recommendations. It appears that advice was given to referrers about making a statutory declaration. Sometimes, the GMC was able to arrange for the colleagues of a doctor who wished to give information about the doctor's health to the GMC to avoid the need for a statutory declaration by channelling their reports through a hospital authority, a PCO or a LMC. However, informants did not always want to do this and the relevant organisations were sometimes unwilling to assist. In certain cases, referral through the GMC's solicitors could be arranged or financial assistance made available to a private individual, to enable him/her to make a statutory declaration. A system of following up enquiries about referrals was developed.

22.42 The annual FTP statistics reveal that, from 1996, the percentage of cases closed on the grounds of insufficient evidence fluctuated widely. For example, in 1999, the statistics show that only one out of the 157 health cases referred was closed for this reason. In 2001, however, the figure was 30 out of 181 cases. The figures for 2002 and 2003 were 13 (out of 202 cases) and six (out of 143 cases) respectively. It is not known how many of these cases were later (or will in the future be) followed by a further health-related referral.

22.43 In Chapters 18, 19, 20 and 21, relating to the conduct procedures, I discussed the consequences of the GMC's unwillingness to gather evidence or to investigate complaints proactively until a very late stage in the disciplinary process. I expressed the view that this unwillingness probably resulted in the loss of some cases to the FTP procedures. It would appear that, at times and to some extent, a similar problem affected the health procedures. I had the impression from the evidence of Dr Mann that, once a case had been referred to her, she would instigate investigation. But it might well be that, on occasion, cases were closed for lack of firsthand evidence before they reached the health screener. It appears that the requirement for a statutory declaration was probably the

cause of the problem in some cases. The stated justification for requiring a statutory declaration in the conduct procedures was to protect doctors from being harassed by unfounded or malicious complaints. I find it difficult to imagine why such measures should have been thought necessary within the health procedures, which are designed to protect the public and to assist the doctor without punishing him/her. Yet the requirement was retained until 2002.

The Seriousness of the Impairment

22.44 Another consideration for the screener was whether the information received raised a question of 'serious' impairment, rather than some mild form of illness. Some of the cases considered by the Inquiry showed that quite difficult issues could arise when the health screeners had to decide whether to 'accept' a case and direct a medical examination, or to close it. It does not appear that there has ever been any guidance on these issues. In the past, this probably did not matter, as such decisions were taken by one of two health screeners, who were very experienced. However, for the future, it seems to me that some guidance and criteria will be needed.

The Adequacy of Any Local Action Being Taken

22.45 Rule 6(4) of the 1987 Health Rules stated that, unless it appeared to the health screener that the matter **'need not proceed further'**, s/he should set in motion the initial steps in the health procedures. Dr Mann said that, when considering whether there was a **'need'** for a case to proceed further, she was required to look at whether the problem had been, or could be, remedied by local action. Evidence of any actual or potential risk to patients would be a relevant consideration. If a doctor's problems were being dealt with locally, she would consider whether the doctor was showing insight, whether s/he was accepting advice about treatment and about his/her fitness to practise and whether s/he was taking appropriate treatment and medication. Dr Mann said that, with a GP, the size of his/her practice was relevant. In a group practice, there was more chance of a problem being spotted and of arrangements being made if the doctor became unfit to practise. Dr Mann said that, in an ideal world, she would like to think that local measures would normally be sufficient for a doctor in stable employment. There were, however, problems with doctors who moved around. There was often no place where their problems could be consistently managed. The GMC would usually invite such a doctor to be medically examined. The GMC was in a better position than local organisations to deal with peripatetic doctors since it could organise supervision countrywide and could refer a doctor to the HC if s/he failed to keep in touch with his/her nominated supervisor.

22.46 The 1999 Evaluation Report revealed that, in the period between 1980 and 1996, 7% of cases referred to the health screener had been closed on the grounds that they were being adequately controlled by local measures. Twenty eight per cent of those cases had resulted in a subsequent health-related referral. There were far fewer second referrals (15% compared with 46%) among cases closed between 1989 and 1996 than among those closed between 1980 and 1988. However, the Report pointed out that there had, by 1999, been less time for a recurrence in cases closed more recently.

22.47 The 1999 Evaluation Report recommended that clear criteria and guidelines should be established to assist health screeners in assessing when a case was being controlled adequately by local measures and when GMC intervention was required. It was suggested that, if a case was to continue to be managed locally, a system of periodic monitoring by the GMC was necessary. The 1999 Evaluation Report was the second occasion when an external body had called upon the GMC to establish clear criteria and guidelines for the assistance of decision-makers. I have already mentioned in the Chapters dealing with the conduct procedures that Professor Isobel Allen called for the establishment of clear standards, criteria and thresholds, to be applied by decision-makers when dealing with conduct cases. The 1999 Guidance produced by the GMC included some sample cases to illustrate the type of problem that could be managed locally and the kind of case that should be referred to the GMC. Although the GMC maintained that the 1999 Guidance set out criteria, it does not seem to me that it did. The sample cases were no doubt helpful but they did not establish criteria for the health screeners to apply.

22.48 Following receipt of the 1999 Evaluation Report, the Health Section developed a system whereby it would follow up the case of a doctor who was being dealt with locally to ascertain that all was well. The follow-up might take place after two, four, or six months, depending on the seriousness of the case and how robust the local procedures were thought to be. Sometimes, there would be regular follow-up over a long period.

Referral to or Consultation with a Medical Screener

22.49 Dr Mann said that, if there was a conduct or performance aspect to a case which was referred directly to her as a health screener, she would refer the case to a medical screener. She might at the same time set the health procedures in motion by asking the staff to write to the doctor. In some cases, there was a dialogue (either face to face or on paper) between the medical and health screeners as to how a case should best be dealt with.

Interim Action

22.50 After the IOC was established in August 2000, it was also open to the health screener, in an appropriate case, to refer a doctor to that Committee. Before that time, the health screener had power to refer a case to the PPC for consideration of the making of an interim order, but only where a decision had already been made to refer the case to the HC and where the health screener thought that it might be desirable for an interim order to be made pending the HC's consideration of the case. If the case was referred to the PPC for the purpose of an interim order, it was not open to the PPC to refer the doctor to the PCC; it could only proceed to the HC.

22.51 Dr Mann said that she had been 'extremely grateful' for the establishment of the IOC. Before it came into being, there was sometimes nothing she could do about doctors who were seriously ill, usually with psychotic disorders, but still in practice. Presumably, these were cases in which it was not appropriate for the doctor to be referred to the HC because s/he had not yet declined to co-operate with the voluntary procedures. I have observed,

in connection with the conduct procedures, that it is surprising that, until 2000, the GMC took no steps to obtain comprehensive powers to make interim orders for the protection of the public. There must have been many cases in which the power would and should have been used. Yet it does not appear that the need for it was recognised until it was found that the GMC could do nothing to stop Shipman from practising although he was under investigation for murdering patients. From Dr Mann's evidence, it appears that there was also a need for a flexible power to make interim orders in health cases. One would have thought that the GMC would have recognised this *lacuna* in its powers before it did.

The Invitation to Undergo Medical Examination

22.52 If the health screener decided that the case should proceed, s/he was then required to direct the GMC staff to write to the doctor, notifying him/her that information had been received by the GMC which appeared to raise a question whether his/her fitness to practise was seriously impaired and indicating the nature of the alleged impairing condition. Dr Mann said that, sometimes, it was impossible to identify the impairing condition at that stage and it was necessary to use some general term of description such as 'substance misuse'. The doctor would be invited to submit to examination by at least two medical examiners, to be chosen by the health screener, and to agree that such examiners should provide reports on his/her fitness to practise. The 1987 Health Rules allowed the doctor 14 days in which to respond to the invitation.

Medical Examiners Chosen by the General Medical Council

22.53 Medical examiners were chosen by the health screener from lists of doctors nominated for the purpose by professional organisations, including the medical Royal Colleges (primarily the Royal College of Psychiatrists) and various committees of the British Medical Association. They were usually of considerable seniority. The most common specialty from which medical examiners were drawn was psychiatry. Dr Mann said that the health screeners tried very hard to identify examiners who were appropriate for the particular condition suffered by the doctor. Cases of alcohol and drug addiction were dealt with by consultant psychiatrists, usually specialists in substance abuse. Examinations would take place in the doctor's locality wherever possible.

Medical Examiners Nominated by the Doctor

22.54 Under the original procedure set out in rule 6(3)(c) of the 1980 Health Rules, the doctor was also informed that it was open to him/her to nominate other medical practitioners to examine him/her and to report to the health screener on his/her fitness to practise. These reports would be prepared at the GMC's expense. In November 2002, the rule was changed to remove the right of a doctor to nominate other medical practitioners to examine him/her. Dr Mann said that the right had not been exercised to any great extent. She was not sure why it had been removed. She said that, in fact, it was still open to a doctor to nominate a medical examiner if s/he wished to do so. However, the GMC would not pay for the report.

Other Information Submitted by the Doctor

22.55 In addition, at the same time as s/he was invited to submit to medical examination, the doctor was invited to provide any submissions or to provide other evidence which s/he might wish to offer as to his/her fitness to practise. From November 2002, the Rules specifically provided that such **'other evidence'** might include medical evidence. Even before that time, however, it was not unusual for the doctor to submit medical evidence to the GMC at this point in the process or, if the doctor was aware at the time of his/her referral to the GMC that s/he had been referred, even earlier. The medical evidence submitted by the doctor might consist, in a conviction case, of reports that had been prepared for the previous court hearing. Alternatively, it might consist of a report from a treating psychiatrist, or from the doctor's GP. Dr Mann estimated that doctors produced medical evidence of their own in about a quarter of cases. She said that such evidence was taken into account by the health screeners. However, she told the Inquiry that, unless there was clear evidence that the doctor's fitness to practise was not seriously impaired and that patients were not at risk, the doctor would be invited to undergo examination by examiners who had been chosen by the GMC, even if s/he had produced medical evidence of his/her own. The examiners chosen by the GMC would be familiar with the GMC's requirements for the content of an examination report and would also provide objective assessments. She said that there had been occasions when a doctor had produced a report from a medical practitioner who was on the GMC's list of medical examiners and where the GMC had accepted and acted on that evidence. In general, however, the GMC would want to obtain two independent reports.

Reports of Previous Medical Examinations

22.56 The information originally received by the GMC, notifying it of concerns about a doctor's health, might include reports written by medical practitioners who had recently examined the doctor. The doctor might, for example, have undergone a medical examination arranged by his/her employers, who might have forwarded the report to the GMC.

22.57 Rule 6(4)(b)(ii) of the 1987 Health Rules provided that, in those circumstances, and if it appeared to the health screener that those reports afforded sufficient medical evidence that the doctor's fitness to practise might be seriously impaired by reason of a physical or mental condition, the health screener should direct the staff to inform the doctor of that fact. In that event, the invitation to the doctor to submit to a medical examination would be dispensed with. Until November 2002, it was still open to the doctor, in these circumstances, to nominate his/her chosen practitioners to examine him/her and to prepare reports at the GMC's expense, in addition to those submitted by the person or body who made the original referral.

Disclosure of Information to the Doctor

22.58 Rule 6(5) of the 1987 Health Rules provided that the health screener might direct the staff to send to the doctor, at the same time as notification that information about his/her health had been received, a summary of that information, together with copies of any reports from medical practitioners who had recently examined the doctor. This was routinely done. If

the health screener considered that there was any material in the reports which was not relevant to the doctor's current fitness to practise, or which it would not be in the doctor's best interests to see, the Rules made it possible for that material to be excluded from the documents sent to the doctor. However, any material excluded in that way could not subsequently be put before the PPC or the HC.

22.59 Dr Mann said that she could not remember an occasion when evidence had been excluded under this provision. She thought that there was more openness now as regards the disclosure to patients of information about their condition than there had been when the Rules were originally drafted.

Warning the Doctor about the Consequences of a Refusal to Submit to Examination

22.60 Rule 6(4)(e) of the 1987 Health Rules introduced a new requirement, namely that the doctor should be informed that, if s/he refused to be examined, or if, having agreed, s/he subsequently failed to submit to medical examination, or if s/he did not reply within 28 days to the GMC's communication, his/her case might be referred to the HC. This provision was presumably added with a view to providing additional encouragement to the doctor to give a positive and timely response to the invitation to submit to medical examination.

Disclosure to the Doctor's Employer or Primary Care Organisation

22.61 By section 35(B) of the 1983 Act, which was inserted in August 2000, the GMC was required to disclose to any person in the UK by whom a doctor was employed to provide medical services, or with whom s/he had an arrangement to do so, the fact that the doctor was undergoing an investigation to determine whether his/her fitness to practise was seriously impaired by reason of his/her physical or mental condition. The disclosure had to be made as soon as was reasonably practicable after the doctor had been invited to agree to submit to medical examination or had been notified that medical reports already received by the GMC appeared to provide evidence that his/her fitness to practise might be seriously impaired. Disclosure would therefore be made to a GP's PCO. Before the duty to disclosure existed, it was possible for a doctor's employer or PCO (particularly the latter) not to be aware that a doctor was being dealt with in the voluntary health procedures. It is not clear to me whether disclosure should also have been made, as a matter of course, to other members of his/her practice. In fact, it seems to me that a GP's partners might well be persons with whom the doctor has an arrangement to provide medical services. I would have thought a general practice partnership agreement would come within that rather wide provision. In any event, the GMC would have had the power to make disclosure to members of the practice under section 35(B)(2) on public interest grounds. However, it appears that the GMC does not, as a rule, inform the partners that the GP is undergoing investigation. In practice, a partner or employer or PCO will often have referred the case to the GMC and so will be fully aware of the situation. However, they may be unaware of a referral by a member of the public, a colleague of the doctor, or a treating medical practitioner.

22.62 Dr Mann observed that the duty to disclose had been a considerable improvement as far as employers and PCOs were concerned. However, she said that she would prefer the

contact to be at local level (i.e. the doctor informing his/her employers or PCO about a health problem), rather than the GMC 'sending down information from on high'. She believed that 'the best way of ensuring that doctors remain fit to practise is that there is understanding of their needs and that they in turn are honest with their employer'.

22.63 I agree that open discussion of the matter between a doctor and his/her employer or PCO is greatly preferable to the employer or PCO being informed by a third party of the doctor's problems. Nevertheless, in some cases, the nature of the doctor's illness – together with concerns about its possible effects on his/her career – will inevitably mean that this will not happen. Disclosure by the GMC does at least mean that employers and PCOs can be aware of the problem at an early stage in the GMC's proceedings and can take whatever steps they deem necessary to support the doctor and to safeguard patients. It seems to me highly desirable also that other members of a GP's practice should be fully aware of any report of health problems made to the GMC.

The Arrangements for Medical Examination

22.64 Rule 7 of the 1987 Health Rules provided that, if the doctor agreed to submit to examination by medical examiners nominated by the GMC, the Registrar (in practice, the GMC staff) would make arrangements for the examinations to take place. The medical examiners were to be sent the information received by the GMC and were to be asked to report, first, on the fitness of the doctor to engage in practice, either generally or on a limited basis, and, second, on their recommendations, if any, as to the management of his/her case. While the GMC would be responsible for arranging the medical examination in principle, practical details such as time and place had to be agreed between the doctor and the medical examiner. Problems could occur at this stage if the doctor failed to co-operate or to attend for appointments.

22.65 When preparing their reports, medical examiners were asked to contact the doctor's GP and any other treating doctor. They were encouraged to interview an additional informant, such as the doctor's spouse, a family member or a friend. This was not always possible; it might be that no one was available, or that the doctor would not consent to such an interview. Dr Mann said that the examination followed very much the pattern of an examination by a doctor of a new patient. However, the examiner's attention was also directed to matters such as the risk to patients, the doctor's fitness to practise and whether there was a serious impairment present. In a case involving the abuse of drugs, one of the medical examiners would carry out objective testing for the presence of drugs. The medical examiners would liaise between themselves to arrange how and by whom this should be done. The examiners did not normally see each other's reports.

Acting on the Medical Evidence

The Content of the Medical Reports

22.66 Once completed, the reports of the medical examinations were forwarded to the GMC for consideration. In addition to the elements usually contained within a medical report, the medical examiners would set out their recommendations about such matters as the need

for medical supervision, treatment and support. They would also, in an appropriate case, recommend what limitations should be imposed on the doctor's practice. They might recommend that the doctor should cease practice for a period.

22.67 The 1999 Evaluation Report emphasised the need for GMC examiners, when reaching their conclusions about fitness to practise and when making their recommendations, to balance the interests of the individual doctor and the wider patient population. The impression of the King's College team was that, on occasion, the perceived effects for the doctor might have been given **'undue weight'** by examiners. If this impression was correct, it is worrying, because the primary objective of the health procedures must be to protect patients.

Disclosure of the Medical Reports to the Doctor

22.68 Rule 8 of the 1987 Health Rules required the health screener, when the reports of any medical examinations were available, to arrange for copies to be sent to the doctor concerned. It was open to the health screener to delete from the reports of the medical examiners chosen by the GMC any material which s/he considered irrelevant or not in the doctor's best interest to see, subject to the fact that the material would then be excluded from subsequent consideration by the PPC, the HC or the IOC. However, during the period up to November 2002, when it was still open to the doctor him/herself to nominate medical practitioners to examine him/her and to report, the health screener could not delete any material from reports prepared by the examiners nominated by the doctor. Dr Mann said that, when material was deleted from the reports of medical examinations, the deletions would 'nearly always' relate to information provided to the medical examiners by third parties.

No Serious Impairment of Health

22.69 The medical examiners might agree that there was no serious impairment of the doctor's fitness to practise. This happened most commonly in cases where the medical examination had taken place following a doctor's conviction for a drink driving offence. It was not a common outcome in other types of case. When it happened, the health screener could take no further action and the case would usually be concluded. The exception was where the case had been referred for a medical examination from the conduct or performance procedures, when those procedures might resume.

The Voluntary Health Procedures

Where the Medical Examiners Agreed that a Doctor Was Unfit to Practise or Unfit to Practise without Conditions

22.70 The most common outcome of a medical examination was a finding that the doctor was fit to practise, subject to restrictions and conditions recommended by the medical examiners. Rule 8 of the 1987 Health Rules provided that, in a case where the medical examiners were unanimous in their view that the doctor was not fit to practise except on a limited basis or under medical supervision or both, the health screener should direct the

staff to seek the doctor's agreement to undertake voluntarily to comply with the recommendations contained in the reports as to the management of his/her case, including any limitations on his/her practice which might have been recommended. If the doctor was not considered by the medical examiners to be fit to practise, even on a limited basis, s/he would be asked to undertake to refrain from practice altogether.

22.71 Undertakings were of two kinds. The first kind comprised those that related to the medical treatment of the doctor's condition. Undertakings of this kind might be to abstain from alcohol or to comply with tests for the presence of alcohol and other drugs. The second kind related to the doctor's practice. These might include an undertaking not to perform any work as a locum or deputy or for a deputising service, or even an undertaking to refrain from practice altogether. In formulating the undertakings, the health screener would confine him/herself broadly to the contents of the examiners' reports, but might add other undertakings as appropriate. The terms of the undertakings were usually derived from a list of 'standard undertakings' which had been developed by the GMC over time. They would be adapted as necessary to suit individual circumstances.

22.72 The 1980 Health Rules made no formal provision for the medical supervision of a doctor within the voluntary health procedures. From the first, however, medical supervision was one of the most important components of the voluntary health procedures and doctors were required to undertake to accept and co-operate with medical supervision. This remained a standard undertaking which was compulsory. Other compulsory undertakings were agreement (in a case of substance misuse) to undergo testing of samples of breath, blood, urine or hair for the presence of alcohol or drugs, and to allow the exchange of information between the medical supervisor and someone in the doctor's workplace. If the doctor was not prepared to give one of the compulsory undertakings, his/her case would be referred to the HC. Dr Mann said that, if a doctor was working, it was normal to include a requirement that s/he should seek the prior approval of his/her supervisor before taking up a new post and should cease working immediately if so advised. She said that it was also important to ensure that the doctor was registered with a GP and that the medical supervisor was in a position to exchange information with that GP. Dr Mann said that there was sometimes some 'negotiation' over certain undertakings. However, she observed that the overriding concern was the protection of the public. Dr Mann said that the health screeners would often require an undertaking that GPs with health problems did not work in single-handed practice, but instead worked in a group or partnership arrangement.

22.73 From about 1997, it was compulsory for a doctor entering the voluntary health procedures to agree that undertakings relating to his/her practice could be disclosed to his/her employers and to anyone seeking information about his/her registration status. If s/he did not agree to such disclosure, his/her case would be referred to the HC. There was no requirement for undertakings relating to the doctor's medical treatment to be disclosed and they were regarded as confidential. The purpose of the requirement for disclosure was to place doctors in the voluntary health procedures on a par with those who had been referred to the HC, and to ensure that members of the public and employers had access to the same information about both. All doctors who were already in the voluntary health procedures were asked to agree to disclosure. The disclosure, to employers and to members of the public making enquiry, of undertakings relating to the doctor's practice is

useful but it does not provide a complete picture. The letter of disclosure, examples of which the Inquiry has seen, might well leave an employer puzzled as to the nature of the doctor's problem. However, as Dr Mann observed, it would be open to an employer to contact the person instructed to act as the doctor's supervisor, although s/he would be able to disclose more information only with the doctor's consent. It is, perhaps, more likely that an employer would speak directly to the doctor and insist that, if the doctor was to remain at work, full details of the problem must be disclosed.

22.74 Mr Howes said that he believed that, towards the end of his time in the Health Section in 2001, the GMC would have kept a doctor's employers or PCO informed about progress and about undertakings relevant to practice. However, the GMC would not have notified a GP's professional partners. He believed that the GMC would have relied on the medical supervisor to keep the doctor's partners aware of what was happening. He pointed out that the partners might have been the original informants, in which case they would be well aware of the circumstances. Mr Howes observed, 'By the time I left this work, our policy was to make sure that everybody who needed to know, knew – everyone who had a proper interest in knowing, knew.'

22.75 The 1987 Health Rules made it possible for the first time to invite a doctor to give an undertaking in circumstances where s/he had recovered from a recurring or episodic physical or mental condition which was in remission at the time of the examination, but which might, in the future, be expected adversely to affect his/her fitness to practise.

Where the Medical Examiners Disagreed

22.76 In a case where the medical examiners did not report unanimously, the health screener had to decide what arrangements for the management of the doctor's case (including limitations on his/her practice) were appropriate **'in the light of the balance of opinion in the reports'**. The doctor would then be invited to undertake to comply with those arrangements.

22.77 Dr Mann said that, on occasion, one medical examiner would say that a doctor was fit to practise and the other would say that s/he was not fit to practise. In those circumstances, she would 'err on the side of caution' and draft undertakings based on the report of the medical examiner who had expressed the view that the doctor was unfit to practise, hoping that the doctor would agree to them. If one medical practitioner recommended that the terms of the undertakings should be stricter than did the other, she would usually invite the doctor to agree to the stricter undertakings, with the possibility of a relaxation of their terms in time, if the doctor progressed satisfactorily.

The Doctor's Response

Where the Doctor Gave Undertakings

22.78 If the doctor undertook to comply with the recommendations contained in the medical reports (or, where the medical reports were not unanimous, with those proposed by the health screener), the health screener might then, if satisfied that the undertakings were being observed, postpone further action on the case. The doctor was then in the voluntary

health procedures. Once the doctor was within the voluntary health procedures, his/her case could not be referred back into the conduct or performance procedures.

Where the Doctor Declined to Co-operate

22.79 If the doctor did not agree to give undertakings, or failed to respond within the specified period, or if s/he refused or failed to comply with a medical examination by the medical examiners appointed by the GMC, the health screener might, if s/he thought fit, refer the case to the HC. In practice, few doctors declined to co-operate at this stage.

22.80 Until November 2002, there was an additional element to the process. Before making a referral to the HC, the health screener was required to consult with at least two other members of the GMC. The GMC maintained a panel of six members ('the panel of six') who were appointed for this purpose. Members of the panel (who could not also be members of the HC) were appointed by the President with the approval of the Council. Their views were not necessarily determinative of the health screener's decision whether to refer a case to the HC, but the health screener was required to take account of those views in reaching his/her decision. If, however, the health screener considered that, in the public interest, it was urgent that the case should be referred to the HC, s/he had the power to give a provisional direction to that effect before consulting the other members.

22.81 Dr Mann said that consultation with the panel of six caused something of a delay. It did enable a health screener to get another opinion on the case, which was helpful. On the whole, however, it did not add anything to the procedures. The original purpose of the requirement to consult other members of the GMC had been, she said, to protect doctors against screeners who, the profession feared, would want to refer every case to the HC. In the event, the fears of the profession had not been justified. The panel of six was abolished in November 2002.

Where the Doctor Was Unfit to Give Undertakings

22.82 In some cases, the medical reports might reveal that the doctor was suffering from a condition (usually a psychiatric condition) which meant that s/he was not fit to give undertakings or could not be relied upon to comply with undertakings, even if given. In such a case, it was open to the health screener to refer the case to the HC without first seeking undertakings from the doctor.

Delays in Bringing Doctors under Supervision

22.83 The 1999 Evaluation Report expressed concern about the time taken from a report about a doctor's health being received by the Health Section to the point when the doctor was placed under supervision. During the period from 1989 until 1996, it took a mean time of almost 50 weeks. Forty per cent of the doctors who were subsequently found to be unfit to practise unsupervised and unrestricted were known to be working at the time of referral. Some of those doctors were receiving treatment and might have been voluntarily restricting their practice, but many might not. The delay in bringing those doctors under supervision represented an obvious risk to patient safety. Until August 2000, however,

when the IOC was established, the health screener had no power to refer a case to the PPC for the making of an interim order unless and until the decision had been taken to refer a doctor to the HC. That could not be done unless there was evidence of failure to co-operate or non-compliance by the doctor.

22.84 The 1999 Evaluation Report identified a number of factors that had contributed to the delays. In the initial stages, there was sometimes a need to await the outcome of police investigations or court proceedings. Another factor was the time taken by some people who reported doctors to the GMC to provide the information required of them. A third factor was the time taken by doctors to respond to communications from the GMC.

22.85 The King's College team observed that, in some of the 40 sample cases which it examined in depth, the GMC had taken positive action to obtain information, sometimes by instructing its solicitors to investigate. However, in other cases, the GMC had waited for a complainant to make contact, rather than actively following up the complaint. Even when the GMC took positive action, this took a long time. The time permitted by the 1987 Health Rules for doctors to agree to examination (14 days) and to respond to the reports of the medical examiners (28 days) also slowed down the process. This was a matter which had been mentioned in the Annual Reports of the health screener as early as 1982. The 1999 Evaluation Report described how, on occasion, the GMC had delayed in appointing examiners and in dealing with problems which had arisen between examiners and doctors. Doctors had sometimes failed to respond promptly and had missed appointments. In four of the 40 cases, the reports of the medical examiners had not been received for as long as three to six months after the examination. There had also been difficulties and delays in appointing medical supervisors.

22.86 The 1999 Evaluation Report pointed out that doctors were free to practise during the period of referral into medical supervision and that patients might therefore be at risk during that time. It recommended that the GMC should introduce a computerised system for processing complaints and for recording the progress of each case through the health procedures. It also recommended that the GMC should follow up the initiation of the arrangements between doctors and examiners to ensure that appointments had been made and examinations had taken place. Examiners who exceeded the target times for submitting reports should be followed up. Also, if an examiner failed to provide requested information s/he should be required to do so. If the GMC found that an examiner persistently failed to meet target times or to provide required information, the use of that examiner should be discontinued. The GMC should monitor the quality of supervision provided and should replace a supervisor where supervision was poor.

22.87 In response to this Report, in July 2000, the GMC introduced service standards, which effectively tackled the problems of delay. These standards were updated in April 2003. The 2003 standards allowed about one month for screening, two months for examinations and two months for decisions to be taken. By then, either the doctor would have accepted voluntary undertakings or s/he would have been referred to the HC. Thus, within five months of receipt, a health case should either have been closed or action would have been taken. In December 2003, the GMC achieved this target in 86% of cases, just short of the target of 90% which it had set for itself. In the event that patients were thought to be

at risk, there was the option of referring the case to the IOC. The 2003 service standards required all cases referred to the IOC to be heard within one month. These service standards had the effect of substantially 'tightening up' the health procedures.

Supervision of Doctors in the Voluntary Health Procedures

22.88 As I have said, the 1980 Health Rules contained no specific provision for the supervision of doctors who had entered the voluntary health procedures. In practice, however, doctors entering the voluntary health procedures were always required to undertake to accept medical supervision. Rule 9 of the 1987 Health Rules formalised this practice. It gave the health screener power, in a case which was being dealt with under the voluntary health procedures, to request one or more medical practitioners to supervise the management of the doctor's case and to report if necessary on the doctor's observance of his/her undertakings and on his/her fitness to practise. The purpose of this supervision was to satisfy the health screener that the doctor was observing his/her undertakings.

22.89 The health screener would select a suitable medical practitioner to supervise the doctor. The medical supervisor might be one of the practitioners who had examined the doctor on behalf of the GMC. He or she might be a practitioner who was already treating the doctor. The role of the medical supervisor was to monitor the doctor's progress and fitness to practise and to report to the GMC. The medical supervisor was also required to ensure that the doctor was getting the support and treatment necessary to assist his/her recovery. The supervisor also had to ascertain whether the doctor was complying with his/her undertakings; s/he did this by carrying out tests for the presence of alcohol and drugs and by collecting information from independent informants and other treating doctors. The frequency of contact between the doctor and his/her medical supervisor was a matter for the supervisor him/herself.

22.90 If the doctor was continuing to practise, the GMC would require a professional supervisor to be appointed. The professional supervisor was selected by the doctor (in consultation, if applicable, with his/her employer). The GMC did not dictate who should fulfil this role. It was to be someone in a senior position who had personal experience of the doctor's work. If the doctor was a GP, it could be the senior partner of the GP practice in which the doctor worked. Dr Mann said that it was easier to get objective feedback if a doctor was working in an organisation or in a hospital, because the doctor would be coming into contact with more people. If s/he was a GP, it was necessary to rely on partners, who might have mixed feelings about the doctor practising, or on a colleague in an organisation such as a LMC or PCT. That person would be working at a distance and would not have the same personal contact with the doctor. Dr Mann said that, if someone within a GP practice was willing to give information about the doctor's progress, the information which s/he was able to give was likely to be valuable, since it would be based on close contact with the doctor.

22.91 It seems to me that the difficulty of obtaining reliable information about the doctor's work represented a weakness in the old health procedures. The health screener really did need to have personal contact with someone who saw the doctor regularly. The screener needed to have some 'feel' for the level of concern which there was about the doctor's practice. I can understand why the health screeners did not establish personal contact

with the doctor under supervision; they needed to remain at arm's length. However, the screeners did need a source of information close to the doctor and this was not always available.

22.92 In a case of substance abuse, the medical supervisor was expected to report to the GMC any lapse in the doctor's behaviour which might affect his/her fitness to practise. The GMC would request progress reports. Dr Mann said that the first report was usually requested three to six months after the doctor was put under supervision. A second report was requested after a further period of about six months. Thereafter, the timing was variable according to circumstances and the recommendations of the medical supervisor. Sometimes, the GMC would receive an unsolicited report from a medical supervisor. This might give news of a change for the worse, but would sometimes inform the GMC of a change for the better and would suggest that the doctor's undertakings should be relaxed. When the GMC requested a progress report, its letter of request would include a list of questions to be answered and the supervisor would be asked to collect information from various sources and to include that information in his/her report. The supervisor would also be asked for his/her views about whether the GMC should conclude the case, or whether the doctor required further monitoring.

22.93 Health screeners had no personal contact with the doctor concerned and were entirely reliant on the medical supervisors to keep in regular contact with the doctor, to collect information about him/her and to be rigorous in carrying out objective testing, where appropriate, for alcohol or drugs. The availability of testing of hair (which can reveal the presence of opiates as long as three months after ingestion) and the carrying out of random tests were, according to Dr Mann, valuable tools in the supervisory process. Usually, there would be no direct communication between the health screener and the professional supervisor. The latter would provide information to the medical supervisor.

22.94 Dr Mann emphasised that the role of the medical supervisor was an onerous, although rewarding, one. It involved a great deal of responsibility, both to the public and to the profession. It was not well paid. Dr Mann said that many medical practitioners regarded it as their duty to contribute to the wellbeing of the profession by acting as GMC supervisors. However, some doctors found it difficult to treat other doctors.

The Treating Doctor as Medical Supervisor

22.95 The 1999 Evaluation Report expressed concern about the fact that, in 22 out of the 40 cases in which the reports of medical supervisors were examined, the supervisor had been a practitioner who was already treating the doctor. The Report observed that this duality of roles increased the difficulty for a medical supervisor in balancing the interests of the doctor and of the wider patient population. It recommended that, save in exceptional circumstances, the GMC should not appoint a treating doctor as the medical supervisor.

22.96 Dr Mann said that most cases in the voluntary health procedures involved mental illness, alcoholism, drug abuse or a combination of more than one of these features. Usually, therefore, the medical supervisors would be psychiatrists. In general, the health screeners would try to appoint a medical supervisor who was not the treating psychiatrist. However, the position was rather different with cases of substance misuse. Dr Mann said that there

had been much debate about the advantages and disadvantages of combining the roles of treating psychiatrist and medical supervisor in cases of substance misuse. The problem with combining the two roles was that the psychiatrist might be subject to a conflict of loyalties, as between the doctor, the GMC and the public. It might be difficult to cope with that conflict. The second problem was the feeling that a medical supervisor who was also the treating psychiatrist might not be truly independent.

22.97 Dr Mann explained that, on the other hand, there were distinct advantages in combining the two roles. First, there were comparatively few practitioners who specialised in substance misuse. General psychiatrists often lacked the necessary expertise and were not able to offer the same help and support to sick doctors, whether as treating psychiatrist or as supervisor. If the doctor was already receiving treatment from an expert in substance misuse, it was less wasteful of resources, and might be more beneficial to the doctor, to appoint that person as supervisor also. A second reason for combining the two roles was to ensure that all the information which should be communicated to the GMC was known to the supervisor. As I have explained, the medical supervisor was expected to report to the GMC any lapse in the doctor's behaviour of which s/he was aware. If the supervisor was not the treating doctor, s/he would be reliant upon the treating doctor to pass on information about, for example, a return by the doctor to taking alcohol or drugs. Dr Mann said that it was easier for one person to have 'all the reins in their hands'. Conversely, there could be a problem if the doctor under supervision did not confide fully in his/her treating doctor because that doctor also took a supervising role. I suspect that there is no perfect answer to this problem.

Problems with Medical Supervisors' Reports

22.98 I have explained that the King's College team examined a sample of reports submitted to the GMC by medical supervisors in the cases of 40 doctors who had been placed under medical supervision in the period 1989 to 1996. The 1999 Evaluation Report pointed out that the supervisors' progress reports were the GMC's principal source of information about the doctor's fitness to practise.

22.99 Delay was one feature noted by the King's College team. In 16 out of the 40 cases, one or more reports was explicitly described in the case notes as being late or having been the subject of repeated requests that it should be provided. In 18 cases, the first progress report was received more than two months after the time for which it had been requested. Delays had been caused by doctors failing to make arrangements with supervisors, by the time taken to obtain information from independent informants and by the time taken by supervisors in responding to requests for reports. There were also significant delays in the provision of subsequent progress reports. Because of the long intervals between reports, three out of the 40 cases had been concluded after only two reports from the medical supervisor had been received. In one case, no reports at all had been received.

22.100 In 16 of the 40 cases, significant information was missing from the supervisor's report. This mainly related to the doctor's fitness to practise, often because of a lack of information from an independent person about the doctor's performance of his/her professional practice. Sometimes, supervisors were reluctant to approach the doctor's colleagues. In

some cases, there were no results of tests for the presence of alcohol or drugs, often because the supervisor was reluctant to conduct random testing. One supervisor observed that s/he did not wish to **'act like a detective'**. Missing information was sometimes recorded in later reports, but this might be as long as 9 to 16 months later. Sometimes, it was never provided. One case was concluded after three years without the results of any testing having been received. The supervisor had repeatedly claimed that he was **'working on an arrangement to carry out random testing'**. In a few cases where the relevant information was not available, the GMC had varied the doctor's undertakings in an attempt to prevent risk to patients. Three of the sample cases had been closed without receipt of the requested information to support a conclusion that the doctor was fit to practise.

22.101 In 11 out of the 40 cases, the file disclosed dissatisfaction on the part of the health screener with the medical supervisor's management of the doctor under supervision. There were references to problems with the content and timeliness of reports, to the supervisor's failure to enforce the restrictions on the doctor's practice and to breakdowns of communication or loss of contact between supervisors and doctors. In six of the 11 cases, the issue was an isolated incident, which was resolved. However, in five cases, there was more enduring concern or criticism. A change of supervisor was often considered in cases where there was dissatisfaction with the existing regime. However, no change was implemented in any case. The reason for this was sometimes the practical difficulties involved in finding a replacement supervisor. However, arguments presented by the supervisor and the doctor about the benefits of their continuing therapeutic relationship were often accepted as reasons for continuing an otherwise unsatisfactory supervisory relationship.

22.102 The 1999 Evaluation Report recommended that the GMC should actively pursue information which was not provided in supervisors' reports and should reach clear agreements with supervisors about the undertaking of testing for alcohol and drugs. It also recommended that greater emphasis should be given to monitoring the quality of supervision and to replacing a supervisor who did not comply with the GMC's requirements.

22.103 Mr Howes said that, in the early days of the health procedures, there was considerable reluctance on the part of medical supervisors to subject doctors to random drug testing for alcohol and other drugs. He said it 'went against the grain' for doctors to impose such procedures on their patients. There was also a degree of scepticism about the usefulness of such tests. More recently, however, the GMC had become much firmer with supervisors. If they did not co-operate, they were no longer used. Dr Mann agreed that the GMC was now much more rigorous in the requirements it made of supervisors. All supervisors in cases of substance abuse were required to ensure that objective testing for the presence of alcohol and other drugs was carried out periodically and to provide the GMC with the results of those tests. If they refused to do this, or if they did not comply with other GMC requirements, they could be removed from a specific case, or from the GMC's list generally. Dr Mann said that this had happened 'perhaps not as often as perhaps it should have done', but it had happened from time to time. There was a greater insistence

on progress reports being provided promptly and on the information which should be contained in such reports.

22.104 In addition, the GMC had established closer links with its supervisors and medical examiners. A leaflet explaining the role of the medical supervisor and his/her responsibility for managing a sick doctor had been produced. In October 1998, the first training day for medical supervisors and medical examiners was held. This was followed by a series of training days and workshops. Dr Mann said that the meetings with medical examiners and supervisors had provided a valuable opportunity to exchange views about problems and to discuss possible solutions to those problems. It had given 'a sense of coherence'. There had been useful discussions about, for example, the advantages and disadvantages of appointing as medical supervisor a substance misuse specialist who was already treating the doctor. Dr Mann said that, over recent years, the GMC had moved towards appointing supervisors as a cohort of practitioners who understood the GMC's procedures and who recognised that a slightly different approach was required when supervising a doctor from that which was usual when just treating the doctor. There had also been attempts to use medical examiners as supervisors in order to promote a greater understanding of the GMC's procedures and requirements. At the time Dr Mann gave evidence to the Inquiry, in December 2003, there had been no meetings with medical examiners or supervisors for a year or so. The Health Section was waiting until the arrangements for dealing with health cases under the new procedures were clear before organising any further meetings.

Action on Receipt of a Medical Supervisor's Progress Report

22.105 During the early stages of a doctor's supervision, if it appeared from the medical supervisor's report that s/he was complying with his/her undertakings and appeared to be making progress, the undertakings might be left unchanged.

Variation of the Doctor's Undertakings

22.106 However, there might have been circumstances which made it appropriate for the undertakings to be relaxed or strengthened. Rule 9 of the 1987 Health Rules introduced a power to vary a doctor's undertakings. If, as a result of a report from a medical supervisor or of information from another source, it appeared to the health screener that the terms of the doctor's undertakings should be varied, the health screener could invite the doctor to agree to that.

22.107 Dr Mann said that, although each case was different, the normal pattern in an 'average case' was for undertakings to be relaxed gradually to give the doctor more freedom in his/her choice of job and, if his/her right to prescribe had been restricted, by relaxing that restriction. This type of relaxation might happen two or three times over a period of two years before the doctor was considered fit to practise unsupervised and unrestricted.

22.108 It is clear from the Annual Reports of the health screener that, in the early 1990s, the health screeners made use of their power to vary undertakings by making them more stringent. For example, the Annual Report for 1990 recorded that the first action of the health

screeners after a breach of a doctor's undertakings had been identified was to send **'a firm letter'** to the doctor, tightening the restrictions on his/her practice. By the late 1990s, however, the GMC had come to believe that the powers to vary undertakings did not include the power to make them more stringent. Later, this view changed again and, where the circumstances made it appropriate, a doctor would be invited to agree undertakings that imposed greater requirements or restrictions on him/her than had originally been the case. Dr Mann said that the perceived inability to tighten an undertaking had been a limiting factor. The health screener might have wished to stop a doctor doing on-call work or from working as a locum but had been unable to make the necessary change without referring the doctor to the HC. This was a cumbersome and time-consuming process.

Cessation of the Doctor's Undertakings

22.109 Rule 9 of the 1987 Health Rules also provided that the health screener might direct that the undertakings should no longer apply, thus bringing the period of the doctor's supervision, and any limitations on his/her practice, to an end. The time at which this happened depended on the nature of the impairment. In cases of substance misuse, Dr Mann said that it would be unusual for a doctor to be released from his/her undertakings within two years after first being put under supervision. If the doctor suffered a recurrence of his/her problem or a relapse, the period of his/her supervision was likely to continue for as long as five years. Supervision might continue for the whole of the doctor's professional life if, as sometimes happened, it appeared to be the fact of supervision (and the threat of action by the HC) that kept the doctor on the 'straight and narrow'. More usually, as I have said, there would be a gradual relaxation of the limitations upon the doctor's practice over a period of years before a final decision was taken that the doctor was fit to practise unsupervised.

22.110 The evaluation by the King's College team of the 40 sample cases from the period 1989 to 1996, in which the doctors had been dealt with under the voluntary procedures, revealed two main criteria used by the health screener when assessing whether a doctor should be released from his/her undertakings and permitted to practise unsupervised. The first criterion was a substantial and consistent improvement in the doctor's health, with evidence that the doctor had been abstinent from alcohol or drugs for a significant period of time (usually, two years). The second criterion was a proven record of the doctor's ability to maintain good clinical performance. The 1999 Evaluation Report recorded, however, that the team's examination of the sample cases suggested that, on occasions, cases had been concluded without substantial evidence of improvement or abstinence. Sometimes, they were concluded on the 'condition' (which would not have been enforceable) that the doctor should remain under the care of the medical supervisor. The King's College team found that the average time for which a doctor remained under supervision during the period 1980 to 1996 was three and a half years. It seems to me that 'proof' that the doctor had maintained good clinical performance might, in some cases, be hard to find. I have mentioned that, for doctors who are not working in a managed employment environment, it might be difficult to find a professional supervisor who had close contact with the doctor. For example, if the professional supervisor of a GP were a colleague on the LMC or at the

PCT, it might not have been possible for the health screener to obtain satisfactory information about the GP's clinical performance.

The Statistics

22.111 Between 1980 and 1990, the number of doctors referred to the Health Section annually was in general between 40 and 60. Between 1991 and 1994, it varied between 71 and 87. In 1996, it reached three figures for the first time. A serious backlog of cases developed in 1996/1997 which necessitated the recruitment of additional staff. The number of referrals dealt with by the Health Section reached a peak of 188 in 2000 and 181 in 2001. In the last two years, the referral rate dropped; 104 doctors were referred in 2002 and 124 in 2003.

22.112 Meanwhile, the number of doctors under supervision has risen. Between 1985 and 1990, it remained steady at between 60 and 68. It rose to 78 in 1991 and, by 1995, had almost doubled to 147. By 1998, 202 doctors were under supervision. Since then, the number has changed little. The 2003 FTP statistics show that 212 doctors remained under supervision in the voluntary health procedures, of whom 54 were GPs. About 100 doctors remained under the jurisdiction of the HC.

The Health Committee

Referral to the Health Committee by the Health Screener

22.113 I have already said that a doctor could be referred to the HC if s/he refused to undergo, or failed to co-operate with, a medical examination or if s/he failed to agree to undertakings or was unfit to agree to or to comply with undertakings. In addition, s/he might be referred to the HC for breach of an undertaking or if his/her condition deteriorated.

22.114 If the health screener learned from the report of a medical supervisor, or by way of information from some other source, that the doctor had ceased to observe an undertaking previously given, the health screener might refer the case to the HC. From 1987, a referral could also be made if the doctor's physical or mental condition had deteriorated. Until November 2002, referral to the HC was subject to consultation with two members of the 'panel of six'. After that time, the health screener was able to initiate a referral without a requirement to consult. In practice, however, the health screener would usually consult with the doctor's medical supervisor when deciding whether to refer a case to the HC.

22.115 The number of doctors referred to the HC annually was always relatively small. There were few referrals to the HC from the other FTP committees. Most referrals came from the health screener. The most common reason for a referral to the HC was a failure, at some point in the doctor's time in the voluntary health procedures, to comply with his/her undertakings.

22.116 In the past, there had appeared to be reluctance on the part of the health screeners to respond to a breach of a doctor's undertakings by referring the doctor to the HC. In the early 1990s, it was said in an Annual Report of the health screener that a doctor would be referred to the HC only if s/he persistently broke his/her undertakings. There was mention

in the Annual Reports also of a perception on the part of the health screener that it was his role to prevent doctors from being referred to the HC. I can appreciate that the aim of the health screener should have been to achieve a doctor's rehabilitation within the voluntary procedures wherever possible. However, the health screener should also have been prepared to refer to the HC a doctor who was not complying with conditions that had been imposed to assist in his/her recovery and/or for the purpose of protecting patients.

22.117 The King's College team found that just over half of doctors identified as having been dealt with under the voluntary health procedures had been reported for breach of one or more of their undertakings. The 1999 Evaluation Report pointed out that this was likely to be an underestimate of the actual incidence of breach. A large proportion of the doctors reported to have breached their undertakings had been working at the time of the breach. Some had breached undertakings to seek the advice of their supervisor before taking up or applying for a post. Some had practised as a locum or single-handed GP in breach of an undertaking not to do so. The most commonly reported breach was of the undertaking by a doctor to abstain from, or limit his/her intake of, alcohol. The number of reported breaches was less in the period from 1989 to 1996 than in the period from 1980 until 1988. Over the whole period from 1980 to 1996, 73% of the doctors who breached one or more of their undertakings had been judged by the medical examiners as fit to practise with restrictions. The 1999 Evaluation Report drew attention to the potential risks to patients caused by doctors who were in practice but were failing to comply with their undertakings.

22.118 Mr Howes said that, during his second period in the Health Section (1997 to 2001), the health screeners had 'tightened up considerably' in respect of breaches. Even so, not every breach of an undertaking resulted in a referral to the HC. Mr Howes said that each case would have to be judged on the seriousness of the breach, whether patients were put at risk, whether the doctor had practised a deception, or whether s/he had immediately afterwards admitted the breach. The supervisor and the screener would come to a view about the seriousness of the breach.

22.119 Between 1980 and 1997, the number of doctors referred to the HC by health screeners in any one year never reached double figures. The most common reason for referral was breach of the doctor's undertakings. In 1998, the number of doctors referred to the HC by the health screeners rose sharply to 21. Fourteen of those referrals were for breach of undertakings. Dr Mann said that she was not sure that there had been a conscious change of policy at that time. However, there was an awareness of concern about leniency and she thought that the health screeners had been 'a little bit stricter' when dealing with breaches of undertakings. She felt that, previously, the GMC had been 'more easy going' with supervision. In 1999, the health screeners referred 16 doctors to the HC; in 2000, they referred 37. The figures for 2001, 2002 and 2003 were 19, 21 and 17 respectively.

Referral from Other Fitness to Practise Committees

22.120 A case might be referred to the HC by the PCC, the Assessment Referral Committee (ARC), the Committee on Professional Performance (CPP) or the PPC.

22.121 As I explain in Chapters 21 and 24, where, in the course of their consideration of a case, a question arose as to whether a doctor's fitness to practise might be seriously impaired

by reason of his/her physical or mental condition, the PCC, the ARC and the CPP had power to refer the case in question to the HC for determination. The doctor would be examined and the HC, having considered the results of the examination, would certify its opinion to the relevant Committee. If the HC took the view that there was no serious impairment of fitness to practise due to ill health, the referring Committee would then resume its consideration of the case and would dispose of it. If, on the other hand, the HC's opinion was that the doctor's fitness to practise was seriously impaired as the result of ill health, the HC would then deal with the case itself and the referring Committee would cease to exercise any functions in relation to the case. By referring a case to the HC for its opinion, the PCC, the ARC and the CPP did not necessarily lose their jurisdiction over the case. If no serious impairment was found, they could proceed to deal with it. None of these three Committees could refer a case to the voluntary health procedures.

22.122 The position was different with the PPC. The PPC, using its power to adjourn, was able to refer cases into the voluntary health procedures. It also had the power to refer cases direct to the HC. However, if it made such a referral and the referral proved inappropriate for some reason (e.g. because, on examination, no – or no serious – health problem was identified), the HC could not take action itself, nor could it refer the case back to the PPC. In such a case, the GMC was powerless to act, even if there was evidence of misconduct (or a conviction) which would have merited action under the conduct procedures.

The Procedure Which Was Adopted

22.123 Rules 11 and 12 of the 1987 Health Rules set out the procedure to be adopted when a decision had been taken to refer a case to the HC. Under rule 11, it was open to the health screener to invite the doctor to undergo medical examination before his/her case was considered by the HC. The medical examination would be conducted by one or more medical examiners selected by the GMC and, if the doctor chose, by a medical examiner selected by him/her. If the doctor agreed to be examined, the GMC staff would make the necessary arrangements. The object of this provision was to ensure that the HC had medical evidence when it came to consider the case. The health screener could take these steps, not only when s/he had taken the decision to refer the doctor's case to the HC him/herself, but also when that decision had been taken by the CPP, the ARC, the PPC or the PCC.

22.124 Rule 12 required the Registrar to serve on the doctor a 'notice of referral', containing certain specified information. That information included an indication of the physical or mental condition by reason of which it was alleged that the doctor's fitness to practise was seriously impaired.

The Powers of the Health Committee

22.125 The powers of the HC were contained in section 37 of the 1983 Act, which virtually reproduced the provisions of section 8 of the 1978 Act. Section 37(1) provided:

> **'Where the fitness to practise of a fully registered person is judged by the Health Committee to be seriously impaired by reason of his physical or mental condition, the Committee may, if they think fit, direct -**

(a) that his registration in the register shall be suspended (that is to say shall not have effect) during such period not exceeding twelve months as may be specified in the direction; or

(b) that his registration shall be conditional on his compliance, during such period not exceeding three years as may be specified in the direction, with such requirements so specified as the Committee think fit to impose for the protection of members of the public or in his interests.'

The Composition of the Health Committee

22.126 The composition of the HC was governed successively by the General Medical Council (Constitution of Fitness to Practise Committees) Rules Order of Council 1980, 1986 and 1996 (the Constitution Rules). Between 1980 and 1996, the HC was composed of the Chairman, the Deputy Chairman, nine medical members and one lay member of the GMC (i.e. 12 members in all).

22.127 The 1980 and 1986 Constitution Rules provided that the President should choose whether he wished to chair the HC. If he chose not to do so, he was required to appoint another member of the GMC as Chairman. The President was also required to appoint a Deputy Chairman. Both appointments were subject to the approval of the Council. Other members of the HC were elected by the Council annually. The legal quorum of the HC was five.

22.128 In 1996, membership of the HC was reduced from 12 (including the Chairman) to nine. Seven members of the PPC were to be medical members and two were to be lay members. The Constitution Rules continued to provide that the HC should be chaired by the President or, if he chose not to act in that capacity, by another member of the GMC appointed in his place. If neither the Chairman nor the Deputy Chairman of the HC was available to chair a meeting, the President had the power to appoint another member of the HC to act as Chairman. From 1996, the legal quorum for the HC was five, including one lay member. In November 2002, the quorum was reduced to three, to include at least one medical and one lay member.

22.129 As I have explained in Chapter 15, in 2000, the GMC was given the power to co-opt non-GMC members, both medical and lay, to sit on its FTP committees. A pool of such persons, who were known first as 'adjudicators', then as 'associates', was recruited. Initially, associates would sit alongside GMC members of the HC on panels to consider cases. After July 2003, panels of the HC would usually consist entirely of associates.

Meetings of the Health Committee

22.130 The HC sat in private and was advised by a legal assessor and two medical assessors. In general, one of the medical assessors would be a practitioner from the doctor's own specialty and the other would practise in the specialty relating to the physical or mental condition from which the doctor was alleged to be suffering. This assessor was usually a psychiatrist. The doctor was entitled to be present and might be legally represented. He or she might also be represented or accompanied by an officer of his/her medical defence organisation, or some other professional organisation of which s/he was a member, or by

a member of his/her family, or by a friend, and might also be accompanied by his/her medical adviser. After 1987, the complainant (if any) was entitled to appear before the HC and to be represented. However, s/he was not entitled to receive any medical reports or information concerning the medical condition of the doctor which the GMC may have obtained, and was excluded from the hearing save for the purpose of giving evidence and hearing the HC's decision. In practice, complainants rarely, if ever, appeared.

22.131 The GMC's representative would then present the case and call witnesses to give oral evidence. The 1987 Health Rules introduced a provision enabling the doctor to request that the author of any document to be considered by the HC should be called as a witness. The complainant (if any) or his/her representative would be invited to address the HC. The doctor or his/her representative was then permitted to address the HC and to adduce evidence as to the doctor's fitness to practise. The GMC's representative would then be invited to address the HC, with the doctor or his/her representative having the last word.

Adjournment or Postponement

22.132 At the conclusion of the proceedings, the HC might adjourn the case in order to obtain further medical reports or other information as to the physical or mental condition of the doctor or in relation to his/her fitness to practise. If the HC did not think it appropriate to adjourn the case, it had to consider whether to postpone its finding as to the doctor's fitness to practise. The power to postpone its finding was introduced by the 1987 Health Rules. The purpose of this power was to enable the HC to place a doctor 'on probation' on the basis of undertakings given by the doctor to the HC, thus avoiding the need to impose formal conditions or to suspend registration. It does not seem that this power was ever exercised.

Sanctions

22.133 If the HC did not consider it appropriate to adjourn the case or to postpone its finding, it had to consider and determine whether the doctor's fitness to practise was seriously impaired by reason of his/her physical or mental condition. If the HC found no serious impairment of the doctor's fitness to practise, it had no power to take any further action. The 1987 Health Rules provided that, in reaching its judgement, the HC should be entitled to regard as a current serious impairment not only the doctor's current physical or mental condition but also a continuing and episodic condition, or a condition which, although currently in remission, might be expected to cause recurrence of serious impairment. In 2003, the HC found that there was no serious impairment of the doctor's fitness to practise in 17 out of 141 cases.

22.134 In a case where the doctor had refused a medical examination or had failed to submit to examination, the HC was entitled, if it thought fit, to find that his/her fitness to practise was seriously impaired on the basis of the information which was available to the HC, together with the doctor's refusal or failure to submit to examination.

22.135 If the HC judged that the doctor's fitness to practise was seriously impaired, it had next to consider and determine whether it was sufficient to direct that the doctor's registration

should be conditional upon his/her compliance with such requirements as the HC might think fit to impose either for the protection of members of the public or in the doctor's own interests. Such requirements would always include a condition that the doctor must accept medical supervision, and might also include limitations on the doctor's practice and conditions relating to medical treatment. The doctor's consent was required to any conditions relating to the medical management of his/her case. The HC was required to specify a period for which the conditional registration should last; the period could not exceed three years. If the HC decided that it was not sufficient to impose conditions on the doctor's registration, it was required to direct that his/her registration should be suspended for a period not exceeding 12 months. In an appropriate case, the HC could order that the suspension should take place immediately, rather than being delayed until the expiration of the appeal period, or, if an appeal was lodged, until determination of the appeal. The HC had no power to refer a doctor back into the voluntary health procedures.

The Decision of the Health Committee

22.136 Decisions of the HC were taken on the basis of a simple majority. If the votes were equal, the question at issue had to be determined in favour of the doctor concerned. The 1987 Health Rules provided that the Chairman should announce the determination or determinations of the HC **'in such terms as the Committee may approve'**. For many years, the HC gave no reasons for its decisions. More recently, the HC included in its decisions an indication of the condition that was seriously impairing the doctor's fitness to practise, together with an explanation for the sanction imposed.

Resumed Hearings

22.137 In a case where the HC had directed that the doctor's registration should be suspended or made subject to conditions, it was required, when announcing its decision, also to indicate that it would resume consideration of the case before the end of the period of suspension or conditional registration. In preparation for the resumed hearing, the HC would require a report from the doctor's medical supervisor and, possibly, from the treating doctor. The HC might also require the doctor to submit to further medical examination before the resumed hearing. The necessary arrangements for a resumed hearing were made by the GMC staff, acting under the instructions of the health screener. In the meantime, it was usual for the health screener to request interim reports from the doctor's medical supervisor, together with the results of testing. If the health screener received information that the doctor was failing to comply with the conditions previously imposed on his/her registration or that there was a reason for varying the conditions, s/he might refer the case for an early resumption of the hearing.

22.138 When the HC had suspended a doctor's registration, it could, at a resumed hearing, direct a further period of suspension not exceeding 12 months, to start immediately after the first period had expired. Alternatively, it could direct that the doctor's registration be subject to conditions from the expiry of the period of suspension. It could direct that the conditions should remain in place for a period not exceeding three years.

22.139 Where the HC had imposed conditions on a doctor's registration, it could, at a resumed hearing, direct that the period of conditional registration should be extended for a period

of not more than 12 months at a time. The HC also had power, at a resumed hearing, to vary or revoke any of the conditions imposed. If the HC judged that the doctor had failed to comply with any of the conditions, it might direct that his/her registration should be suspended for a period not exceeding 12 months.

Indefinite Suspension

22.140 Over the years after the inception of the health procedures, the number of doctors under the jurisdiction of the HC increased steadily. Some doctors suffered from chronic conditions and were unlikely to be fit to return to practice for many years, if ever. Until 1996, the only course open to the HC when dealing with such doctors was to suspend them for 12 months, to bring them back for a review of their case towards the end of the period of suspension and then to suspend them again. This created an unnecessarily heavy workload for the HC, was wasteful of resources and could be very stressful for the doctor concerned. The HC explored various possible strategies for eliminating this problem; it proposed a form of shortened hearing and the use of conditional registration in place of suspension. It also suggested that it should have the power to impose longer periods of suspension. In 1996, the problem was solved when the HC acquired the power to suspend a doctor indefinitely. This power could be exercised when the doctor had already been suspended for two years or more. The doctor could apply for review of a direction for indefinite suspension, but not before two years after the date on which it took effect and then not more than once in any period of two years. The power to impose indefinite suspension enabled the HC to conclude some of its most intractable cases. Between 1996 and 2003, about 50 doctors were suspended indefinitely.

Appeals

22.141 Appeals from decisions of the HC were governed by section 40 of the 1983 Act. Until April 2003, a doctor who was the subject of a direction for suspension or for conditional registration (or variation of the conditions imposed by a direction for conditional registration) had a right of appeal to the Judicial Committee of the Privy Council. From April 2003, appeals lay to the High Court. Until 2003, an appeal lay on a question of law only. In 2003, that restriction was removed.

The Operation of the Health Procedures

Integration of the Health Procedures with the Other Fitness to Practise Procedures

22.142 Mr Howes said that it was a relatively rare occurrence for a doctor who was being dealt with in the voluntary health procedures to be the subject of a subsequent report of potential misconduct. If such a report was received, his own 'instinct' would have been to look for a health element, related to the doctor's illness, which might have accounted for the alleged misconduct. If no such link had been apparent, he would have recommended conduct action. If there had appeared to be any linking factor, he said that he would have 'left it to the health and conduct screeners to fight it out as to which route the case ought to go down'. It was very rare for a doctor to have a health and conduct case progressing at the same time.

22.143 If a case was progressing through the performance procedures and health concerns arose that warranted referral into the health procedures, the performance action would be 'frozen'. Conversely, if a case gave rise to concerns about both health and performance, it would be assumed that the performance problems were health-related. There would not be a referral into the performance procedures. Once the doctor had regained his/her health, an attempt would be made to ease him/her back into practice after a programme of retraining organised by the local postgraduate dean but no performance assessment would be carried out.

Views about the Old Health Procedures

22.144 Dr Mann said that she certainly did not consider referral into the voluntary health procedures to be a 'soft option' compared with referral into the conduct procedures. The voluntary health procedures could last for years, even for the remainder of the doctor's professional life. The undertakings were often quite stringent, with considerable obligations on the doctor to adhere to them. She said that at the back of everyone's mind was the fact that, if the doctor did not adhere to the obligations under the voluntary procedures, then s/he could be referred to the HC which might lead to indefinite suspension.

22.145 Mr Howes emphasised that, at the time he worked in the Health Section, it did not appear to him that the voluntary health procedures were a 'soft option' when compared with the conduct procedures. He conceded that a doctor whose case was being dealt with under the voluntary health procedures was not at risk of erasure. However, he pointed out that, if a doctor was referred to the PCC, he might be admonished, judgement might be postponed or s/he might have his/her registration suspended for a short time. Even if his/her name were erased from the register, s/he might be restored 'a couple of years later' (this was at a time when the first application for restoration could be made ten months after erasure, so that even a doctor who made one unsuccessful application could still be restored on his/her second application within two years). By contrast, the HC had no power to admonish. Consequently, virtually every case where a serious impairment of fitness to practise was found resulted in the suspension of, or the imposition of conditions on, the doctor's registration. In most cases, the doctor would come back before the HC on one or two occasions and would be dealt with by way of further suspension or conditions. Indefinite suspension had also been available latterly. Mr Howes said that he thought the HC was 'quite a tough Committee now'. It had 'learnt to bite the bullet'. He observed:

> **'Even though it is comprised principally of doctors, they have learnt that they are not just treating a sick doctor, they are protecting the public and they grasped that fairly early on in the 1980s. It was a culture shock for a Committee of doctors but they grasped it fairly early on and learnt that it even helps the doctor to impose some sort of sanction in many cases.'**

22.146 Dr Mann identified as one of the strengths of the health procedures the fact that they had been acceptable to a large number of (although not all) doctors whose health was at one time or another called into question. She felt that the procedures provided a real incentive to remain abstinent from drink or drugs because of the implications of suspension on a

doctor's livelihood. She also felt the GMC had developed a good network of competent specialists to examine and supervise sick doctors. It was also achieving a quick turnaround of cases.

22.147 Dr Mann perceived the main weakness of the health procedures to be their separation from issues of performance. There was a need to monitor both simultaneously. She said that it would be nice to have some 'easy assessment' of a doctor's performance that could tie in with health and other issues. The GMC's full performance assessments, although detailed and helpful, took a long time and were cumbersome and expensive in terms of both money and doctors' time. She said that, if appraisal produced hard evidence about a doctor's performance following assessment, that might solve the problem. However, it seems to me that the problem will not be solved in that way, at least so far as GPs are concerned. At present, the appraisal of GPs does not include any form of assessment.

22.148 Mr Howes said that the rehabilitation of sick doctors was a problem. If a doctor had been compelled to give up work as a result of his/her illness (whether voluntarily or as a result of suspension), s/he might be 'rusty' by the time s/he was fit to return to work. Often, a doctor would wish to change specialties at that point and might need to learn new skills in order to do so. Mr Howes said that the GMC was very conscious of the problem and would have liked to have seen a system (perhaps a NHS system) whereby such doctors could receive 'refresher training' in their own specialty, or be retrained in a different specialty. As it was, the GMC would rely on the postgraduate deans to devise *ad hoc* refresher schemes for doctors who were re-entering the same specialty as previously. The position of a doctor who wished to change specialty was more difficult. Over the years, the GMC has encouraged initiatives such as the introduction of local liaison advisers to support doctors in their rehabilitation and the provision of supernumerary posts without clinical responsibility for the retraining and rehabilitation of doctors recovering from a period of illness. However, these schemes can only cater for a few and there are still serious problems in managing the rehabilitation of doctors who have been absent from work for some time and have become de-skilled as a result.

22.149 Dr Mann said that the solution to the problem of rehabilitation varied from case to case. It depended on which part of the country the doctor was in. If a doctor was off work for some time, efforts would be made to organise a training programme. A hospital doctor might be able to take up a supernumerary post while being assessed. However, such a post was not always available and, even if it was, the supervision and assessment might not be of good quality. The local postgraduate deans might be involved but they were 'under pressure'. It seems to me that the lack of any assessment to ensure that a doctor's clinical performance and competence were satisfactory before s/he was allowed to return to practice after a period of ill health was a real *lacuna* in the operation of the health procedures.

The Inquiry's Examination of Cases

22.150 As I have said, both Dr Mann and Mr Howes were of the view that the health procedures were working well, provided a proper degree of protection to patients and public and were not a 'soft option' for doctors. In order to test these views, the Inquiry considered a large

number of files of cases which had entered the health procedures. Some were discussed during Dr Mann's evidence. The Inquiry was, of course, interested in cases that bore some resemblance to that of Shipman in 1976. I particularly wished to explore the interaction of the conduct and health procedures in cases which involved elements of misconduct and ill health.

Cases Closed by the Health Screeners

22.151 The Inquiry considered sixteen cases which had been closed by Dr Mann between 2000 and 2003. None of those cases gave rise to any concern that a case had been closed without proper regard being paid to the need for public protection. I wish to mention only one case, that of Dr KI 01, because it illustrates the way in which conduct issues were often dealt with and demonstrates the potential unfairness to doctors which could arise through the operation of the procedures.

Dr KI 01

22.152 Dr KI 01 was a surgeon. On one occasion, he attended for work whilst under the influence of alcohol. He began to conduct an operation and it was soon apparent to the nursing staff that he was having difficulty in using the necessary tools and equipment. The nursing staff called for help but, before this arrived, the doctor had fallen onto an instrument trolley. He was removed from the theatre. The hospital trust instituted disciplinary hearings. The doctor did not dispute the allegation that he had been under the influence of drink. It was accepted that he had been under considerable stress both at home and at work. He had taken drink on this one occasion to help him to cope with stress. It appears that he did not have a chronic drink problem. He was given a final written warning and was allowed to return to work under closely supervised arrangements.

22.153 The trust also reported the case to the GMC. The case was perceived by the GMC to be a health rather than a conduct case and was referred to Dr Mann. There was contact between the GMC and the Medical Director of the hospital trust. The Medical Director did not wish the GMC to become involved. He considered that the trust had the situation well under control. Dr Mann was impressed by the measures being taken locally. She formed the view that the situation was indeed under control and that there were no patient protection reasons to institute the health procedures. She decided to close the case. When she was asked at the Inquiry hearings why she had not referred the case to the medical screener for consideration of the conduct issues, Dr Mann could not remember. That is not surprising, as she deals with many cases, but it does underline the wisdom of recording reasons for decisions at the time they are taken. At the Inquiry hearings, there was some discussion of why she might have decided not to refer the case to the medical screener. One possibility was that the doctor had already received a final written warning in the context of his employment and Dr Mann might have thought that there was little point in him being given another warning by the PPC or PCC. In any event, the result of Dr Mann's decision was that the doctor avoided any disciplinary action by the GMC and escaped the possibility of a FTP record. If the case had been referred into the conduct procedures, the screener must surely have referred it to the PPC. Whether the PPC would

have referred the case to the PCC or have closed the case with a warning letter or a letter of advice, I cannot say.

Comment

22.154 The point I want to make is that how a case is dealt with at the GMC is largely a matter of chance. If the case had been reported, not by the hospital trust, but by the patient who had found out what had happened, the case would almost certainly have been perceived initially as a conduct case. The medical screener might have consulted with Dr Mann as to whether a health issue arose. If Dr Mann had then arranged a medical examination or had consulted with the hospital trust, she would presumably have formed the view, as in fact she did, that there was no reason to institute health procedures. The case would have proceeded as a conduct issue and should, given its seriousness, have gone to the PPC. They might have issued a warning or they might have referred the case to the PCC. In that event, it seems likely that some sanction would have been imposed, probably a warning. The doctor would have had a FTP record. The potential for differences of treatment that depend not on the facts of the case, but upon matters of chance, is a cause for concern. Moreover, the recording of a warning, as a FTP history, may be important for patient protection. If a similar incident were to occur in future, it ought to be considered against the background of the first one.

Cases Handled within the Voluntary Procedures

Dr JB 08

22.155 The case of Dr JB 08 well illustrates the way in which, until the late 1990s, the health screeners were sometimes reluctant to refer cases to the HC notwithstanding repeated, serious breaches of undertakings. In the early 1980s, the doctor, a GP, was convicted of obtaining palfium tablets by deception and of unlawful possession of that drug. A large number of offences were taken into consideration by the court and it was apparent that the doctor had been taking these tablets himself over a substantial period of time. The case was considered by the PPC, which adjourned the case for 12 months on the first occasion, then adjourned for a further four months for medical reports. When received, the reports disclosed that the doctor was no longer dependent on palfium. The PPC then closed the case with a warning. I pause to observe that the facts of this case were similar to those of Shipman's case. Although the health procedures were already in operation at this time, Dr JB 08 was not referred into them; his case was dealt in the same way as Shipman's had been in 1976.

22.156 About three years later, the GMC received information from a PCO that suggested that the doctor might be suffering from mental illness and drug-related problems. It appears that he had recently given up practice. Nine months later, the GMC invited the doctor to undergo medical examination. Two reports were obtained from different medical examiners. They were delivered nearly a year apart in time. Both said that the doctor was unfit to practise owing to his abuse of alcohol and drugs. Just under two years after the PCO report, the doctor agreed to give undertakings. He was to place himself under supervision, to refrain from any form of medical practice and to abstain absolutely from

alcohol and self-medication. Six months later, the first report from the medical supervisor was discouraging. The doctor was drinking alcohol and had been issuing prescriptions for tranquillisers, ostensibly for his cohabitee, but the supervisor thought that the doctor was taking at least some of them himself. It was clear that there were multiple breaches of the undertakings. The doctor was advised that he was to remain under supervision and would not be referred to the HC at that stage. The medical supervisor's next report concluded that the doctor was complying with his undertakings but was unfit to practise on account of grossly impaired psychological functioning. Six months later, the supervisor reported that the doctor was drinking alcohol. Also, the doctor had been taking benzodiazepines prescribed by his GP as well as those prescribed by the medical supervisor; he had deceived his GP into prescribing them. Again, the health screener did not refer the case to the HC. There followed a further period of six years during which all save two of the supervisor's reports showed that the doctor was continuing to breach his undertakings. Eventually, nearly ten years after the doctor's problems had been reported by the PCO, the case was referred to the HC. The HC suspended him from practice and renewed the suspensions periodically until a few years ago, when it suspended him indefinitely.

Comment

22.157 I accept that there was no evidence that this doctor breached his undertaking not to practise medicine. Thus, there was no evidence that he was a risk to patients. However, it does appear to me that the health screener was very tolerant of the doctor's repeated breaches. In my view, it would have been better if the doctor had been referred to the HC several years before he was. First, for his own sake, if he had been suspended, he would not have been able to prescribe drugs and one form of temptation would have been removed. Second, it seems to me that the GMC must not lose sight of its role as regulator. There is a danger that it will assume the role of treating doctor at one remove. Of course, as the Merrison Committee recognised, when recommending the institution of the health procedures, that the GMC must have humane ways of dealing with sick doctors. However, the GMC must find the right balance between the need for humanity and the proper role of a regulatory body. I can see that it may be difficult to do so.

Dr JE 02

22.158 The case of Dr JE 02 illustrates many of the difficulties which can be experienced by the GMC in operating the voluntary health procedures and highlights some of the shortcomings of those procedures.

22.159 Dr JE 02's difficulties began in the early 1990s when he took to using controlled drugs, ostensibly to relieve stress, while working as a GP. He told his partners about this; they adjusted his workload and all appeared well. However, about two years later, one of his partners noticed that the doctor had been making a large number of entries in the practice's controlled drugs register. The doctor denied that he had relapsed into drug taking but the partners were sufficiently concerned to report him to the GMC.

22.160 The complaint was passed to the health screener. The caseworker's memorandum referred to the doctor's denial of drug misuse and to the absence of any direct evidence

of it. However, it appears that the health screener was suspicious and asked the doctor to submit to medical examination. The doctor agreed and the GMC obtained reports from two medical examiners. The first examiner found it difficult to reach a conclusion about recent drug abuse because of the lack of clear evidence. He observed, **'the evidence favouring the view that he was resorting to opiates again ... is quite compelling'**. The examiner noted that the doctor's usage of opiates, ostensibly for professional purposes, was ten times that of his partners. He concluded that Dr JE 02 probably had been abusing opiates and expressed the view that any misuse was not the product of, or associated with, any formal mental disorder. The examiner advised that the doctor was fit to practise subject to restrictions. The second examiner noted that there was little evidence of drug taking and that the urine tests were negative. He advised that the doctor was fit to practise without restrictions.

22.161 Thus, there was no agreement between the examiners as to whether Dr JE 02 had reverted to abusing opiates. When asked whether this issue should have been determined before it was decided how to proceed, Dr Mann expressed the view that she did not think that that would have achieved much. The evidence was uncertain, but the point was that there were real grounds for suspicion that the doctor had been abusing drugs. Therefore, the GMC would take the view that restrictions should be placed on the doctor for the protection of patients even though the facts had not been established. As I observed in the case of Dr JO 04, which I discussed in Chapter 20, there were occasions when, despite the fact that it had not been established that they were dependent upon, or addicted to, drugs, doctors were dealt with under the voluntary health procedures. I can see that such an approach might be justified on the grounds of patient protection, although it seems to me that it could cause problems in the future. Dr Mann was asked what, in a case such as this, would have happened if the doctor, after initially agreeing to voluntary undertakings, had refused to abide by them. She said that she thought that the giving of undertakings would be taken as a tacit acceptance that the doctor had a drug problem. However, if the case had been referred to the HC for breach of the doctor's undertakings, the HC would have had to decide whether there was a serious impairment of fitness to practise by reason of a physical or mental condition. It seems to me very doubtful that a 'tacit acceptance' would have been sufficient to establish such an impairment. Also, if, at some later stage, the doctor had again been reported to the GMC, it would have been open to him to say that it had never previously been established that he had abused drugs, or that he had suffered from a serious impairment of fitness to practise by reason of ill health.

22.162 In the event, the health screener asked Dr JE 02 to give voluntary undertakings, including undertakings (i) to refrain from all self-medication (ii) to comply fully with the controlled drugs regulations and (iii) not to engage in single-handed general practice. Noticeably absent was any restriction in relation to the doctor's prescribing rights. Dr Mann explained to the Inquiry that, at the time when these undertakings were devised, there was some reluctance to divulge information about undertakings to the doctor's colleagues. If a restriction had been placed on his prescribing rights, any doctor with whom he entered into partnership would have had to be told. She said that, at that time, to break a doctor's confidentiality in this regard was a heinous crime. Patient protection had assumed a higher profile in more recent times.

22.163 The doctor agreed to provide the undertakings and a medical supervisor was appointed and supplied his first report six months later. The supervisor referred to the fact that Dr JE 02 had recently started work in a new GP practice and that the new partner knew nothing of the doctor's previous health problems. In giving her evidence to the Inquiry, Dr Mann conceded that hiding the restrictions on the doctor's practice from those who needed to know was a 'foolish way' of conducting supervision. With regard to the current position, Dr Mann said that a doctor would be expected to inform his/her partners of voluntary undertakings that s/he had given.

22.164 Not long after giving his undertakings, the doctor moved to a different locality. This made contact with the medical supervisor difficult and the health screener expressed concern about the infrequency of reports. Eventually, the supervisor suggested the appointment of a different supervisor nearer to the doctor's place of work. Dr Mann made the point that too great a distance between medical supervisor and doctor lessened the chance of effective supervision. So, of course – as it seems to me – will frequent changes in supervisor. In this case, over the years, Dr JE 02 had no fewer than five supervisors; the changes occurred for various reasons. Dr Mann pointed out that this loss of continuity of care was a particular problem if the doctor was a locum and had no settled place of work.

22.165 Subsequently, the partner at Dr JE 02's new practice wrote to the GMC, stating that the doctor had been ordering large quantities of diamorphine and had admitted to self-administering diamorphine and pethidine. The partner considered Dr JE 02 to be unfit to practise. Thus, at this stage, the doctor was in breach of his undertakings. This was not even pointed out to him when the GMC wrote to him about his relapse. Dr Mann was unable to explain this, since she was not the health screener at the time. However, she said that, at that time, referral to the HC was not often considered. Since she had been a health screener, it had been her practice not to refer a doctor to the HC for a single breach of an undertaking although if there was evidence of repeated breaches or of real deceit, she would do so. She added that, once a case was in the health procedures, there was no mechanism for referring it into the conduct procedures. The only way in which a doctor could get back into the conduct procedures was if another allegation of misconduct or a conviction was reported.

22.166 In the light of the doctor's relapse, the health screener decided to appoint a specialist in drug addiction as medical supervisor. Dr Mann explained that this is now usual practice. The health screener also required the doctor to undertake to refrain from medical practice until permission to resume was given. The new supervisor's first report stated that Dr JE 02 had admitted to opiate misuse for about four years and to the misappropriation of drugs from the GP practices at which he had worked. However, he claimed that he was now drug-free. The supervisor advised that Dr JE 02 was fit to practise, provided that he remained drug-free; the supervisor recommended the imposition of restrictions, namely that the doctor should not work in general practice or prescribe Schedule 2 drugs. Dr JE 02 later gave undertakings to that effect.

22.167 The supervisor's next report was received over a year later. It reported that the doctor had received voluntary residential treatment for his drug problem. He was preparing for a new career in occupational health. A urine test had been positive for benzodiazepines but

negative for opiates. The taking of benzodiazepines constituted another breach of the doctor's undertakings, although possibly not a serious one. Five months later, the supervisor reported that the doctor had told him that the urine test had been positive because he had taken a single temazepam tablet to help him sleep the previous night. The supervisor wished to be released for geographical reasons.

22.168 Some months later, a new supervisor was appointed. He reported that the doctor was working in occupational medicine. There had been some suspicion that he had stolen a Cyclimorph tablet from a GP but this was denied. Supervision was to continue. The following year, the supervisor's report was most promising. There had been full co-operation and excellent progress. The doctor was still working in occupational health. By this time, Dr Mann had become a health screener. She agreed to continue supervision with an additional requirement that the GMC should be able to disclose the existence of practice restrictions to any enquirer. Dr Mann explained that she had been keen to introduce this undertaking into all cases being dealt with in the voluntary health procedures.

22.169 Over a year elapsed before the medical supervisor submitted his next report. Dr Mann commented that the practice of allowing 12 months to elapse between reports has now stopped and the normal frequency is six months. The supervisor reported that Dr JE 02 was still making excellent progress and was fully complying with his supervision and undertakings. Drug testing was again negative. The supervisor advised relaxing the undertakings to allow Dr JE 02 to undertake locum posts. Dr Mann agreed.

22.170 A year later, the report was, once more, wholly favourable. The supervisor advised that the doctor was fit to practise and recommended that supervision should cease. After noting that the doctor had been drug-free for over two years and that there had been no problems when his undertakings had been relaxed, Dr Mann decided that supervision could end.

22.171 Unfortunately, however, Dr JE 02 suffered a relapse almost immediately afterwards. The former supervisor notified the GMC that Dr JE 02 had been misusing opiates and had been dismissed from his employment. The supervisor had taken the doctor back into care for out-patient assessment and possible treatment. A hair analysis was positive for both pethidine and dihydrocodeine. As the doctor was not subject to undertakings at that time, he was not in breach of any conditions on his registration. Dr Mann said that she was disappointed to learn of the doctor's relapse. It appeared that he was able to resist substance misuse when external controls were in place but not otherwise. This was not uncommon, although the very short time interval in this case was unusual in Dr Mann's experience. She noted that the doctor had been prescribed pethidine following surgery the previous year and thought that this might have been a factor in his relapse.

22.172 Medical examinations were arranged. However, before the reports were available, further evidence came to light about the extent of the doctor's relapse. He had received a police caution for non-compliance with controlled drugs regulations. Also, the GMC received a copy of a report by the doctor's treating psychiatrist. This advised that the doctor was co-operating with treatment, but would need indefinite supervision. The doctor was fit to practise, but should be prevented from writing prescriptions. After receipt of the two medical examiners' reports, Dr Mann considered that the doctor was extremely vulnerable

to further relapse, his prescribing rights should be restricted and he should be placed under medical supervision for the remainder of his working life.

22.173 The doctor gave voluntary undertakings and was placed under supervision. The first report from the medical supervisor was satisfactory. The second showed such good progress that the supervisor recommended that conditions and supervision should cease, save for informal voluntary contact. Dr Mann did not agree to this, in the light of the previous history. The most recent report showed that progress had been maintained. Again, it was suggested that supervision should cease. Again, Dr Mann had directed that it must continue. She told the Inquiry that she was doubtful that it would ever be possible to cease supervision in this case.

Comment

22.174 The case, which spans a period of ten years, illustrates some of the improvements that were made in the operation of the health procedures during that time. In the recent past, reports were obtained more frequently; more information was given to colleagues and employers and the health screeners were less tolerant than they had been of breaches of undertakings. There remained great emphasis on the rehabilitation of the doctor, but the protection of patients seemed to be given greater prominence.

22.175 The case also illustrates how the voluntary procedures can assist in keeping a doctor 'on the rails'. The procedures provide support, but are backed by the threat of suspension if the doctor lapses or fails to co-operate. However, Dr Mann expressed the view that local management would be preferable for doctors who require long-term supervision and support. I agree with her. I do not think that the provision of long-term support is wholly appropriate for a regulator. I think that the GMC should seek to divest itself of this function, which should be taken over by local PCOs or employers. A PCO can impose conditions on a doctor's practice and can provide a package of support and supervision. Provided that it is clear to the doctor that the package has the approval of the GMC and that failure to co-operate will result in a referral straight to the GMC's HC, the local procedures should not be any less effective than the GMC's voluntary procedures.

22.176 I realise, however, that if the doctor were peripatetic, the GMC would have to retain responsibility. In one of the cases examined by the Inquiry, that of Dr JK 03, the doctor was under supervision for nearly six years. During that time, he moved from hospital to hospital on three or four occasions. Continuity of supervision was difficult, even for the GMC, but it would have been almost impossible for a local NHS trust.

Dr JO 01

22.177 The case of Dr JO 01 was of interest to the Inquiry as it illustrates the way in which a local organisation can work effectively in concert with the GMC. The doctor, a GP, had admitted to his partners that he had been abusing alcohol and drugs for a period of 10 to 15 years. The Chief Executive of the PCT attended a meeting at the doctor's practice and then investigated the extent of the problem by visiting practices at which the doctor had worked in the past. It appeared that the doctor had used prescriptions fraudulently to obtain his

supplies of drugs. Also, there had been concern about his performance in both his present and previous practices. There were reports that, at times, he was 'vague and disconnected', he fell asleep during consultations, he wrote medical reports that did not make sense, he occasionally prescribed inappropriately and he sometimes spoke inappropriately to patients. The PCT retained the services of a consultant who specialised in addiction and who was also an approved GMC medical supervisor. With his help, a set of undertakings was agreed with the doctor. The undertakings were very similar to those that the GMC would have imposed in its voluntary procedures and included regular medical supervision.

22.178 Despite having set up this package of measures, the PCT reported the matter to the GMC. The case was referred to the health screener with a memorandum which pointed out that the local measures appeared to be **'very robust'**. He or she suggested that, as the undertakings already in place were virtually identical to those which would be required by the GMC, it might not be necessary for the GMC to take action. However, the PCT became aware that the caseworker had expressed that view and they made plain that they wanted 'GMC back-up' as well. The screener agreed to accept the case into the voluntary health procedures despite the fact that it appeared that the local measures were appropriate. The GMC wrote to inform the doctor of this and advised him that he would be written to separately in respect of his apparently fraudulent use of prescriptions. In fact, no conduct proceedings ensued.

22.179 The GMC instructed two of its approved medical examiners to examine the doctor. They reached substantially the same conclusions as had the PCT's consultant and recommended very similar measures. The doctor agreed to undertakings drafted by the health screener. These continued in force and were likely to do so for a considerable time. It seems to me that the PCT had done a very good job in respect of this doctor. However, I can well understand why it wished to have the 'back-up' of the GMC. The threat of suspension by the HC must be a real incentive to compliance. It seems to me that, in a case where reports have been submitted by an employer or PCO and appear to have come from examiners who are independent of the doctor concerned, it would be reasonable for the GMC to rely on the reports and to formulate undertakings for the doctor to agree on the basis of their contents. What should, in my view, be avoided is reliance on reports commissioned by or on behalf of the doctor.

Dr JO 02

22.180 The case of Dr JO 02 is of interest to the Inquiry because it involved allegations of quite serious misconduct coupled with concerns about the doctor's dependence on drugs. It shows that, even in recent years, the GMC tended to focus upon the rehabilitation of the doctor and to assume that any misconduct was merely part of the drug problem and that there would be no recurrence once the doctor had been cured of his/her dependence.

22.181 The GMC received a report that the doctor had been cautioned by the police for being in unlawful possession of heroin and cannabis. The amounts were not large. The doctor subsequently admitted himself to a private nursing home where he underwent 'detoxification'. Three months later, and before the GMC had taken any decision as to how

the report of the caution was to be handled, the GMC received a letter from the woman with whom the doctor had lived for about eight years. She alleged that the doctor had been abusing hard drugs for a considerable time and had often been to work, in various hospitals (which she named), while under the influence of cocaine, crack cocaine and heroin. She expressed surprise that the doctor's colleagues had not apparently noticed the signs of drug taking and wondered whether in fact they had noticed but had been unwilling to make any report. She also alleged that, although the doctor had recently undergone treatment, he had not given up drug taking; in fact, she said, he had taken crack cocaine on the very day he had left the nursing home. She said that he was now living with another doctor who was also under investigation by the GMC for similar addiction problems and for allegedly stealing drugs from hospitals. She also alleged that the doctor had been driving a motor car while under the influence of drugs and that she had witnessed many incidents of reckless or aggressive driving. She said that the doctor had been banned from driving for a time.

22.182 If these allegations were substantially true, it seems to me that the doctor might well have been guilty of SPM; he would have been attending work while under the influence of drugs. He would have been putting patients at risk. However, no one ever found out whether these allegations were true. The caseworker in the conduct section contacted Dr Mann to see whether the latter thought that the case should be referred into the health procedures. The caseworker was of the view that the caution alone might reach the SPM threshold. However, she thought that that misconduct might be considered as secondary to the doctor's dependency problem. Admission to the health procedures might be appropriate. Dr Mann thought that the case should be dealt with as a health matter. She considered that the letter from the doctor's former partner should be **'viewed with circumspection'**. In her experience, former wives and partners often made false allegations after the breakdown of the relationship. In the event, the letter from the former partner was completely ignored. No attempt was made to find out whether there was any truth in it, despite the fact that some of the allegations could easily have been checked. In fact, there might have been some truth in the former partner's tale because later, when medically examined, the doctor admitted that he had been abusing cocaine for seven years and heroin for one. Presumably, he had been working in various hospitals, as the former partner alleged, during that time.

22.183 In the event, the case was transferred into the voluntary health procedures. The doctor gave undertakings as required by Dr Mann and, at the time of the most recent report before she gave evidence, appeared to be doing well. He was about to begin vocational training with a view to becoming a GP. He remained under supervision. Dr Mann regarded his progress within the voluntary health procedures as indicative of success.

22.184 When Dr Mann was giving evidence before the Inquiry, Leading Counsel to the Inquiry asked her what steps had been taken by the GMC to find out whether any concerns had been expressed about the doctor and his performance at the hospitals at which he had worked. She replied that that was not a matter for her; her role had been to advise whether the health procedures were appropriate. I accept that that is so. She also said that medical examiners instructed by the GMC were expected to make enquiries about performance from people who had provided information to the GMC. She expressed surprise that no

concerns appeared to have been reported about this doctor. She agreed that, if a hospital was concerned about the behaviour or performance of a locum, it might just not employ him/her again in the future, rather than investigate itself or initiate a report to the GMC. It seems to me quite clear that the answer to Counsel's question was that no enquiries had been made about the doctor's performance. That is apparent from the GMC file and from the medical examiners' reports, which focus wholly on the doctor, his feelings about life and medical practice and his 'dysfunctional relationship' with his former partner. Dr Mann acknowledged that the GMC had perhaps not been as diligent as it might have been in collecting the relevant information.

Comment

22.185 It is not for me to judge whether the former partner's letter was untruthful or even exaggerated. However, it does seem to me that the GMC failed to take any reasonable steps to investigate the quite serious allegations of misconduct, which clearly had implications for patient safety. I accept entirely that supervision within the health procedures provides a safeguard for patients. However, the GMC must not be surprised that the public does not have confidence in it if it sweeps aside allegations such as those made in this case without making any attempt to discover the truth.

Dr JO 07

22.186 This case was of interest to the Inquiry because the circumstances were quite similar to those of Shipman's case in 1976. Dr JO 07's addiction to drugs and her criminal conduct came to light a few years ago when a pharmacist noticed that the doctor had presented two private prescriptions for diamorphine within the same week. The police were informed and it was found that the doctor had stolen diamorphine from the hospital where she worked and had also obtained the drug by deception by the fraudulent use of prescriptions. She was prosecuted, apparently in respect of drugs obtained over a period of about a month. Thus, her conduct was not unlike that of Shipman, although his was known to have persisted for much longer than did hers. Also, the doctor reported her forthcoming court appearance to the GMC quite voluntarily. The Magistrates imposed a community punishment order and directed that the doctor should pay compensation.

22.187 At the GMC, the case was referred to the IOC. In preparation for the hearing, the doctor's solicitors (instructed by her medical defence organisation) presented two psychiatric reports. These expressed the view that the doctor had begun using diamorphine while suffering from depression. There was no long history of substance abuse. The doctor was fit to practise, provided that she received psychiatric supervision and support. The IOC in effect accepted these reports and imposed conditions on the doctor's registration for a period of 18 months. These comprised a requirement to submit to psychiatric supervision, to work only in supervised posts approved by her postgraduate dean and to notify all potential employers of the conditions under which she was practising. Six months later, the IOC reviewed the case and continued the restrictions. Soon afterwards, the doctor was advised that her case had been referred to the PPC. Her solicitors wrote to the GMC, asking that she should be dealt with through the health procedures and, when the case

came up for consideration by the PPC, it adjourned it for consideration under the voluntary health procedures. A month later, the doctor was advised that her case would be dealt with under the voluntary health procedures. She had not been and, so far as I can see, never was examined by a medical examiner instructed by the GMC. She was invited to give undertakings to accept medical supervision, to confine her practice to posts approved by her postgraduate dean and not to prescribe drugs listed in Schedules 1 to 3 of the Misuse of Drugs Regulations 2001.The doctor gave the undertakings, the IOC order was revoked and, presumably, the conduct proceedings were closed. The medical supervisor's first report, which was provided within three months, was wholly favourable. It was then just over a year since the doctor's conviction. The second report, received six months later, suggested that the doctor could now practise without restriction. However, the health screener decided to maintain supervision for a further six months to monitor continued progress. That was the position at the time when the Inquiry obtained the file in 2003. It was clear that, if the next report were satisfactory, the doctor would be allowed to practise without restriction. That would be just over two years after her conviction.

Comment

22.188 This case is so similar to that of Shipman that it appears likely that the way in which it was handled is indicative of the way in which Shipman's would have been treated if it had been reported in the recent past. The health procedures appear to have operated well. I note, however, that the PPC referred this case into the health procedures on the basis of reports submitted by the doctor's medical defence organisation. Although this was permissible under the Rules, it was not an ideal way of proceeding. It will usually be preferable to obtain reports from the GMC's own approved examiners, in order to ensure independence, rather than to accept reports commissioned by or on behalf of the doctor.

The Future of the Health Procedures

The General Medical Council's Internal Arrangements

22.189 At the time when she gave evidence to the Inquiry, Dr Mann was expecting to cease acting as a health screener within a few months. She said that she, her fellow health screener Dr Wilson and other colleagues in the GMC were concerned that the expertise that she and Dr Wilson had acquired could be lost. In the past, there had been continuity of health screeners, with the more junior screener learning from the senior screener and then taking over when the senior screener left. At the time Dr Mann gave evidence, the GMC was still attempting to recruit a consultant psychiatrist as a case examiner who would assume responsibility for health cases. However, it had not been successful in doing so and Dr Mann was concerned that there would not be an adequate period of overlap between the existing health screeners and the case examiner who, as she expected at that time, was to assume their role. Another problem was that many of the caseworkers who had experience of the health procedures had left in anticipation of a removal of the Health Section to the GMC's new Manchester office. Dr Mann said that she and Dr Wilson were 'very keen' to make sure that the procedures which seemed to be 'running more smoothly now than they were some years ago' were not 'cast back'.

22.190 I share Dr Mann's concerns. In my view, she and her colleague have reason to be proud of the work they have done in the health procedures in recent years. I think that it would be a tragedy if the expertise which Dr Mann, Dr Wilson and their team of staff built up were to be lost. However, I have other concerns about the future. It now appears that the role of the health screener is not to be transferred to a case examiner at all. It appears that that role will, to a large extent, be assumed by members of the GMC staff. Such staff members would not, as I understand it, be medically qualified. They would certainly not be psychiatrists of good standing and long experience as the health screeners have generally been.

Conclusions

22.191 As I have indicated, in my view, the GMC has cause to be proud of the way in which the health procedures have operated in recent years. One of the reasons that they are as good as they are is that, in the late 1990s, the GMC invited an independent evaluation of the procedures as they were then operating and improved their procedures in the light of that evaluation. This evaluation, and the GMC's response to it – for which, in my view, it is to be congratulated – demonstrates the value of an independent professional view. Careful examination of 40 sample cases demonstrated the problems that beset the health procedures at that time and allowed them to be corrected.

22.192 Another reason for the success of the procedures has been the expertise of the health screeners. They and their staff have been a small but stable group which has been able to develop consistency of practice and decision-making. I shall return in Chapter 25 to consider the way in which the health procedures will operate in future. However, I must say now that, if the expertise and experience of the team which was in place in late 2003 has been lost, it will take a long time to replace.

22.193 Having said that, it seems to me that there were a number of remaining weaknesses within the health procedures as operated up to 2004. First, the practice of referring a case of alleged drug abuse into the voluntary health procedures without the facts of the matter having been established was not satisfactory. It might have been convenient and it might have appeared to provide protection for patients in a case in which there was a risk that the PCC might find that the doctor was not guilty of the misconduct alleged. However, it led to a fudging of the issues. Establishing the true facts was necessary for several reasons. If the doctor entered voluntary health procedures without the facts having been established, it might have been impossible for the HC to act if the doctor breached his/her undertakings or if, following a relaxation of the conditions, the doctor then suffered a relapse. I shall say more about the need to establish a factual basis before dealing with a doctor within the voluntary health procedures in Chapter 23.

22.194 There has until now been very little investigation of the extent to which a health problem of whatever kind has affected the doctor's clinical practice and might do so in the future. Such information is vital if the conditions imposed on the doctor are to be accurately tailored to the risks they have to cover. Investigations of this kind might involve quite a lot of delving, especially if the doctor is a locum or has moved from post to post. At the Inquiry seminars, there was discussion about the provision of a central database which would,

when it had been in operation for a few years, provide useful information about doctors' *curricula vitae*. Such a database would be very useful for enquiries of this nature. In the past, such enquiries as have been made have been left to medical examiners. It does not seem to me to be an appropriate function for them. They may not consider it to be appropriate to delve into the doctor's past. In any event, they are likely to have limited resources.

22.195 There has been a lack of standards and criteria for deciding whether the doctor is suffering from a serious impairment of fitness to practise by reason of a physical or mental condition. Since such decisions have been taken mainly by one or other of the two very experienced health screeners, there does not appear to have been any great problem of inconsistency in the past. However, members of the HC would not have the same degree of experience as the health screeners. In any event, achieving consistency is not the only reason why there should be standards and criteria. They are also required in order to provide transparency. It ought to be possible to test the decision against a set of objective criteria so that its reasonableness can be demonstrated. If, under the new FTP procedures, decisions about whether fitness to practise is impaired by reason of adverse health are likely to be taken by a large number of panellists, case examiners and staff members, clear criteria will be urgently required.

22.196 It seems to me that, in recent years, the arrangements for medical supervision were satisfactory. However, the arrangements for professional supervision were less good. For a doctor who is allowed to practise subject to conditions, a professional supervisor is essential. He or she should be in frequent contact with the doctor concerned and should also have direct contact with the GMC decision-maker. In the past, contact has been indirect, through the medical supervisor. I think that the GMC decision-maker needs to have a good 'handle' on how the doctor is coping at work and how colleagues feel about working with him/her. Professional supervisors should have their role explained to them, as medical supervisors do.

22.197 The inability under the old procedures to consider performance at the same time as health problems was a difficulty but that should now be resolved under the new procedures. There will be some cases in which an assessment of both performance and health will be required before any decision is taken. The resource implications of such assessments are significant. At the moment, performance assessments are slow and expensive. There is a need for a quicker and less expensive assessment process. I wondered whether something along the lines of the NCAA assessment might be sufficient, at least to establish whether a problem exists. I can see that something more thorough might be required if evidence is to be put before a FTP panel to back up an allegation that there is sufficient impairment of fitness to practise to justify action on registration. I also think that a simple form of assessment should be developed for use when a doctor is about to return to practice after a period of suspension or restricted practice. The GMC has facilities for administering Professional and Linguistic Assessment Board (PLAB) tests. I wonder whether those facilities could be used for assessments of this kind.

22.198 For many years, the information provided to PCTs and to the partners of GPs involved with the health procedures was very limited. In recent years, the position has improved to some

extent in that at least they are now told that the GMC is involved. However, the amount of information is still quite meagre. It seems to me that, if a doctor is to be allowed to practice notwithstanding that s/he has a problem (such as a drink or drug problem), it should be on condition that the doctor's partners and PCT are given all the essential information; at the very least they must be told the diagnosis, the prognosis and the recommendations of the medical examiner. Partners are responsible for the practice's patients and PCTs have clinical governance responsibility for the quality of care provided by the practice. It is not satisfactory for them to be dependent upon what information the doctor him/herself is prepared to divulge or what the medical supervisor is prepared to tell them.

22.199 For the future, the good management of doctors under supervision in the health procedures is essential. In the recent past, the procedures worked well, with health screeners and staff having their own roles. The system of referring doctors to the HC if they breached their undertakings was working well. I am concerned that the changed arrangements under the new procedures will create a risk that the standards established in the last few years might not be maintained. I urge the GMC to think again about the decision to use staff, rather than case examiners, for much of the management of doctors under health supervision.

22.200 One problem at least should be resolved as soon as the new procedures are in operation. Under the old procedures, when a doctor was convicted of criminal offences associated with a health problem, the GMC did not in general mark the serious nature of the conviction in the context of medical practice. Instead it dealt with such cases on a purely rehabilitative basis, by giving the doctor the benefit of the chance to rehabilitate under the voluntary health procedures. Convictions for drug abuse, for example, could have been sent to the PCC but, were in fact invariably referred into the voluntary health procedures. Thus, the public did not know what the GMC was doing about the doctor. This was not so much a weakness of the health procedures as a weakness in the way the GMC chose to deal with a certain type of case. Under the new procedures, most conviction cases should be referred to a FTP panel. There will be a public hearing and, if the doctor later has conditions imposed on his/her registration or is referred into the voluntary health procedures, at least the public will know that that has been done.

CHAPTER TWENTY THREE

How the General Medical Council Deals with Cases of Drug Abuse

Introduction

23.1 In Chapter 16, I described how the General Medical Council (GMC) dealt with the report it received of Shipman's convictions in February 1976. Those convictions were for a series of offences of unlawful possession of pethidine, dishonestly obtaining pethidine and forgery of prescriptions for pethidine. He had been dishonestly obtaining large quantities of pethidine in Todmorden for a period of about 18 months before he was eventually detected. He claimed that he had obtained the drug to satisfy his own habit and, having considered all the evidence, I am satisfied that that was indeed the case. When the convictions were reported to the GMC, the Penal Cases Committee (PeCC) decided to close the case with a warning to Shipman not to repeat his previous misconduct.

23.2 Following Shipman's convictions for murder in January 2000, there was considerable public disquiet when it became known that he had previously been convicted of controlled drugs offences. A number of the relatives of his victims expressed the view that a doctor who has misused controlled drugs, as Shipman had, should never again be allowed to practise medicine, at least not without appropriate monitoring and supervision.

23.3 In the light of the public disquiet expressed about the way in which the GMC permitted Shipman to continue in practice following his conviction, I wanted to examine how the GMC had handled cases similar to his over the past 30 years. My discussion will be confined to cases where a doctor has misused controlled drugs by consuming them him/herself. I shall not deal with the situation where the doctor has prescribed irresponsibly for patients or non-patients or has otherwise been involved in the supply of drugs to others. Quite different considerations apply to that sort of case.

23.4 In Chapter 16, I concluded that the PeCC's approach to Shipman's case was typical of its approach to similar cases at that time. The GMC took what amounted to a rehabilitative approach to such cases although the health procedures were not then in place. I described the health procedures, which came into effect in 1980, in Chapter 22. The evidence received by the Inquiry suggests that, since 1980, virtually all cases involving the misuse of controlled drugs have been dealt with through those procedures. Dr Sheila Mann, a health screener from 1998 until 2004, told the Inquiry in December 2003 that, if Shipman's case had come to the GMC then, he would almost certainly have been referred into the voluntary health procedures. However, the Inquiry became aware of evidence that suggests that the GMC may have recently begun to take a different approach to some cases of this type. The Inquiry has come across one case involving a doctor convicted of drugs offences who was dealt with through the conduct procedures rather than being referred into the voluntary health procedures, despite there being some evidence that he had a related psychiatric problem. The result was that the Professional Conduct Committee (PCC) erased the doctor's name from the register. There may be other such cases of which I am not aware. Thus it cannot be assumed that, if Shipman were to have been convicted in late 2002 or 2003, he would necessarily have been dealt with in the

voluntary health procedures. Moreover, as I shall explain in Chapter 25, under the new fitness to practise (FTP) procedures, convictions for offences connected with drug abuse are likely to be referred to a FTP panel. The panel will have the power to impose conditions upon the doctor's practice or to refer the doctor into the voluntary health procedures but it will have other sanctions available to it.

23.5 In this Chapter, I propose to examine the recent case in which the drug abusing doctor was erased from the register and the circumstances in which it came to be dealt with as it was. I shall consider another case of a similar kind which, at almost the same time, was referred into the voluntary health procedures. I shall then examine the rationale behind the GMC's approach to cases of this kind and will consider what, in my view, the approach should be under the new procedures. These questions are of particular importance because the Inquiry's Terms of Reference require me to recommend any changes that I consider necessary for the protection of patients in the future.

23.6 Drug abuse is a significant problem in the medical profession, although the precise extent of it is not known. Moreover, the problem is unlikely to decrease. Professor Sir Michael Rawlins, former Chairman, Advisory Council on the Misuse of Drugs, and current Chairman, National Institute for Clinical Excellence, spoke at one of the Inquiry's seminars of the significant problem of misuse of controlled drugs by students, including medical students. Surveys suggest that cannabis is used by between 10% and 20% of pre-registration house officers and 'Ecstasy' by between 5% and 10%. This is a 'grave worry for the future' because, according to Sir Michael, as these doctors progress in their careers they will have much greater and easier access to 'more nasty drugs' than the rest of the population has.

Two Cases Considered by the Preliminary Proceedings Committee in November 2002

A Change of Approach following the Case of Crabbie

23.7 The meeting of the Preliminary Proceedings Committee (PPC) which took place in November 2002 was the second meeting after the Privy Council had delivered its judgement in the case of Crabbie v General Medical Council[1]. Mr Finlay Scott, Chief Executive of the GMC, told the Inquiry that this case should, in principle, have had an important effect on decisions made by the PPC.

23.8 In Crabbie, the doctor had been convicted of causing death by dangerous driving. It was a very bad case. She had driven a motor car while under the influence of drink and had collided head-on with another vehicle, killing one person and seriously injuring two others. She was sentenced to five years' imprisonment. Although there was evidence that her dependence on alcohol amounted to an illness, Dr Crabbie's case was referred to the PCC and her name was erased because of the nature and gravity of the offence. It must inevitably have brought the profession into disrepute. Her appeal to the Privy Council was founded on the argument that the PCC should have referred her case to the Health Committee (HC) for the imposition of conditions on her registration. I interpose to point out

[1] [2002] 1 WLR 3104.

that, had that been done, her name could not have been erased from the register. The Judicial Committee of the Privy Council held that the PCC's approach had been correct and its decision reasonable. The judgement was delivered on 23rd September 2002.

23.9 The Privy Council added a rider to its judgement, to the effect that GMC decision-makers should not refer a case to the HC if there were any possibility that the doctor's name might be erased from the register. At first sight, that seems no more than common sense, because, once a case had been referred into the health procedures, erasure would never be available and the GMC would have deprived itself of an important means of protecting the public. The judgement in Crabbie did not seek to affect the approach that the GMC had historically taken to any particular type of case. It did not seek to suggest that the GMC ought to be erasing more doctors from the register. It said only that, if erasure were a possibility, the case should go through the conduct procedures (in practice to the PCC) until erasure had been considered. If erasure were ruled out, the case could then, if appropriate, be referred to the HC. Mr Scott said that Crabbie should have important implications for the way in which such cases as Shipman's were dealt with. He said that such convictions were so serious that they must give rise to a possibility of erasure and that all cases in which erasure was a possible sanction should, as a matter of principle, be referred to the PCC (under the old procedures) or to a FTP panel (under the new procedures). It should no longer be appropriate in any case in which erasure was a possibility to refer the doctor into the voluntary health procedures at a preliminary stage.

23.10 As Mr Scott conceded, this would have entailed a considerable difference of approach to cases involving drug abuse from that which had been taken previously. Mr Scott did not say that the new principle had already been put into effect under the existing procedures – only that the logic of the judgement in Crabbie would suggest that it should. Although Mr Scott confined his evidence on this issue to conviction cases, there could be no logical distinction between conviction cases and cases where there was an allegation of drug abuse involving dishonesty but where there had been no conviction.

23.11 At the November 2002 meeting of the PPC, two cases involving doctors convicted of offences of dishonesty in the context of drug abuse came up for consideration.

The Case of Rogers

23.12 In November 2001, Dr John Rogers, a general practitioner (GP), pleaded guilty to a series of offences of obtaining a Class A controlled drug by deception and of unlawful possession of Class A controlled drugs. He had obtained them for the purpose of self-administration. Those were the same offences of which Shipman had been convicted; other doctors whose cases I have examined in Chapter 22 had also committed similar offences. The Magistrates' Court committed Dr Rogers to the Crown Court for sentence, a course which suggested that the Magistrates regarded their sentencing powers (a maximum of 12 months' imprisonment) as inadequate. The Judge remarked that the offences amounted to a serious breach of the trust that the community placed in a GP. Dr Rogers had damaged his own reputation and that of the profession. He observed that no one else had been harmed by the doctor's actions. The same remarks might well have been made in Shipman's case in 1976 or, indeed, in any one of a large number of similar

cases I have looked at. After noting that the doctor had been suffering from depression, the Judge imposed a suspended sentence of imprisonment.

23.13 At the GMC, Dr Rogers' case was referred to the PPC which first considered it at a meeting in May 2002. One medical report, which had been prepared for the criminal proceedings, was already available. It expressed the view that Dr Rogers' offending had been secondary to his longstanding depressive illness. The PPC adjourned the case for further medical reports, a typical decision for the PPC in this type of case. The case was next considered in November 2002, when two further medical reports were ready. Although these reports confirmed that the doctor had been suffering from depression at the time of the offences, at least one of the medical examiners felt unable to reach a clear diagnosis of the extent of Dr Rogers' medical problem. The discussion of this case included consideration of the effect of the Privy Council's observations in Crabbie on the instant case. The PPC formed the view that Dr Rogers' convictions were sufficiently serious for there to be a possibility of erasure. Accordingly, the case was referred to the PCC.

23.14 This represented a new approach to convictions for drug-related offences. Instead of being referred into the voluntary health procedures, where the focus would be entirely upon rehabilitation, the case was – quite appropriately – to receive the detailed attention of a PCC panel, which would have all options, including erasure and referral to the HC, available to it. Not only that, but the hearing would be in public.

Dr JO 09

23.15 At the same meeting in November 2002, the PPC had to consider the case of Dr JO 09. He was a locum senior house officer. The previous year, suspicions had arisen at hospital A that he might be stealing pethidine but there was no proof of it. He moved to hospital B where it was noticed that he was apparently using pethidine on a number of patients in circumstances where it would not be usual practice to do so. On one occasion, the doctor was seen to swap syringes shortly before injecting a patient. He injected some of the liquid (which was supposed to be pethidine) and gave the syringe to a nurse with instructions to discard the remaining contents. She did not; instead she sent the liquid for analysis and it was found to be water. The doctor had stolen the pethidine he had prescribed (probably unnecessarily) for the patient and had injected the patient with a small quantity of water. The doctor was not reported to the police. I pause to observe that, when offences of dishonesty are discovered within NHS organisations, they are often not reported to the police. However, the doctor was reported to the GMC.

23.16 At the GMC, there was a difference of view between the screeners as to how the case should be handled. The health screener thought that the voluntary health procedures were appropriate but the medical screener wished to keep open the possibility of conduct proceedings. The GMC sought advice from its solicitors as to how it should proceed. The solicitor advised that the case should be referred to the PPC so that it could consider the medical reports and decide down which route the case should go. The case was referred to the PPC and also to the Interim Orders Committee (IOC), which imposed conditions on the doctor that would last for a period of 18 months. That was the maximum period for which the IOC could impose conditions. It often applied the maximum period, so that the

order would cover the time that might elapse before the case could be dealt with substantively. The conditions on Dr JO 09 required him to remain under medical supervision, to refrain from self-medication, to restrict his medical practice to supervised posts in the NHS, not to work as a locum and to notify his supervising consultant or any prospective employer of the conditions under which he was practising. At its next meeting, the PPC adjourned its decision and ordered medical examination by two psychiatrists.

23.17 The medical reports were ready for consideration at the PPC meeting in November 2002. The first psychiatrist said that there was no need to refer the case into the voluntary health procedures; the existing restrictions imposed by the IOC were sufficient. He suggested that the doctor should undergo random testing for drugs. The second psychiatrist considered that the doctor was fit to practise subject to the restraints currently imposed by the IOC. There was no need to restrict his prescribing rights. The PPC **'noted the allegations'** against the doctor, which were of theft, forgery of prescriptions and, in respect of the incident I described, depriving a patient of pethidine after it had been prescribed. It noted that both psychiatrists instructed by the GMC considered that the doctor required supervision. A further report from the psychiatrist who was treating the doctor stated that he was making good progress and was not using drugs of any kind. Somewhat surprisingly, in the light of the decision taken on the same day in the case of Rogers, the PPC decided that the case should not be referred to the PCC for inquiry. It decided instead that the doctor should be referred into the voluntary health procedures, saying that **'there was no public interest argument for referring the allegation to the PCC'**. So, in that case, the usual practice of referring cases of this type into the voluntary health procedures was followed.

A Comparison of the Two Cases

23.18 It is of course axiomatic that decisions of the PPC must turn upon the facts of the individual case. I also recognise that, from the papers available to the Inquiry, it may not be possible for me to make such a detailed assessment of a case as is possible for the PPC. However, the GMC should aim for broad consistency of treatment between cases of a similar type and gravity. I shall now seek to compare and contrast the cases of Rogers and of Dr JO 09, in an attempt to understand why the same constitution of the PPC reached different decisions in respect of these two cases.

23.19 One criterion for the PPC must always be the seriousness of the doctor's misconduct. An analysis of the misconduct of these two doctors shows great similarities. Assuming, as we must for present purposes, that Dr JO 09 would have been found guilty as charged by the PCC, both he and Dr Rogers had obtained controlled drugs of Class A by dishonest means. Both had done so, not on an isolated occasion, but over a period of time. The mechanisms by which they achieved their ends were different, but those differences were accounted for by the circumstances in which they worked. A doctor working in a hospital can take opportunities to steal drugs that have already been prescribed and dispensed. He or she may also have access to a drugs cupboard or store and be able to steal from stock. A GP cannot usually do that. GPs who obtain drugs illicitly generally do so by false prescribing. So the methods used by Dr Rogers and Dr JO 09 were different but both doctors had behaved dishonestly. It is not possible to say whether the amounts of the drug

involved in the two cases were different but, that consideration apart, the gravity of the misconduct was, to my mind, very similar. There was an additional factor in the case of Dr JO 09 that was not present in the case of Dr Rogers. It was alleged that Dr JO 09 might have deprived a patient of a drug that s/he needed. There was also a suggestion that the patient had been subjected to an unnecessary injection, which, if true, might have amounted to a criminal assault. Certainly, it appeared that Dr JO 09 was prepared to involve patients in a way that did not arise in Dr Rogers' case.

23.20 An examination of the medical evidence available shows that both doctors had a problem of drug dependence. In both cases, their misconduct was said to be related to the dependence. Although the reports in the case of Dr JO 09 appeared to focus in greater detail on rehabilitative measures, there was no reason, so far as I could see, to suppose that Dr Rogers was not capable of rehabilitation.

23.21 So far, it is difficult to see why one case gave rise to a possibility of erasure and must therefore be referred to the PCC and the other did not. However, there were some differences between the cases. One difference was that Dr Rogers had been convicted in the courts and his misconduct was, therefore, already proved. Dr JO 09's guilt had not yet been proved; that would have been a matter for the PCC to decide. However, there appears to have been no shortage of evidence and, from the medical evidence, it appears that the doctor had accepted that he had a drug problem. The fact that there was proven misconduct in one case and not in the other could not justify different treatment. Another possible difference that might have been present in the minds of the PPC is that, because the case of Rogers had been aired publicly, he had brought the profession into disrepute. Dr JO 09 had not, because his alleged misconduct had not been reported to the police. But that difference could surely not justify the different treatment of these two doctors. The fact that the hospital authorities had chosen not to make a report to the police was Dr JO 09's good fortune, but it did not mean that his misconduct, if proved, was any less serious than Dr Rogers'. In short, I cannot see how a proper analysis of the relevant issues in these two cases could have led to such different treatment.

The Outcomes

23.22 I turn to consider the two eventual outcomes. Dr JO 09 was referred into the voluntary health procedures. The allegations against him were never fully investigated and important issues were never resolved. We do not know whether or not he was guilty of the alleged misconduct. All the GMC proceedings took place in private. Dr JO 09 was not subjected to the stress and potential public disgrace that would have followed if, on referral to the PCC, he had been found guilty of the alleged misconduct. He entered the voluntary health procedures and restrictions were imposed on his practice. These were designed to protect the public and to facilitate the doctor's rehabilitation. There is no evidence to suggest that, in his particular case, the conditions imposed did not provide adequate protection for the public.

23.23 Dr Rogers came before a PCC panel, which decided to erase his name from the medical register. In giving its reasons, the panel noted that the doctor had been suffering from a depressive illness at the time of his offences. It is clear from the case report that there was

a medical opinion that the doctor's offending had been **'secondary to his illness'**. Nevertheless, the PCC panel said that it had formed the view that the doctor's current state of health was not sufficiently impaired to warrant referral to the HC. The panel then turned to discuss the seriousness of his conduct, in particular his dishonesty. It said:

> **'The Committee acknowledge you have not been subject to GMC procedures prior to this hearing. However, these factors do not detract from your inexcusable and dishonest behaviour. The Committee take a grave view of dishonesty in whatever form and disapproves of any action that undermines public confidence in the profession or compromises the trust that patients place in doctors. They have therefore been bound to consider most carefully whether the public interest demands that they should take action in respect of your registration.'**

23.24 The PCC then considered the suitability of the less serious sanctions available to it and decided that Dr Rogers' name must be erased. I pause to observe that, if Dr JO 09 had been found guilty as alleged, the words cited above would have been just as apposite to him as they were to Dr Rogers and, if a grave view should be taken of **'dishonesty in whatever form'**, then a grave view should also have been taken of the allegations of dishonesty against Dr JO 09.

23.25 Dr Rogers appealed to the High Court on three grounds. All failed and only two are of interest in the present context. The first ground related to the way in which the PCC panel had dealt with the health issues. The Judge, Mr Justice Mitting, held that the panel's decision not to refer the case to the HC had been taken at too early a stage of its deliberations. The Judge observed that, following the decision in the case of Crabbie, the PCC should not have considered a referral to the HC until after it had ruled out erasure as an appropriate sanction. It had in fact considered (and decided against) referral to the HC before considering erasure or any other sanction. However, the Judge held that this error had not vitiated the panel's decision because it was clear that its reasons for imposing erasure were that the offences were so grave that the public interest demanded nothing less.

23.26 Dr Rogers also contended that erasure was too severe a sanction and was disproportionate to the gravity of his offences. The Judge upheld the PCC's reasoning on that issue. He noted the PCC panel's view that dishonesty was always serious in a doctor, especially where it undermined the trust placed in the doctor by the community. He drew attention to the various aggravating features of the case: not only were these offences of dishonesty, they involved Class A controlled drugs; they were not isolated offences; they were not peripheral to the doctor's professional duties – indeed, they were committed in the course of his professional duties. I pause to observe that every one of those aggravating features was present in the allegations against Dr JO 09. Both cases involved a breach of trust. The Judge also mentioned the mitigating factors in Dr Rogers' case, the absence of any previous record and the effect of the illness. He observed that the PCC panel had had to carry out a balancing exercise. It had not erred in law in reaching its conclusion. Indeed, Mitting J expressly stated that he agreed with the view of the PCC

panel. It must be assumed that the GMC also agreed with the PCC panel's decision. It had sought to uphold it on appeal.

23.27 Mitting J summarised the gravity of Dr Rogers' case by saying that the offences demonstrated a clear abuse of the trust that is placed in any medical practitioner and a breach of the principles of good medical practice. He said that such conduct inevitably undermined the confidence which members of the public place in the profession. In my view, exactly the same could be said of the conduct of Dr JO 09, if proved, and of the conduct of Shipman and of countless other doctors who have, over the years, been referred privately into the voluntary health procedures.

23.28 It is not for me to say that the decision in Rogers was right or wrong. I seek only to draw attention to the different ways in which these two cases were handled and to the potential unfairness which can arise if the GMC does not have clear criteria for taking decisions. The November 2002 Screeners' Handbook contained advice about the effect of the judgement in Crabbie. How great an effect that advice had on screeners (and on the PPC) is not clear. The Inquiry has not conducted an audit of cases but it appears that many doctors (save for a few like Dr Rogers) reported to the GMC for convictions for dishonesty associated with drug abuse during 2002, 2003 and early 2004 were dealt with under the old practice and were referred into the voluntary health procedures rather than being referred to the PCC. Yet, as soon as the new procedures are operative, it is intended that such doctors will be, as they should be in my view, referred to a FTP panel.

23.29 It appears to me that some general lessons can be learned from consideration of these two cases. The GMC has now recognised that doctors reported to the GMC for convictions arising out of drugs offences must be referred to a FTP panel. A definite instruction is to be given to that effect. However, allegations of conduct of that kind cannot be dealt with by rule of thumb. There must be individual consideration of the allegations and the evidence available to support them. What in my view must be made plain to decision-makers is that cases such as that of Dr JO 09 must not be referred into the voluntary health procedures without there having been any resolution of the factual issues. Allegations of misconduct should be determined, if not admitted, so that there can be a proper assessment of the seriousness of the doctor's misconduct. Only then can a decision be taken as to whether, in the light of the medical evidence available and any other features in aggravation or mitigation, the doctor should be erased or suspended from the register or should be allowed to practise subject to conditions. Only then will any subsequent hearings involving the doctor be able to proceed on the basis of known facts rather than a medical history.

23.30 Second, these two cases underline the need for clear criteria to be developed for decision-taking. As I have shown, it is hard to detect any rational basis for the distinction drawn between them. I am concerned that the difference of treatment was due to the fact that in one case the doctor's misconduct was already proved and in the other it was not. Also, it appears that considerable weight was attached to what the Judge had said when imposing sentence in the criminal court. What the Judge said was very sensible and appropriate but it seems that it served to underline to the GMC the seriousness of the case of Rogers. There was no equivalent statement in the case of Dr JO 09.

23.31 Third, in my view, allegations of misconduct such as arose in these two cases should be dealt with in public. The public has a legitimate interest in knowing what the doctor has done and what the GMC has decided to do about it. In my view, the GMC is failing the public if it deals with such cases in private. Moreover, the interests of the profession and of the GMC itself are better served by openness of treatment. Of course, the doctor is entitled to medical confidentiality. This can be achieved if the FTP panel considers the medical evidence in full but makes only brief reference to it in giving the reasons for its eventual conclusion.

The Limited Relevance of the Sentence Passed by the Criminal Court in a Conviction Case

23.32 In the case of Rogers, to which I referred above, the Judge had imposed a suspended sentence of imprisonment. He plainly took a serious view of the case. It is possible that the fact that the doctor's conviction had been met with a sentence of imprisonment was a factor which caused the PCC panel to take the course it did; this was not a factor which was mentioned in the panel's decision, so I mention it as a possibility only.

23.33 It does appear that, in the past, the GMC's assessment of the seriousness of the doctor's misconduct, in cases where doctors have been convicted of controlled drugs offences, has been strongly influenced by sentence imposed by the criminal court. There has been little attempt to assess seriousness from the point of view of the impact or potential impact of the misconduct on the doctor's practice. In Chapter 16, I observed that, when Shipman's convictions were reported to the GMC in 1976, the Registrar, Mr Martin Draper, would not allow the case to go to the PeCC until precise information was available about the amount of the fine and compensation orders imposed by the Magistrates' Court. However, there was no investigation into the effect that Shipman's drug abuse and dishonesty had had upon his clinical practice. That was typical of the way in which the GMC investigated such cases.

23.34 In my view, the sentence passed by the criminal court is of very limited relevance to the seriousness of the doctor's misconduct from the point of view of the GMC. I can see that, as a very broad guideline, if the judge imposes a sentence of immediate imprisonment, it is reasonable to treat the case as serious. However, the converse should not be assumed. The fact that the court has imposed a very low penalty or even none at all should not lead the GMC to the conclusion that the case is not serious in the context of GMC proceedings. The GMC should, of course, pay heed to the factual findings of the court and/or to the factual basis for the sentence imposed. However, the role of the GMC in protecting patients involves different considerations from those taken into account by the criminal courts when passing sentence. For example, an offence of dishonesty or of indecency committed by a doctor will have implications in the context of medical practice that go well beyond the considerations that the courts will take into account. What may appear relatively trivial in the context of the general criminal law may be quite serious in the context of medical practice. The GMC should take care not to base its assessment of seriousness on the sentence passed by the court, particularly where the doctor has been sentenced by a Magistrates' Court, where the reasons for passing sentence are not always fully explained. It must also be borne in mind that the court might have imposed a more lenient sentence than would otherwise have been considered because it had been said on the

doctor's behalf that he was likely to be 'struck off' by the GMC and that his career was in ruins.

The General Medical Council's Approach to Cases of Drug Abuse

23.35 As I have said, in the past, the GMC's approach to drug abusing doctors has been to facilitate rehabilitation so that, once the doctor's condition is successfully treated, his/her compulsion to obtain drugs disappears and it can be expected that the doctor will revert to his/her normal patterns of behaviour. Thereafter, once a reasonable period has been allowed to pass, during which the danger of a relapse recedes, the point is reached where it can safely be said that the doctor is fit to resume unsupervised practice. The successful rehabilitation into practice of many doctors who have been through the GMC's voluntary health procedures can legitimately be used to justify the approach taken. That approach has been endorsed by Parliament in the Medical Act 1978 and in subsequent legislation. Although doctors suffering from other types of ill health are also dealt with under the health procedures, it was envisaged from the first that the procedures would be used to rehabilitate drug abusing doctors.

23.36 It is clear from Mr Scott's evidence to the Inquiry that the old approach is no longer acceptable. The GMC now recognises that it must have available its full armoury of sanctions when dealing with doctors convicted of drugs offences. The assumptions that used to be made, that the best course in all such cases was referral into the voluntary health procedures, has gone. I hope that the GMC will take the same view about cases in which allegations of a similar nature are made, but where, for one reason or another, there is no conviction or caution.

23.37 Two questions now arise for consideration. How is the GMC to investigate cases involving drug abuse so as to ensure that those who have to take important decisions on sanction have all the relevant information available? What are the criteria that should be applied when deciding upon sanction?

Common Factors in Cases of Drug Abuse

23.38 Before considering those two questions, it may be helpful to outline the types of misconduct which have to be considered. The facts and circumstances vary from case to case, but there are a number of features that are typical of such cases. It is common for a GP to obtain supplies by prescribing controlled drugs in the names of patients who do not need them. The doctor presents the prescription at a pharmacy and collects the drugs, telling the pharmacist that s/he will deliver them to the patient's home, but in fact keeping them back for him/herself. Shipman did that. Sometimes, the GP prescribes in the names of non-existent patients and collects the drugs from the pharmacy, purporting either to be that patient or to be acting on that patient's behalf. Sometimes, the doctor enters into a collusive relationship with a patient, prescribing more drugs than the patient needs. The patient collects the drugs and gives part of the consignment to the doctor. In some cases, the GP orders the controlled drugs from a pharmacy or wholesaler on requisition or signed order, falsely representing that the drugs are for practice stock. He or she will avoid making any entry in the practice controlled drugs register and will keep the drugs for

him/herself. Shipman did that. Doctors who work in hospitals have a greater opportunity than GPs to steal drugs from a stock cupboard. Others will prescribe drugs for hospital patients who do not need them and will take possession of the drugs when they have been delivered to the ward. Such methods were referred to in research carried out by the National Addiction Centre and published in 1991[2], based on examination of the medical records of all doctors who had been treated for alcohol and drug misuse at the Maudsley and Bethlem Royal Hospitals over the previous 20 years. All these methods involve dishonesty in the course of practice.

23.39 The facts that drug abuse very often leads to dishonesty and that dishonesty in doctors is a serious matter must not be allowed to obscure the fundamental problem caused by drug abuse. Dr Douglas Fowlie, Consultant Psychiatrist, Grampian Primary Care NHS Trust, and an eminent member of the Royal College of Psychiatrists, has had a special interest in substance abuse for many years. His evidence to the Inquiry stressed that one of the important effects of drug taking is the way in which the person's perceptions of the world and his/her general values are distorted. He said:

> **'It is important to be aware ... that one of the facets of an illness of dependence is a selectively distorted perception of one's own behaviour. As a dependence escalates, the priority of the individual is obtaining the next fix of the drink or the drug. This is the overwhelming priority and other factors external to this diminish in their importance. When the perceptions become distorted, a lack of insight develops, and the illness can cause a distortion of what the previously non-dependent individual regarded as right and wrong.'**

23.40 Such distorted perception no doubt explains the behaviour of doctors who think that it is acceptable to use dishonest means to obtain drugs. It also explains the conduct of those who treat patients while under the influence of drugs or while craving another dose. Presumably, doctors who do this persuade themselves that it is acceptable for them to treat patients shortly after taking a mind-affecting drug. Their perception of their own abilities and of their patient's best interests is badly distorted. Whether such distorted perceptions persist after the dependence has ceased, I do not know.

23.41 The facts of some of the cases I have read demonstrate how the misuse of controlled drugs can have a direct impact on patient safety. In the case of Dr JO 09, the doctor injected the patient with water and kept for him/herself the controlled drug prescribed for the patient. I have read a report of a doctor who kept falling asleep at work, even during consultations. In another case about which I read, a junior doctor was found collapsed on a hospital ward, having injected himself with a controlled drug while on duty. Shipman collapsed on several occasions when in practice in Todmorden. This was diagnosed at the time as being due to 'idiopathic epilepsy' but was in fact a consequence of his addiction. In these cases, the implications for patient safety are highly visible. In other situations, the risks to patients are less easy to observe. However, the judgement of a

[2] Brooke D, Edwards G, Taylor C (1991). 'Addiction as an occupational hazard: 144 doctors with drug and alcohol problems', British Journal of Addiction, Vol 86: pp 1011–1016.

doctor must always be suspect when the craving for controlled drugs is dominant in his/her mind.

23.42 There can be no doubt that doctors who are misusing drugs present a substantial risk to patient safety. It seems to be universally accepted that any doctor who is thought to be taking drugs should not be allowed to practise and that any doctor who has only recently given up the habit must be supervised so that any relapse will soon be recognised.

Dishonesty in Cases of Drug Abuse

23.43 The element of dishonesty which is almost invariably present in this category of case also has important implications for patient safety. It is clear from 'Good Medical Practice' that the GMC regards the honesty and integrity of a doctor as being of fundamental importance. Sir Donald Irvine, President from 1995 to 2002, said at the Inquiry seminars that honesty is one of the fundamental tenets of the relationship between doctor and patient and that it is essential to the integrity of the clinical process. In his witness statement to the Inquiry, Sir Donald said that the starting point for the GMC's consideration of cases involving dishonesty must be that dishonesty amounts to a dereliction of a basic duty and constitutes serious professional misconduct; his view was that, in the absence of remarkably good reasons in mitigation, it should lead to erasure of the doctor's name from the medical register.

23.44 At that stage, Sir Donald was speaking about cases of dishonesty in general, not in the specific context of drug abuse. He said that there was an **'unresolved issue'** in addiction cases, where dishonesty could be said to be secondary to the addictive habit itself. He said that there was a need for wider debate on the issue of dishonesty in that context, which could be clarified by a broader consensus on sanctions to be reached between the public and the medical profession. I agree, and I hope that this Chapter may provide further stimulus for such debate.

23.45 This **'unresolved issue'** involves what is apparently the almost unanimous view of psychiatrists from whom the Inquiry received evidence that dishonesty in the context of drug abuse is 'all part of the illness' and a natural concomitant of the abuse. In Chapter 16, I explained this belief and quoted the evidence of Dr Fowlie. Briefly, the theory is that dishonesty in the context of drug addiction in a doctor is not indicative of a fundamentally dishonest personality. On the contrary, the need to obtain the drug of addiction is so overwhelming that it becomes a compulsion and the person, who would normally be quite honest, behaves dishonestly only for the purpose of obtaining drugs. If the drug dependence is cured, the dishonesty will disappear.

23.46 The Inquiry wished, if possible, to explore how far that theory could properly be taken. Should it apply in all cases? If not, in which cases should it not apply? These questions were to some extent prompted by consideration of the case of Shipman. He acted dishonestly in order to obtain pethidine in the 1970s. When his misconduct had been detected, he was treated and cured of his dependency. Yet, as I found in my First Report, Shipman remained deeply dishonest after that time. In the First Report, I described a number of the ways in which this manifested itself. He used many dishonest methods to obtain diamorphine with which to kill his patients. He frequently lied to the families of

patients about the circumstances of the deaths of those he had killed. He made false entries in patients' medical records to provide natural explanations for the deaths he had caused. Those acts of dishonesty were related to the killing of patients. But he was dishonest in other contexts too. In the immediate aftermath of the discovery of his drug dependence in 1975, he was deceitful in a job application. He did not tell the Durham Area Health Authority that he was facing prosecution when applying for a post in child health. He disclosed his conviction only because he was advised to do so by the consultant psychiatrist who was treating him and did so only after he had been offered the job. Of course, I accept that Shipman's may have been a completely exceptional personality. However, his case does justify asking the question whether there is a risk that the dishonesty practised to feed a drug habit is likely to endure beyond the end of that habit. Does the risk that such dishonesty will continue render the doctor permanently untrustworthy and unfit to practise as a doctor?

23.47 One witness suggested to the Inquiry that, once a person has resorted to dishonest conduct – especially if that conduct has been repeated on several occasions – it may become a habit or 'life-skill' and s/he may be dishonest again in other contexts in the future. The thinking was that, once a doctor has been dishonest in order to obtain drugs, s/he cannot be trusted in future and is, therefore, generally unfit to practise medicine, at least without close supervision. It is suggested that such a person, when faced with a clinical situation requiring probity and integrity, could not be relied upon to display those qualities. If s/he makes an error, for example, s/he would be more likely to seek to cover up what had happened than to be open about it. This may be correct but there is no evidence to suggest that it is. At one stage in the Inquiry, I thought it would be useful to focus attention on dishonesty in the context of drug abuse by doctors. Having heard all the evidence, I no longer think it will be profitable to do so. Dishonesty, it seems to me, is only one component of the dysfunctional character of the drug abusing doctor.

23.48 Because Shipman was a known case of a person who did not fit the generally accepted theory that dishonesty will disappear when dependence is cured, it occurred to me that there might be other exceptions to that rule and, if so, it would be important to be able to recognise them, in other words to recognise those doctors in which dishonesty is just a concomitant of drug abuse and those in which it is more deeply rooted. Those doctors might be regarded as unfit to remain as doctors.

23.49 In considering how far the basic theory about dishonesty can be taken, it appears to me that there are a number of important questions to ask. Does the manner in which the dependence develops have any bearing on the extent to which the dishonesty will resolve when the dependence is cured? It seems to me that it might. There must be a stage at which the doctor begins to take a drug but is not yet addicted to or even dependent upon it. If the means used at that stage are dishonest, can it be said that the dishonesty is a concomitant of dependence? It would seem to me that it cannot. I recognise that some doctors suffer from organic illnesses for which they are prescribed strong analgesic drugs, sometimes including opioids. They should not become addicted to those drugs if their consumption is properly supervised, although it may be that some do. I suspect that there are few doctors (or people) who become addicted in such circumstances. There will also be some cases in which the doctor self-medicates

unwisely in the context of a psychiatric disorder such as depression. I can see how, in the context of illness, the doctor's judgement may be affected and s/he may not take the sensible course of seeking independent medical advice. There will be other cases where self-medication begins during a period of personal distress resulting from an experience such as bereavement or marriage breakdown. In such cases, the doctor's control mechanisms have broken down and s/he may stray into behaviour which, in ordinary circumstances, s/he would recognise as wrong and would avoid. I imagine that some doctors in that kind of situation begin to self-medicate with something like a benzodiazepine and that some then 'graduate' onto more addictive drugs such as opioids. I must confess that I find it quite hard to accept that there is any excuse, in that kind of situation, for a doctor to progress to the self-medication of opioids. However great the personal distress, I would have thought that any doctor who is not actually ill would recognise the danger of stepping over that line and into conduct which is not only inappropriate but also almost bound to entail dishonesty.

23.50 In addition to those cases where there is a more or less understandable explanation for the commencement of the habit, it seems to me that there must be a number of cases where there is no satisfactory explanation for the doctor beginning to take drugs. Nowadays, quite a lot of people take drugs for recreation. In those cases, there must be a 'lead-in' period where the doctor is exercising 'free will' in deciding to 'experiment' with drugs. His or her judgement is not at that time overborne by craving. It seems to me that a doctor, who should know of the dangers of taking addictive drugs, should not simply be regarded as an innocent 'victim' of the drug. I would have thought it unwise to assume that doctors who were prepared to obtain drugs by dishonest means at a time when they were not yet dependent would necessarily revert to honest behaviour when cured of their dependence. I also suspect that many drug abusing doctors, having been 'found out', advance false explanations of the circumstances in which their dependence began. They seek to provide an 'acceptable' explanation for their dishonest behaviour. In my view, the circumstances in which the doctor became addicted are always worthy of exploration.

23.51 Second, the depth or strength of the dependence or addiction may vary greatly. I accept that some are so deeply affected that obtaining their 'next fix' becomes an obsession which drives out all other thoughts. However, in many of the cases I have read, the doctor was not addicted to that extent. Shipman was a case in point. He was able to give up using pethidine at times. For example, when he went away on holiday it appears that he managed without it. I have seen medical reports in which it is said that he was 'habituated' to the drug but not deeply addicted. Dishonesty in such cases cannot be explained on the grounds of compulsion or irresistible craving.

Evidence Obtained by the Inquiry

23.52 To assist with the understanding of the issues surrounding drug abuse in doctors and how the GMC should deal with it, the Inquiry obtained expert evidence from Dr Andrew Johns, Consultant Forensic Psychiatrist, South London and Maudsley NHS Trust, who has considerable experience in the psychiatry of addiction. Dr Johns' evidence dealt with the issues of substance misuse by doctors, the risks posed by a rehabilitated doctor, the likelihood of relapse into drug taking and assessing the risk of relapse. His views were

similar to those expressed by Dr Fowlie. Dr Johns said that 'dishonesty' is not a fixed personality trait but is a form of behaviour which could be used to achieve a range of diverse ends and which could have a range of causes. He said that it would be a mistake, therefore, to suppose that dishonest behaviour by an individual in one context necessarily predicted dishonest behaviour by that individual in an entirely different context. Once the drug addiction is treated, the 'imperative' to forge prescriptions or to steal drugs is substantially reduced. A number of participants at the seminar agreed with that view.

23.53 Dr Johns said doctors with drug and alcohol problems who receive appropriate treatment 'do well'. He referred to data from the USA, cited in the 1991 paper to which I referred in paragraph 23.38, which showed that, with proper rehabilitation, 75% of such doctors were practising and drug-free at follow-up periods of between two and eight years. The data demonstrates a creditably high success rate for the treatment of drug abusing doctors. However, it also means that no fewer than 25% of doctors returned to drug taking within eight years.

23.54 Dr Johns said that it would be extremely difficult to assess the risk of future criminal behaviour in an individual case of a drug abusing doctor because of the difficulties in predicting human behaviour. He said that a risk factor could be anything which had a statistical association to a future event and, although steps could be taken to analyse risk, it could not be accurately predicted. He said that he did not have any personal experience of a doctor whom he had treated for drug misuse and who had later been discovered to have committed a criminal offence. He said that he suspected that the proportion of doctors who, having committed an offence of dishonesty in connection with drug misuse, went on to commit a further offence of dishonesty was extremely low. I think he was referring to doctors other than who relapsed into drug taking. I do not think he was asserting that the incidence of further dishonesty was low; I think he accepted that he would not usually be aware of what happened to his patients after they had been discharged from his care.

23.55 At the Inquiry's seminars, Dr Fowlie repeated and enlarged upon what he had said in his witness statement. He said that, during treatment for the addiction, 'clarification' of the dishonest behaviour is an 'important therapeutic weapon'. If the individual is able to confront his/her dishonest behaviour, that is, he said, a good prognostic indicator. I take that to mean that the prospects for full and permanent rehabilitation are enhanced if the doctor has fully accepted that s/he was dishonest and that this dishonesty was unacceptable. The converse might well suggest that doctors who continue to make false excuses for themselves (such as 'I started to self-medicate because of a back injury' – which was an explanation advanced by Shipman) are less likely to do well.

23.56 This evidence seems to me to point to two conclusions. First, even if a drug abusing doctor is treated and appears to have been rehabilitated, there is a risk of relapse of the order of 25% over a period between two and eight years afterwards. It may be that more research should be undertaken into the incidence of relapse among drug abusing doctors. Second, the extent to which dishonesty associated with drug abuse may be 'excused' as being a part of the illness and may be expected to resolve once the dependence has been cured may depend upon at least two factors, the strength or depth of the addiction and the extent

to which the doctor has fully understood and 'confronted' his/her own dishonesty. Putting forward false excuses for how it all started might be a bad indicator.

What Should the General Medical Council's Approach Be in Drug Abuse Cases?

23.57 Throughout the period examined by the Inquiry, the GMC has focussed upon obtaining medical evidence to ascertain whether and how the doctor's drug abuse was being treated and upon the prospects for rehabilitation. That approach should now change, in my view. I consider that it is essential that certain findings be made about the circumstances of the abuse. These findings must be made even in cases in which the doctor has been convicted of offences and his/her misconduct is therefore proved.

23.58 First, if the allegation of drug abuse is disputed, there must be a proper resolution of the dispute and the facts must be found. They must not be fudged. I was told that, in the past, if a doctor gave the voluntary undertakings required by the health screener, this would be regarded as an acknowledgement by the doctor that s/he did at least have a drug problem. I can understand why that short cut to the voluntary health procedures must have seemed attractive. It avoided the time and cost of an investigation, as well as the risk of a finding that the doctor was 'not guilty'. However, the effect of taking such a course was that there were then no findings about the misconduct, if any, of which the doctor had been guilty. There was no assessment of the seriousness of that misconduct or of its implications for patient safety. It appears to me that it is almost impossible to form a proper view about whether a doctor is fit to practise medicine if serious allegations against him/her are left unresolved in this way.

23.59 Second, if it is found or admitted that the doctor has been abusing drugs, it should not be assumed that s/he has been the unfortunate victim of circumstances beyond his/her control. The GMC must attempt to find out when and how the abuse began. The doctor's explanation of how s/he came to be addicted should be subjected to careful scrutiny and the story should be checked by consulting with people who were in contact with the doctor at the material time and, if appropriate, by examining medical records. The GMC should find out for how long the abuse has persisted and by what means the doctor obtained the drugs. It must discover what deceptions were practised and upon whom. There should be a proper assessment of the depth or strength of any addiction or dependence. If the doctor was able to manage without drugs at will or if s/he was withdrawn from them with more than usual ease, the conclusion might be that the doctor was not fully addicted. If so, the inference might be that the doctor was not subject to an overwhelming compulsion to obtain supplies and the decision-makers should be less ready to overlook any dishonesty of which the doctor has been guilty.

23.60 Third, there should be an examination of the way in which the doctor's practice was affected. Were patients involved in the obtaining of drugs? How did the doctor behave while addicted? Was patient care affected? This kind of information might well affect the decision on sanction. In particular, if conditions were thought appropriate, such information would help the GMC to devise appropriate conditions. This kind of information would be gathered from the doctor's colleagues and would have an additional beneficial

effect in that it would enable the colleagues who would be responsible for the welfare of patients to identify those patients who had been at risk.

23.61 Finally, if and when it was suggested that the doctor was rehabilitated, there should be some assessment of the extent to which the doctor had regained insight and had fully accepted the seriousness of what s/he had done. In some of the medical reports I have seen, the psychiatrist has addressed that issue; in others, that factor does not seem to have been considered and the emphasis is on the period of time for which the doctor has been able to abstain from drugs. I am not saying that that is not important; it is, but there should be other considerations as well.

23.62 Undoubtedly, an assessment of the doctor's health will be required and to that end one or two psychiatric reports will be required. However, the investigation of background factors should not be left to the psychiatrists. It would be unreasonable to ask them to undertake the kind of investigations that I am advocating. It may be necessary to examine patient and/or practice/hospital records, including the doctor's own medical records. It may also be necessary to interview the doctor's colleagues, practice staff and patients. These enquiries should be carried out by GMC investigators and the information gathered should be shared with the psychiatrists, as it may affect their opinion. For that reason, it will usually be inappropriate to accept a report from the doctor's treating psychiatrist; s/he may not wish to delve into background matters in the way in which I am suggesting that the GMC should do. If all these steps are taken, the evidence should shed greater light on the risks that the doctor's drug abuse has presented in the past and may present in the future.

Conclusions

23.63 It appears that the case of Crabbie triggered some reconsideration within the GMC as to how doctors convicted of drug offences should be dealt with. Mr Scott, at any rate, fully understood its implications in respect of convictions and I am sure that the GMC will have appreciated that those implications extend to cases in which unproven allegations of a similar nature have been made. The GMC has issued draft guidance that should ensure that doctors convicted of drugs offences will, under the new procedures, be referred to a FTP panel.

23.64 I have explained how cases of drug abuse should be investigated before they reach a hearing. These investigations must take place in both conviction cases and those involving an as yet unproven allegation. If those investigative steps are taken, the FTP panel will be in a much better position than decision-makers have ever been in in the past to decide whether the case warrants erasure or suspension or whether the imposition of conditions will be appropriate and will adequately protect the public and patients.

23.65 There is a thread running through many of the Chapters of this Report that deal with the GMC. It is that, if the GMC is to achieve an acceptable degree of consistency (and predictability, as doctors should know what is likely to happen to them if they transgress), it must establish some agreed standards, criteria and thresholds. By 'agreed', I mean not only agreed within the GMC (although that would be helpful), but agreed between the

GMC and the public. There must be public discussion and debate about what is the right response to, and the right sanction for, the types of case that come up again and again. Doctors who commit drug abuse are but one example of the problem. Until this work on standards, criteria and thresholds is done, there will be continued dissatisfaction with, and criticism of, the GMC.

23.66 It is not for me to dictate how this should be done. I have suggested as one option a method of debate and consultation similar to that of the Sentencing Advisory Panel. In the case of Rogers, Mr Justice Mitting suggested that reports of cases of that kind should be collected so that it would be possible to see in which types of situation other PCC panels (or judges) had thought erasure or suspension or conditions were appropriate. I agree that this should be done, although at the moment there are virtually no such decisions available. As such cases go through to FTP panels and decisions are made, they should, in my view, be collated into a body of case reports, available for future reference. That would serve two purposes. It should help to provide a measure of consistency between similar cases but it should also form a factual basis on which consultation could take place about what sanctions are appropriate in different types of case.

23.67 There should also be a debate within the GMC about the nature of the conditions that should be imposed when it is thought appropriate that a doctor who has been abusing drugs should be allowed to continue in practice. In the past, decisions about conditions have usually been taken by health screeners, who developed a good deal of expertise. In the future, such decisions will be taken by FTP panels and, where voluntary undertakings are concerned, by case examiners assisted by GMC staff. In any event, some very clear guidance will be necessary. I also consider that it would be beneficial if further research were to be done into the relapse rate of doctors who have been through the GMC health procedures. The American research quoted by Dr Johns suggests that there remains a significant risk of relapse after the two-year drug-free period which, in the past, the GMC has taken as a rough guide as to when a doctor should be allowed to resume unrestricted practice. It may be that the GMC health procedures have a greater success rate than the American methods. I do not know but I think that the GMC should find out. This could affect the length of time for which supervision is thought to be necessary.

23.68 In my Fourth Report, I discussed the power granted to the Home Secretary under section 12 of the Misuse of Drugs Act 1971 to direct that the right of a medical practitioner to prescribe controlled drugs should be removed or restricted. In recent years, this power has fallen into disuse. It appears that the view has been taken that the GMC is better placed than the Home Office to assess the need for such restrictions to be imposed. I was told that the repeal of section 12 was under consideration. I recommended that, before taking any decision on the repeal of section 12, the Home Office should commission a review of the use which the GMC makes of its power to impose prescribing restrictions on doctors. From the cases that I have examined, I have the impression that the GMC does not often impose a condition preventing a doctor from prescribing or possessing controlled drugs. I repeat that there should be a review of the cases in which such restrictions are imposed.

CHAPTER TWENTY FOUR

The General Medical Council's Performance Procedures

Introduction

24.1 In July 1997, the General Medical Council (GMC) introduced its performance procedures, which enabled it to take disciplinary action in respect of doctors whose professional performance was seriously deficient. In this Chapter, I propose to examine the origin of these procedures, the way in which they were brought into operation and the way in which they worked until recently. I shall consider a number of problems which arose in their operation. Finally, I shall consider a few cases which the Inquiry has examined. As I shall explain, these procedures were not brought into effect until just over a year before Shipman was arrested and, in effect, ceased practice. None of the reports that the GMC received about Shipman would have been likely to result in a referral into the performance procedures, even if they had existed at the time. The procedures are, however, relevant to the Inquiry's remit for two reasons. First, they formed an important part of the GMC's armoury in protecting patients against doctors who might cause them harm. Second, the new fitness to practise (FTP) procedures will underpin the GMC's revalidation of doctors. The way in which issues of poor performance are handled within the new FTP procedures is plainly important in that context, and the only guide currently available as to how performance issues will be handled in future is how they have been handled in the past.

The History

24.2 In the 1980s, there was increasing concern about the competence of some doctors and about the inability (or, as some saw it, the unwillingness) of the GMC to deal with issues of competence by means of its conduct procedures. Outside the GMC, the case of Alfie Winn (see Chapter 17) in 1982 had resulted in attempts by Mr Nigel Spearing MP to introduce a Private Member's Bill establishing an offence of 'professional misconduct', with a threshold lower than that for serious professional misconduct (SPM). The GMC was successful in opposing those attempts and the Bill failed. However, even within the GMC, some members who sat on the Professional Conduct Committee (PCC) were becoming increasingly concerned about cases where, although SPM was not proved, there was nevertheless evidence of poor practice. The GMC was powerless to act in such a case.

24.3 Although Mr Spearing's Bill failed, his attempts led directly to the establishment, in 1987, of a GMC working party, which was charged with the task of considering the need for competence procedures, as an adjunct to the existing conduct and health procedures of the GMC. The working party reported in 1989. It recommended that the GMC should give consideration to the establishment of competence procedures and that proposals for such procedures should be formulated as a basis for discussion with the profession and with other bodies. A year later, a decision was taken to establish a further working party to **'consider arrangements for the identification and handling of serious deficiency in a doctor's professional performance and to make recommendations'**.

24.4 Sir Donald Irvine, who was a member of the GMC in 1979 and its President from 1995 to 2002, described in his book, 'The Doctors' Tale'[1], the unwillingness on the part of some within the GMC to tackle the problems of incompetence and poor performance. He spoke of the pressure being put on the GMC by the Government of the time to **'grip the question of the incompetent doctor and grip it soon'**. If the GMC did not do so, it was told, the Government itself would act through Parliament. Sir Donald concluded this part of the history:

> **'... the received wisdom today is that the GMC's decision to go with what was to become the performance procedures in the 1990s was as a result of strongly pro-active action. It was not. Such action had to be dragged out of the Council, as many of the medical members glanced over their shoulders, perhaps quite understandably, at what their colleagues might say in other places, such as the craft committees of the BMA** (*British Medical Association*)**.'**

24.5 In May 1992, the working party, which had been set up two years before under the Chairmanship of the President of the GMC, Sir Robert (later Lord) Kilpatrick, reported. It recommended the establishment of performance procedures modelled on the relatively new health procedures. The performance procedures were designed to deal with cases where a doctor's behaviour or actions seemed to suggest a pattern of seriously deficient performance (SDP) that could not be dealt with effectively under the existing conduct and health procedures. A novel element in the performance procedures was to be the performance assessment, which would be designed to identify gaps in a doctor's knowledge and skills and to assess whether these were capable of remediation. At that time, it was envisaged that most doctors entering the performance procedures would be dealt with by means of voluntary procedures (as in the health procedures) and would eventually return to unrestricted practice after a period of remedial action. In the event that a doctor failed to co-operate, or that his/her performance failed to improve after remedial action, a FTP committee of the GMC (subsequently titled the Committee on Professional Performance (CPP)) would be able – as a last resort – to suspend or impose conditions on the doctor's registration.

24.6 The proposals of the working party, which were adopted by the GMC, met with considerable opposition within the profession. There was anxiety about the prospect of testing doctors' clinical knowledge or skills. There was a suggestion from those representing hospital doctors that the performance procedures should not apply to them, since any problems with performance could be dealt with by their employers, in conjunction with the BMA or the relevant medical Royal College. Eventually, however, there was a general acceptance within the profession that the performance procedures were necessary and must apply to all doctors.

24.7 Primary legislation was required for the establishment of the procedures. The necessary Parliamentary time was found in December 1995 and the Medical (Professional Performance) Act 1995 (the 1995 Act) was passed, making the necessary amendments to the Medical Act 1983. In the meantime, work had begun on developing the instruments

[1] Irvine, Donald (2003) 'The Doctors' Tale'. Oxford: Radcliffe Medical Press.

to be used in the performance assessments. Following the passage of the 1995 Act, a further 18 months passed before the performance procedures eventually came into operation on 1st July 1997.

24.8 Sir Donald told the Inquiry that he had believed that the performance procedures would close a 'gaping hole' in the GMC's procedures, a hole which he had observed 'time and time again' when sitting on the PCC. He said:

> **'... you would find that facts could not be proved, or you could not arrive at a decision about serious professional misconduct, but you knew perfectly well from what you had seen in the evidence, the records you may have looked at and so on ... that the doctor just should not be practising'**.

He said that, as a general practitioner (GP), he knew about the 'sizeable volume' of people who either should 'have some attention given' to their practice or should not be practising at all. He had seen the introduction of the procedures as a way of strengthening local processes and procedures. He had had 'high expectations' of them.

The Distinction between 'Performance' and 'Competence'

24.9 I have described how, in the first instance, the suggestion was that the GMC should establish 'competence procedures'. Within a short time, however, the emphasis had changed from 'competence' to 'professional performance' and the procedures, when eventually they came into effect, were concerned with performance, rather than competence.

24.10 'Competence' describes knowledge and skills, i.e. what the doctor 'can do'. 'Performance' describes what the doctor does within actual practice, i.e. what s/he 'does do'. A doctor who does not possess the requisite knowledge and skills can never perform well. However, a doctor may be competent (i.e. s/he may possess the requisite knowledge and skills) but, nevertheless, his/her attitude and behaviour may be such that his/her performance is – at least on occasion – deficient. Professor Dame Lesley Southgate, Professor of Primary Care and Medical Education, University College London, explained at an Inquiry seminar that, sometimes, doctors who 'can do' have a problem about whether they 'will do'. She said that problems of attitude, which sometimes stem from an arrogant personality, can be very difficult to cure. The performance procedures were designed to deal with these wider problems, as well as with incompetence.

24.11 The change of focus from competence to performance had implications for the collection of the evidence necessary to prove SDP. A doctor's competence can be assessed by testing his/her current knowledge and by observing his/her current clinical skills. If the doctor is still in practice, his/her current performance can be assessed by observing him/her consulting with or treating patients and by reviewing and discussing medical records in current cases. However, if a doctor is for some reason no longer practising (for example, if s/he has been suspended) or if s/he is working in a specialty different from that in which s/he was working at the time of the original complaint against him/her, the only available measure of his/her 'performance' is not what s/he 'does' but what s/he 'has done'.

Local Mechanisms for Dealing with Poor Performance

24.12 At the time when the GMC's performance procedures came into operation, local NHS bodies – in particular, primary care organisations (PCOs) – had very limited mechanisms for dealing with poor performance. If a PCO had concerns about a GP's performance, it might seek the co-operation of the local medical committee (LMC) in invoking the informal 'Three Wise Men' procedure and try to resolve the problem in that way. If a patient complained about a 'performance' issue, that might be the subject of an independent review panel (IRP) hearing. If a PCO believed that a GP had breached his/her terms of service, there was the possibility of disciplinary action although, after 1996, such action became very rare. In any event, both IRP hearings and disciplinary proceedings were primarily designed to deal with single incidents giving rise to complaints, rather than with repeated incidents which might suggest a pattern of poor performance.

24.13 Following the introduction of the GMC's performance procedures, NHS organisations were encouraged, by the Department of Health, to set up their own procedures for dealing with poorly performing doctors. One reason for this was that the GMC's procedures were designed to deal only with doctors whose performance was 'seriously' deficient. It was recognised from the first that there would be doctors performing at an unacceptable standard who would not reach the GMC threshold, but in respect of whom it was necessary to take some action to protect patients. In Chapter 5, I described the local procedures that have been developed by PCOs since 1998. The process of development is continuing.

24.14 In order to assist NHS organisations to deal with problems of poor performance, in April 2001, the National Clinical Assessment Authority (NCAA) was established. It provides a support and advice service, and also carries out performance assessments in a limited number of cases where these are deemed necessary. These assessments are aimed at establishing whether a doctor is fit to work in the setting in which s/he is currently working. The assessment may result in a recommendation that the doctor should work in a different setting. It may recommend some form of remedial action. The NCAA is not a regulatory body and cannot itself take disciplinary action or impose sanctions. However, it can refer a doctor to the GMC, if, for example, serious concerns arise during an assessment, particularly if they affect patient safety. It may also advise the doctor's employer or PCO as to whether a referral by them to the GMC is appropriate.

The Development of the Instruments for Performance Assessment by the General Medical Council

24.15 When the GMC decided that it wished to introduce performance procedures, it was recognised that it would be necessary to devise some form of objective assessment of a doctor's performance. Such assessment would have to be fair and decisions based upon it would have to stand up to legal challenge. In 1994, the then President of the GMC (Lord Kilpatrick) invited Dame Lesley Southgate, who was then Chief Examiner of the Royal College of General Practitioners (RCGP), to lead a group which would be responsible for the development of a method and a set of instruments for the assessment of performance. No such methods or instruments had at that time been developed in any other part of the

world. Dame Lesley assembled a team, drawn mainly from the medical Royal Colleges, and, over a period of three years, produced the method and instruments which were to form the basis of the GMC performance procedures. When published later, this work gained worldwide recognition. The method and instruments of assessment have been described as 'state of the art' and 'the leading edge of direct assessment of performance'. They provide for a very thorough assessment and are, as an almost inevitable consequence, expensive to undertake.

24.16 As I shall later explain in greater detail, the assessment of performance falls into two phases. Phase I comprises a review of the doctor's performance at his/her place of work undertaken by a team of assessors. If, at the end of Phase I, the team is not satisfied with the doctor's performance, the doctor will undergo Phase II, which comprises a series of objective tests.

Witnesses

24.17 The Inquiry heard oral evidence about the performance procedures from Mr Alan Howes (Head of the Performance Section from 1995 until April 2001), Mr Neil Marshall (Head of the Performance Section from April 2001 until March 2002) and Miss Jackie Smith (a casework manager in the Performance Section from November 2001 until April 2002 and thereafter Head of the Performance Section). Sir Donald Irvine (President of the GMC at the time of the introduction of the performance procedures), Professor Sir Graeme Catto (the current President), Mr Finlay Scott (Chief Executive of the GMC since 1994) and Dr Krishna Korlipara (a member of the GMC and a medical screener since 1998) also gave relevant evidence. Professor David Hatch, Chairman of the CPP, provided a witness statement.

The Legislative Framework

24.18 The 1995 Act added a new section 36A to the Medical Act 1983. Section 36A provided:

> **'... (1) Where the standard of professional performance of a fully registered person is found by the Committee on Professional Performance to have been seriously deficient, the Committee shall direct –**
>
> **(a) that his registration in the register shall be suspended, (that is to say, shall not have effect) during such period not exceeding twelve months as may be specified in the direction; or**
>
> **(b) that his registration shall be conditional on his compliance, during such period not exceeding three years as may be specified in the direction, with the requirements so specified.'**

24.19 It should be noted that the power to take action arose when the CPP found that the doctor's performance had been (i.e. in the past) seriously deficient. The significance of these words was not to become apparent until a challenge to the CPP's powers was raised in

the case of Krippendorf v General Medical Council[2], to which I shall refer later. It should be noted that no power was given to the CPP to direct that a doctor's name should be erased from the register. However, the CPP had the power, at the expiration of a period of suspension, to direct that the period of suspension should be extended for up to 12 months and, when a doctor had already been suspended for at least two years, the CPP then had the power to direct indefinite suspension. I shall discuss these sanctions in greater detail later in this Chapter.

24.20 It is important to note that the performance procedures applied only to a doctor's performance after 1st July 1997, the date on which the 1995 Act came into force. Evidence of poor performance prior to that date could not be used to support a complaint of poor performance against the doctor. The GMC decided (apparently on legal advice) that it was not possible, immediately after the introduction of the performance procedures, to deal with doctors about whom there had been longstanding concerns. Instead, it was necessary to wait until a body of evidence had been accumulated after 1st July 1997 to support the contention that the doctor's performance had been seriously deficient. This meant that the GMC's performance procedures got off to a slow start. The legal advice received may have been correct, although I cannot see any statutory prohibition on the consideration of evidence of poor performance occurring before the commencement of the power to impose sanctions for SDP. I would have thought that the opposite view would, at least, have been arguable. Given that the purpose of the new procedures was the protection of patients, it was perhaps unnecessarily conservative for the GMC to take so narrow a view of the commencement provisions. In any event, it was expected that many doctors whose performance was thought to be seriously deficient would agree to enter into voluntary undertakings. Such doctors would be unlikely to mount a legal challenge to the GMC's powers.

The Process for Dealing with Complaints about Performance

24.21 The General Medical Council (Professional Performance) Rules Order of Council 1997 (the 1997 Performance Rules) came into force in July 1997. They set out the process to be followed when a complaint was made or information was received (I shall use the term 'complaint' to describe both) about a doctor's performance. Broadly, the process consisted of the following stages:

- staff in the Screening Section considered the complaint
- the complaint was screened by a medical screener
- if the case proceeded beyond screening, the doctor was invited to undergo a performance assessment
- if the doctor did not agree to a performance assessment, the Assessment Referral Committee (ARC) would consider the case and decide whether a performance assessment was necessary

[2] [2001] 1 WLR 1054.

- if the doctor agreed to a performance assessment, or if the ARC directed an assessment, a case co-ordinator would be appointed
- the case co-ordinator would appoint an assessment team, of which one member was the lead assessor
- the assessment was carried out and a report was written. The lead assessor was responsible for this
- the performance assessment report was considered by the case co-ordinator and, if s/he thought that the contents of the report warranted it, s/he would draw up a statement of requirements for remedial action over a specified period
- the doctor was invited to agree to undertake the remedial action set out in the statement of requirements
- once the period of remedial action was at an end, the doctor would undergo further assessment.

24.22 In certain circumstances, the case might be referred to the CPP, which would consider the case and would decide whether to direct a performance assessment (if one had not already been carried out) or to impose a sanction on the doctor.

24.23 I shall deal with the various stages in the process separately. I shall describe the process which was in place in late 2003, when the Inquiry heard evidence about the performance procedures.

The Source of Complaints about Performance

24.24 First, I should say something about the complaints received by the GMC in relation to doctors' performance. Most complaints about performance come from doctors' employers (usually NHS trusts) or PCOs. Typically, those NHS organisations will have been attempting for some time to resolve the doctor's problems by means of local procedures, but will have been unsuccessful in doing so. They will usually refer a performance issue to the GMC when they believe that the doctor's deficiencies are so serious that only GMC action on registration will be sufficient to deal with the problem. Alternatively, the doctor may have been unwilling to participate in local remedial action. Sometimes, a NHS body has not had the opportunity to deal with the problem: for example, when a doctor has been employed as a locum and has moved on elsewhere.

24.25 Complaints about performance are sometimes made by postgraduate deans, tutors and advisers, or by a doctor's medical colleagues. Some are also received from patients, although patients' complaints often relate to isolated incidents, rather than to patterns of behaviour. It may be impossible for anyone to know whether the incident complained of, if true, was an isolated lapse or a manifestation of wider performance problems. As I have explained in Chapter 18, until recently, it was not the practice of the GMC, upon receipt of a complaint from a private individual, to make enquiries of the doctor's employer or PCO in order to see whether there had been any other complaints or concerns relating to the doctor. Thus, it is likely that many complaints to the GMC, which were in fact manifestations of wider performance problems, have been screened out because they

were neither serious enough to amount to SPM nor (so far as the GMC knew) part of a pattern which might amount to SDP. It is to be hoped that the arrangements which the Inquiry has been told are now in place for discussions between the GMC and doctors' employers and PCOs at an early stage after receipt of a complaint will lead to greater recognition of the value of patient complaints in revealing evidence of problems with performance.

24.26 Some complaints from patients and a doctor's medical colleagues relate to the performance of doctors in the private sector. Miss Smith told the Inquiry that she could not herself recall a referral from an employer in the private sector, although she could not say that this had never occurred. If it is the case that no or very few such referrals are received, this gives rise to some cause for concern, as it seems unlikely that deficient performance occurs only within the NHS. I can envisage reasons why a commercial organisation might not wish its doctors to become involved with the GMC performance procedures. There might be a fear that the good name of the organisation will be affected if it becomes known that a doctor has been employed about whose performance serious concerns had arisen. Such an organisation might be unwilling to allow the GMC to undertake an assessment of the doctor at his/her place of work. It might simply be easier to dismiss the doctor and to be rid of the problem. This is a cause for concern because, if doctors whose performance gives rise to concern are not reported, they are free to move on and may cause problems for other patients and other organisations.

Consideration of a Complaint by the Staff in the Screening Section

24.27 In recent years, the first stage of the procedures following receipt of a complaint into the Screening Section was for a casework manager to assess, *inter alia*, whether there was any prospect of the complaint being resolved by means of local action. In a potential performance case, the casework manager would wish to ascertain whether local performance procedures had been used and whether there had been any consultation with the NCAA. The November 2002 and April 2003 editions of the FTP Casework Manual (the Casework Manual), prepared for the assistance of staff in the Screening Section, advised that, if it was **'not entirely clear'** that local procedures had been exhausted, casework managers should, at the triage stage, contact the referring body to discuss how the case should be handled. Where there was **'any question of an immediate danger to patients'**, the Casework Manual advised that **'the GMC may need to act'**. The Casework Manual went on to observe that one possible result of such discussion with a referring body was that the referrer would withdraw the referral and take other measures locally before referring back to the GMC if necessary.

24.28 Mr Marshall told the Inquiry that the GMC sometimes received referrals from NHS bodies that wished to put the GMC **'on notice'** that they had got a difficulty with a doctor, but did not consider it necessary to invoke the GMC's conduct or performance procedures at that stage. In other cases, he said that it might be less clear whether the referring body wanted GMC action or not. In that event, GMC staff would contact the referring body and discuss the various options. This might have led to a three-way discussion between the GMC, the referring body and the NCAA. Usually, the initial discussions with the referring body were

conducted by telephone. However, on occasion, it might be necessary to have a meeting. Mr Marshall observed:

> **'I think what we want to achieve by that is to be perfectly happy that all the organisations involved in looking at a particular doctor know what their role is, know the way the thing is going to be taken forward and know exactly what safeguards we might put in place in the meantime.'**

24.29 Mr Marshall told the Inquiry that, until the middle of 2001, GMC staff classified cases as 'performance' or 'conduct' cases at an early stage. Cases that were classified as 'performance cases' were dealt with by a performance screening team and then, if appropriate, the performance assessment team. Cases classified as 'conduct cases' were processed within the Screening Section (which was then part of the Conduct and Screening Section). Mr Marshall said that decisions on classification were made **'too early'** and that had **'led to one or two cases perhaps ending up in the wrong route'**. In mid-2001, a decision was taken to postpone classification until a later stage and to **'leave that decision to the screener'**.

Screening

24.30 After mid-2001, all cases were screened in the same place (the Screening Section). Complaints that suggested that the standard of a doctor's performance might have been seriously deficient were considered by a medical screener. As I have said earlier, medical screeners were also responsible for considering complaints of potential SPM. Once a decision had been taken by the screeners, cases which had been 'screened in' progressed along one of the health, conduct or performance paths. This classification of cases resulted in what the GMC called 'the silo effect'. Once a case was allocated to one set of procedures, it could not always be moved into a different set, even if it transpired later that another set of procedures might have been more appropriate. Under the new FTP procedures, the silo effect should be avoided as, although different methodologies will be used in dealing with the conduct, health and performance aspects of cases, FTP panels will be able to consider all the evidence relating to a doctor at the same time.

The Decision to Be Made by the Screeners

24.31 Rule 5(1)(c) of the 1997 Performance Rules provided that the medical screener should take no action in connection with a case unless the complaint was in writing and unless it:

> **'suggests to the medical screener that –**
>
> **(i) the standard of the practitioner's professional performance may have been seriously deficient; and**
>
> **(ii) it may be appropriate to take action ...'**.

The words **'may be'** were amended in November 2002 to read **'is'**. Also in November 2002, rule 5 was further amended to provide that the medical screener should take no action in respect of a complaint or information received by the GMC five years or more after the events giving rise to it, unless, in his/her opinion, the public interest **'requires'**

action **'in the exceptional circumstances of the case'**. That amendment had the effect of introducing into the performance procedures a 'limitation period' similar to that which was introduced at the same time for the conduct procedures.

24.32 The **'action'** which the medical screener had to decide whether or not to take consisted of the issuing of an invitation to the doctor to undergo a performance assessment. The threshold for issuing an invitation to a doctor to undergo an assessment was a low one. The complaint had to **'suggest'** to the medical screener that the standard of the doctor's conduct **'may have been seriously deficient'** and the complaint had to **'suggest'** to the medical screener that it was (until November 2002, **'may be'**) 'appropriate' to take action.

The 'Rule 5 Letter'

24.33 Until November 2002, before making a final decision whether to invite a doctor to undergo a performance assessment, it was necessary to give him/her notice of the fact that such a course was being considered and to afford him/her an opportunity to submit any observations s/he might have. A 'rule 5 letter' would be sent to the doctor, together with copies of the complaint and of any previous complaint(s) to be taken into account (see paragraph 24.36) and a copy of any statutory declaration (if the complainant was a private individual). The medical screener would then take any observations submitted by the doctor into account when reaching his/her decision whether an assessment should take place. The 1997 Performance Rules provided no opportunity for the complainant (whether a private individual or a public body) to respond to the doctor's observations. Sometimes, receipt of the doctor's observations resulted in a change of mind on the part of the medical screener. For example, in 2000, out of 126 cases in which a 'rule 5 letter' had been sent, medical screeners decided not to pursue 12 cases after receipt of the doctor's observations. In November 2002, an amendment to the 1997 Performance Rules removed the obligation to seek preliminary observations from the doctor and the 'rule 5 letter' was no longer required.

The Power to Seek Further Information

24.34 Rule 5(2) of the 1997 Performance Rules provided that, for the purposes of considering a case, the medical screener might seek information about or observations on the case from any person who, in the opinion of the medical screener, might assist him/her in deciding whether there might be reason to believe that the standard of the doctor's professional performance had been seriously deficient. Thus, it was open to the medical screener to initiate enquiries to assist him/her in making the decision as to whether the case should proceed to an assessment. This was in contrast with the position in a case of potential SPM, where the medical screener had no such specific power.

The Involvement of a Lay Screener

24.35 Rule 5(6) of the 1997 Performance Rules required that, before a decision was taken by the medical screener that no action was needed, a lay screener should be consulted and should agree. If the lay screener did not agree that no action needed to be taken, an invitation to undergo a performance assessment had to be issued.

Consideration of an Earlier Complaint

24.36 Where the screeners decided to take no action in relation to a complaint, rule 4 of the 1997 Performance Rules provided that the complaint might nonetheless be taken into account by a medical screener in connection with the consideration of any subsequent complaint, with a view to determining whether **'together they indicate a pattern of professional performance which is seriously deficient'**. However, when considering a subsequent complaint, an earlier complaint could be taken into account only if, at the time that the doctor was notified that no further action was to be taken in relation to it, s/he was sent a statement informing him/her that the earlier complaint might be taken into account if in the future a further complaint was received. A copy of that statement had to be sent to the person or body who made the earlier complaint, together with an explanation of the reason why a decision had been made to take no action in relation to that complaint. The 1997 Performance Rules imposed no time limit after which an earlier complaint could not be considered. This was in contradistinction to the position where complaints of misconduct or reports of convictions were not acted upon immediately; they could be revived only within two years of the decision to take no action. It seems that, from the first, however, the GMC operated an informal 'cut-off period' of three years for performance cases.

The 1997 Screeners' Handbook

24.37 At the time that the performance procedures came into operation, the first Handbook for screeners, the 1997 Screeners' Handbook, was produced. The Handbook advised medical screeners that a complaint should be treated as a potential performance case only after the medical screener had concluded, first, that referral to the health procedures was not justified and, second, that the case should not be pursued as a case of SPM. A lay screener had to endorse the second conclusion. Only then could the medical screener go on to consider whether there was evidence of SDP. If there was, the medical screener should consider action under the performance procedures. It was open to medical screeners, exercising their powers under rule 5(2) of the 1997 Performance Rules, to ask the GMC staff to make enquiries to establish if the complaint was an isolated one or if there was a pattern of concern locally about the doctor. The 1997 Screeners' Handbook suggested that information might be obtained from the medical adviser or chief executive of a GP's PCO, from the medical director of a NHS trust, from a senior medical executive of an employing organisation, from the chairman or secretary of the LMC or from the chairman of the medical staff of a hospital. The Handbook emphasised the need for **'tact and discretion'** and for confidentiality when making such enquiries. The doctor concerned was to be informed of the complaint before such enquiries were made. It was to be explained to the person from whom information was being sought that the GMC was simply making preliminary enquiries and that no decision about possible GMC action had yet been taken. Any approach made, and the outcome, was to be recorded. All this seems very sensible. However, the evidence I have heard suggests that it did not happen in practice. Until May 2004, when a single complaint was received (which was not serious enough in itself to raise a question of SPM), it was closed without any enquiries being made of local organisations with a view to finding out whether or not there were other concerns about the doctor. I discussed this problem in Chapter 18 and recorded the

reaction of Dr Korlipara to the suggestion that such enquiries should be made. In short, he thought that it was not for the GMC to go 'fishing' for information from which to construct a case against a doctor. From May 2004, the GMC has announced its intention, in certain circumstances, to consult with employers and primary care trusts (PCTs) at an early stage after receiving a complaint.

24.38 In deciding whether a complaint should be taken forward, screeners were advised to consider:

> '• **Is there good evidence relating to the doctor's performance since 1 July 1997, that the doctor may be repeatedly or persistently failing to comply with the professional standards appropriate to the work the doctor is doing?**
>
> • **Does that evidence suggest that there may be a pattern of deficient performance, as opposed to evidence only of one or two incidents of deficient performance, which could be isolated lapses?**
>
> • **Are the alleged deficiencies so serious that, if they cannot otherwise be resolved, there might be grounds for suspending or imposing conditions on the doctor's registration?'**

24.39 Screeners were enjoined to be **'particularly concerned'** where the evidence suggested that the standard of the doctor's professional performance might be placing patients in jeopardy, or where the doctor was repeatedly and persistently failing to comply with the GMC's guidance in 'Good Medical Practice'.

24.40 The Screeners' Handbook advised medical screeners that, in a case where the allegations contained in the complaint did not, in the medical screener's view, warrant action under the performance procedures (the example given in the Handbook being an **'isolated lapse'** in performance with no **'pattern'** of SDP), informal action under Chapter XV of the GMC's Standing Orders might be appropriate. I described the Chapter XV procedures in Chapter 19.

Screening Decision Forms

24.41 As I have explained in Chapter 19, in 1999, the screeners began to use screening decision forms (SDFs) which had been designed by the Policy Studies Institute (PSI) in consultation with the GMC. The purpose of the SDFs was to introduce greater structure and consistency into the screening process.

24.42 The version of the SDF in use from June 1999 until August 2001 contained this advice to screeners:

> **'SDP is normally indicated by a repeated or persistent failure to comply with relevant professional standards.'**

24.43 After August 2001, the advice was changed to read:

> **'SDP is normally indicated by a pattern of serious failure to comply with relevant professional Standards.'**

I was concerned about that change, at least if it was taken literally by screeners. Surely a single **'serious failure to comply with relevant professional standards'** would warrant action under the conduct procedures, as it would raise a question of SPM. The difference between SDP and SPM was that SDP might be evidenced by a series of failures which, taken individually, would not warrant action but which would do so when considered collectively. The new guidance appeared to import a requirement of both seriousness and repetition before SDP could arise. It seemed to me that this might not afford adequate protection for patients.

24.44 However, this change in language might not have had any adverse effect upon the decisions of medical screeners because, at the same time, other advice was given which appeared not to suggest the need for seriousness as well as repetition. From August 2001, the SDF contained a list of criteria which, it stated, were **'not exhaustive but may be an indicator of sdp'**. The medical screener was invited to tick all those criteria that applied to the complaint being screened. The criteria were:

- a tendency to use inappropriate techniques
- a lack of basic knowledge/poor judgement
- a lack of familiarity with basic clinical/administrative procedures
- a failure to keep up-to-date records
- a lack of insight
- a range of inadequacies, namely:
    - outdated techniques
    - attitude
    - inadequate practice arrangements
    - concerns over referral rates
    - poor record keeping
    - inadequate hygiene arrangements.

24.45 The medical screener then had to decide whether the case raised an issue of SPM (in which case it should have been referred to the Preliminary Proceedings Committee) or whether there was a suggestion that there might have been SDP (in which case an invitation to undergo a performance assessment should have been sent). If the medical screener could not judge whether either was applicable, further information might be required. If the medical screener believed that the case raised issues of both SPM and SDP, s/he had to declare whether, in his/her view, the case should proceed by way of the conduct or the performance procedures. The November 2002 Screeners' Handbook (and the subsequent April 2003 version which was still in use at the time of the Inquiry hearings) observed that, in many cases, this would be **'a fine judgement'**. If the medical screener decided that the case raised no issues of SPM or SDP, the agreement of a lay screener had to be obtained before the case was closed.

Invitation to the Doctor to Undergo a Performance Assessment

24.46 If the medical screener decided that the case should proceed, the 1997 Performance Rules required the doctor to be informed of the fact. Until November 2002, under the provisions of rule 6, the doctor (who would already be aware of the complaint and of the fact that an invitation to undergo assessment was being considered, having received the 'rule 5 letter') would be sent a statement setting out the reasons why the medical screener considered that an assessment was necessary. He or she would also be sent a copy of any further information which had been obtained as a result of any further enquiries initiated by the medical screener and taken into account by the medical screener when making his/her decision. Until November 2002, the 1997 Performance Rules provided that the complainant should not be sent the medical screener's statement or any of the information referred to above.

24.47 From November 2002, when the 'rule 5 letter' was abolished, the letter sent after the medical screener's decision could be the doctor's first notification that a complaint had been made to the GMC about his/her performance. The amended rule 6 required the doctor to be sent all the information which would previously have been enclosed with the 'rule 5 letter', together with the invitation to undergo assessment sent in accordance with rule 6.

24.48 The doctor would then be invited to agree within 28 days (until November 2002, the period was 14 days) to an assessment being carried out and to submit within the same period any observations that s/he might wish to make on the case. If the doctor agreed to the carrying out of a performance assessment, the case would be passed to the Performance Section, where arrangements for the assessment would be put in train. If the doctor did not agree to an assessment within the specified period, the medical screener could refer the case to the ARC. Alternatively, having considered the doctor's observations or other information, the medical screener might decide (subject to the agreement of the lay screener) that no further action needed to be taken in connection with the case. Miss Smith told the Inquiry that she was not aware of a case where a medical screener had changed his/her original decision at this stage.

Consideration of the Case by the Assessment Referral Committee

24.49 The 1997 Performance Rules provided that a referral to the ARC might be reversed if the doctor subsequently agreed that an assessment should be carried out or if the medical screener subsequently received information which caused him/her (with the agreement of the lay screener) to decide that no further action needed to be taken in connection with the case. However, if the referral was not reversed, the ARC would proceed to consider the case.

The Composition of the Assessment Referral Committee

24.50 The composition of the ARC was governed by the General Medical Council (Constitution of Fitness to Practise Committees) Rules Order of Council 1996 (the 1996 Constitution Rules), as amended. It comprised 17 members. It was chaired by the President, or some

other member of the GMC appointed by him. Two members were appointed by the President to act as Deputy Chairmen. The appointments made by the President had to be approved by the full Council. The remaining 14 members were elected annually. From August 2000, medical and lay screeners were not eligible for election to the ARC. The total membership of the ARC comprised 13 medical and four lay members. Until November 2002, the legal quorum for the ARC was five, including at least one lay member. After that time, the quorum was three and had to include at least one medical and one lay member.

The Provision of Legal and Medical Advice

24.51 The ARC sat with a legal assessor and with at least one specialist adviser appointed by the Chairman from a panel appointed by the GMC. At least one of the specialist advisers had to be a person who was practising or had practised in the specialty in which the doctor whose performance was under scrutiny generally practised. The function of the specialist adviser was to advise the ARC on the medical issues before it. He or she would give advice on any question referred to him/her by the ARC. In addition, s/he could give advice on his/her own initiative if it appeared to him/her that, but for such advice, there was a possibility of a mistake being made, either in judging the medical significance of any information before the ARC or because of the absence of information. The advice of the specialist adviser had to be given in the presence of the doctor and his/her representative, if they attended the hearing. If the advice was given after the ARC had begun to deliberate as to its findings, the specialist adviser was required to inform the doctor what advice had been given in his/her absence.

The Functions of the Assessment Referral Committee

24.52 Mr Howes said that that the original purpose of the ARC had been to provide a safeguard against the GMC becoming 'trigger happy' and sending doctors for assessment when the evidence did not justify it. The task of the ARC was not to determine whether or not a doctor's performance was seriously deficient. Rather, its functions under rule 15 of the 1997 Performance Rules were to decide whether the standard of a doctor's performance **'may have been seriously deficient'** and, if so, to decide whether an assessment **'needs to be carried out'**. This test appeared to set a slightly higher threshold than that set by the screening test, which required that the complaint should **'suggest'** to the screener that the doctor's performance might have been seriously deficient and that **'it is** (*formerly* **'may be'**) **appropriate to take action'**. Mr Marshall told the Inquiry that the test for the ARC (in contrast to that applied by the screeners) was twofold. If the ARC decided that a doctor's performance might have been seriously deficient, it then had to ask whether, 'despite that', it 'would not want to assess this particular doctor'.

The Procedure at a Hearing before the Assessment Referral Committee

24.53 At a hearing before the ARC, the GMC was represented by a solicitor or counsel. Both the complainant and the doctor were also entitled to be represented. Before the hearing, members of the ARC would receive copies of the document sent to the doctor under the provisions of rule 6 (previously rules 5 and 6) and of any observations from, or further correspondence with, the doctor.

24.54 Hearings of the ARC were held in private. The ARC might obtain any information in writing, or call any person to give oral evidence, which it considered might assist it in carrying out its functions. The complainant could give evidence and s/he or his/her representative could address the ARC. The complainant was not, however, entitled to hear the other evidence adduced before the ARC. Mr Marshall told the Inquiry that most performance cases arose as a result of referrals from public bodies. The referring body would be invited to send a representative to the hearing before the ARC. It was not, however, usual for that representative to give evidence. Mr Marshall observed that the GMC would 'make the most vigorous argument it can that the case should proceed, referring to the papers in hand'. He said that it was 'very rare' for the referring body to have anything to add to the papers which the GMC already had. The doctor might give evidence. Except for the complainant, the doctor and any person whom the ARC chose to call, no one else was permitted to give oral evidence. It seems to me to be unfortunate that the complainant (usually the representative of a public body) was not permitted to hear what the doctor had to say. He or she was the person most likely to have detailed knowledge of the case and to know whether or not what the doctor had said was reasonable or was capable of being refuted. It seems to me that that person should have been present throughout the hearing so that, if appropriate, s/he could communicate with the GMC representative.

24.55 If, at the conclusion of the evidence, the ARC decided that a performance assessment needed to be carried out, it would direct that an assessment should be conducted and the case would immediately pass to the Performance Section for the appropriate arrangements to be made.

24.56 If the ARC decided that no assessment was necessary, the case would be closed. A decision by the majority of members was taken as the decision of the ARC. If the votes were equal, the Chairman had an additional casting vote. The ARC was not required to give reasons for its decisions and, if it found in favour of the doctor, did not do so. This absence of reasons gave rise to a considerable amount of concern on the part of NHS bodies who were given no explanation of why a decision (contrary to that of the medical screener) had been taken not to take action in a case which they had regarded as serious enough to refer to the GMC. I shall return to this topic later in this Chapter.

The Performance Assessment

The Appointment of a Case Co-ordinator

24.57 Once it had been decided that a performance assessment should be carried out, the 1997 Performance Rules required the appointment of a case co-ordinator. Until July 2003, the case co-ordinator had to be a medical member of the GMC. In practice, the GMC authorised two of the medical screeners to act in that capacity. The first performance case co-ordinators were Dr Robin Steel (the principal medical screener) and Professor Hilary Thomas. In March 2004, two of the recently appointed medically qualified case examiners were appointed as performance case co-ordinators, pending the introduction of the new FTP procedures. The first function of a case co-ordinator was to appoint the members of the Assessment Panel which was to carry out the performance assessment. Panel members were appointed from the list of performance assessors who had been authorised by the GMC to carry out performance assessments.

Performance Assessors

24.58 Performance assessors are not members of the GMC. They are medically qualified and lay people who have been selected and trained by the GMC to act as assessors. Initially, 400 people (250 medical and 150 lay) were selected, of whom only half were trained immediately. Others were trained as the need for more people to participate in assessments increased. Performance assessors receive intensive training (including a five-day residential course) in their role. After their initial training, they receive ongoing training and support at workshops and other events. In addition, assessors who are not on the GMC's list have also been appointed on an *ad hoc* basis to assist with individual assessments. Both Sir Donald Irvine and Dame Lesley Southgate emphasised the value of the participation by lay people in the assessment process.

The Assessment Panel

24.59 Members of staff in the Performance Section would send to the doctor a 'portfolio' to complete. The doctor would be asked to provide a description of the nature of his/her practice, an account of his/her professional training and experience and other details. The staff would then attempt to identify suitable members for the Assessment Panel. The case co-ordinator would approve the constitution of the Assessment Panel and would formally appoint the panel members before the assessment took place.

24.60 Under the 1997 Performance Rules, Assessment Panels had to consist of two doctors and a lay person, with a doctor as the lead assessor. The lead assessor would be a doctor from the same specialty as the doctor being assessed. From November 2002, the Rules provided that, where an assessment was to include **'structured tests of the doctor's professional knowledge and skills'** (which, as I shall explain, usually constitute Phase II of the assessment), the case co-ordinator could appoint one or more additional members to the Assessment Panel. Those members would be involved in the assessment only for the purpose of assessing the doctor's performance in those tests. The appointment of additional members for this purpose ensured that the assessment of the doctor's performance in Phase II was approached with a fresh eye and without any preconceptions based on his/her performance in Phase I.

The Work of the Assessment Panel

24.61 The Assessment Panel would be provided with all the relevant papers in the case, including the original complaint and the doctor's observations on it. The Assessment Panel would tailor the way in which it carried out the assessment to the individual circumstances of the doctor being assessed. The 'portfolio' completed by the doctor assisted in this process. During the assessment, performance assessors might act alone or in different combinations.

24.62 Phase I of the performance assessment was known as the 'peer review'. It usually occupied about two and a half days. The performance assessors would interview the doctor, usually on several occasions. On at least one such occasion, the doctor had to be interviewed by all members of the Panel together. The doctor was entitled to be

accompanied at interviews with the performance assessors, save when details of particular cases of named patients were being discussed. Panel members would also interview the complainant (if s/he agreed) or, if the complainant was (as was usually the case) a public body, they would interview a representative of that body and possibly the members of staff with direct knowledge of the matters giving rise to the concerns or complaint. The Assessment Panel would visit the doctor at his/her place of work (if applicable) and would inspect a number (usually about 50) of sample sets of his/her medical records. From those records, the Panel would select certain cases which would subsequently form the basis of detailed discussions with the doctor. They might also observe how the doctor conducted consultations with patients. If the complaint related to a hospital doctor's surgical skills, the performance assessors might observe him/her at work in the operating theatre. Performance assessors would also speak to a doctor's colleagues and to others with firsthand knowledge of the doctor's performance; these might be nurses, practice staff (if the doctor was a GP) or senior managers (if the doctor worked in a hospital). The 1997 Performance Rules provided that the doctor might nominate no more than five persons whom s/he wished to be interviewed in the course of the assessment and the Assessment Panel was required to make reasonable efforts to ensure that those persons were interviewed by at least one Panel member. During the assessment, performance assessors might act alone or in different combinations. As the assessment progressed, the assessors would enter their comments in a specially designed database. They graded each entry as 'acceptable', 'cause for concern' or 'unacceptable'. 'Acceptable' meant that the evidence demonstrated that the doctor's performance was consistently above the standard for fitness to practise. 'Cause for concern' meant that there was evidence that suggested the performance might not be acceptable but there was not sufficient evidence to suggest SDP. 'Unacceptable' indicated that there was evidence of SDP.

24.63 The 1997 Performance Rules required the Assessment Panel to disclose to the doctor any written information or opinion received by the Panel which the Panel believed might influence its assessment, and to give the doctor an opportunity of commenting on it. The practice was that all interviews with third parties were transcribed. In the past, transcriptions of third party interviews were not always made available to the doctor while the assessment was in progress. Following the judgement in the case of Sadler v General Medical Council[3], given in July 2003, it became clear that this must be done, so that the doctor could have an opportunity to comment on the content of those interviews before the final assessment report was prepared.

24.64 Phase II of the performance assessment consisted of tests of competence which were designed to suit the doctor's specialty. Phase II consisted of a test of knowledge, a simulated surgery with trained actors playing the role of patients, and objective structured clinical examinations (OSCEs), whereby the doctor was placed in certain clinical situations to which s/he had to react. The GMC has recently opened a new assessment centre for the assessment of doctors coming to practise in the UK from overseas. Mr Scott told the Inquiry that it was intended that the assessment centre should also be used in the future to conduct Phase II of performance assessments.

[3] [2003] 1 WLR 2259.

24.65 The doctor's scores on the Phase II tests were assessed against a control group of doctors in the same specialty who had completed the same tests. The minimum scores for the tests were deliberately set low, well below those that would be attained by the vast majority of doctors. For example, 75% of GPs would have scored 85% or above in the knowledge test but the score that gave rise to a 'cause for concern' in the assessment was set at 68.8%. Similarly, 75% of GPs would score over 72% in the simulated surgery tests, whereas the score that gave rise to 'cause for concern' in the assessment was set at only 50%. In the OSCEs, 75% of GPs would score over 80%, but the score giving rise to 'cause for concern' was set at 70%[4].

24.66 The doctor was asked to proceed to Phase II only if, as a result of Phase I, the Assessment Panel considered that there was a potential problem with the doctor's performance. If the Assessment Panel agreed at the conclusion of Phase I that the doctor's performance was not seriously deficient and that nothing would be gained by proceeding to Phase II, the assessment would be halted there. At the Inquiry, there was some discussion about whether it would be sensible to reverse the order in which the two Phases were conducted. Phase I was very 'resource-intensive' and, therefore, very expensive. It could often take quite a long time to set it up and, as a result, delays occurred. Phase I also depended to a very large degree on subjective judgements about the reliability of observations made by interviewees. On the other hand, Phase II was more objective. The argument for change was that, if a doctor performed well (or even adequately) in the objective tests, the Panel might well be able to reach the conclusion that no real concerns arose. If s/he performed inadequately, s/he would have to complete the assessment process (the present Phase I). Such a change would produce savings in both cost and time. It seemed to me that the most important consideration was whether the taking of the Phase II objective tests would provide a reliable indicator on the basis of which it would be safe to make a decision to discontinue the process. Dame Lesley Southgate was of the view that it would not be safe. She said that a doctor cannot perform well unless s/he has a sound knowledge base. However, the converse is not true; a doctor with a sound knowledge base can still perform badly. It appears, therefore, that there is no easy answer to problems of resources resulting from the Phase I assessment.

24.67 In the past, there were very severe delays in carrying out assessments and in producing the reports. In August 2001, a service standard was introduced with a target of completing an assessment within five months of the doctor having agreed to, or been directed to, undergo it. However, assessments could still take longer to complete, particularly if it was difficult to find suitable assessors who were available.

24.68 The form of the performance assessment was reviewed from time to time. Miss Smith told the Inquiry that, from a time shortly before she gave evidence, the practice had been to conduct more case-based discussions with the doctor and to cut down on the number of interviews with third parties. Recent experience had suggested that the reliability of third party interviews and/or the impartiality with which they were recorded might be successfully attacked by the doctor at a hearing before the CPP. Suspicions had arisen

[4] Southgate L, Campbell M, Cox J, Foulkes J, Jolly B, McCrorie P, Tombleson P (2001) 'The General Medical Council's Performance Procedures: the development and implementation of tests of competence with examples from general practice', Medical Education, Vol 35 (Suppl. 1): pp 20–28.

that some complaints had been made as the result of a particular doctor being made the scapegoat for a problem within a department or even as the result of racial discrimination. It is clear that the accounts given by members of staff or patients to an Assessment Panel cannot be subjected to cross-examination and there must be a danger that the Panel might be less than objective in its judgements. Where judgements are based on what the doctor him/herself said about his/her cases, these risks would be much reduced. Also, the results of Phase II, being calibrated by reference to the performance of a large number of doctors, would provide objective and reliable material.

24.69 The 1997 Performance Rules required all members of the Assessment Panel to meet together during the assessment to review its progress. They were then required to meet again to consider the conclusions to be reached on the assessment and the content of their report.

24.70 Once completed, the performance assessment report was sent to the case co-ordinator unless the assessment was carried out in accordance with the direction of the CPP (see paragraph 24.93, in which case the report was sent to the CPP. The report had to include the opinion of the Assessment Panel on some or all of the following matters, namely whether:

> **'(a) the standard of the practitioner's professional performance has been seriously deficient;**
>
> **(b) the standard of the practitioner's professional performance is likely to be improved by remedial action;**
>
> **(c) the practitioner should limit his professional practice, or cease professional practice;**
>
> **(d) no further action needs to be taken on the Report.'**

24.71 An Assessment Panel was required to give its reasons for the opinions expressed. If members of the Panel disagreed, the 1997 Performance Rules required that the report should include a statement of any dissenting opinion and the reasons for it.

Failure to Co-operate with an Assessment Panel

24.72 If a doctor did not co-operate with the Assessment Panel, his/her case would be referred to the CPP. Sometimes, it was not easy to know whether the doctor was failing to co-operate or whether there was some genuine difficulty giving rise to that impression. It was not unusual for a doctor to assert that s/he was ill while the performance assessment was going on. In those circumstances, the case co-ordinator had to make a judgement as to whether the doctor's conduct in reality amounted to a deliberate failure to co-operate or whether the assessment should be postponed to allow his/her health to improve. It was recognised that being the subject of assessment can be extremely stressful and that this might have a genuine effect upon a doctor's health. If necessary, the case could be referred to the CPP and the CPP could consider referring the case to the Health Committee

(HC). Miss Smith said that staff in the Performance Section tried 'not to leave cases lingering for months on end without resolution'.

Consideration of the Performance Assessment Report

Seeking the Doctor's Observations on the Assessment Report

24.73 When the case co-ordinator received the assessment report, s/he was required to send a copy to the doctor, together with an invitation to submit written observations on it within 21 days. At the expiration of that period, the case co-ordinator had to consider the report and any observations submitted by the doctor. It should be noted that the 1997 Performance Rules specifically provided that the complainant should not receive a copy of the assessment report. This was the case even though the complainant was usually the doctor's employer or PCO and might have been able to make observations every bit as germane to the issues as those of the doctor.

The Decision Made by the Case Co-ordinator: No Further Action

24.74 In making his/her decision on the appropriate course of action to be adopted after receipt of the assessment report, the case co-ordinator was not bound by the Assessment Panel's opinion, although it would form a central part of his/her consideration. Miss Smith told the Inquiry that case co-ordinators did sometimes take a different view from that of the Assessment Panel. The Inquiry has seen the papers in one such case, that of Dr KA 05. However, Miss Smith observed that it did not happen very often.

24.75 The case co-ordinator had three options open to him/her. The first option was to close the case without further action. If the case co-ordinator was of the opinion that no further action should be taken in the case, s/he was required to consult a lay adviser before closing the case. A lay adviser was a lay member of the GMC appointed to act for this purpose. Only if the lay adviser agreed could the case be closed without further action. If the lay adviser did not agree with the case co-ordinator, the case co-ordinator had to refer the case to the CPP together with a copy of the performance assessment report, a statement of his/her opinion and a statement of the opinion of the lay adviser. A decision by a case co-ordinator (and agreed by a lay adviser) to take no further action was likely to arise only when the Assessment Panel had reported that the doctor's performance had not been seriously deficient. Miss Smith told the Inquiry that it was her impression that it was unusual for an Assessment Panel to find that the doctor's performance had not been seriously deficient. However, the GMC's FTP statistics do not entirely bear this out. In 2002, 21% of assessments resulted in a finding that the doctor's performance was acceptable. In 2003, the figure was 31%. Dame Lesley Southgate told the Inquiry at the seminars that it sometimes appeared that complaints of poor performance against a doctor had been made as the result of victimisation of one sort or another, rather than because his/her performance was deficient.

24.76 When an Assessment Panel reported that there had been practice which, although unacceptable, did not in the Panel's view amount to SDP, Miss Smith said that the case co-ordinator would have no option but to close the case. She said that no other action

would be taken. The effect of this was that the doctor's employers or PCO (and, if s/he was a GP, other members of the practice) would not be informed of any continuing concerns about the doctor's unacceptable practice, as revealed by the performance assessment, or given any advice about the steps they might take to deal with it.

The Decision Taken by the Case Co-ordinator: Referral to the Committee on Professional Performance

24.77 The second option open to the case co-ordinator was to refer the case to the CPP. Rule 25 of the 1997 Performance Rules required a case co-ordinator to refer a case to the CPP if, at any stage after an assessment had been carried out, s/he was of the opinion that it was necessary for the protection of members of the public or would be in the best interests of the practitioner for a direction for suspension or for conditional registration to be made.

24.78 The case co-ordinator would usually refer a case to the CPP if the Assessment Panel had reported that there were serious deficiencies in the doctor's performance which were unlikely to be improved by remedial action. In certain circumstances, the case co-ordinator might decide to refer a case, despite the Panel's view that remedial action was likely to be effective.

The Decision Taken by the Case Co-ordinator: a Statement of Requirements

24.79 The third option for the case co-ordinator was to formulate a written statement of requirements, with which the doctor would be invited to agree to comply. The doctor's agreement would usually include an agreement to take certain specific steps to remedy identified deficiencies. It might also involve agreeing to limitations being placed on his/her practice. In considering whether to deal with a case by way of a statement of requirements, a case co-ordinator would consider whether a statement of requirements would sufficiently protect patients. A statement of requirements was, the Inquiry was told, unlikely to be considered where the doctor did not admit the Assessment Panel's findings or where s/he showed limited insight into his/her deficiencies. Miss Smith said that the presence or absence of insight and the seriousness of the problems identified were the two most important factors she would have expected a case co-ordinator to have in mind when deciding whether a statement of requirements was appropriate.

The Statement of Requirements

24.80 If the case co-ordinator decided that a statement of requirements was appropriate, s/he would proceed to draw it up and send it to the doctor. The statement had to be based on the findings and opinion in the performance assessment report and might, as the case co-ordinator deemed appropriate, include any or all of the following matters:

> **'(a) the aspects of the practitioner's professional performance which he is required to improve;**
>
> **(b) the standard of professional performance which the practitioner is required to achieve;**

(c) the aspects of the arrangements for the running of his professional practice which the practitioner is required to improve;

(d) the limitations which the practitioner is required to impose on his professional practice'.

24.81 The statement might require the doctor to undertake training in some aspect of his/her practice and might also specify limitations on his/her practice, to which the doctor had to agree. The statement also had to set out the date on which the doctor was expected to have fulfilled any requirements and the period for which the statement of requirements was to have effect. It was also required to include a provision that further assessment was to be carried out after the date on which the doctor was expected to have fulfilled the requirements. That date had to be no later than a year from the date on which the doctor agreed to comply with the statement of requirements.

24.82 The 1997 Performance Rules provided that, where the doctor agreed to comply with the statement of requirements, s/he must signify his/her agreement in writing within 14 days and must undertake to comply with the statement of requirements and to undergo reassessment after the date on which s/he was expected to have fulfilled the requirements. The doctor was also required to agree to his/her employer or professional partner or **'any organisation or person with whom s/he has a professional relationship'** being told by the GMC of his/her agreement to comply with the statement of requirements and of the nature of those requirements. It appears that patients were not deemed to be included in the classes of persons with whom the doctor had **'a professional relationship'**, so that they would not be informed automatically. However, the doctor had to agree to the GMC disclosing the information to any person who made a specific enquiry about his/her registration. This rule was designed to ensure that doctors who were dealt with by way of a statement of requirements entered into voluntarily were put on a par with doctors who were the subject of directions made by the CPP. Such directions would be discloseable in response to enquiries about the doctor's fitness to practise. So, a patient who 'got wind' of the imposition of requirements could find out about them but patients were not automatically told. As I have said, the doctor's employers, partners and the PCT were not entitled to see the performance assessment report itself. This applied even where the doctor had agreed to a statement of requirements. If a doctor did not signify within 14 days his/her written agreement to comply with the statement of requirements, the case co-ordinator would refer the case to the CPP.

Compliance with the Statement of Requirements

24.83 Once the doctor had undertaken to comply with the stated requirements, it was up to the doctor him/herself to address any deficiencies that had been identified and to arrange to undergo any necessary retraining or education. He or she was expected to liaise with the regional postgraduate dean or with the regional director of postgraduate education for this purpose. Miss Smith told the Inquiry that it could be difficult for doctors to make these arrangements. Locums could experience particular difficulty obtaining the support necessary to fulfil the requirements. I shall refer to these difficulties later in this Chapter. Miss Smith also told the Inquiry that it was customary for a case co-ordinator to require a

quarterly report on the progress of the doctor from a person assisting in his/her re-education programme, to ascertain whether the doctor was complying with the requirements.

24.84 Rule 25 of the 1997 Performance Rules required the case co-ordinator to refer a case to the CPP if, in his/her opinion, the doctor was failing to comply with the requirements set out in the statement of requirements or if s/he was failing to benefit from and was unlikely to benefit from any education or training which s/he was undertaking in accordance with the statement of requirements.

24.85 The case co-ordinator was also required to refer a case to the CPP where s/he was of the opinion that the practitioner's fitness to practise might be seriously impaired by reason of his/her physical or mental condition. A case co-ordinator had no power to refer the doctor direct to the HC or into the voluntary health procedures.

Modification of the Statement of Requirements

24.86 The 1997 Performance Rules permitted the case co-ordinator to modify the statement of requirements with the agreement of the doctor. If the doctor did not agree to such modification, the case co-ordinator could refer the case to the CPP or could notify the doctor that the original statement of requirements would continue to have effect.

Further Assessment of the Doctor's Performance

24.87 The 1997 Performance Rules also provided for a further assessment to be carried out at the end of the period covered by the statement of requirements. A second Assessment Panel was appointed by the case co-ordinator as before. This assessment would focus on the deficiencies identified in the first Assessment Panel report and on the requirements contained in the statement.

24.88 The task of the second Assessment Panel was to assess whether the doctor had satisfactorily fulfilled the requirements of the statement and whether, as a result, the standard of his/her performance had improved sufficiently to enable the Assessment Panel to suggest that no further action should be taken. In the course of the second assessment, the Assessment Panel was required to interview the doctor and to consider any information about, or observations on, the case which were received from anyone who had assisted the doctor with any advice, education or training in connection with any remedial action taken by the doctor during the period of the statement of requirements. The report of the Assessment Panel was then sent to the case co-ordinator.

24.89 On receipt of the second Assessment Panel report, the case co-ordinator was required to decide, as before, whether to refer the case to the CPP, to take no further action in the case (only with the agreement of a lay adviser) or to seek the doctor's agreement to a second statement of requirements. Miss Smith said that, in her experience, if a second Assessment Panel felt that the doctor had not demonstrated that s/he had improved, the case co-ordinator would be reluctant to agree another statement of requirements and would be more inclined to refer the case to the CPP. If, however, some progress had been made, the case co-ordinator might give the doctor more time to make further

improvements. The 1997 Performance Rules provided for the possibility of a third assessment to be arranged in the same way as previously described.

Consideration of the Case by the Committee on Professional Performance

24.90 The 1997 Performance Rules provided for the reversal of a referral to the CPP in an appropriate case, e.g. if the doctor changed his/her mind and agreed to an assessment, or if the case co-ordinator received information which caused him/her to believe that it was no longer necessary for the CPP to hold an inquiry into the case. However, if the referral was not reversed, the CPP would proceed to consider the case.

The Composition of the Committee on Professional Performance

24.91 The composition of the CPP was governed by the 1996 Constitution Rules as amended. The CPP consisted of 26 members. It was chaired by the President or by a GMC member appointed by him. Two members were appointed by the President as Deputy Chairmen. The remaining 23 members were elected annually. The total membership of the CPP comprised 21 medical members and five lay members. The President's appointments were required to be approved by the Council. The CPP sat in panels. Until November 2002, the legal quorum for a CPP panel was five, including at least one lay member. In November 2002, the quorum was reduced to three, including at least one medical and one lay member. From 2000, non-members of the GMC (known as associates) were permitted to sit on the CPP and did so regularly. After July 2003, it was unusual for a member of the GMC to sit on a CPP panel. CPP panels sat with a legal assessor and with at least one specialist adviser.

24.92 The 1997 Performance Rules provided that the proceedings of the CPP should be held in private, unless the doctor requested that they be held in public. This rarely happened. If a hearing was held in public, it was open to the CPP to direct that confidential medical information about any individual should be received in private. In 2000, consideration was given to a change whereby the CPP would sit in public but, after consideration, no such change was thought appropriate. Some information about cases in which the CPP found the standard of a doctor's performance to have been seriously deficient were published from the inception of the procedures. In addition, after July 2003, the minutes of CPP hearings were published.

Assessment Hearings

24.93 Hearings by the CPP might occur where no assessment had been carried out. In a case where no order for an assessment had previously been made by the CPP (i.e. if the doctor had originally agreed to the assessment, then failed to co-operate, or if the ARC had directed the assessment and the doctor had not co-operated), the CPP had to decide whether to direct that an assessment should be carried out. The procedure for such hearings (known as 'assessment hearings') was similar to that for hearings by the ARC. If the CPP had previously directed that an assessment should be undertaken and the doctor had failed to co-operate, it was open to the CPP to suspend or to attach conditions to his/her registration. In such a case, the hearing was similar to that of the ARC, save that

there was no opportunity for the complainant to give evidence. That was because the requirement for an assessment had already been established; the question at issue was why the doctor had not complied with the requirements of the Assessment Panel. Miss Smith said that she was aware of one case when, following an assessment hearing on the grounds of a doctor's failure to co-operate with an Assessment Panel, the CPP had decided that an assessment was not necessary. It was not clear why this decision had been taken as, at that time, reasons were not given for the CPP's decisions. Subsequently, the CPP began to give reasons for its decisions in cases where it found the doctor's performance to be seriously deficient. More recently, it extended the giving of reasons to all cases, whatever the finding.

Performance Hearings

24.94 Hearings before the CPP might also occur when a performance assessment had been carried out and had revealed deficiencies which were so serious that the case co-ordinator considered it appropriate to refer the case to the CPP, or where a lay adviser disagreed with a case co-ordinator's decision to take no action after a performance assessment had been carried out. These hearings were known as 'performance hearings'. Other circumstances in which a performance hearing might take place were where the doctor had failed to agree to comply with a statement of requirements or a modified statement of requirements, or where the case co-ordinator was of the opinion that s/he was not benefiting, or was not likely to benefit, from any education or training s/he was undergoing or where the case co-ordinator believed there might be some health problem.

24.95 So far, I have mentioned only the circumstances in which a case might be referred to the CPP by a case co-ordinator. The 1997 Performance Rules also provided for a doctor to refer his/her own case to the CPP. When a performance assessment had been ordered by the ARC, the doctor could request that the standard of his/her professional performance should be considered by the CPP.

24.96 At a performance hearing, the complainant could be represented and could give evidence and address the CPP. However, the complainant was not entitled to hear other evidence given to the CPP. The GMC's representative was also permitted to call evidence including, usually, evidence from the lead assessor of the Assessment Panel.

24.97 The 1997 Performance Rules stated that, in advance of the hearing, the GMC should provide the doctor with copies of reports, written statements and other documents in the case. The GMC was required to inform the doctor whether or not it intended to call the author of a report, written statement or other document to give oral evidence at the hearing. The doctor then had the opportunity to make further written observations on the case and to indicate to the GMC if s/he wished the author of any of the documents sent to him/her to be called to give evidence. If the doctor wished the author of any relevant documents to be called, arrangements would be made for that person to attend the hearing. The 1997 Performance Rules provided that the lead performance assessor should be treated as the author of the performance assessment report. If s/he was not available to give evidence at the hearing, the case co-ordinator would decide which of the other members of the Assessment Panel should be called to give evidence in the lead

assessor's place. The CPP might itself obtain information in writing or call any person to give oral evidence where it considered this would assist it in carrying out its functions. The doctor might give oral evidence and might call witnesses. Miss Smith told the Inquiry that, in one recent case, the doctor had called 36 witnesses who had been responsible for writing documents relevant to the doctor's case.

The Decision of the Committee on Professional Performance

24.98 The CPP would then decide whether it found the standard of the doctor's performance to have been seriously deficient. If the CPP found that there had been no SDP, the case was closed. There was no power to do anything if the doctor's conduct was found to have been deficient but not, in the view of the CPP, to such an extent as to amount to SDP. Mr Scott, Chief Executive of the GMC, acknowledged in evidence that this was unsatisfactory. In Chapter 25, I will discuss the way in which it is proposed to solve this problem under the new FTP procedures.

24.99 The 1997 Performance Rules provided that the decision of the majority of the CPP who were present constituted a decision of the CPP. If the votes were equal, the decision should be in favour of the doctor. The CPP was not required to give reasons for its decision and did not generally do so when it decided that the doctor's performance had not been seriously deficient. This failure to give reasons was the subject of criticism and the practice has recently been changed. I shall return to this issue later in this Chapter.

24.100 If, having heard the evidence in the case, the CPP took the view that the doctor had or might have been guilty of SPM (as well as or instead of SDP) and that erasure of his/her registration might, therefore, be appropriate, it had no power to refer the case to the PCC. Miss Smith acknowledged that this was 'unsatisfactory'. This difficulty will be solved under the new FTP procedures, as erasure will be available in cases with a performance element.

24.101 If the CPP made a finding of SDP, it would then go on to consider the appropriate sanction. The CPP had no power, once a finding of SDP had been made, to take no action. Nor could it issue a reprimand. It had to impose one of two sanctions: suspension or conditional registration.

Sanctions

24.102 Suspension of a doctor's registration, if imposed, had to be for a specified period not exceeding 12 months. Alternatively, the CPP could impose conditions on the doctor's registration for a period not exceeding three years. In an appropriate case, the CPP could order that a suspension should take effect immediately. The CPP had no power to direct erasure, but, as I have explained, it had the power, in certain circumstances, to direct indefinite suspension.

Remedial Action after the Decision of the Committee on Professional Performance

24.103 If conditions on registration or suspension were imposed, it was for the doctor to initiate action, with the assistance of the postgraduate dean or postgraduate tutor in general

practice, to arrange any necessary re-education or training. No supervision was exercised to ensure either that this was done or that it was done promptly. Miss Smith told the Inquiry that, as at December 2003, no regular report on the doctor's progress was required by the CPP, as was the case when a doctor was dealt with by means of a voluntary statement of requirements. Miss Smith said that the GMC tended to have more contact with a doctor who was practising under a voluntary statement of requirements than with a doctor who was practising under conditions imposed by the CPP. The role of the case co-ordinator was, she said, limited once a case had been referred to the CPP. Sometimes, a person who was supervising the doctor might contact the GMC unprompted. This was usually when things were not going well. In the majority of cases, however, nothing was heard about the doctor's progress until the staff asked for information from the supervisor, or from the local postgraduate dean or postgraduate tutor in general practice, in preparation for a resumed hearing before the CPP. Miss Smith agreed that it would have been a better safeguard if, in a case which had been dealt with by the CPP, there had to be quarterly reports. Alternatively, perhaps, a case co-ordinator could have been appointed within the GMC to supervise the remedial arrangements. Bearing in mind that the CPP dealt with the more serious cases and the cases where the doctor was unwilling to co-operate, it seems strange that the supervision should have been less close following an order made by the CPP than in a case where there was a statement of requirements. In my view, this anomaly requires attention.

24.104 The Inquiry received some evidence about the problems that arose when the GMC imposed conditions upon a doctor's registration and the postgraduate deaneries were expected to provide support and remediation. First, I noted a study[5] of the process and outcomes of referrals from the GMC and health authorities to deaneries over a period of two years. In summary, it was found that, although the information provided to the deanery by the GMC was usually adequate and timely, the GMC sometimes required action that was not appropriate or feasible. Also, in the majority of cases, the cost of remedial training and education had to be borne by the deanery concerned. Letters received by the Inquiry in early 2004 from two different deaneries tended to confirm that these problems still remained. One acting Regional Director of Postgraduate Education told the Inquiry that, when the GMC imposed conditions on a GP, the GP was left to make his/her arrangements with the deanery. It was felt that the doctor's PCT should take an active part in making arrangements and should provide the necessary funding. This deanery felt well equipped to undertake educational remediation but was not prepared to engage in remediation connected with problems of health, attitude or personal circumstances. Another postgraduate dean spoke of similar problems. He confirmed that doctors were left to make their own arrangements for remediation. He said that it was difficult to provide the right environment for remediation and to find doctors willing to undertake the work of supervision and mentoring. He mentioned concerns about exposing patients to poorly performing doctors who might have personality and other problems. Remediation had to be undertaken by experienced doctors, who were already busy with their own practices and had to engage locums to cover the time they spent away from their patients.

[5] Bahrami J and Evans A (2002) 'Underperforming doctors in general practice: a survey of referrals to UK Deaneries', British Journal of General Practice, pp 892–896.

Remediation is necessarily expensive and funding can be a problem, particularly if the doctor is a locum without an established relationship with a PCT prepared to take responsibility. Notwithstanding these difficulties, this deanery had embarked on a programme of recruitment and training of doctors in training practices who would be willing and able to undertake this work. I had the impression, certainly from these respondents, that the spirit of the deaneries was very willing but the resources were scarcer than needed.

Resumed Hearings

24.105 When the CPP suspended or imposed conditions on a doctor's registration, the 1997 Performance Rules required the CPP to state that it would resume consideration of the case at a hearing (a 'resumed hearing') before the end of the period of suspension or conditional registration. The CPP was required to specify what information it would require at the resumed hearing and whether a further assessment should be carried out before the resumed hearing. In practice (and unlike the position where a statement of requirements had been agreed), further assessments were not always required by the CPP. Miss Smith told the Inquiry that it was not unusual for the CPP to direct that some form of assessment should take place but neither was it a particularly frequent occurrence. If a doctor had been suspended, the CPP would expect him/her to have taken steps to remedy the deficiencies in his/her practice before the resumed hearing. The steps the doctor would have been able to take would necessarily be limited by the fact that s/he had not been able to practise during that period. I draw attention to the fact that the CPP was required to hold a resumed hearing before the end of a period of suspension or conditional registration whereas the PCC was not obliged to do so and often did not do so. The Inquiry was told (and has seen an example of one case where it occurred) that, on occasion, a doctor who had previously failed Phase II of the performance assessment (i.e. the tests of knowledge and skills) would be required by the CPP to undergo a Phase II reassessment before being allowed to resume practice.

24.106 The CPP might bring the resumed hearing forward, for example if the doctor was not complying with the conditions imposed on his/her registration. Before the resumed hearing, the 1997 Performance Rules provided for the distribution to the doctor and members of the CPP of any relevant documents which had come into existence since the previous hearing (e.g. a further performance assessment report) and for the doctor to be given the opportunity to request that the author of any relevant document should be called to give evidence at the resumed hearing. The procedure for the hearing was similar to that for the original hearing, save that there was no provision for the complainant to give evidence. At a resumed hearing, the CPP had the power to extend a period of conditional registration for up to three years, to revoke or vary any of the conditions previously imposed or to direct that the doctor's registration should be suspended for up to 12 months. Where the doctor had been suspended at the original hearing, the CPP could extend the period of suspension for up to 12 months or impose a period of conditional registration for up to three years. In a case where the CPP had already directed periods of suspension lasting at least two years, the CPP could make a direction for indefinite suspension. Such a direction might be reviewed at the request of the doctor, but not

before two years after the date on which the direction took effect and not more than once every two years thereafter. In this way, the CPP acquired what amounted almost to a power of erasure.

Referral of a Case to the Health Committee

24.107 The CPP had the power to refer a case to the HC. The doctor would be medically examined and the HC, having considered the results of the examination, would form a judgement about whether the doctor's fitness to practise was seriously impaired by reason of a physical or mental condition. If, in the HC's judgement, there was no serious impairment, it was required to certify its opinion to the CPP. The CPP panel would then resume its consideration of the case and dispose of it. If, on the other hand, the HC's judgement was that the doctor's fitness to practise was seriously impaired by reason of his/her condition, the HC was required to certify its opinion to the CPP and then to proceed to dispose of the case. The CPP would then cease to exercise its functions in relation to the case. By referring a case to the HC for its opinion, therefore, the CPP did not necessarily lose its jurisdiction over a case. If no serious impairment of fitness to practise was found, the CPP could proceed to deal with the case. The CPP had no power to refer a case to a health screener to be dealt with by means of the voluntary health procedures. The ARC had a similar power to refer a case to the HC.

Interim Orders

24.108 Until 2000, there was no provision for the making of an interim order of suspension or for the imposition of interim conditions on registration in a performance case. From August 2000, medical screeners, case co-ordinators, the ARC and the CPP had the power to refer a case to the Interim Orders Committee (IOC) if it appeared to any of them that the IOC might wish to make an interim order. At the same time, the CPP was given the power to amend an order made by the IOC.

Appeals

24.109 Appeals from decisions of the CPP were governed by section 40 of the Medical Act 1983. Until April 2003, a doctor who was the subject of a direction for suspension or for conditional registration (or variation of the conditions imposed by a direction for conditional registration) had a right of appeal to the Judicial Committee of the Privy Council. After April 2003, appeals lay to the High Court. Until 2003, an appeal lay on a question of law only. In 2003, that restriction was removed.

The Operation of the Performance Procedures

24.110 In May 1999 and May 2000, the Performance Section presented reports on the operation of the performance procedures to the full Council of the GMC. Thereafter, statistics relating to cases dealt with under the performance procedures have been included in the annual GMC FTP statistics.

The Numbers of Cases Dealt with under the Performance Procedures

24.111 As I have already mentioned, the performance procedures got off to a slow start. The first cases entered the procedures in the early part of 1998 and, during that year, the GMC initiated action under the performance procedures (the 'initiation of action' being at that time defined by the GMC as the sending of a 'rule 5 letter' to the doctor) in ten cases. In May 1999, nine doctors had agreed to be assessed or had been required by the ARC to undergo assessment. Only three full assessments had been completed. During 1999, action was initiated by the GMC in 26 cases.

24.112 In its 2000 Report, the PSI team expressed surprise that so few complaints about poor treatment or substandard clinical practice had been referred by screeners into the performance procedures. The PSI team carried out an analysis of the reasons given by medical screeners during the period from June to December 1999 for deciding that cases did not raise an issue of SDP. The common reason (given in 33% of cases) was that the case did not show any evidence of SDP. The second most frequent response (24% of cases) was that there was **'no pattern of poor performance'**. The third most frequently given reason was that **'the case showed only a single incident – and no pattern'**. This does not seem to have led to reconsideration of the practice whereby the GMC did not usually enquire locally about further concerns to ascertain whether any pattern did in fact exist. The 2000 PSI Report observed:

> **'... screeners ... clearly felt restricted by the requirement for a case to show a pattern of poor performance before it could be referred under the performance procedures. Since most of the cases they saw related to single incidents, and no investigation had taken place to establish whether there was a pattern of poor performance, it was not surprising that this was the conclusion they came to.'**

24.113 In 15% of cases examined by the PSI team, the reason given was that the complaint related to matters that had occurred before July 1997. It is clear, therefore, that, even two years later, the decision not to admit evidence of events before that date was still exerting an effect.

24.114 By March 2000, eight assessments had been completed. However, in 2000, the pace quickened markedly. During that year, action was initiated by the GMC in 126 cases. Twenty eight assessments were completed during that year. In 2001, action was initiated by the GMC in 70 cases and 57 performance assessments were completed. During 2002, action was initiated in 80 cases and 67 performance assessments were completed.

24.115 In November 2002, the requirement to send 'rule 5 letters' was removed. The point at which the GMC 'initiated action' was, therefore, redefined. Curiously, it was now defined as the point at which arrangements were made to set up an Assessment Panel. I say 'curiously' because the first action taken by the GMC in a case in which a screener had decided that an assessment was appropriate was to send the doctor an invitation to undergo assessment; one might have expected, therefore, that it would be the sending of that letter which would have been regarded as the initiation of action. The new definition might account for the apparent decrease in the number of cases in which action was

initiated after November 2002. However, the recent figures do suggest that the number of cases entering the performance procedures had stabilised and may even have been decreasing. In 2003, the GMC initiated action in only 42 cases and the same number of performance assessments were carried out.

Delays

24.116 By 2000, there was considerable concern both within the GMC and outside about the delays in dealing with performance cases. This was at a time when the GMC was struggling to deal with a growing backlog of cases and its FTP procedures were under great pressure generally. Within the GMC, the delays in dealing with performance cases were attributed to the pressure of work in the office. Difficulty in obtaining the necessary evidence from referring bodies was also said to be a factor. Mr Howes told the Inquiry that, by the time the GMC's performance procedures came into operation in July 1997, the GMC had been working on their development for several years. Local NHS bodies had not had the same period of preparation as the GMC and were not equipped to deal with issues of poor performance. He said that, with time, referring bodies became better and better at cataloguing the problems they were having with doctors and, as 1st July 1997 receded, they were able to relate a longer history of problems in support of their concerns.

24.117 The Performance Section's Annual Report, given to Council in May 2000, indicated that the problems of delay had been addressed by recruiting additional staff and by better liaison with referring NHS bodies. As I have said, it certainly appears that far more cases were dealt with in 2000 than previously.

Statistics Relating to the Assessment Referral Committee

24.118 The Annual Reports and annual FTP statistics also contained details about the activities of the ARC. The ARC considered seven cases between the inception of the performance procedures and 31st March 2000. In all but one of the cases, the ARC decided that the doctor should be required to undergo an assessment. In the other case (heard prior to May 1999), the ARC concluded that the evidence of potential SDP after 1st July 1997 was insufficient to justify an order that the doctor should be assessed. During 2000, the ARC received nine cases and directed that assessments should be undertaken in seven of those cases. The 2001 FTP statistics contain no information about the activities of the ARC. In 2002, 40 doctors were referred to the ARC. In 15 cases, the ARC directed a performance assessment. In 17 cases, it decided that no assessment was necessary. In a further eight cases, voluntary erasure was granted. In 2003, the ARC received 19 cases. In nine cases, the ARC directed a performance assessment. In four, it decided that no assessment was necessary. Voluntary erasure was granted in two cases and four cases were awaiting hearing at the time the statistics were compiled.

24.119 The statistics relating to hearings by the ARC reveal, first of all, that quite a large number of doctors refused to undergo performance assessments when requested to do so. This had not been anticipated when the performance procedures were introduced. Furthermore, they reveal a significant number of cases where the ARC decided not to direct that a performance assessment should take place.

24.120 Mr Marshall said that it was not for him to 'second guess' the decisions of the ARC, particularly since he was not present at most of the hearings and was not privy to the ARC's discussions. However, he observed that it was 'on the face of it surprising' that, in 2002, more cases had been closed at this stage than had proceeded for assessment. This was particularly so since the test which should have been applied by the ARC was very similar to the screening test. Mr Marshall pointed out that the ARC often had more information (particularly from the doctor) available to it than did the screeners. An uncooperative doctor might not have responded to the invitation to submit observations to the medical screener. At a hearing before the ARC, however, s/he might give evidence and arguments would be put forward on his/her behalf, usually by a legal representative. As I have already mentioned, it was not usual for a complainant (or a representative of a complainant body) to be called to give evidence before the ARC. The hearing was, therefore, likely to be a one-sided process.

Statistics Relating to Assessment Panel Reports

24.121 Up to 2001, it was unusual for an Assessment Panel report to result in a finding that a doctor was fit to practise and that no GMC action was, therefore, necessary. Miss Smith's impression was that this rarely happened. However, as I have already mentioned, the GMC FTP statistics for 2001, 2002 and 2003 show that such a finding became quite common. In 2001, 18 out of 57 (i.e. 32%) completed assessments resulted in a finding that the doctor's performance was 'acceptable'. In 2002, the figure was 14 out of 67 (i.e. 21%) of assessments. In 2003, 13 out of 42 (i.e. 31%) assessments resulted in a finding that the doctor's performance was 'acceptable'.

Statistics Relating to the Statement of Requirements

24.122 In 1999 and 2000, there were very few cases in which, following a performance assessment, a statement of requirements was agreed. Most cases were referred to the CPP. In 2001, a statement of requirements was agreed in six out of 57 cases (i.e. 11%) where a performance assessment had taken place. In 2002, the figure was eight out of 67 cases (i.e. 12%). In 2003, statements of requirements were agreed in 17 out of 42 cases (i.e. 40%).

Statistics Relating to the Committee on Professional Performance

24.123 Up to March 2000, the CPP had held five performance hearings and had in each case found the performance of the doctor to have been seriously deficient and had imposed a period of suspension of registration. In 2000, the CPP held four performance hearings. In each case, it made a finding of SDP. It imposed periods of suspension in two cases and imposed conditions on the registration of the other two doctors. In 2001, there were 23 performance hearings. In three cases, the CPP found the doctors' performance to have been 'acceptable'. In 20 cases, there was a finding of SDP. In seven cases, suspension was imposed and 13 resulted in the imposition of conditions on the doctors' registration. In 2002, there were 27 performance hearings. In nine cases, the doctor's performance was found to have been 'acceptable'. Of the remaining 18 cases, where SDP was found,

seven resulted in suspension and 11 in conditions being imposed on the doctor's registration. In 2003, out of 21 performance hearings, the CPP found the doctor's performance 'acceptable' in two. Four cases resulted in suspension and 12 in the imposition of conditions on registration. Of the remaining three, two were adjourned and one resulted in voluntary erasure.

24.124 Miss Smith told the Inquiry that she could not speculate upon why the CPP had found the doctor's performance 'acceptable' in such a significant proportion (33%) of cases during 2002. However, she said that, in her experience, there was considerable dispute at hearings about not only the original complaint but also the report of the Assessment Panel and the way the assessment had been carried out. The length of CPP hearings had increased over the years. She mentioned the recent case, to which I have referred, where the doctor had called no fewer than 36 witnesses.

Statistics Relating to Suspensions

24.125 Information provided to the Inquiry by the GMC reveals that 21 doctors were suspended from practice by the CPP between 1998 and the end of 2003. Of those 21 doctors, five have been indefinitely suspended, ten remain under suspension and two are now practising without restriction. Four have since been erased; three took voluntary erasure and one was erased for failure to respond to correspondence sent to his/her registered address.

Statistics Relating to the Making of Interim Orders in Performance Cases

24.126 During 2002, 18 cases classified as 'performance cases' were referred to the IOC. Mr Marshall pointed out that this classification was probably made retrospectively since, if a case was referred to the IOC by a medical screener at an early stage, it would not necessarily be clear at that time whether it was a conduct, a performance or a health case. The statistics show that six referrals to the IOC were made by performance case co-ordinators and one each by the ARC and the CPP. The other ten must, presumably, have been made by medical screeners. Mr Marshall told the Inquiry that he suspected that a higher percentage of performance cases than of conduct cases were referred to the IOC. The figure of 18 cases referred in 2002 represented 23% of cases referred to the performance procedures and 32% of those cases where the GMC had initiated action by writing a rule 5 letter.

Judicial Decisions on the Performance Procedures

The Case of Krippendorf

24.127 In November 2000, the Privy Council gave judgement in the case of Krippendorf v General Medical Council[6]. This was an appeal by a doctor from a determination of the CPP that the standard of her professional performance had been seriously deficient and a direction that her registration should be suspended for a period of 12 months with immediate effect.

[6] [2001] 1 WLR 1054.

24.128 From October 1996 until January 1998 (when she was suspended), Dr Manjula Krippendorf worked in the UK as a consultant in community paediatrics. She had obtained a certificate of full registration from the GMC in October 1996. Prior to that time, she had been working abroad in specialties which were different from, but related to, community paediatrics. In 1998, one of her former employers, a NHS trust, complained to the GMC about the techniques employed by Dr Krippendorf in administering BCG vaccines to 227 children during an immunisation programme in September 1997. These techniques had led, it was said, to an unusually high incidence of side effects. The same NHS trust also complained about Dr Krippendorf's role as consultant paediatrician in two potential child protection cases. The complaints gave rise to an invitation by the GMC to Dr Krippendorf to undergo a performance assessment, to which she agreed.

24.129 Delivering the judgement of the Privy Council, Sir Christopher Slade said that the performance assessment had been directed primarily at assessing Dr Krippendorf's professional competence in a number of areas of work, falling within what the Assessment Panel had perceived to have been her various job descriptions since 1997. The Assessment Panel had assessed her on the work which **'might come a community paediatrician's way'** within the post in which she had been employed at the time when the complaint against her was made. The Assessment Panel had expressed the view that community paediatrics required a knowledge of, and experience in, general and developmental paediatrics. The Assessment Panel had regarded clinical competence as essential when responsibility was taken for clinical care. The Assessment Panel had found that Dr Krippendorf did not possess the necessary knowledge and experience. They had tested her in basic life support techniques and had found that she demonstrated an inability to perform them. However, there was apparently no evidence that she had ever been required to use such techniques during the course of her work in the UK. During Phase I of the assessment, interviews had been carried out in places where Dr Krippendorf had worked, medical records had been examined and case discussions had taken place. Phase II had consisted of objective tests of paediatric knowledge and practice.

24.130 At the conclusion of the assessment, the Assessment Panel stated in its report that the standard of Dr Krippendorf's professional performance had been seriously deficient, that the standard of her professional performance as a paediatrician was likely to be improved only with full retraining in general paediatrics, as well as in any specific specialty such as community paediatrics, and that she should limit her professional practice to non-clinical work. The assessment report indicated that, even within that sphere, she required retraining.

24.131 At the hearing before the CPP, counsel for the GMC indicated that, the performance assessment having taken place, the GMC would not be relying on the original complaints made against Dr Krippendorf. At the request of Dr Krippendorf's representative, the Director of Public Health who had made the original complaint (and from whom the GMC had obtained a statement) was called to give evidence. When giving her own evidence, Dr Krippendorf admitted that, judged on the basis on which the assessment was carried out, she had not passed. She also expressed her intention to do no clinical work in the future, except in the field of public health. She accepted

that, even before working in that field, she should undergo retraining in some aspects of the work, as suggested by the Assessment Panel. She appealed the decision of the CPP on the ground that the Assessment Panel had not approached its function in the correct way.

The Judgement of the Judicial Committee of the Privy Council

24.132 The Privy Council found that the assessment report demonstrated that the Assessment Panel had made a basic error in its approach to its functions. Section 11(1) of the 1997 Performance Rules required the Assessment Panel to **'adopt such procedures as appear to them to be necessary having regard to the nature of the practitioner's work to assess the standard of his professional performance'**. This, the Privy Council pointed out, reflected the wording of section 36A of the Medical Act 1983, which indicated that it was the past professional performance – not the professional competence – of the practitioner in the work which s/he had actually been doing to which the Assessment Panel and the CPP should direct their attention.

24.133 It went on to observe that:

> **'... everything in the Rules suggests that it is the duty of the CPP and the Panel to have regard to the track record of the practitioner in the work which he has actually been doing. It is not their function to conduct an examination equivalent to that of a student's examination board. Theoretical questions are relevant only insofar as the answers may throw light on the practitioner's professional performance in the specific areas of work which he has actually been doing.'**

24.134 This had not been the approach adopted by the Assessment Panel when assessing Dr Krippendorf. Moreover, the assessment report had included no investigation of and no findings in connection with the original complaint about Dr Krippendorf's injection techniques. No explanation was given for that. The Assessment Panel had regarded the complaint merely as a 'backdrop' to its report. It considered that the complaint had triggered the setting up of the assessment, but that it had no further relevance from the perspective of the Assessment Panel. The Privy Council also observed that Dr Krippendorf had been asked many questions about her professional competence in dealing with the kind of problems that a general paediatrician might come across in the course of practice in the UK, without regard to whether she had ever had to deal with them in the course of her actual work. The judgement continued:

> **'Their Lordships would accept that on occasions questions directed to a practitioner's knowledge and clinical skills may throw light on his professional performance in work which he has actually been doing, in cases where there is reason to suspect that his performance in such work may have been seriously deficient. In their Lordships' opinion, however, the questions directed to and answered by the appellant** (*Dr Krippendorf*) **in the Portfolio were of far too extensive and detailed a nature properly to constitute part of the basis on which the Panel were entitled to reach their conclusion.'**

24.135 In reaching its decision, the CPP had stated that it had not relied on the original complaint against Dr Krippendorf, but instead had focussed on the evidence in the assessment report. As I have said, the Privy Council found that report to be flawed. The first reason for that was the fact that the Panel had failed to assess Dr Krippendorf's professional performance by reference to the work she had actually been doing since 1997. The second reason was the failure of the report to deal with the original complaint. The judgement said:

> **'Their Lordships do not go so far as to hold that in every case the complaint which triggers an assessment requires investigation by the Panel and the CPP. On the facts of the present case, however, the complaints should, in their Lordships' opinion, have been investigated because nothing related more directly to the standard of the appellant's actual professional performance over the relevant period. The failure of both the Panel and the CPP to investigate the complaints reflects their erroneous concentration on her professional competence, rather than her actual professional performance. ...**
>
> **In the context of fairness, their Lordships add that, in their opinion, in the particular circumstances of this case, fairness demanded that the appellant should be given a proper opportunity to refute, if she could, the serious complaints which directly related to her professional performance and had led to the assessment.'**

24.136 The Privy Council concluded that the CPP had misdirected itself in law in reaching its determination. It advised that the appeal should be allowed and that the determination of the CPP should be quashed.

After the Case of Krippendorf

24.137 The decision in the case of Krippendorf caused consternation at the GMC. Mr Scott told the Inquiry that he and his colleagues were 'somewhat flummoxed' to be told that the GMC should be investigating the initial complaints, rather than launching into an investigation by way of a performance assessment. Sir Donald Irvine said that the effect of the Krippendorf case was 'profoundly unsettling'. After this decision had been delivered, work on performance assessments was held back to enable some adjustments to be made. In December 2002, the Medical Act 1983 (Amendment) Order 2002 came into force. It introduced into the Medical Act 1983 a provision that **'"professional performance" includes a medical practitioner's professional competence'**. It also made clear that an assessment of a doctor's professional performance might include an assessment of a doctor's professional performance at any time prior to the assessment, as well as an assessment of the standard of his/her professional performance at the time of the assessment. It was intended that this should put paid to the problems that had arisen in Krippendorf.

The Case of Sadler

24.138 The case of Sadler v General Medical Council[7] concerned an appeal to the Privy Council by Mr Anthony Peter Sadler, a consultant in obstetrics and gynaecology, against a determination by the CPP, in July 2002, that the standard of his professional performance had been seriously deficient in the area of good operative care. The CPP imposed conditions on his registration, requiring him not to undertake any major gynaecological surgery, to undertake an appropriate remedial training and assessment programme if he wished to return to major gynaecological surgery and to notify the GMC promptly of any professional appointment that he undertook.

The Complaint

24.139 In December 1997, the Medical Director of the NHS trust responsible for the hospital where Mr Sadler worked had complained to the GMC about various matters, including a number of specific incidents which had occurred during surgery performed by Mr Sadler. These included two incidents of severe post-operative bleeding. By the time of the complaint, Mr Sadler had been suspended from his post.

The Report of the Assessment Panel

24.140 Having considered the case, the medical screener directed that Mr Sadler should be invited to undergo a performance assessment. Mr Sadler declined the invitation but the ARC directed that an assessment should take place. The Assessment Panel found that there were severe deficiencies in his obstetric and gynaecological practice, but recommended that he should undergo targeted retraining and supervision, with limited restrictions on his practice. Accordingly, the performance case co-ordinator drew up a statement of requirements with which Mr Sadler undertook to comply. After a period of delay, he embarked upon a period of retraining at a hospital in Bristol. Shortly afterwards, he began to operate under supervision. On the third day, he severed a patient's right ureter while carrying out an abdominal hysterectomy. As a result of this, his retraining placement was terminated. He was unable to obtain another placement and could not, therefore, comply with the statement of requirements. The case co-ordinator referred the case to the CPP.

24.141 The performance assessment report (which had been prepared before the decision of the Privy Council in the case of Krippendorf) did not concentrate on the five surgical cases identified in the original complaint. Instead, it relied largely on interviews, especially with staff at the hospital where the incidents had occurred. Mr Sadler had no opportunity of challenging the third party interviews during the preparation of the assessment report, as he was not given transcripts of those interviews until some time afterwards.

The Hearing before the Committee on Professional Performance

24.142 At the hearing before the CPP, evidence was called in connection with three of the surgical cases mentioned in the original complaint and also in relation to the incident which had

[7] [2003] 1 WLR 2259.

occurred during Mr Sadler's retraining placement. I shall call these four cases the 'index cases'. Evidence about the assessment report was also called. The hearing occupied 16 days. On the 15th day, the legal assessor advised the CPP that it should not rely on the contents or conclusions of the assessment report, or on anything adverse to Mr Sadler in the third party interviews. This was because the assessment report was flawed in some of the same respects as had been the assessment report in Krippendorf. In particular, it did not distinguish between past performance and competence and did not subject the index cases to close scrutiny. In addition, Mr Sadler had had no opportunity to challenge the third party interviews on which the report relied. The CPP took the legal assessor's advice and its decision, therefore, depended on the evidence relating to the index cases.

24.143 The CPP expressed its overall conclusions thus:

> **'The Committee find that in ... Cases 1, 2 and 5, and in Case A** (*i.e. the index cases*) **you did not meet the professional standard appropriate to the work you were doing. The Committee are sure that these cases disclosed deficiencies in your surgical practise** (*sic*) **and that these deficiencies, whether considered individually or cumulatively, were serious. Each of them discloses a worrying reliance upon unsafe surgical techniques which form no part of the normal practise** (*sic*) **followed at the relevant time by surgeons in this country.'**

The Judgement of the Judicial Committee of the Privy Council

24.144 Before the Judicial Committee of the Privy Council, the decision of the CPP was attacked on a number of grounds. In particular, it was submitted that index cases could not constitute a 'pattern' of seriously deficient behaviour. Reference was made to the definition of SDP contained in the publication 'When Your Professional Performance Is Questioned'. The November 1997 edition stated:

> **'''Seriously deficient performance'' is a new idea. We have defined it as ''a departure from good professional practice, whether or not it is covered by specific GMC guidance, sufficiently serious to call into question a doctor's registration''. This means that we will question your registration if we believe that you are, repeatedly or persistently, not meeting the professional standards appropriate to the work you are doing – especially if you might be putting patients at risk. This could include failure to follow the guidance in our booklet Good Medical Practice.'**

24.145 The Privy Council rejected the submission that the index cases could not constitute a pattern of behaviour which came within the definition of SDP, saying:

> **'Although in *Krippendorf* the Board did not criticise the phrase ''repeatedly or persistently'' in the GMC's guidance, it is important to bear in mind that that guidance is a generalisation seeking to cover a very wide range of professional performance. The professional demands made on a general practitioner are very different from those**

made on a consultant surgeon. A continuing failure to organise the efficient management of a general practice may (in a sufficiently bad case) amount to seriously deficient performance, but in the nature of things it must be assessed on very different evidence from that relating to shortcomings of technique in major surgery. It would plainly be contrary to the public interest if a sub-standard surgeon could not be dealt with by the CPP unless and until he had repeatedly made the same error in the course of similar operations. But as a general rule the GMC should not (and their Lordships have no reason to suppose they would) seek to aggregate a number of totally dissimilar incidents and alleged shortcomings in order to make out a case of seriously deficient performance against any practitioner.'

24.146 The Privy Council concluded that the CPP's decision was justified and recommended that the appeal be dismissed. It made the following observations on the judgement in Krippendorf:

'But without casting any doubt on the decision their Lordships feel that the distinction between competence and performance, drawn in *Krippendorf*, should not be taken too far. It is important that any assessment panel should have proper regard to the complaint or other information which originally set the assessment in motion. But in most cases there is an obvious correlation between competence and performance. Moreover the assessment panel is concerned, not only with assessing past professional performance, but also with what needs to be done to improve a practitioner's performance, both in the public interest and in the practitioner's own best interests ... The process of assessment must include forming a view as to the standard of past performance, but if it is to achieve its objectives the process must not be restricted to that sort of backward-looking exercise.'

And

'... their Lordships think it right to reiterate that the process of assessment involves not only the examination of past performance but also assessment and planning (in all but the worst cases) for improvement and rehabilitation. Many assessments and statements of requirements lead to a satisfactory outcome, and a formal hearing before the CPP proves to be unnecessary. Their Lordships do not wish to send out a message that assessment by an assessment panel should be regarded as solely, or even primarily, designed as a process of collecting evidence in order to establish a prima facie case against a practitioner. Where a formal hearing before the CPP is unavoidable parts of the assessment panel's report may still be inapposite to the determination of the first question that the CPP has to decide; but the whole report is likely to be relevant to the subsequent issue of disposal if it arises.'

The Standard of Proof

24.147 In the case of Krippendorf, the legal assessor had said when advising the CPP:

> **'The burden of proving seriously deficient performance rests on the Council throughout, as is conceded and you should not make such a finding unless you are sure on the evidence that such was the case.'**

24.148 In opening the case of Sadler to the CPP, the GMC's counsel had indicated that the appropriate standard of proof was the criminal standard of proof and that the legal assessor in Sadler had advised the CPP in appropriate terms. Before the Privy Council, counsel for the GMC did not seek to put forward a lesser standard of proof, but sought guidance on the appropriate standard of proof for future cases. In giving such guidance, the Privy Council said this:

> **'The function of the CPP is not penal. It is to protect the public and to rehabilitate (if possible) practitioners whose professional standards have fallen too low. In the first of its tasks (that is deciding whether the standard of a practitioner's performance has been seriously deficient) the CPP has to ascertain the primary facts (which in many cases may not be seriously in doubt) and then to exercise their judgment (in the case of some but not all the members of the CPP, their professional judgment as experienced doctors). In this exercise the standard of proof of the primary facts ought not, in the generality of cases, to be an issue which gives rise to much difficulty. So far as it is a material issue the standard should in their Lordships' view, in the generality of cases, be the ordinary civil standard of proof. There may be exceptional cases (probably cases in which the practitioner is fortunate to be facing the CPP rather than the Professional Conduct Committee) in which a heightened civil standard might be appropriate ...'**.

24.149 The Privy Council went on to echo what had previously been said by the Privy Council in the case of McAllister v General Medical Council[8]:

> **'In charges brought against a doctor where the events giving rise to the charges would also found serious criminal charges it may be appropriate that the onus and standards of proof should be those applicable to a criminal trial. However there will be many cases, where the charges which a doctor has to face before the committee could not be the subject of serious or any criminal charges at all. The committee is composed entirely of medical men and women learned in their profession and to require that every charge of professional misconduct has to be proved to them just as though they were a jury of laymen is, in their Lordships' view, neither necessary nor desirable. What is of prime importance is that the charge and the conduct of the proceedings should be fair to the doctor in question in all respects.'**

[8] [1993] AC 388.

24.150 The Privy Council pointed out that the passage from McAllister was not wholly apposite to a committee which must now have at least one lay member but, subject to that qualification, they observed that the passage applied still more strongly to a hearing before the CPP than to a hearing before the PCC. It should be noted that the Privy Council's remarks on standard of proof were made at a time when a finding of SDP could not result in erasure. It is possible that its view might have been different if erasure had been available, as it will be in future.

24.151 Before leaving the case of Sadler, I wish to draw attention to the position, highlighted by the facts of the case, of patients who are treated by doctors whose performance either has been found to be seriously deficient or has given rise to serious concerns and who are operating under the terms of a statement of requirements. It is not clear to me whether patients are told the full facts about the status of a doctor who is about to operate on them. In 1999, the Performance Issues Working Group (PIWG) (under the Chairmanship of Professor Hatch) was examining various issues including **'consent to treatment in cases where the treatment is to be given by a doctor receiving remedial training following a performance assessment'**. The PIWG recommended to Council that patients must be given sufficient information to enable them to give informed consent to treatment by a doctor undergoing retraining. The PIWG drafted some sample letters that might be sent to patients. At its meeting in November 1999, the GMC decided that further work should be done on these issues. It appears that no further progress has been made. In Chapter 27, I have made a recommendation about the provision to patients of information relating to doctors undergoing retraining.

The Inquiry's Examination of Cases

24.152 In addition to the cases of Krippendorf and Sadler, the Inquiry examined the files, provided by the GMC, of five cases considered by the CPP since 2000. They are useful as they illustrate a number of the difficulties the GMC has experienced in connection with the operation of the performance procedures, and they provide a basis for discussion about possible improvements in the procedures. The main problems are those of delay, the complexity of the procedures and the difficulty in arranging remediation. The cases also give rise to concern about the absence, in some cases, of any formal assessment before the doctor was allowed to resume unrestricted practice. In discussing these cases, I am anxious to preserve the anonymity of the doctors concerned. For that reason, I have not quoted the dates upon which the main events took place. However, the timespan covered by the proceedings is a matter of importance. I have therefore explained the chronology by reference to the time that elapsed from the time of the first report to the GMC.

The Cases KA 01 to KA 05

Dr KA 01

24.153 In the case of Dr KA 01, who was a single-handed GP, the PCO reported concerns about the doctor's general performance to the GMC. Clinical governance assessments had identified his performance as 'seriously deficient'. Numerous complaints about him had

been received from colleagues and patients. It was thought that prescribing errors of a serious kind were putting patients at risk of harm. The case was screened into the performance procedures and, three months after the first report, the doctor agreed to assessment. The assessment report was ready at the eight-month stage. It concluded that the doctor's performance was seriously deficient. In particular, I note that the doctor failed all three elements of Phase II. Dame Lesley Southgate told the Inquiry that a doctor cannot be performing well if s/he does not have an adequate knowledge base.

24.154 However, the assessment report expressed the view that the doctor was aware of his deficiencies and was keen to remedy them. The Assessment Panel thought remediation could be effective. It proposed a series of undertakings, which would have left the GP practising, although not alone. He was to have a mentor and was to work in various ways towards improvement of his systems of work. He was to be reassessed in 12 months' time. He agreed to the undertakings. However, the PCO was less than happy about the arrangements. It was now almost a year since the case had been referred to the GMC and its officers were very worried about the prospect of delay for another 12 months when, they said, **'every day he is doing harm'**. Very properly, the GMC case co-ordinator referred the case to the CPP.

24.155 A hearing followed; it took place 14 months after the initial complaint. The doctor's performance was found to be seriously deficient in six respects and he was made subject to conditions for two years. Essentially, the doctor was to continue in practice (although not alone) and was to become involved in a variety of remedial activities. Two of these, which were of considerable importance, involved following advice on retraining to be given by the postgraduate dean and the Clinical Governance Lead of the PCO. After the hearing, a salaried partner was employed to work in the doctor's practice. However, nine months later (23 months from the initial report), the GMC discovered that the doctor had not contacted either the postgraduate dean or the Clinical Governance Lead. The following month, the doctor was asked for an explanation for this; he said that he had thought that these persons would get in touch with him. He was sent a 'mild' letter of warning.

24.156 Just over a year later (that is three years and one month from the initial complaint), it was discovered that the doctor had not been complying with the condition that required him to accept the advice of the postgraduate dean and Clinical Governance Lead. It seems that he was referred to the IOC, which made an order suspending him from practice with immediate effect. The following month, there was a resumed hearing by the CPP, as the two years since conditions were originally imposed was about to expire. The doctor did not attend the hearing. The CPP panel received some evidence that he had co-operated in his remediation. However, it was not satisfied that his clinical practice had improved. The CPP panel decided that the doctor continued to present a risk to patient safety and that it would not be sufficient for the protection of the public to impose conditions on his registration. Therefore, the doctor's registration was suspended for a period of 12 months. At the resumed hearing, which would take place shortly before the expiry of the suspension, the doctor would be able to present evidence of steps taken to remedy his deficiencies.

Comment

24.157 This history shows that the doctor had practised for a period of three years after being reported to the GMC. Throughout that time, he had presented a risk to patient safety. The case has highlighted the need for the GMC to take some proactive steps to ensure that, at the very least, a doctor who is subject to conditions is complying with them. Even that would not be a guarantee that s/he was not practising at a seriously deficient level, but at least it would afford a degree of patient protection. Under the old FTP procedures, when a doctor accepted a voluntary statement of requirements, the GMC required a quarterly report of progress. I hope that the GMC now recognises the need for a similar arrangement to be made in cases where conditions are imposed by a committee or panel, rather than agreed voluntarily. However, I am not sure that this has been recognised, as I can see no provision for supervision in the new procedures. The GMC says, and I well understand its point, that it is not responsible for making the arrangements necessary for compliance with a doctor's conditions; that must be for the doctor him/herself. However, in the interests of patient protection, the GMC must be made aware of whether the doctor is complying because, if s/he is not, s/he should be brought back for more stringent measures to be considered. It seems to me that this case also calls into question the wisdom of imposing conditions for as long as two (or even three) years without any intermediate hearing. It might sound as though the imposition of conditions for three years is a tougher sanction than conditions for one year; but, if the effect were to be to leave the doctor to practise at a seriously deficient level for three years, the sanction would in fact be inadequate and would leave the public at risk.

Dr KA 02

24.158 A PCO reported to the GMC a wide variety of concerns about Dr KA 02, a GP. These included concerns about clinical competence and judgement, unreliability in relation to out of hours duties, poor hygiene within the surgery premises, breaches of patient confidentiality, lack of audit, failure to undertake continuing education, disregard of controlled drugs regulations and lack of insight in respect of his shortcomings. Almost a year later, the GMC invited the doctor to undergo assessment, to which he agreed. Phase I took place 14 months after the initial report. The assessment presented considerable difficulties because the doctor had left his former single-handed practice and had taken employment in another practice. This had been terminated and, at the time of the assessment, the doctor had only about 56 patients. The report of Phase I expressed many concerns about the clinical care provided. Phase II was not completed until ten months later because of the doctor's ill health. The doctor failed some aspects of the tests rather badly but his combined results were just acceptable. The assessment report was produced two and a half years after the original concerns had been reported. The Assessment Panel concluded that the doctor's performance was seriously deficient in a significant number of respects and recommended that he should not practise unsupervised until he had completed a period of defined remedial training under the guidance of a suitably trained GP. The doctor accepted the report and recommendations.

24.159 Despite the doctor's acceptance, the case was (appropriately) referred to the CPP and a hearing took place two years and eight months after the initial report. The doctor's

performance was found to be seriously deficient and conditions were imposed for 12 months. Principally, the doctor was permitted to work only under the supervision of a GP trainer in a training practice; he was not to work for a deputising service. He had to seek the advice of the postgraduate dean and was required to provide the GMC with information about his activities. As is usual with CPP cases, there was no feedback about progress; Miss Smith told the Inquiry that feedback usually came in only if things were not going well.

24.160 At the resumed hearing, three years and eight months after the initial report, the conditions were renewed for a further six months; at the next hearing, they were revoked. The CPP said that it felt that there was sufficient evidence of improvement to warrant that decision, although no further assessment had been carried out. Presumably, the CPP had received a report from the supervisor. Also, the doctor had signed an undertaking not to practise single-handed. No doubt that undertaking was given voluntarily. However, I do not see how it could be enforceable.

Comment

24.161 At the Inquiry hearings, I expressed concern that a doctor whose registration had been subject to conditions should have the conditions removed without any further formal assessment. In the case of a voluntary statement of requirements, the Rules required a second assessment before the restrictions were lifted. This was not so with conditions imposed by the CPP. In its final submissions to the Inquiry, the GMC accepted that the arrangements under the old procedures gave an appearance of inconsistency and that conditions or restrictions should not be lifted without adequate evidence that this was appropriate. I can see that, in some cases, a formal assessment might not be necessary: for example, where a doctor has worked under close supervision and there is a detailed report from his/her supervisor. However, where the supervision has been of a mentoring or advisory nature, I am concerned that the supervisor might not be in a position to provide a sufficiently detailed view of the doctor's progress to permit a safe decision to be made to remove the conditions. Also, I would have thought that, where a doctor has failed any aspect of the Phase II tests, s/he should be required to retake them and should not be free to practise without restriction unless and until the results are satisfactory.

Dr KA 03

24.162 The concerns expressed about Dr KA 03, a GP, related to a variety of problems, some of which sounded rather more like misconduct than poor performance. For example, it appeared that a large number of patients had been removed from the doctor's cervical cytology recall system and there was concern that this had been done, not for clinical reasons, but to allow the doctor to meet a particular target (which would, I think, trigger a payment). However, there were also concerns about his prescribing practices, particularly in relation to controlled drugs, and his management of repeat prescribing. It appeared that much of the clinical activity within the practice was dictated by the doctor's wife who was the practice manager. After some discussion between Mr Howes and a medical screener, it was agreed that further, more detailed, information should be

obtained. However, owing to an 'oversight', that was not done and the case went back to the medical screener seven months after the initial report. The screener decided that this was a performance case. Three months later, the doctor agreed to be assessed. Phase I took place just over a year after the initial complaint and Phase II another two months after that. The report was produced 18 months after the initial complaint. The report described the doctor's performance as unacceptable in several respects and as being a **'cause for concern'** in others. The doctor failed two of the three tests in Phase II. The Assessment Panel nonetheless considered that the doctor should be allowed to continue to practise, provided that he was supervised, that he did not take on any more patients and that there was a development plan for his re-education. Also, the doctor was to be required to improve his surgery premises. The doctor did not accept the assessment report and the case was referred to the CPP for hearing.

24.163 The CPP panel hearing took place three months after production of the assessment report. The CPP panel found that the doctor's performance was seriously deficient in several important respects. I note, with some interest, that this finding was made notwithstanding the reception of a large number of testimonials and a patients' petition in support of the doctor. I mention this because it demonstrates that patients may not be aware of deficiencies in their doctor's performance. Also, I think they are sometimes, possibly often, willing to write a letter of support without bringing all their critical faculties into play. The CPP rejected the Assessment Panel's suggestions for remediation as impracticable and suspended the doctor's registration for a year. In the meantime, it was suggested that the doctor should take the advice of the director of postgraduate education about the steps to be taken to remedy his deficiencies. A year later, the doctor was allowed to practise under conditions. He was to work in supervised practice. He was not to work for a deputising service. He could prescribe benzodiazepines and other controlled drugs only with the agreement of his supervisor. The doctor was told that, before these conditions could be lifted, he would be required to undergo reassessment or, alternatively, to show that he had passed the examination for Membership of the RCGP. Nine months later, the doctor underwent the Membership examination but failed. He also retook the Phase II tests. He scored just above the minimum in two of the three tests and narrowly failed the third. Four months later, at a hearing, the CPP received reports on the doctor's progress and stated that it was satisfied that **'the public are now sufficiently protected'** for it to remove the restrictions on registration.

Comment

24.164 This case gives rise to two matters of interest. The first raises the question of what test the CPP ought to have applied before deciding whether to remove restrictions. The Medical Act 1983 did not specify the test that should be applied at this stage. However, the jurisdiction of the GMC in performance cases was based upon 'seriously deficient' performance. Did this mean that if, on later consideration of the case of a doctor whose performance had earlier been found to be seriously deficient, it was found that his/her standard of performance had risen to just above the level of 'seriously deficient', the restrictions had to be lifted, even though his/her performance still gave rise to some concerns for patient welfare? The test apparently applied in the case of Dr KA 03 was not

the 'seriously deficient' test; it was said to be a higher test of 'sufficient protection for the public'. That seems a more sensible and satisfactory test, but whether it would withstand a legal challenge from a doctor I am not sure. In any event, I am not sure whether the CPP consciously considered what test it should apply; it may be that the panel just thought that the conditions should be lifted.

24.165 The second matter of interest is that the CPP found that the doctor had passed the higher test of 'sufficient public protection' notwithstanding his poor showing in the Phase II reassessment. These are objective tests set at a level where most doctors would pass easily. If this was the best that this doctor could do after a fairly intensive period of remediation and study for the RCGP Membership examination, it does not inspire confidence in his performance after a return to unrestricted practice. In short, this case shows that, at least in some cases, the performance procedures could only seek to lift seriously deficient doctors off the bottom rung of the performance ladder onto a rung just above that level. This is of considerable importance in the context of the revalidation of doctors, a subject to which I shall return later in this Report.

Dr KA 04

24.166 Dr KA 04 was a GP working in a deprived area and had a very large patient list. The PCO expressed concerns about him which were very serious and covered many aspects of patient care, including prescribing, clinical knowledge, record keeping, note taking, history taking, physical examination, communication skills and liaison with other agencies. It was also said that he signed blank prescriptions and gave them to his staff to write repeat prescriptions. Four months after the initial complaint, the doctor agreed to undergo assessment. However, shortly afterwards, he was taken ill and remained off work for five months. An Assessment Panel was appointed four months after that and the assessment was not completed until 15 months after the initial complaint. The doctor failed two of the Phase II tests and passed one. Production of the report took another two months. The Panel reported that the doctor's performance had been seriously deficient and that this had been inevitable because of the conditions under which he had been practising. However, the Assessment Panel was now of the view that the doctor's performance was no longer seriously deficient. It listed some respects in which the doctor's performance still gave rise to concern. The doctor did not respond when sent a copy of the report. The case co-ordinator felt that there was insufficient evidence that the doctor's performance was no longer seriously deficient and referred the case to the CPP.

24.167 The hearing took place two years and one month after the initial report. During that time, the doctor had been practising, save for the five months of his ill health. The CPP panel found the doctor's performance to have been seriously deficient. In particular it said that his record keeping was an **'impenetrable jumble'** and that, bearing in mind the extensive use made of locums within the practice, this put patients at risk. Records were not the only cause for concern; the doctor's assessment of patients' condition and his provision of investigations and treatment were unsatisfactory. The CPP panel imposed conditions on the doctor's registration for 12 months. In summary, these required him to establish relations with a mentor and the local Clinical Governance Lead and to work with them on

a programme of continuing education and remediation. He was to heed the advice of the PCO about the size of his list and about arrangements for the staffing of his practice.

24.168 Nearly six months later (i.e. two and half years after it had reported its concerns about Dr KA 04), the PCO wrote to the GMC, expressing further concerns. The letter said that there were huge gaps in the doctor's knowledge and that he seemed unable to improve. Patients were at risk. The PCO was consulting the NCAA and was taking steps to find out whether the doctor had a medical problem. Soon afterwards, the PCO exercised its new list management powers and stopped the doctor from practising as a GP. The doctor was then to work in a new specialty.

24.169 At the resumed hearing (just over three years after the initial complaint), the CPP panel considered whether to refer the doctor to the HC but decided there was insufficient evidence to do so. It considered that the doctor had made efforts to comply with his conditions but had been unable to do so owing to difficult circumstances. It imposed new conditions for a period of nine months. In essence, the doctor was to practise only under supervision and in his new specialty. At a further hearing nine months later (just under four years after the initial complaint), it appears that there was a substantial measure of agreement between the lawyers representing the doctor and those representing the GMC. This covered both the evidence and the proposed condition which was that, for a period of three years, the doctor was to practise only in his new specialty. There was no requirement for supervision or for reassessment. The CPP panel agreed to deal with the case on the basis of this agreed condition, although its members expressed some reservations about the limited nature of the evidence that the doctor was capable of practising to the necessary standard in this new specialty. Thus, Dr KA 04 was free to practise unsupervised within his new specialty for the following three years. That period has not yet expired.

Comment

24.170 I have two concerns about this case. First, the doctor was allowed to practise in his new specialty without having undergone any formal assessment of his competence or even a retake of the Phase II tests which he had previously failed. That had not been required, despite the fact that there was cause to suspect that his performance in that regard would not have improved. Second, provided that the doctor complied with the condition that he should practise only within his new specialty, it seemed likely that the restriction would be removed at the expiration of the three-year period. He would then be free to practise again in any capacity in which he could find employment. I do wonder whether the public has been adequately protected in this case.

Dr KA 05

24.171 This is the only one of the five cases examined by the Inquiry that did not relate to a GP. For that reason, I shall not describe it in any detail. It is also the only one of the five cases in which the CPP found that the doctor's performance was not seriously deficient, even though that had been the conclusion of the Assessment Panel.

24.172 Dr KA 05 was a locum orthopaedic surgeon. He had been the subject of a report from Hospital P to the GMC in the mid-1990s. It was said that he had carried out an operation particularly badly. A report by a group of 'Three Wise Men' also mentioned that he was said to upset nurses, patients and medical staff. The following year, another report was received from a patient, enclosing a letter from a different hospital (Hospital G), expressing concern about the doctor's surgical practice and also saying that his employment had been terminated because of several complaints about his attitude and behaviour. At this time, the performance procedures had not been brought into effect and the case was eventually dealt with two to three years after the first report to the GMC by a letter of advice under the Chapter XV procedures.

24.173 Some time later, a further expression of concern was received from another hospital, Hospital J. I shall refer to this as the index complaint. Its content was very similar to the previous ones. There were concerns about the complication rates and infection rates following surgery; there were also concerns about the doctor's 'attitude' and working relationships. The report mentioned that the reference that had come from a hospital at which the doctor had previously worked (Hospital B) was favourable as to his technical competence but mentioned difficulties in professional relationships. That means that there had been problems over working relationships at four different hospitals. However, the GMC had, from the outset of the performance procedures, taken the view that it could only consider matters arising since July 1997.

24.174 Following further initial enquiries, the doctor was invited to undergo assessment and he agreed. That was eight months after receipt of the index complaint. Owing to a shortage of lead assessors in orthopaedics, the assessment did not take place for another year. By that time, the doctor had moved on, not once but twice. First, he had worked at Hospital T and he suggested that two colleagues there should be interviewed by the Panel. However, when his placement came to an end and he moved back to Hospital B, he did not wish the two colleagues from Hospital T to be interviewed. The assessment took place at Hospital J and at Hospital T. Another six months passed before the report was ready and was sent to the doctor. The original complaints about infection and complication rates at Hospital J seemed to have disappeared into the background. The infection rates might have been due to a dressings technique used by the nurses, and the complications rate was not so different from that of another doctor as to allow any adverse conclusion to be drawn. Now the focus of criticism was on the doctor's poor working relationships. He was arrogant and 'talked down' to subordinates. Similar concerns were expressed by staff from Hospital T and there was also a complaint that he had taken on surgery beyond his capability despite being advised not to. The doctor had denied that there were relationship problems and claimed that, at Hospital J, he had antagonised the nurses by making justifiable criticisms of their dressings techniques. Any other complaints of that nature were, he said, unwarranted. The doctor had passed all the Phase II tests, albeit with some **'worrying gaps'** in knowledge and other concerns. The report said of the doctor that **'within well defined and ... limited areas of trauma ... and orthopaedics he is knowledgeable and technically competent'**. The assessment report concluded that the doctor was **'unsuitable for independent consultant practice'**. The case co-ordinator decided to refer the case to the CPP.

24.175 At the hearing, which occurred two and a half years after the index complaint, the CPP panel found that there was insufficient evidence for a conclusion that the doctor's performance was seriously deficient. The CPP did not give reasons for that conclusion. However, the GMC provided the Inquiry with a full transcript of the hearing so I have been able to form a view of what happened. Very briefly, it was clear that the Assessment Panel had not fully understood what was required of it and it had not complied with a number of formal requirements. It was far from clear what view it had formed about the doctor's overall performance. Second, it was clear that the evidence of surgical incompetence either was not extensive or else had not been properly investigated. It did not amount to much and the doctor was able to offer a reasonable explanation for the circumstances in which it was said he had taken on a task beyond his expertise. The doctor maintained that the complaints about personality problems were due, in effect, to prejudice against him, as a locum. None of the staff members who had spoken to the assessors about this was called to give evidence and it appears that the CPP panel felt that there was something in the doctor's explanation. It was not, of course, aware that similar complaints had been made about him some years previously, before the performance procedures came into operation.

Comment

24.176 I have given this account because I want to take the opportunity to make some observations about the conduct of this hearing which I hope will be of value for the future. My comments are not intended to imply that the CPP panel reached the wrong conclusion. My impression from reading the transcript is that the GMC was 'wrong-footed' in two respects. First, the Assessment Panel had made a number of technical mistakes in the completion of the assessment process. This allowed the doctor's counsel to make valid criticisms which to some extent discredited the GMC's case. Yet I am not sure that these technical criticisms actually had much to do with the merits of the case. They just seemed to. Plainly, it is important that assessors are properly trained and do not make technical errors. Also, the GMC did not call any of the witnesses who had made allegations about the doctor's behavioural problems; the CPP received the written assessment report and heard the live evidence of two of the assessors. I realise that it would be impracticable and highly undesirable for the GMC to call every person who had provided information to the assessors. However, not calling any of those witnesses 'live' enabled the doctor to claim that the witnesses had been biased against him without there being any opportunity for the CPP panel to judge for itself whether that was so.

24.177 Dame Lesley Southgate expressed concern to the Inquiry about the way in which the lawyers who represent doctors before the CPP can 'pick holes' in the performance assessments. She compared the assessment to a pointillist picture comprising thousands of small dots. Each statement or point in the assessment was a dot which went to make up the whole picture. If the lawyers were able to remove some of the dots in the assessment, it would lose its strength and credibility, just as the picture would become unintelligible if some of the dots of paint were removed. I understand her concern although I do not share it. Lawyers must be able to attack evidence on behalf of their clients. If all they succeed in doing is to remove a few dots, the CPP panel should still be able to see and understand

the picture. But, if the lawyers succeed in removing a whole swathe of dots, then the validity of the assessment may be undermined.

24.178 I mention these forensic difficulties because it seems to me that, under the new procedures, the GMC may have to present rather complex cases to a FTP panel. It is possible that, in future, a single hearing may have to consider allegations of misconduct and deficient performance and problems of health. If the panel is to consider cases in a holistic way, the investigation of the facts, the preparation of evidence and the management of its presentation will all become more difficult than at present. I shall return to these topics later in this Report.

Further Comments on the Five Cases

24.179 All these cases illustrate the problems of delay. The GMC has said that it recognises delay has been a problem and that, in the recent past, it provided better resources for the performance procedures. I have no reason to doubt that that was so. The Performance Procedures Working Group, which reported in April 2004 and to which I shall refer later in this Chapter, drew attention to concerns about delay and urged that further attempts should be made to reduce delays which occurred for reasons which were within the GMC's control. It seems to me that there is always likely to be an element of delay in performance cases, even with improved resources. If so, patients may be at risk from doctors whose shortcomings have been recognised locally but not yet proved to the GMC. Patients can be protected by interim measures to suspend or impose conditions on a doctor's registration and, as I have said, after 2000, the IOC made interim orders in performance cases. I note, however, that in none of the five cases examined by the Inquiry was there a referral to the IOC before the full assessment. I can see that, in the absence of hard evidence of harm to patients, the IOC might be reluctant to order interim suspension. It occurred to me that, once it has been decided that a doctor should be assessed, the sooner s/he underwent the Phase II objective assessment, the sooner the IOC would be in a position to make an informed interim decision. I take as an example the case of Dr KA 01. The PCT had expressed real concern for patient safety. The doctor carried on practising. In the event, he failed all three of the Phase II tests. Perhaps, in cases where the local organisation is concerned about patient safety, there should be a rapid referral to a Phase II centre and automatic referral to the IOC if the doctor fails any part of the test.

24.180 The case of Dr KA 01 led indirectly to a discussion at the Inquiry's seminars about the use of PCT list management powers. In that case, the PCT must have been very worried when, ten months after the CPP hearing, so little had happened. It had reported its concerns; the doctor had been assessed and the concerns had been found to be valid. Yet, two years later, the only real change was that there was an additional doctor working in the practice. It might also be said that Dr KA 01 had been made fully aware of his deficiencies. However, in other respects, nothing had happened to ensure that the doctor did not make the same kind of errors as he had been making in the past.

24.181 At the seminars, there was some discussion about whether a PCT in the position of that one should use the list management powers which it had had since 2002 to suspend

or remove a doctor from its list, in the interests of protecting patients. The view was expressed that a PCT would hesitate to do so where the GMC, the professional regulatory body, had considered the case and had decided upon a different course. The PCT would tend to defer to the GMC's view. That is understandable, particularly in a case like that of Dr KA 01, where the PCT was not even in existence when its predecessor had referred the doctor to the GMC. However, the view was expressed by several participants that PCTs should be prepared to use their own powers and to exercise their discretion if the remedies offered by the GMC appeared less than adequate. I note that, in the case of Dr KA 04, the PCO did stop a doctor from providing GP services. He had been through the GMC performance procedures and conditions had been imposed on his registration. The PCO remained worried about patient safety and used its own powers. I think that is appropriate. Parliament has provided these powers, presumably because it has recognised that local bodies sometimes have a closer view of what is going on than a national body and are better able to assess the needs of their own communities.

The Performance Procedures Review Group

24.182 In November 2002, the Fitness to Practise Policy Committee established the Performance Procedures Review Group, chaired by Dame Deirdre Hine, former Chief Medical Officer for Wales and former Chairman of the Commission for Health Improvement, to carry out a review of the performance procedures. The Review Group presented a draft report in November 2003 and its final report in April 2004. Members of the Review Group included Professor Alastair Scotland, Chief Executive and Medical Director of the NCAA, and Dame Lesley Southgate.

24.183 The final report of the Review Group noted that the GMC's performance procedures represented a **'major step forward in the modernisation of medical regulation'**. It went on:

> **'For the first time, the GMC had at its disposal reliable and internationally recognised tools to assess, fairly, consistently and accurately, the standard of a doctor's professional performance in any major branch of medicine. The achievements of the procedures as they stand are considerable.'**

24.184 It was noted that, with the introduction of the new FTP procedures, the present performance procedures would cease to exist. The remit of the Review Group was to consider whether the original objectives of the procedures needed to be amended and to make recommendations for the future consideration of performance issues and the use of the assessment instruments.

24.185 The Review Group explained that, before the introduction of the performance procedures, it had been expected that most doctors would be dealt with by way of voluntary procedures (modelled on the existing health procedures) so that the CPP would be a **'committee of last resort'**. It had been assumed that most doctors referred to the procedures would be capable of remediation and would be able to return to unrestricted

practice after a period of targeted re-education or training. It had also been assumed that doctors would be willing to undergo remediation and would agree to a voluntary statement of requirements for this purpose. Another assumption had been that most referrals would involve hospital consultants who had failed to keep up with the latest techniques, or doctors at early stages of their careers, whose problems could readily be **'nipped in the bud'**. In the event, these assumptions were not borne out once the procedures were introduced.

24.186 The Review Group considered that the most striking feature of the data which it had collected was the very small number of cases between 1998 and 2002 (15) in which a statement of requirements had been agreed. The Review Group observed that it was not clear whether this was because of a lack of cases in which a statement of requirements would have been appropriate, or because case co-ordinators had been unwilling to offer statements of requirements or because of a reluctance on the part of doctors to accept statements of requirements. However, the majority of cases went to the CPP for decision. It suggested that there was some evidence that the performance cases coming to the GMC were complicated by the doctors' reluctance to take advice or to seek help.

24.187 The Review Group drew attention to the number of cases in 2001 and 2002 in which a decision by a medical screener that a doctor should be invited to undergo a performance assessment had been overturned by the ARC. Its final report identified two possible reasons for this. First, the screening threshold might be too low, as a result of which 'weak' cases had been referred for assessment. Second, the fact that the doctor was able to give oral evidence before the ARC, it was suggested, might lead to a decision which was **'reasonable at the screening stage'** being **'rightly set aside when a fuller picture becomes clear'**. The draft report had suggested a third reason, namely that, as the complainant might not always appear at the ARC hearing, the decision might sometimes have been made not to assess a doctor in circumstances where, had the full picture been known, it would have been more appropriate to have undertaken such an assessment. Given the fact that it is not intended that the new FTP procedures should contain any equivalent of the ARC, the Review Group did not proceed to consider which of the possible explanations was the most likely. However, it might be valuable to analyse the reasons why screening decisions were overturned by the ARC. It might be that the effect of a 'one-sided hearing' (without the benefit of the complainant's evidence) tends to produce a particular result. If so, such hearings should be avoided in future.

24.188 The Review Group also referred to the increase in the length of performance hearings by the CPP. The average length of a performance hearing was two days in 1999 and over three days in 2002. The CPP panel sat for 15 days in 2000, 54 days in 2001, 120 days in 2002 and 90 days up to September 2003. The Sadler case alone took 16 days.

24.189 The Review Group referred to the part played by the GMC's FTP procedures in the wider framework for protecting patients. It highlighted a perception that the performance procedures did not provide adequate feedback to those with local responsibility for doctors. In particular, it drew attention to the fact that performance assessment reports were not made available to a doctor's employer or PCO. The Review Group criticised this approach, saying:

> **'If an assessment report reveals that a doctor has serious performance problems, it is important that the organisation responsible for managing the doctor locally should see the assessment report. It cannot be regarded as a private document between the GMC and the doctor.'**

24.190 The Review Group expressed no concluded view as to whether assessment reports should be disclosed to employers or PCOs in cases where the doctor's performance was found not to be seriously deficient, or where deficiencies which were not deemed serious enough to justify action on registration, but were nevertheless sufficient to warrant the issuing of a warning, had been disclosed. The Review Group recommended that the GMC should give further consideration to these issues. In my view, all assessment reports should be disclosed to employers and PCOs.

24.191 The Review Group also mentioned the failure of the ARC and the CPP to give reasons for decisions which went in favour of a doctor. Its draft report had observed that, even where reasons were given, they were **'too sparse to enable proper understanding of the position'**. The Review Group observed that the publication, from 1st July 2003, of CPP decisions on the GMC's website was **'a step forward'**. However, it considered that further measures needed to be taken in order to ensure effective feedback. It observed:

> **'... it is essential that the GMC gives reasons for every decision it makes on fitness to practise, including decisions not to take any action. An employer's role is made harder if no information is available to explain why apparently serious concerns have not been taken forward.'**

The GMC has accepted that recommendation and, in the recent past, it was the practice of the CPP to give reasons for all its decisions.

24.192 The Review Group referred also to the fact that hearings of the CPP were held in private, unless the doctor requested a public hearing. It expressed the view that performance hearings should normally be held in public, unless the CPP panel decided otherwise. In its draft report, the Review Group had observed that **'private hearings are not compatible with openness, transparency and accountability'**.

24.193 The Review Group went on to address the issue of evidence. The report pointed out that (unlike the situation that existed when the performance procedures were first introduced) doctors who are referred to the GMC in the future are likely to have been through some sort of local remedial process which has been deemed to have failed. The report raised the question of whether the GMC should be able to use evidence that might be available from other sources at the time of referral. Hitherto, such evidence had played little part once a decision to undertake a GMC assessment had been made. The report stated:

> **'... the intention** (*this presumably refers to an intention on the part of the GMC*) **is to move towards a model where reliable information gathered locally or by other organisations, is more systematically considered and plays a greater part in the GMC's overall investigation and assessment of a doctor's fitness to practise'**.

Such an approach would, the report pointed out, avoid duplication of time, resources and effort. It would also be consistent with a **'team approach'** to protecting patients and maintaining standards.

24.194 The Review Group suggested that potential sources of evidence which might be used by the GMC would be complaints (whether substantiated locally or not), reports of IRP hearings or Ombudsman's investigations or other such findings, results of **'routine or exceptional audits'** and reports of assessments carried out by the NCAA or equivalent bodies in other parts of the UK. Mention was also made of the fact that, in the future, assessments following the model of the NCAA might also be carried out at a local level. The Review Group referred to the distinction between the summative (i.e. pass/fail) character of the performance procedures (which, notwithstanding their emphasis on remediation, could result in suspension and would in the future have the potential to end in erasure) and the formative (i.e. educational) nature of the local performance procedures and intervention by the NCAA. The latter were aimed at remedial action. Nonetheless, the report suggested that it should be possible, where evidence was already available, to **'build'** a picture of performance in the round, making use of that evidence. The Review Group considered that any evidence used in this way must be attributable to the performance of the individual doctor (and not teams or systems), must be obtained and presented fairly, must be robust and reliable and must be used to achieve fair and consistent judgements across all the areas in 'Good Medical Practice'. In order to ensure that those criteria were fulfilled, the report suggested that:

> **'... employers and local bodies will need clear guidance (either from the GMC or through ''centres of excellence'' identified or created to disseminate best practice) about how to ensure that their processes led to evidence which meets these standards. ...**
>
> **Obviously, such a process would take time, effort and resources.'**

24.195 The Review Group considered that the **'direction of travel'** should be to move towards the use of local evidence wherever possible. Only where the local evidence was insufficient or inappropriate should the GMC use its own assessment instruments to investigate the doctor's performance further. The Review Group considered that, in the long term, it would be preferable for a single national body to undertake all assessments to defined national standards. It did not attempt to address the question of who should do this.

24.196 The report pointed out that the performance procedures had, from their inception, emphasised remediation far more than was customary in the conduct procedures. It observed:

> **'The fact that spm could lead to erasure whilst sdp could not, sent a powerful signal in its own right.'**

The Review Group observed that, when the procedures were devised:

> **'... remediation was rightly made a central theme of the policy model, both because it was desirable to achieve a professional consensus on the fledgling procedures, and because there was an almost complete**

absence of structured, local arrangements to support doctors in difficulty'.

24.197 The Review Group recognised that, in future, most doctors referred to the GMC with performance problems will have undergone a remedial process which has failed, or will be deemed to have failed. The Review Group noted that some people had suggested that the GMC should dispense entirely with any ambition to enable poor practice to be remedied and should instead focus exclusively on what action needs to be taken to protect the public. Nevertheless, the Review Group believed that there were **'sound reasons'** for the GMC to retain remediation as an aim and thus to retain the facility to offer a voluntary route for dealing with performance concerns. The report suggested that, most importantly, such a voluntary route provided an incentive for a doctor to co-operate with the process. The Review Group believed that, if the GMC simply abolished the existing voluntary procedures, the result would be that every doctor referred to the GMC with a serious performance problem would contest the process at every stage. This would involve significant cost and delay. The Review Group believed that, even if such an approach could be justified in terms of proportionality (which it believed it could not), such delay would not be in the public interest and would be an extremely ineffective use of resources.

24.198 In its draft report, the Review Group had stated that, nevertheless, **'the emphasis should always be on patient protection'**. This should be so particularly when the voluntary route was considered inappropriate and a case had been referred to a hearing. While remediation should not be ruled out, it was said that the objective of the CPP (in future, a FTP panel) should primarily be to decide what action needed to be taken to protect patients and the public in a case where a finding was made that the doctor's fitness to practise was impaired. This seemed to imply that, once remediation within the voluntary procedures had been ruled out, the focus should shift away from attempts to remediate the doctor and should, instead, be directed at removing him/her from practice either temporarily or permanently. As I shall explain later in this Chapter, this was the thrust of Mr Scott's oral evidence on this topic.

24.199 In the final report of the Review Group, the relevant passage had been modified and no longer appeared to suggest any change of focus away from remediation.

The Future

24.200 Notwithstanding the modification to which I have just referred in the final report, the work of the Review Group will be of great potential value to the GMC as it enters the era of its new FTP procedures. One of the points raised in its report and also stressed to the Inquiry by Mr Scott, Chief Executive of the GMC, is that many of the doctors who will in future be referred to the GMC on account of poor performance will already have been through some form of local assessment and attempts at remediation. At present, a doctor whose practice gives rise to cause for concern may undergo an assessment either by his/her local NHS body (along the lines of the assessment designed by the NCAA) and/or, possibly, by the NCAA itself. Following that assessment, the doctor may well undertake a programme of remediation, which may entail practising under supervision and/or

extensive contact with a postgraduate dean. If those measures fail, the doctor may well be reported to the GMC.

24.201 In the past, when a doctor was reported to the GMC, there had to be a completely new assessment. The local or NCAA assessment was not suitable as a basis for GMC performance procedures. It was not designed to withstand the kind of legal challenge which the GMC assessments had to weather. I do not say that in any sense of criticism. I was impressed by the evidence of Professor Scotland, who explained the NCAA's holistic approach to performance assessment. The NCAA recognises that the doctor may have health, personal or personality problems, or problems in his/her working environment. An assessment based on NCAA principles has three main elements: occupational health, behaviour and clinical practice. In short, the purpose of the assessment is to find out what is wrong and why, with a view to making things better. It is not designed to enable a decision to be made on objective criteria as to whether the doctor's performance is seriously deficient; nor would it, in future, provide a basis on which a FTP panel could decide whether the doctor was fit to practise.

24.202 The GMC has recognised that, for a variety of reasons, it is undesirable that a doctor should have to undergo repeated assessments. They are costly, time-consuming and very stressful. Sir Graeme Catto told the Inquiry that the GMC was currently engaged in discussions with the NCAA about the development of a single form of assessment which would suffice for all purposes. I do not know whether this will be feasible. Plainly, a single process would be preferable for many reasons, if it can be so devised as to achieve all its desired ends. I would think that a staged or modular process whereby information is gathered along the way might provide the answer. Both Sir Graeme Catto and Mr Scott said that the modular accumulation of evidence in support of a performance case was under consideration; at the time of the Inquiry's hearings, discussions were taking place with the NCAA about a common protocol for the collection of evidence and about the standardisation of performance assessments.

24.203 When performance problems first come to light, the primary aim must be to assess and rectify them at local level. I would have thought that all three elements of the NCAA assessment should be an essential feature of any process that seeks to resolve or ameliorate the doctor's problems. I have the impression that they form a better basis from which to devise remedial measures than the GMC procedures and that the GMC procedures do not lend themselves particularly well to that process. I may be wrong about that; it may be that the difficulties in devising suitable remedial measures have arisen because GMC Assessment Panels and members of CPP panels have not been expert in devising remediation, whereas NCAA advisers and postgraduates deans are. If a NCAA type of assessment might eventually form part of the evidence on which the GMC will wish to rely, it will have to be undertaken to a high standard and according to agreed protocols. It should incorporate some of the methodology of Dame Lesley Southgate's work. Assuming that such an assessment protocol could be devised, I do not think that local NHS bodies can be expected to carry out the assessment without support and advice. I am convinced of the need for the NCAA (or a body very like it) to provide such advice and support. I would think also that some expert assistance would be needed in evaluating the results and in devising appropriate remediation. Remediation must involve the

postgraduate deaneries, in liaison with the local NHS body. The deaneries have expertise in this area which a local NHS body will not have. Also, the deaneries should be encouraged to set up courses and to provide placements within practices where the necessary expertise is available for supervision and mentoring. The local NHS body should be responsible for funding the remediation and the overall supervision of the doctor's progress, to be effected through close attention to clinical governance measures. It may need to use its list management powers if the doctor is unwilling to co-operate or makes no progress with his/her remediation.

24.204 If all goes well and the doctor improves, the GMC need never become involved. But, if the remedial measures fail or if they are 'deemed to fail' because the doctor does not co-operate, then the GMC must take over and must decide whether the doctor is fit to practise. By this time, there should be a dossier of evidence on the doctor, comprising the initial assessments and reports from those involved in the doctor's remediation and supervision. Provided these records and reports are of a sufficiently high standard, I do not see why they should not form part of the evidence on which the GMC relies. However, I do not think they would be enough. I think that, at this stage, there would be a need for some objective testing of the doctor that would, of itself, withstand legal challenge. I would have thought that the existing Phase II tests would have a part to play. Whether there would have to be something more, I could not say. It seems to me that what is wanted at this stage is material that is as objective as possible. I would have thought that, if a doctor were to fail those objective tests, which might be set, for a GP, at the level of summative assessment, it would be appropriate to suspend the doctor forthwith unless and until s/he had passed those tests to a satisfactory level. If there were other concerns, as there might well be, the case would have to proceed to a FTP panel, where the GMC would have to present a mixture of factual and opinion evidence so as to provide a sufficiently clear picture of the doctor to allow an objective judgement to be made.

24.205 Dame Lesley told the Inquiry that she understood that the GMC would like to divest itself of responsibility for carrying out performance assessments. Under the modular or cumulative approach I have described, the GMC would not, in any event, be involved with the early assessments carried out by local NHS bodies. It might have to do assessments of doctors working in the private sector for whom there would be no other mechanism. It would seem to me to be sensible for the GMC to retain control over the final stage. If it does not, it would at least have to set the standards to be applied at that stage and to ensure that the procedures were quality assured. Whoever is to carry out assessments, it seems to me that there is an urgent need for a process which is very largely objective and which cannot be affected by allegations of bias or an attack on the procedures adopted by the assessment team. I would have thought that for a GP at least, summative assessment would provide a balanced examination and a standard that any GP might be expected to achieve.

24.206 Another problem which the GMC must face is that of decision-making by panels. It must decide on the standards to be applied generally when performance issues are raised. In the past, the standards to be applied were incorporated in the assessment itself. The assessment included an opinion as to whether the doctor's performance was 'seriously

deficient'. This made the CPP's task relatively straightforward. Sir Donald Irvine, who sat on some of the earliest performance cases, said that:

> **'It was a matter of hearing the evidence, of asking questions about the assessment . . . but not of actually trying to ''second guess'' the assessment.'**

Then, he said, the process became complicated, partly because of the Krippendorf case. A line of questioning developed where there was a tendency for the CPP to try to run a second assessment. It seemed that it became possible for the CPP panel to apply a lower threshold than the assessors themselves which, Sir Donald said, 'could not be right'. Dame Lesley Southgate spoke of her concern (and I sensed her frustration) at the way in which the results of assessments based upon the instruments devised by her team, which she likened to a pointillist picture, were 'picked at' by the lawyers with the result that the CPP could lose sight of the main picture and find the doctor's performance to be acceptable when, in her view, the assessment had clearly and objectively shown that it was not. The loss of a few 'points' from the assessment should not have this effect. However, if a major criticism in the assessment is shown to be unjustified, the panel might conclude that what remains is insufficient for an adverse finding. What the panel must not do is to apply different standards from those applied in the assessment.

24.207 In future, when the issue for the FTP panel is not whether SDP has been proved but whether **'fitness to practise is impaired to such a degree as to justify action on registration'**, FTP panels are going to be completely at sea unless a proper structure is provided for them. SDP was not a simple or wholly objective concept, although the use of the assessment instrument provided useful criteria. Moreover, the assessors received training, although it must be admitted that they did not always carry out the assessment as they should have done. If the present assessment instrument is no longer to be used, those criteria and the expertise of the assessors will be lost. Even assuming that a standardised format for local assessment could be introduced, it cannot contain judgements that the GMC could rely on; the FTP panel would have to use it only as a source of evidence. Members of the FTP panel will have to make their own judgements. If those judgements are to be fair, consistent and reliable, they will have to be guided by clear standards and criteria. The problem for the FTP panel may also be complicated by the inclusion of health and conduct issues. If standards and criteria are not provided, there will be unfairness to doctors and a potential failure to protect patients.

24.208 Mr Scott spoke at the Inquiry about the GMC's future attitude to attempts at remediation. He said that the **'short message'** from the GMC was now that **'remediation is still very important, but not for us'**. As I understood it, he was saying that the days were over when the GMC would impose conditions involving remediation as a form of support for the doctor or as a 'carrot' to encourage improvement. In future, that stage should be completed locally before the case reaches the GMC. The GMC should be using its power to suspend or impose conditions on a doctor more as a 'stick' to force the doctor to reform or else be struck off. That would represent a considerable change on the part of the GMC from the philosophy which has guided it in the past. Sir Donald told the Inquiry that, in the early days, the performance procedures were 'doctor-centred'. Indeed, he had seen the

CPP 'bending over backwards to save the doctor'. There was great emphasis on remediation. He did not object to that but thought that too great an emphasis on remediation could 'distort the decision about public protection'. Mr Scott's view was plainly influenced by the contents of the Performance Procedures Review Group's draft report. In view of the apparent change of view evident in the final report, it is not certain whether the GMC's attitude to remediation will change in the future.

24.209 In my view, the change of philosophy suggested in the Review Group's draft report was attractive. It should not be the function of a regulator to provide help and support; that is an important function but it should be for others. The function of a regulator should be to decide who is fit to be on the register and who is not. However, it may not be easy for the GMC to avoid involvement in remediation. Local procedures will not produce a 'perfect' set of results. Not every case referred to the GMC will warrant either suspension or erasure. Indeed, if it did, it would almost certainly mean that not enough cases were being referred to the GMC. Moreover, if local provision for support and remediation remains patchy, there will be some cases where the GMC will feel obliged to give a further opportunity for change. However, that said, it does seem to me that the change in philosophy is sensible and it is to be hoped that it will be possible to put it into effect.

24.210 At present, it is not entirely clear how cases of deficient performance will be handled when the new procedures come into force. It is apparent that the GMC has developments in mind besides the procedural changes which are about to occur. In my view, if the GMC is to continue to impose conditions aimed at remediation on the registration of a doctor whose performance has been found to be deficient to a serious degree, it must tackle the shortcomings to which I have referred in my discussion of the five case files. In particular, it must accept responsibility not for arranging the remediation itself but for ensuring that progress is being made and that the doctor is not just waiting 'in limbo' for something to happen. It must also, in my view, ensure that an adequate assessment of the doctor's performance is made before conditions are lifted and the doctor is permitted to practise unrestricted.

CHAPTER TWENTY FIVE

The General Medical Council's New Fitness to Practise Procedures

Introduction

25.1 In the preceding Chapters, I have described in some detail the General Medical Council's (GMC's) fitness to practise (FTP) procedures as they have operated over the years since Shipman's case was considered by the GMC in 1976. It will be apparent that there have been many changes during that time, not least the introduction of the health and performance procedures. The conduct procedures, including the GMC's way of dealing with doctors convicted of criminal offences, have undergone evolutionary, but not radical, change. For some years, beginning in the late 1990s, the GMC has been aware that its procedures were not satisfactory, and were in need of fundamental change. By November 2003, when the focus of the Inquiry hearings was on the GMC, the process of change was well underway and it was expected that the 'new' procedures would be brought into effect by the spring of 2004. In the event, there was some delay and the relevant Rules came into effect only recently, on 1st November 2004.

25.2 In this Chapter, I propose to examine the way in which the new procedures are expected to operate. As will be apparent from this Chapter, the proposals have changed considerably even during the period in which the Inquiry has been focussing its attention upon them. However, at a Council meeting on 15th September 2004, the GMC approved the draft Rules which were to form the basis of the new procedures. With the exception of a few minor changes, those draft Rules were identical to the Rules which came into force in November. It is by reference to the November 2004 Rules that I shall discuss the operation of the new procedures. However, to some extent, my work is likely to become out of date even as I write, because it is almost inevitable that some changes will be made to the new procedures as the result of early experience.

25.3 It is, in my view, important that the Inquiry considers the new procedures in detail. The Inquiry has identified various shortcomings in the way in which the old procedures operated. In some respects, they did not provide adequate protection for patients. Some cases that should have entered the procedures were closed by the administrative staff at the initial stage. In general, there was no investigation in the early stages, so that the potential seriousness of some allegations was not fully appreciated and others, although obviously serious, foundered. Some cases were closed at the screening stage or by the Preliminary Proceedings Committee (PPC) as a result of the wrong application of the appropriate tests or the application of the wrong tests. Lack of standards, criteria and thresholds for decision-making produced inconsistent outcomes. Any of these shortcomings can give rise to a danger that a doctor who presents a risk to patients is not detected and dealt with. Another problem with the old procedures was that they lacked transparency. In the modern world, the public expects and is entitled to see what is being done by a regulatory body and to understand why. For those reasons, it is important that the Inquiry examines the extent to which the new procedures will correct the shortcomings of the old.

25.4 I also regard it as important to see how the proposals for the new procedures have developed over the last three years. As will become apparent, there have been many changes of direction: some quite minor, some major. In the context of the development of new procedures, some changes are inevitable. Some have led to improved proposals that will result in greater consistency and openness, and will provide improved patient protection. Those changes have been made in part as the result of consultation and in part as the result of the GMC's awareness of the evidence given to this Inquiry. Other changes appear to me to have been retrograde. It is important, in my view, to examine those changes and to try to understand why the GMC has made them. If the GMC has made a change that results in reduced patient protection or reduced transparency, that is a cause for concern, as it might suggest that the GMC has not fully accepted the need to improve patient protection and transparency. It raises the risk that further such change might occur in the future.

25.5 At times in this Chapter, I suggest that the GMC should consider doing things in a different way. It may be said that it is not part of my remit to make detailed recommendations about internal matters. In my view, it is within my remit. If I had come to the conclusion that I should recommend that the GMC should lose its FTP function altogether, there would be no point in making detailed suggestions for change. However, as I have not, I think it is necessary to descend into the particulars of those aspects of the new procedures that I consider do not provide adequate protection for patients. I make these suggestions in a constructive spirit in the hope that they will be given serious consideration by the GMC and also because they might be useful to the Council for the Regulation of Healthcare Professionals (now known as the Council for Healthcare Regulatory Excellence (CRHP/CHRE)), in seeking to promote patient protection and transparency across all the healthcare regulatory systems.

25.6 As before, all references to the old procedures are made in the past tense and I shall speak of the new procedures as if they will come into force in the future.

Preparations for Change

25.7 In 1997, the Fitness to Practise Policy Committee (FPPC) of the GMC was established. It was chaired by the then President, Sir Donald Irvine. The functions of the FPPC included responsibility for reviewing the statutory framework governing the FTP procedures and for making proposals for amendment where appropriate.

25.8 The FPPC set up several working groups, including the Professional Conduct Committee (PCC) Working Group, to which I referred in Chapter 21, and the Screening and PPC Working Group. The reports of both Working Groups became available in 1999. Following the publication of those reports, and the debate which they provoked, the FPPC produced a discussion document, seeking ideas for changes to the FTP procedures. The discussion document sought views from members of the GMC on a wide range of issues, including the purpose of the GMC's FTP procedures, appropriate sanctions, interim orders, restoration to the register, the possible integration of the conduct, health and performance procedures and the operation of the FTP procedures generally.

25.9 In March 2001, the GMC issued a Consultation Paper, 'Acting fairly to protect patients: reform of the GMC's fitness to practise procedures' (the 2001 Consultation Paper), which set out a number of options for reform of the FTP procedures and sought views on them. It also set out some principles that it was considered should underlie the development of the new procedures, together with criteria by which they were to be judged. The criteria required that the procedures must be, *inter alia*, fair, objective, transparent, free from discrimination, effective, prompt, proportionate, understandable, compatible with the Human Rights Act 1998 and regarded with confidence by the public and the profession.

25.10 The 2001 Consultation Paper identified those features which the GMC perceived as the strengths of the old FTP procedures. The first of these was that enquiries which were **'obviously trivial or incoherent'** or **'not relevant to the role of the GMC'** could be dealt with quickly within the GMC office. Second, it was said that the recently acquired (in 2000) powers to impose interim suspension or conditions on registration pending investigation and determination of a complaint against a doctor meant that the GMC could act quickly when it appeared that a doctor was a danger to the public or to him/herself. Third, the 2001 Consultation Paper pointed out that the new performance procedures permitted investigations to proceed along a formal, but voluntary, route, with the co-operation of the doctor, so that the doctor's problems could be investigated and, if possible, put right **'without the delay and expense of the doctor having to appear before a committee simply to agree points which have already been conceded'**.

25.11 The 2001 Consultation Paper also identified certain disadvantages of the old conduct and performance procedures. First, there was limited investigation before a decision was made on what to do with a case. Second, it was said that the tests applied when determining whether a case should proceed had very low thresholds. It was suggested that this might result in **'groundless cases'** being referred to the PCC. As well as the thresholds being very low, it was suggested that the tests applied to conduct cases at each of the various filtering stages (by the office staff, the screener and the PPC) were very similar, which raised the question of whether all three stages were needed. Fourth, it was said that the decision on how to take a case forward (especially the choice between the conduct and performance routes) was taken at a very early stage and could not later be reversed, even when further evidence would have made that desirable. Finally, the 2001 Consultation Paper observed that the arrangements for issuing letters of advice to doctors lacked transparency and were not regarded as fair or effective by complainants or doctors.

25.12 The 2001 Consultation Paper also acknowledged that the old procedures did not satisfy most of the criteria by which it had suggested that the new procedures should be judged. It observed that the processes involved in the existing FTP procedures could be slow and cumbersome and involved considerable duplication of effort by GMC members and office staff. They also lacked transparency. It referred to successive judicial reviews of conduct cases in which, it was said, the tests to be applied in the early stages had been interpreted as allowing very little discrimination to decision-makers, with the result that those stages were not effectively sifting out the cases which should not be considered fully by the PCC. The FTP procedures did not, the 2001 Consultation Paper suggested, command the confidence of the public or of doctors. A new approach was required **'which builds on**

the strengths of the existing system but which addresses its structural weaknesses'. I am not sure that the weaknesses identified were exclusively structural. However, it is clear that the GMC was contemplating radical change.

25.13 In May 2001, the Fitness to Practise Review Group (the FTP Review Group) reported the results of the consultation process to the full Council. Detailed proposals were then developed and a paper (which appears to have been produced by the FTP Review Group) was considered by the Council at its meeting in November 2001. At that meeting, a number of important decisions of principle were taken relating to the new procedures; I shall refer to some of these in due course. During 2002, there were further discussions within the GMC about the detail of the proposals for reform. Those discussions resulted in the production of an internal discussion paper, 'Review of Fitness to Practise: The New Model', in October 2002. That paper subsequently underwent amendment; the version in the Inquiry's possession is dated 22nd November 2002. A further paper produced by the FPPC was discussed by the Council at its meeting in November 2002. Some amendments were made to the proposals at that stage.

25.14 Before the new procedures could be adopted, changes to the legislation were required. Accordingly, in December 2002, the GMC obtained certain amendments to the Medical Act 1983 (the 1983 Act). These were effected by the Medical Act 1983 (Amendment) Order 2002. New Rules were also needed. Accordingly, in July 2003, the GMC published the draft General Medical Council (Fitness to Practise) Rules 2003 (the 2003 draft Rules), with accompanying Guidance. A period of consultation on the 2003 draft Rules followed. That period of consultation finished at the end of October 2003.

25.15 In November and December 2003, witnesses from the GMC gave oral evidence to the Inquiry. Some of them – in particular Mr Finlay Scott, Chief Executive, and Professor Sir Graeme Catto, President – gave evidence about the new procedures. As I have said, it had been intended that the new procedures would be in place by the spring of 2004. By the time of the Inquiry hearings, however, it was clear that their introduction was going to be delayed. In the early part of 2004, the GMC reviewed its proposals for the new procedures. This review was carried out partly in response to concerns about the original proposals that had been raised at the Inquiry and partly as a result of issues that had emerged from the consultation process. The review resulted in important changes to the new procedures which, in turn, necessitated substantial changes to the 2003 draft Rules. In May 2004, the GMC published a revised version of the draft Rules (the May 2004 draft Rules), together with further Guidance. A short period of consultation on the May 2004 draft Rules followed.

25.16 In July 2004, the GMC published a third version of the draft Rules (the July 2004 draft Rules). They were accompanied by further Guidance. The July 2004 draft Rules contained further significant changes to the proposed new procedures. A fourth version of the draft Rules followed in September 2004. These contained only minor changes to the July 2004 draft Rules. They were accompanied by yet further Guidance. The September 2004 draft Rules (with a few further minor changes) were adopted by the GMC at its Council meeting on 15th September 2004 and came into effect, as I have said, on 1st November 2004. I shall refer to this fourth version as the November 2004 Rules.

25.17 During the five years for which the new procedures have been under discussion, there have been a number of fundamental changes to the arrangements proposed. I do not intend to trace all those changes in detail. Instead, I shall discuss the new procedures as they were proposed in 2003, when the first set of draft Rules was produced. I shall then examine the very different procedures now proposed. Before doing so, I shall summarise briefly the way in which the new procedures are intended to operate.

The Operation of the New Procedures: a Summary

25.18 Under the new procedures, cases will be dealt with in two stages: the investigation stage and the adjudication stage. The new section 35C(4) of the 1983 Act, as amended, provides that, when an allegation is received by the GMC that the fitness to practise of a doctor is impaired, the GMC's Investigation Committee (IC) shall investigate the allegation and decide whether it should be considered by a FTP panel. Under section 35C(2), a doctor's fitness to practise shall be regarded as impaired by reason only of misconduct, deficient professional performance, conviction or caution, adverse physical or mental health or by reason of a determination of another relevant professional regulatory body to the effect that his/her fitness to practise is impaired. For brevity, I shall refer to this last ground as 'a determination'.

25.19 As I have said, the purpose of the investigation stage is to decide whether an allegation should be considered by a FTP panel. The 1983 Act does not lay down a test to be applied when making this decision. Nor do the Rules. However, the GMC has decided that this test (the investigation stage test) should be whether there is a realistic prospect of establishing that the doctor's fitness to practise is impaired to a degree justifying action on registration. Only cases which satisfy the investigation stage test will progress to the adjudication stage.

25.20 Decisions at various points during the investigation stage will be made (depending upon the circumstances of the case) by members of the GMC staff (who will, as under the old procedures, carry out a preliminary 'sift' of cases), by medical and lay persons contracted to work for the GMC (to be known as case examiners), and by panels of the IC. It is likely that the vast majority of cases reported to the GMC will not progress beyond the investigation stage.

25.21 If, at the investigation stage, it is decided that the case should not be considered by a FTP panel, a decision may be made either to warn the doctor about his/her future conduct or performance or to close the case. There will also be cases involving a health or performance element where the investigation stage test is satisfied, but where the case will nevertheless not proceed to the adjudication stage. Such cases will be dealt with by the doctor giving voluntary undertakings in the same way as was previously possible under the voluntary health and performance procedures. The GMC is considering the possibility of extending the availability of voluntary undertakings to all categories of case; I shall discuss this proposal later in this Chapter. Cases dealt with by way of voluntary undertakings will remain in the investigation stage, with the possibility of being referred to the adjudication stage if, at any point, the doctor concerned fails to accept or co-operate with the voluntary arrangements or if his/her health or performance deteriorates or

otherwise gives rise to further concern about his/her fitness to practise. It should be noted that all this is subject to the qualification that there may be changes to the future arrangements for cases involving issues of health or performance as a result of the recent report of the Performance Procedures Review Group (to which I referred in Chapter 24) and of any recommendations which may be made by the Working Group currently undertaking a review of the old health procedures.

25.22 Cases referred to the adjudication stage will be heard by a FTP panel. The new section 35D of the 1983 Act provides the powers for a FTP panel to restrict or remove a doctor's registration if it finds that his/her fitness to practise is impaired. FTP panels are to replace the committee panels which previously dealt with issues of fitness to practise, namely panels of the PCC, the Health Committee (HC) and the Committee on Professional Performance (CPP). FTP panels will be composed of persons who are not members of the GMC but who have been appointed, selected and trained by the GMC for their role as panellists. Many of the associates who have, since 2000, been appointed by the GMC to sit on panels of its FTP committees will in the future sit on FTP panels. A FTP panel's task will be to decide whether the doctor's fitness to practise is impaired. If a FTP panel finds that a doctor's fitness to practise is impaired, it will then have to decide on the appropriate sanction to be imposed or on any other action to be taken.

25.23 There will be a separate Interim Orders Panel (IOP) for considering cases where it may be appropriate to impose an interim order restricting or suspending a doctor's right to practise pending investigation and determination of his/her case. This will replace the Interim Orders Committee (IOC) which, since its inception in 2000, has dealt with such cases.

The Separation of Functions within the Fitness to Practise Procedures

25.24 I shall now consider one of the principles which, according to the GMC, has underlain the development of its new FTP procedures, namely the separation of functions within those procedures.

25.25 In the past, the GMC's FTP procedures comprised two distinct functions. The first was (broadly speaking) to decide whether there was evidence that raised a question about a doctor's conduct, performance or health, which should be referred to a FTP committee or into the voluntary health or performance procedures, and to make any appropriate referral. This first function was comparable to the role of a prosecution service. The second function consisted of the hearing and determination of cases by a FTP committee. This function was comparable to the role of a court or tribunal and required administrative and other support. Initially, in its proposals for change, the GMC called the two functions the **'prosecution'** and the **'determination'** functions. Later, it adopted the terms **'investigation'** and **'adjudication'** functions. It should be noted that, in this context, the term **'investigation'** refers to an investigation as to whether a case should be referred to a FTP panel, and not to **'investigation'** in the sense of evidence gathering. In other words, it does not denote **'investigation'** in the sense that most people would understand the term. The term **'investigation'** is also something of a misnomer because the investigation

stage of the new GMC procedures includes a decision (or adjudication) as to whether the case is sufficiently serious to be referred to a FTP panel.

25.26 Historically, the same GMC members could be involved in both functions; sometimes, they could even be involved in both functions relating to the same case. Until the early 1970s, for example, the President acted as medical screener and chaired the Penal Cases Committee (the predecessor of the PPC); those roles were both part of the first **'prosecution'** or **'investigation'** function. The President could also chair the Disciplinary Committee (the predecessor of the PCC) which carried out the second **'determination'** or **'adjudication'** function. In practice, this ceased to happen in 1973, although it was permitted by the Rules until 1980, when the Rules were changed to restrict the President's decision-making role to either screening and Chairmanship of the PPC or Chairmanship of the PCC and/or the HC. The Rules were also amended to provide that no member of the GMC should sit on a case at the PCC, the HC or the CPP if s/he had previously been involved in making a decision in the case at an earlier stage, for example by screening the case or being a member of the PPC which had considered the case.

25.27 By 2000, the GMC had decided that the time had come to separate the two functions more clearly. This decision was, in part, prompted by the coming into force, in October 2000, of the Human Rights Act 1998, which incorporated into UK law the entitlement of a person to **'a fair and public hearing ... by an independent and impartial tribunal'** in the determination of his/her civil rights and obligations. However, the GMC had also become convinced that the existing arrangements gave rise to an appearance of unfairness. Doctors, it was said, perceived that the same organisation was both prosecuting them and sitting in judgement on them, and they considered that to be unfair. The GMC decided, therefore, that there was a need for the functions to be separated, so that everyone involved in complaints about doctors would be able to see that the organisation and the people making the final decision on a case were different from those who had taken the decision that it should be heard and from those representing any of the interested parties.

25.28 The GMC raised its proposal to separate the two functions in a Consultation Document, 'The Structure, Constitution and Governance of the GMC', published in October 2000. The proposal received general support.

25.29 In its 2001 Consultation Paper, the GMC put forward four possible models by which separation of the two functions might be achieved. The first model involved the retention by the GMC of both functions, although those functions would be carried out quite separately by different groups of personnel within the GMC. The intention was that the staff, management, legal support and records of the two groups would be located in two **'distinct organisational structures'** with separate arrangements for **'reporting and accountability'**. The 2001 Consultation Paper referred to the view of the supporters of this model that both investigation and adjudication functions were crucial to a regulatory body and that **'to hive off one or both of them would weaken professionally-led regulation by severing the feedback loops between fitness to practise and standards and education'**. The advantage of this model was said to be that:

> **'Professional ownership of the decision-making process is retained at all stages, and for some supporters of this model, it is the retention of ownership that defines professionally-led regulation.'**

25.30 The weakness of the model was said (in the 2001 Consultation Paper) to be the fact that decisions taken in both the investigation and adjudication stages would continue to be identified with the GMC. In addition, the arrangement might not have the appearance of fairness. The 2001 Consultation Paper acknowledged that there was a **'risk'** that the model would not **'go far enough'** to reassure the GMC's critics. However, the 2001 Consultation Paper also made clear that this model was the one preferred by the GMC.

25.31 The second model – and the GMC's second preference – was an arrangement whereby the GMC would retain the investigation function, with the adjudication function being **'contracted by the GMC to a completely independent, outside organisation'**. It was suggested that, in this model, it was **'the GMC, as guardian of standards and guarantor of the public interest, which should identify cases potentially raising questions about doctors' fitness to practise but that the decisions on those cases should be made by another organisation'**. The strength of this model was said to be the absolute separation that it created between the investigation and adjudication functions. It was suggested that the adoption of this model would absolve the GMC from blame when controversial decisions were made and might insulate the GMC from the disproportionate damage to confidence in the organisation and in **'professionally-led regulation'** caused by occasional controversial outcomes in FTP cases. It was suggested also that, with this model, the public might have greater confidence that decisions were being made purely on the merits of a case. The most obvious weakness of the model was said to be that the GMC would lose control over decisions concerning individual doctors and might still be perceived as responsible for the outcome. Furthermore, the fact that another organisation was ultimately responsible for the outcome of FTP cases might, it was suggested, undermine confidence in the GMC. Other disadvantages of the model were said to be the considerable resource implications involved and the fact that accountability might be weakened. I interpose at this stage to say that, in my view, the GMC was right to recognise the advantages of this model, although it also noted some drawbacks. In Chapter 27, I recommend that the GMC adopts this model, in order to achieve the separation of function which is, in effect, required by the Human Rights Act 1998.

25.32 The third model (described in the 2001 Consultation Paper as the **'mirror image'** of the second model) was an arrangement whereby the GMC would retain the adjudication function, but not the investigation function. GMC members and others appointed by the GMC would sit on FTP committees and GMC staff would be responsible for organising and servicing those committees. An outside organisation would be responsible for the initial stage of sifting complaints and referrals and deciding which cases raised questions about doctors' fitness to practise and should proceed. The 2001 Consultation Paper expressed the view that, by adopting this model, the GMC **'would be taking the view that its core business concerned only the final determination of the small proportion of cases which reached the stage of a committee hearing'**. It identified a risk that **'the links between fitness to practise and other core GMC functions would be weakened'**. I interpose to say that the 2001 Consultation Paper did not explain how those links operate and how the risk of weakening would arise. This is not clear – to me at least. The 2001 Consultation Paper declared that the process of investigation, in particular decisions about which cases to investigate, must be **'rooted in the GMC's own values'**. The

possibility that accountability would be weakened by the involvement of two organisations in the FTP procedures was also mentioned. In the 2001 Consultation Paper, the GMC expressed the view that **'hiving off the investigation function'** would **'seriously weaken public confidence in the organisation as protector of the public interest'**. It was said to be **'essential to confidence in professionally-led regulation'** that the GMC should be seen to **'act vigorously on questions about doctors' fitness to practise'**. However much another organisation tried to base its approach on the profession's values and ethical standards as embodied in the GMC, it was said, it would always be **'at one remove'**.

25.33 The fourth model would have delegated both the investigation and adjudication functions to separate outside organisations. A complaint would be investigated by one body and brought before another for adjudication. The GMC would have no involvement in either stage beyond, possibly, acting as the recipient for complaints before handing them on to the outside body for investigation. The 2001 Consultation Paper pointed out that this model would effectively end the GMC's involvement in fitness to practise. It suggested that it **'would be a clear statement that it** (*i.e. the GMC*) **no longer had a role in policing unfit doctors'**. The 2001 Consultation Paper suggested that the model would **'lack coherence and credibility and would not meet the expectations of either the public or the profession regarding what was expected of a professional regulatory body concerned with medicine'**.

25.34 The vast majority of medical organisations and individuals who responded to the 2001 Consultation Paper favoured the first model, i.e. the retention by the GMC of both the investigative and the adjudication functions. Patients' representatives were marginally in favour of the first model, with several preferring the second model.

25.35 In the event, the new FTP procedures appear to be based largely on the first model described. The GMC will retain responsibility for the investigation function. It will carry out the preliminary sifting of cases and will be responsible for the decision whether or not a case should go forward for a full hearing. The preliminary sift will be carried out by the GMC staff and the decisions as to whether or not those cases which survive the sift go forward to a full hearing will be taken by case examiners, who will be medical and lay people, contracted to work for the GMC on a part-time basis. Some such decisions will be taken by the IC.

25.36 The decision-making at FTP panel hearings will be undertaken by associates, both medically qualified and lay, who will not be members of the GMC but who will have been selected and appointed by the GMC to sit on those panels. Members of the GMC will not sit on FTP panels, although some of the panellists will be former members. Over 200 associates have already been appointed to sit on panels and, since 2000, they have sat on panels of the old FTP committees. Further panellists will be appointed as and when necessary. Panellists are expected to commit at least 20 days a year to their work for the GMC. They are selected for appointment against specific criteria and after an open competition. Appointment is subject to a two-day training programme. The training and evaluation of panellists is undertaken by the GMC. The GMC provides guidance for panellists on the approach to sanctions and other matters and will continue to do so. It is

intended that panellists, once appointed, will undergo regular appraisal and performance management, to be undertaken by the GMC. In the event that concerns arise about a panellist's suitability to continue to sit on a panel, a sub-group of the Fitness to Practise Committee will consider those concerns and may, if it thinks fit, terminate a panellist's appointment. If the GMC considers that a FTP panel has reached an inappropriate decision, the chairman of the panel may be given advice, presumably about where s/he and his/her panel have gone wrong. Members of the GMC staff will retain responsibility for organising and administering adjudication hearings and for choosing panel members to sit in individual cases.

Comment

25.37 The GMC started from the premise that it would be right to separate the investigation and adjudication functions. There were good, sound reasons for wishing to achieve that end. Yet this has not happened. The GMC has kept complete control over the investigative function which it has extended so that it encompasses some decisions on final disposal other than closure (the giving of warnings and the acceptance of voluntary undertakings) but it has not relinquished control of adjudication. Under the new procedures, it will have almost exactly the same degree of control over adjudication as under the old. For many years, PCC panels comprised GMC members only. However, by 2000, the pressure of work on the GMC was such that it was obliged to recruit extra people to serve as panellists alongside GMC members. As I have explained, from 2003, when the number of GMC members was reduced to 35, FTP committee panels were, in the main, composed entirely of associates. This situation is to be carried through into the new procedures. So, despite the GMC's recognition of the need for some separation of functions and some independence at the adjudication stage, nothing is going to change.

25.38 The GMC has retained very close control over the adjudication process. It has the power to select and appoint FTP panellists. It will train them, appraise them and provide them with guidance; it may dismiss them. It must not be thought that I am suggesting that training, appraisal and guidance are not required; they are. But nor must it be thought that there is any separation of functions just because the panellists are not members of the GMC. The GMC cannot control the outcome in a particular case, although, as I have said, it will 'advise' a panel chairman when it considers that a FTP panel has erred. Also, as I shall later explain, it has indicated, in recent draft Guidance, that it intends to inform doctors whose cases are referred to a FTP panel what outcome it is seeking in their cases; thus, it would appear, the GMC hopes to be able to influence the way in which the case is dealt with (or at least the sanction which is to be imposed) by the FTP panel.

25.39 Furthermore, it appears that at least some GMC members would have liked to retain an even more substantial degree of control over the outcome of individual cases. At a meeting of the Council in May 2004, it was proposed that the GMC should (subject to further work and consultation) request further legislation to introduce a system whereby the GMC had to ratify decisions of its FTP panels before those decisions came into effect. It was explained that the object was to give the GMC the opportunity to intervene when it regarded a decision as **'clearly perverse'**, to reject the decision and to refer the case to another FTP panel for re-hearing. The proposal was supported by the President, and

Mr Scott spoke in its favour. A number of Council members pointed out that a system whereby the GMC could, within its own procedures, ratify or reject a decision of a FTP panel would be entirely inconsistent with the concept of separation of the investigation and adjudication functions. In the event, the proposal was abandoned and a decision was made instead to seek legislation enabling the GMC to appeal to the High Court against decisions of its FTP panels. However, the mere fact that a system of ratification could have been given serious consideration demonstrates that some within the GMC do not appear fully to understand the concept of separation of the two functions.

25.40 I have a further concern about the position of FTP panellists. Adjudication is a skill which needs regular practice. It is sometimes said that a judge or tribunal member is 'as good as how often s/he sits'. I am concerned that panellists may sit for as little as 20 days a year. They will have little opportunity to develop real expertise. Also, the fact that there will be 200 or more panellists at any one time means that there are likely to be real problems with ensuring consistency of decision-making. It has occurred to me that other healthcare regulators must also have to appoint and train panellists for their FTP procedures. I have wondered whether it might be feasible to appoint a body of full-time or nearly full-time panellists who could sit on panels of all the healthcare regulatory bodies. This would provide a measure of independence from any one particular body, such as the GMC, and would also ensure that panellists developed experience and expertise.

The Tests to Be Applied

The Concept of Impairment of Fitness to Practise

25.41 One of the GMC's main objectives in introducing its new procedures has been to leave behind the compartmentalised approach that had developed under the old procedures for historical reasons. The conduct procedures were the foundation of the GMC's disciplinary processes. The health procedures and the performance procedures were added in 1980 and 1997, respectively. Although it was possible, in some circumstances, for a doctor to be transferred from one set of procedures to another, a case could not be handled within more than one set of procedures at any one time. Understandably, the GMC wanted to overcome this difficulty. The solution it arrived at was to adopt the concept of 'impairment of fitness to practise' as a doctor. This concept, which, as I have said, is embodied in the 1983 Act, forms the foundation of the tests to be applied by decision-makers at both stages of the GMC's new procedures.

Definition of the Term

25.42 The advantage of the concept of 'impairment of fitness to practise' is that it is capable of embracing any or all of the types of problem that the GMC habitually encounters, i.e. misconduct (including breaches of the criminal law leading to convictions or cautions), deficient professional performance, adverse health and determinations.

25.43 The disadvantage of the concept is that it is not at all clear what it means. The concept is not defined in the 1983 Act or in the Rules which are to govern the operation of the new procedures. The only relevant legislative provision is at section 35C of the 1983 Act, where

it is said that a doctor's fitness to practise shall be regarded as 'impaired' by reason only of misconduct, deficient professional performance, a conviction or caution, adverse physical or mental health or a determination. That section imposes a limitation upon the routes by which a doctor's fitness to practise might be found to be impaired, but it does not help in understanding what an impairment of fitness to practise is. I have said elsewhere in this Report that the expressions 'serious professional misconduct' (SPM) and 'seriously deficient performance' (SDP) were difficult to define or even to recognise. I believe that even greater difficulty will be encountered with 'impairment of fitness to practise' unless it is clearly defined.

25.44 The question whether a doctor is fit to practise as a doctor may mean many different things in different contexts. If a doctor is suffering from ill health (for example, severe depression), one might say that s/he is not fit to practise because his/her concentration is so affected that s/he cannot make effective decisions on diagnosis and treatment; s/he presents a risk to patients. If a doctor's performance is found to be deficient (for example, because s/he has 'botched' one or more operations), one might say that s/he is not fit to practise because s/he cannot provide an adequate standard of care to patients and exposes them to risk of harm. If a doctor has been found guilty of offences of indecency, one might say that s/he is not fit to practise because there is a risk that s/he will act indecently towards patients. If a doctor is found guilty of an insurance fraud, one might say that s/he is unfit to practise because s/he is a disgrace to the profession and has brought it into disrepute. Similar considerations might apply to the doctor found guilty of causing death by dangerous driving while drunk. In either of the last two cases, the doctor might be first class so far as his/her clinical practice is concerned. If a doctor has forged prescriptions to obtain controlled drugs for his/her own use, one might say that s/he is unfit to practise because s/he might at any time be under the influence of drugs and unable to make sensible decisions about diagnosis and treatment and/or because s/he is dishonest and cannot be trusted. If a doctor were to give private information to a newspaper about a patient who was a well-known personality, one might say that the doctor was not fit to practise because s/he had breached confidentiality, one of the fundamental tenets of the profession. Another such tenet is the requirement that patients should consent to treatment. A doctor who conducted a research project without obtaining the informed consent of the patients might be said to be unfit to practise.

25.45 The examples I have given are cases where the conclusion might well be that the doctor is completely unfit to practise. However, the concept of an 'impairment' of fitness to practise introduces a difficulty. One dictionary definition of 'impairment' is 'damaged; injured; made less effective; devalued'. Doctors usually use the word in connection with an impairment of function, for example, impaired hearing or impaired mobility. In those contexts it simply means 'reduction'. Some of the ways by which 'impairment of fitness to practise' may be demonstrated under section 35C lend themselves easily to the concept of impairment in the sense of 'reduced'. For example, if a doctor's performance is deficient, one might well say that his/her fitness to practise is 'impaired'. The concept of 'impairment of fitness to practise' may also be quite apposite in cases of ill health. But, in most cases of misconduct and convictions, 'impairment of fitness to practise' is not a helpful concept. For example, if a doctor has been found guilty of the theft of a pair of

shoes from a shop, s/he has been found to be dishonest. Some might say that this has nothing to do with his/her fitness to practise medicine. Others might say that s/he is a disgrace to the profession and is completely unfit to practise. The one thing that you could not sensibly say is that his/her fitness to practise medicine is 'impaired'. I take another example, this time involving clinical practice. If a doctor has been found to have falsified medical records, some might say that s/he is unfit to practise because s/he cannot be trusted. Some might say that s/he is a disgrace to the profession. Others might take a less serious view and observe that, although this kind of behaviour is to be deprecated, it does not affect the doctor's fitness to practise. Although different people might take differing views about the seriousness and relevance of the misconduct, I do not think that anyone would think of saying that the doctor's fitness to practise was 'impaired'.

25.46 So, although I can well understand why the GMC has adopted the all-embracing concept of 'impairment of fitness to practise', and although I recognise its major advantage, it does have disadvantages. It is not easy to define; it means different things in different circumstances and, in some circumstances, it is almost without meaning. Some concepts are difficult to define but relatively easy to recognise when found. It is often said that elephants fall into this category but I have never understood why; definition cannot be too difficult. However, I fear that an 'impairment of fitness to practise' will be not only difficult to define but also not easy to recognise, because (unlike recognising an elephant) recognising 'impaired fitness to practise' involves making a value judgement.

25.47 Even in cases in which the concept of 'impairment of fitness to practise' is obviously appropriate, such as cases of ill health or deficient performance, it will not be every slight impairment that gives rise to the need for intervention by the GMC. If there are gradations of impairment, what level will justify the referring of a case through the procedural stages and at what level will action on registration be justified? All those involved in the FTP procedures will know that not every impairment of fitness to practise will justify action by the GMC. To take an extreme example, one might say that if a doctor goes to work suffering from a headache, his/her fitness to practise may be impaired but no one is going to suggest that the GMC should intervene. The GMC can provide guidance for its staff, case examiners and panellists, but how is the public to understand why a decision was taken and how can the courts decide whether a decision was reasonable if the test is as amorphous as 'impairment of fitness to practise'? There is, in my view, a need for a test which the public understands and by which the courts can judge whether a decision was lawful in the sense of complying with the test.

25.48 Another potential problem arises with the time when fitness to practise is measured or assessed. The 1983 Act permits a FTP panel to take action on registration if it finds that the doctor's fitness to practise is impaired. That implies that the impairment must be present at the time of the hearing. So, if a doctor has committed a serious act of misconduct a year ago, does that indicate that his/her fitness to practise is currently impaired? I understand that the GMC has been advised that, although section 35D(2) of the 1983 Act refers to a finding that a doctor's fitness to practise is impaired, present impairment of fitness to practise can be founded on past matters. That seems sensible. The doctor's current fitness to practise must be gauged partly by his/her past conduct or performance. It must also be judged by reference to how s/he is likely to behave or perform in the future. Having

said that, I think that there will be arguments about the extent to which a past (serious) misdemeanour makes a doctor's fitness to practise impaired at the present time. It would be most unsatisfactory if a doctor was able, by delaying the hearing of a case, to reduce the risk of a finding that his/her fitness to practise was impaired.

25.49 I have made these observations about the concept of 'impairment of fitness to practise', not because I am going to suggest that the GMC should abandon it but to draw attention to some of the problems of decision-making that will be inherent in the new procedures and which, I think, the GMC must take steps to resolve.

25.50 I think it will be helpful, in the resolution of the problems that I am about to outline, if I analyse the reasons why a decision-maker might conclude that a doctor is unfit to practise or that his/her fitness to practise is impaired. In the examples I discussed above, four reasons for unfitness recurred. They were (a) that the doctor presented a risk to patients, (b) that the doctor had brought the profession into disrepute, (c) that the doctor had breached one of the fundamental tenets of the profession and (d) that the doctor's integrity could not be relied upon. Lack of integrity might or might not involve a risk to patients. It might or might not bring the profession into disrepute. It might be regarded as a fundamental tenet of the profession. I think it right to include it as a separate reason why a doctor might be regarded as unfit to practise, because it is relevant even when it arises in a way that is quite unrelated to the doctor's work as a doctor.

The Investigation Stage Test

25.51 The new FTP procedures will begin with the receipt of an allegation. Allegations will be sifted by GMC staff and not all will be referred into the investigation stage. I shall consider that sifting process later in this Chapter. If an allegation survives the preliminary sift, it will be referred (except in the case of some convictions) to case examiners. It is convenient at this stage to discuss the test that the case examiners (and, when the case examiners cannot agree, the IC) will apply at the conclusion of the investigation stage in deciding whether to refer a case to a FTP panel.

25.52 Section 35C(4) of the 1983 Act provides that the IC shall investigate an allegation and decide whether it should be referred to a FTP panel. The section does not specify what test should be applied at that stage. Nor do the November 2004 Rules or any of the drafts which preceded them. This is surprising because it was the lack of a clear straightforward test that gave rise to problems under the old procedures. The problems were lack of clarity about which cases should go through the various filtering processes, and inconsistency of decisions. If the new procedures are to be transparent and are to produce consistent decisions, there should be a clear statutory test for each stage of the process. If there is not, there will be a danger that cases may be filtered out that ought to go forward. If that happens, patients are not adequately protected.

25.53 The test which the GMC has decided should be applied at the end of the investigation stage is whether there is a realistic prospect of establishing that the doctor's fitness to practise is impaired to a degree justifying action on registration. Action on registration means erasure, suspension or the imposition of conditions upon the doctor's right to practise.

25.54 In the course of the Inquiry hearings, I expressed some concern that the test to be applied by those making decisions at various stages of the FTP procedures made no mention of the protection of patients. It seemed to me that the test focussed exclusively on the sanction to be applied to the doctor and not at all upon the nature and gravity of his/her actions or their effect upon patients. In an apparent attempt to meet those concerns, the GMC added a preamble to the investigation stage test, which appears in various guidance documents:

> **'The Investigation Committee or case examiners must have in mind the GMC's duty to act in the public interest which includes the protection of patients and maintaining public confidence in the profession, in considering whether there is a realistic prospect of establishing that a doctor's fitness to practise is impaired to a degree justifying action on registration.'**

What I actually had in mind was a test that incorporated the protection of patients as an integral part of the test.

25.55 In any event, the investigation stage test as presently formulated seems to me to give rise to a number of problems.

A Problem of Principle

25.56 As a matter of principle, in any legal process, if there is to be a preliminary process which seeks to filter out cases which should not go through to final adjudication, the test applied to that process should have the effect of filtering out only those cases which, taken at their highest, could not satisfy the test to be imposed at the final stage. In a disciplinary process, the preliminary process should, as a matter of principle, filter out only those cases that, taken at their highest, cannot satisfy the test for disciplinary action.

25.57 The test for disciplinary action under the 1983 Act is whether the practitioner's fitness to practise is impaired. If it is, the FTP panel has jurisdiction to take action on registration. As a matter of principle, therefore, the preliminary screening process should allow through any case in which it is possible (or, if it is preferred, realistically possible) for there to be a finding of impairment to practise. Because 'impairment of fitness to practise' is so imprecise a concept, that screening test would set a very low threshold and would result in a lot of very minor cases being referred through to a FTP panel. I think it must have been in order to avoid that result that the GMC set the investigation stage test at a much higher threshold. It will allow through only those cases in which there is a realistic prospect of a finding of impairment sufficient to justify action on registration.

25.58 I can understand why the GMC would wish to set this higher threshold. It is in no one's interest to have a lot of trivial cases going through to a FTP panel hearing, at the end of which there is no possibility of action being taken on registration. But, in attempting to do this, the GMC has, in my view, created problems of construction and of circularity of definition which deprive the investigation stage test of clarity and which will result in lack of transparency of decision-making.

A Problem of Construction

25.59 The test as currently stated poses a problem of construction. Does it mean:

(a) that the decision-maker has to decide whether, in his/her opinion, what is alleged, if proved, shows that the doctor's fitness to practise is impaired to a degree justifying action on registration and that the evidence available is such that there is a realistic prospect of proving what is alleged; or

(b) that the decision-maker has to decide whether there is a realistic prospect that a FTP panel will find that what is alleged shows that the doctor's fitness to practise is impaired to a degree justifying action on registration and also whether the evidence available is such that there is a realistic prospect of proving what is alleged?

25.60 At the moment, the test does not distinguish between these two possibilities. It is not clear whether the decision-maker is supposed to make a personal judgement about the gravity of the matters alleged or whether the process is one of assessing what the view of a FTP panel might be. That ought to be clarified. However, in my view, neither is satisfactory because both involve the making of a value judgement (either firsthand or secondhand) about the fitness to practise of the doctor if what is alleged about the doctor is proved. A preliminary decision such as the decision to be made at the end of the investigation stage should involve as little value judgement as possible; it should be based, so far as possible, upon an objectively ascertainable threshold.

The Problem of Circularity

25.61 A further problem with the investigation stage test as currently drafted is that it is circular. The case examiner or IC must make a judgement about whether the matters alleged appear to show an impairment of fitness to practise such as would justify action on registration. So, for example, in a case involving an allegation of misconduct, the test involves consideration of whether what the doctor appears to have done is serious enough to justify action on registration. That question immediately prompts a second question, namely: how serious does what s/he has done have to be before it is serious enough to justify action on registration? And the only answer available to that second question is that it has to be serious enough to justify action on registration. We have come full circle. There is no benchmark, no objective standard. The answer to 'how serious does it have to be?' involves a purely subjective judgement by the decision-maker. I accept, of course, that some element of discretionary judgement will always be required in decisions of this kind; decision-makers often have to decide upon which side of a threshold a particular case falls. The problem here is that there are no thresholds. This means that decisions at the investigation stage can never be adequately tested. The decision-making process can never be transparent.

What Should Be Done?

25.62 I suggest that the GMC should think again about the investigation stage test. Because I recognise that it is easy to criticise the work of others and less easy to suggest better ways of doing things, I have tried to devise a test that will be clear and will depend, not upon

an open-ended value judgement (whether at firsthand or secondhand), but upon some more objective criteria.

25.63 The test I propose has two stages. The object of the first stage of the test will be for the decision-maker to decide whether the allegation, if proved, might show that the doctor's fitness to practise is impaired. At the second stage, s/he will have to consider the adequacy of the evidence. At the first stage, I have related 'impairment of fitness to practise' to the underlying reasons why the doctor's fitness to practise might be impaired, which I identified earlier. These reasons are that s/he is a risk to patients, that s/he has brought the profession into disrepute, that s/he has breached one of the fundamental tenets of the profession or that his/her integrity cannot be relied upon. Those concepts are far easier to recognise than 'impairment of fitness to practise'. So, the two stages are:

1. Is there one or more than one allegation of misconduct, deficient professional performance or adverse health and/or one or more than one report of a conviction, caution or determination which, if proved or admitted, might show that the doctor:

   (a) has in the past acted and/or is liable in the future to act so as to put a patient or patients at unwarranted risk of harm; and/or

   (b) has in the past brought and/or is liable in the future to bring the medical profession into disrepute; and/or

   (c) has in the past committed a breach (other than one which is trivial) of one of the fundamental tenets of the medical profession and/or is liable to do so in the future; and/or

   (d) has in the past acted dishonestly and/or is liable to act dishonestly in the future.

If so:

2. Is the available evidence such that there is a realistic prospect of proving the allegation?

25.64 I would suggest that a doctor should be regarded as 'liable to' act in a certain way if a reasonable and well-informed person would consider, in the light of what is known about the allegation and about the doctor's past and present circumstances, that there is a real risk that s/he might act in that way. The evidence of a single past event might be serious enough, standing alone, to satisfy the investigation stage test. For example, evidence that a doctor had harmed a patient, as Shipman was believed to have harmed Mrs Renate Overton, by giving her an inappropriate dose of morphine (see Chapter 10), would satisfy the test. Evidence of a less serious error, for example, the kind of prescribing error that Shipman made in the case of Mr W (see Chapter 6), might not be sufficient standing alone, but would be sufficient if coupled with other evidence that suggested that the doctor was liable to make careless mistakes. Evidence of poor communication skills, contained in a performance assessment report, might well pass the test, even if there was no significant past incident in which harm had been caused; it might pass on the basis that the doctor was liable to cause unwarranted harm in the future. I would suggest that 'unwarranted risk of harm' should be defined as a risk of harm over and above that which would be expected to arise from the advice or treatment had it been given or administered with reasonable

skill and care. Insofar as there is no agreement on the fundamental tenets of the medical profession (some of which appear in 'Duties of a Doctor'), a list could be developed and agreed.

25.65 In my view, the application of that two-stage test would give case examiners and the IC something more objective to focus upon than 'impairment of fitness to practise'. It would avoid those people having to 'second guess' the view that the FTP might take about the need to take action on registration and it should also avoid trivial cases being sent through to the FTP panel. Finally, I think also that it would satisfy the public's reasonable expectation about the kind of case that ought to go through to a FTP panel. If correctly applied, it should ensure that all those cases that ought to proceed (for reasons of patient protection) do in fact proceed to a FTP panel.

The Adjudication Stage Test

25.66 At the present time, the test to be applied by the FTP panel is simply framed in the words of the statute. The statutory test is whether or not the doctor's fitness to practise is impaired. It is not, as the GMC's Guidance to Panellists suggests, whether or not the doctor's fitness to practise is impaired to a degree justifying action on registration. I suspect that FTP panels will have great difficulty in applying the statutory test in a consistent way. The test requires a value judgement that is not underpinned by any objective criteria. Nowadays, where a statute gives a decision-maker a discretion, it usually provides a list of the kind of things that should be taken into account.

25.67 In devising an adjudication stage test (to be applied by FTP panels under Rule 17(2)(k)), I have tried to focus the panel's mind on its true purpose. I suggest that:

> Do our findings of fact in respect of the doctor's misconduct, deficient professional performance, adverse health, conviction, caution or determination show that his/her fitness to practise is impaired in the sense that s/he:
>
> (a) has in the past acted and/or is liable in the future to act so as to put a patient or patients at unwarranted risk of harm; and/or
>
> (b) has in the past brought and/or is liable in the future to bring the medical profession into disrepute; and/or
>
> (c) has in the past breached and/or is liable in the future to breach one of the fundamental tenets of the medical profession; and/or
>
> (d) has in the past acted dishonestly and/or is liable to act dishonestly in the future.

25.68 If the FTP panel finds that the doctor's fitness to practise is impaired, it should go on to consider sanction under Rule 17(2)(n). It is at this stage (and not before) that the statutory scheme requires the FTP panel to consider whether the doctor's fitness to practise is impaired to a degree justifying action on registration. At this stage, I suggest that the panel asks itself:

> Would a reasonable and well-informed member of the public conclude that the doctor's fitness to practise is impaired to the extent that, in the interests of patient

protection and/or of the maintenance of public confidence and of standards in the medical profession, the doctor's registration should be erased or suspended or have conditions imposed upon it?

In a case which depends wholly or mainly on findings in relation to the doctor's ill health, erasure will not be available. I have incorporated into the second limb of the test the view that would be taken by an informed member of the public because I am firmly of the view that the standards, criteria and thresholds that are to be applied by FTP panels must be acceptable to society as a whole. That they have not been in the past has been one of the major causes for public criticism and lack of confidence in the GMC.

25.69 I hope that the GMC will give serious consideration to these proposed tests. When a final decision has been taken, the tests for both the investigation and the adjudication stages should be enshrined in legislation. There are several reasons why this should be done. The GMC should be able to say that the tests to be applied have been sanctioned by Parliament. The public should know that the GMC is applying the law of the land and not just a formula of its own making. It should not be possible for the GMC to change the tests to be applied without proper consultation and without the approval of Parliament. Furthermore, it is important that there should be statutory tests by reference to which the courts can examine any decision, whether on judicial review in respect of the investigation stage decision or on appeal from the decision of a FTP panel.

Section 35C of the Medical Act 1983 and the Ways of Proving Impairment

25.70 It will be seen that, in drafting the tests that I have proposed for the investigation and adjudication stages, I have adopted the five categories of allegation by means of which, under section 35C of the 1983 Act, an impairment of fitness to practise may be demonstrated. However, in my view, there is a *lacuna* in these five categories. There is a category of allegation which does not fall easily within the range of 'deficient professional performance' or of 'misconduct'. Misconduct, as I explained in Chapter 17, generally connotes behaviour which has been undertaken deliberately or recklessly. In order to give the GMC jurisdiction to deal with cases of serious negligence which put patients at risk, the bounds of SPM were extended to embrace negligent acts or omissions, usually arising in a clinical context, provided that they were sufficiently serious. However, to describe some of these cases as 'misconduct' required some 'stretching' of the use of the language. A typical example might be that of a doctor who gave a gross overdose of a dangerous drug. He or she might have done so because s/he was very careless about the size of ampoule s/he picked up or because s/he had not bothered to find out the correct dosage. Another example might be operating on the wrong arm, leg or kidney. Such cases of serious negligence might equally well – or even more appropriately – be described as cases of 'deficient clinical practice'. With the advent of the performance procedures came the concept of SDP. This was usually characterised by a pattern of unacceptable clinical practice, although it could relate to organisational or behavioural problems. Such a pattern might result from ignorance, from a failure to keep up to date, from laziness, from poor health or from a concatenation of social or professional difficulties. So, there were then two concepts, SPM and SDP, neither of which comfortably accommodated a case of serious negligence such as that

I described above. Such a case could not sensibly be termed SPM; nor, if it was a 'one-off' incident, could it possibly amount to SDP. Under the old procedures, there was a real danger that such cases would fall through the net and would be closed at a preliminary stage.

25.71 Unfortunately, section 35C has perpetuated this problem. There is still no place for the isolated or nearly isolated serious error, committed not deliberately or recklessly, but negligently. Nor is there a place for a case of two or three 'lower level' incidents which do not demonstrate the 'pattern' necessary to constitute deficient performance but which may nonetheless put patients at risk. It seems to me to be obvious that such cases ought to enter the FTP procedures because they could be cases of impairment of fitness to practise. I suggest that, if the legislation is to be amended, a further category should be added to the means by which impairment may be proved, namely 'deficient clinical practice', which could relate to one or more than one incident. The aim would be to ensure that the 'routes' to impairment of fitness to practise embrace all the circumstances which might put patients at risk.

25.72 So far in this Chapter, I have discussed the broad issues relating to the new procedures. I have made certain suggestions for change. I shall now move on to consider, in some detail, the provisions under which the new procedures will operate in the immediate future.

The Roles of the Investigation Committee and of the Case Examiners

25.73 Before describing the various processes comprised within the investigation stage, I shall first explain the roles currently envisaged for the IC and the case examiners. This will also involve a discussion about the GMC's intentions with regard to the involvement of lay people in decisions made at the investigation stage.

The Investigation Committee

The Functions and Composition of the Investigation Committee: the 2003 Position

25.74 The new section 35C(4) of the 1983 Act requires the IC to investigate every allegation made to the GMC that a doctor's fitness to practise is impaired. However, it was never intended that the IC should itself make the decision about how to deal with the allegation in every case. Section 35CC of the 1983 Act, therefore, provides that Rules may be made, enabling the Registrar (in practice, members of the GMC staff exercising his legal powers) or any other officer of the GMC (in practice, the new case examiners) to exercise the functions of the IC, whether generally or in relation to such classes of case as may be specified in the Rules.

25.75 Until very recently, the GMC had intended that the IC should play a pivotal role in the investigation stage, not only in the making of decisions in relation to individual cases (its 'casework function'), but also in the supervision and management of the investigation stage as a whole (its 'governance function').

25.76 At a meeting held in October 2003, the Council considered a briefing paper dealing with the proposals for the purpose, functions, structure and membership of the new IC. These

proposals were said to be subject to the general review of the role of GMC committees and their working methods which was then going on. At the meeting, the Council took the formal decision that the IC should perform both a governance function and a casework function. It was also decided that the IC should be composed of nine members of the GMC who would volunteer for membership. An election would take place only if there were more volunteers than places. The intention was that the nine members would discharge the IC's governance function. It was also plainly envisaged that some (if not all) of the nine members of the IC would sit on IC panels to deal with decision-making in individual cases. It was proposed that the IC should have the power, where necessary, to co-opt additional panellists from the list of trained panellists who had been appointed by the GMC. In other words, it was proposed that decision-making on individual cases was to be undertaken by a mixture of GMC members and non-members. The IC's governance function would be exercised exclusively by GMC members. There would be an overlap of IC members performing both functions. It seems from the minutes of the meeting that these proposals were accepted in principle.

25.77 The IC's governance function was to involve overseeing the investigation stage and defining the criteria to be applied by case examiners, GMC staff and IC panels when making decisions in individual cases. The IC was also to review all aspects of the decisions made at the investigation stage and was to put in place and supervise an appropriate quality assurance and audit process. It was to agree service standards for the processing of cases and was to review and monitor performance against those standards. It was to review the numbers and types of cases dealt with at the investigation stage and to ensure that the relevant processes were working effectively and efficiently. It was to report regularly to the Council on the operation of the investigation stage.

25.78 It was originally intended that, as part of its governance function, the IC should have the power to decide on the extent to which it was appropriate to delegate its casework function to case examiners and to other GMC staff. The 2003 draft Rules provided that decisions about how an individual case should be dealt with could be taken either by the IC or by case examiners. The intention was that the IC would decide the extent to which it was prepared to delegate its decision-making powers at any given time. The expectation was that it would begin by delegating only a limited range of decisions to case examiners but that, over time, the extent of delegation would increase as the IC gained confidence in the abilities of the case examiners to take appropriate decisions. However, it was agreed at the October 2003 meeting that the delegation of casework should **'develop quickly'**.

25.79 At the time of the Council meeting in October 2003, it was not clear to what extent case examiners would be authorised to take decisions in individual cases. A briefing paper presented to the Council at that meeting suggested that **'a minimum starting position'** should be that decisions that had not required the involvement of the PPC under the old procedures should not require the involvement of the IC under the new procedures. The briefing paper referred to the **'clear advantages'** of delegating decision-making to case examiners in **'the vast majority of cases'**. It plainly contemplated that most decision-making would be done by individual case examiners. The briefing paper went on:

> **'It would deliver efficiency and flexibility and would help to meet one of the key themes of the Fitness to Practise review – streamlining and speeding-up the process. It would also limit the resources required to service a fully functioning casework committee. The Committee** (*i.e. the IC*) **would set the protocols and policy for making decisions on cases and would monitor and review the outcomes on cases.'**

25.80 Under the arrangements envisaged in October 2003, the IC's power would have been formidable, given the supervisory role that it was intended the IC should have and the fact that it was to be responsible for setting the criteria for decision-making within the whole of the investigation stage. It would also have had the power to decide which cases or types of case it was prepared to delegate to case examiners and which it preferred to keep exclusively within its own control.

The Functions and Composition of the Investigation Committee: the 2004 Position

25.81 I have described above the proposals for the functions and composition of the IC that were current at the conclusion of the Inquiry's hearings in December 2003. However, by the middle of 2004, those proposals had changed completely. The GMC received legal advice to the effect that, under section 35CC(1) of the 1983 Act, it is the Council itself – not the IC – which has the power to delegate the IC's decision-making functions to case examiners and other staff. Furthermore, the precise extent of the delegation should, so the GMC was advised, be set out in the relevant Rules. In the event, having considered the matter, the GMC found it impossible to identify for inclusion in the Rules any specific classes of case in which it considered that responsibility for decision-making could be delegated by the Council to case examiners.

25.82 As a result, the GMC revised the arrangements for the investigation stage. It decided that case examiners should be given specific powers by the Rules to take decisions in the majority of cases. It decided that the decision-making role of the IC should be confined to only two types of case, i.e. those where the case examiners disagreed and those in which it was necessary to hold an oral hearing in order to decide whether to issue a warning. I will discuss these types of case later in this chapter. As a consequence, the likely caseload of the IC was reduced. The proposed reduction in the IC's casework function in turn led to a reconsideration of its composition and proposed governance function. At the July 2004 Council meeting, the Fitness to Practise Committee made recommendations to the Council about these matters.

25.83 The Fitness to Practise Committee proposed that the IC should have no governance role and that responsibility for overseeing the investigation stage should instead devolve to the Fitness to Practise Committee itself. It proposed that the IC should be constituted as a casework committee only. Under these proposed new arrangements, the IC would not, as had previously been intended, have a static membership of nine GMC members. Instead, it would consist solely of panels which would have a 'floating membership'. Panels would be convened specifically to make decisions in individual cases. It was proposed that the panels should be drawn primarily from a pool of GMC members who would volunteer for the purpose. Those GMC members would have to undergo training and assessment.

Associates would also be co-opted to sit on IC panels as and when necessary. In order to preserve the separation of functions, it was proposed that those persons who were selected and appointed to sit as panellists should be required to opt to sit on either IC panels or FTP panels; they would not be permitted to sit on both.

25.84 The Fitness to Practise Committee considered that, in view of the IC's involvement with casework, it would be inappropriate for it to undertake any audit or review of decisions in individual cases. It proposed, therefore, that audit and review should be undertaken by the Fitness to Practise Committee. The Fitness to Practise Committee would then have an overarching responsibility for co-ordinating and monitoring the operation of both the investigation and the adjudication stages of the new procedures. That idea seems also to raise a problem of separation of functions. The description of the first model for separating the investigation and adjudication functions set out in the 2001 Consultation Paper had specifically provided for the investigation and adjudication stages to have separate arrangements for **'reporting and accountability'**: see paragraph 25.29.

25.85 The Fitness to Practise Committee outlined an alternative arrangement, whereby the IC would retain a static membership of GMC members who would be responsible for governance of the investigation stage (including audit and review of decisions), but who would delegate casework to panels of associates. However, its preference was for the model I have previously described.

25.86 When the proposals put forward by the Fitness to Practise Committee were discussed by the Council at its July 2004 meeting, there was considerable difference of opinion among those present. It was said that the IC (which is established by statute) was being 'downgraded' into 'just a casework committee', while the Fitness to Practise Committee (which is not a statutory committee) took over the governance functions which it had always been intended that the IC should undertake. A number of Council members supported a suggestion that, far from losing its governance role, the IC should assume entire responsibility for the supervision of the new FTP procedures (i.e. governance of both the investigation and the adjudication stages), with the current Fitness to Practise Committee becoming redundant. This would, of course, have the effect of extending the role of the IC well beyond that which had originally been envisaged for it. Other Council members pointed out that to give to the IC, which has a statutory responsibility for casework at the investigation stage, a supervisory role over the FTP panels responsible for decision-making at the adjudication stage would completely negate the principle of separation of functions. Nevertheless, some Council members advocated this solution. An alternative view was that the IC should retain, in addition to its casework function, a limited governance role involving responsibility for auditing and training case examiners.

25.87 The Fitness to Practise Committee also expressed the view that membership of the Fitness to Practise Committee and of IC panels should be mutually exclusive, because of the potential conflict of interests that might arise if the same individual were involved with the making of decisions in individual cases and with the audit and quality assurance of those decisions. Some Council members agreed with this view and expressed reservations about the principle of having Council members involved both in casework (as members of IC panels) and in a governance role (as members of the Fitness to Practise Committee).

It was suggested that it would be more appropriate for IC casework to be undertaken only by associates. There was, however, no agreement about this matter.

25.88 The debate did, however, result in a limited amount of agreement. The minute recording that agreement states:

> **'Fitness to Practise: Investigation Committe**
>
> **11. Council agreed that there should be three groups of functions, namely:**
>
> **a. Policy, audit, oversight and other governance functions, covering both investigation and adjudication.**
>
> **b. Investigation casework.**
>
> **c. Adjudication casework.**
>
> **12. The aim was to have a single committee with governance responsibilities, overseeing investigation casework and adjudication casework. For both investigation casework and adjudication casework, group decision making and hearings should be undertaken by panels. Council recognised that the aim of a single committee could not be achieved within the law as it stood. Until the Medical Act 1983 could be amended, responsibilities should be:**
>
> **a. Policy, audit and oversight – Fitness to Practise Committee**
>
> **b. Investigation casework – Investigation Committee (meeting as panes) and case examiners.**
>
> **c. Adjudication casework – fitness to practise panels and interim orders panels.'**

25.89 For the present, the General Medical Council (Constitution of Panels and Investigation Committee) Rules 2004 (the Constitution Rules 2004) provide that membership of the IC shall comprise medical and lay panellists (including at least one person taken from the list of panellists eligible to sit as Chairman of a panel) selected by the Registrar to sit on a particular occasion. Members of the GMC may act as IC panellists. The IC will have no static membership. The legal quorum for an IC panel will be three, comprising the Chairman (who may be medically qualified or lay), together with one medical and one lay panellist.

25.90 It is not clear whether the IC will ultimately assume the functions of the **'single committee'** referred to in the minute. No agreement about that was reached at the July 2004 Council meeting. Nor was any decision reached on the issue of whether IC panels would be composed of a mixture of GMC members and associates, or only of associates. A recent letter written by the GMC to the Inquiry stated that, although the November 2004 Rules permit Council members to sit on IC panels, the **'operational intention'** is for the panels to be composed of appointed associates. It is not clear whose **'operational intention'** this is, since there does not appear to have been any Council decision to this effect.

Comment

25.91 These late changes to the new procedures appear to have been forced upon the GMC as the result of its failure to understand the effect of the amending legislation which it had asked for. This gives the impression that the GMC had not given sufficient thought to how the new procedures were to work before it asked for legislation to be drafted.

25.92 The original proposals would have given rise to an unsatisfactory position. The IC would have been enormously powerful. Not only would it have been responsible for the policy of the investigation stage decisions, including standard-setting, it would itself have made many of the casework decisions and would have been responsible for the supervision of the case examiners and the audit of all investigation stage decisions. Self-audit is not acceptable, as has now apparently been recognised.

25.93 For the moment, it appears that the powers of the IC will be limited to taking decisions on individual cases. The functions of governance, supervision, audit, standard-setting and the issuing of guidance to staff and case examiners in respect of the investigation stage will be passed to the Fitness to Practise Committee. It will place a very considerable burden on that Committee but at least – for the time being – the functions of decision-making and governance will be separated.

25.94 At present, it is not clear what the GMC's ultimate intention is. At the meeting in July 2004, it was suggested that the IC should have responsibility for the adjudication stage. I do not think that that is now intended, although there were some GMC members who thought it appropriate. The position for the future is not entirely clear and this degree of uncertainty at a time when the new procedures are actually coming into effect is unfortunate.

25.95 In my view, the functions of the IC should be, as they apparently will be in the immediate future, limited to casework. It is not appropriate that any committee should have total responsibility for all aspects of the investigation stage of the FTP procedures, even down to auditing its own decisions. To give one small committee complete control of the whole investigation stage carries risks. However, it is equally unsatisfactory for one committee to have control of the governance of the investigation stage and the adjudication stage, as was recognised in the 2001 Consultation Paper. I realise that this might give rise to difficulties for the new GMC with only 35 members.

25.96 At present, it appears to be the intention that, after amendment of the 1983 Act, one committee will have responsibility for the governance of both the investigation and adjudication stages. It appears that the Fitness to Practise Committee considers that, if two committees are involved in governance of the different stages, there will be confusion and inconsistency. I can see that it is desirable that the same group of people should set the standards, criteria and thresholds applicable to both stages; these must be compatible. However, it seems to me that the supervision and audit of the two stages should be separate, first because the power of the single committee over the whole process would be too great – some checks and balances are desirable – and, second, because the GMC claims that it wishes to maintain some separation between the investigation and adjudication functions.

Case Examiners

25.97 The introduction of case examiners is an integral feature of the new procedures. In 2003, the GMC appointed five people (three medically qualified and two lay) to fulfil the role of case examiners. Further case examiners have been appointed subsequently and the GMC has advertised for more. When the first case examiners were appointed, it was expected that the new procedures would be in place by the spring of 2004. In March 2004, when it had become clear that the introduction of the new procedures was going to be delayed, the GMC appointed the case examiners to act as screeners for conduct and performance cases under the old procedures. In addition, two of the medically qualified case examiners were appointed to act as health screeners and two were appointed to act as performance case co-ordinators. These arrangements were to continue until the new FTP procedures came into operation. The appointment of the case examiners as screeners was made subject to the case examiners being mentored by existing screeners and subject to 100% of their work being audited by GMC staff. It was expected that, by the end of June 2004, the previous screeners would have ceased to carry out their screening duties and that the case examiners would have assumed total responsibility for screening.

25.98 The case examiners are contracted to work for the GMC for a minimum of eight days a month and, when working, are based at the GMC's offices. They will be trained, directed and appraised by the GMC and, as I have said, their work will be subject to audit. During the selection process, considerable emphasis was placed on the need for analytical abilities, for a capacity to undertake high level decision-making and for an ability to exercise impartial and independent judgement. Medically qualified candidates were required to have been in active practice within the last three years and to be **'participating in revalidation'**. The job specification for case examiners stated that they should have the **'ability to carry out an investigatory appraisal to establish facts'**.

Comment

25.99 It seems to me that there are a number of potential advantages attaching to the appointment of case examiners to undertake the functions formerly carried out by screeners. First, the case examiners will be working in dedicated time. Screeners had to fit their GMC duties into the interstices of days already occupied with a busy medical practice or a demanding job. Also, because the work will be done at the GMC's premises, there should be much closer communication between case examiners and staff and between case examiners. Screeners worked from home and communication was less easy. Case examiners will be employed by the GMC and can be required to carry out their duties in a particular way. They could, for example, be given instructions that all cases of a certain category must be referred to a FTP panel. This was not possible with screeners; they were members of the GMC and could not be required to conform to instructions. I described in Chapter 19 the way in which some medical screeners sabotaged the GMC's efforts to encourage consistency of treatment at the screening stage by creating categories of misconduct which would be 'SPM by definition' and which should automatically have been referred by screeners to the PPC. It seems that the screeners persuaded members of staff to change the standard documents so as to circumvent the

system that had been agreed. It seems highly unlikely that employed case examiners would be able to do that and, if they did, they would be at risk of disciplinary action. Another advantage is that case examiners will have only one set of functions. Screeners had often had experience of sitting on the PPC or the PCC in the past and it seems that they were sometimes unwilling or unable to confine themselves to their screening role.

25.100 The only potential disadvantage of the use of case examiners appears to be that there is a danger that they might be insufficiently independent; they might be too closely directed by GMC members or committees and might not be permitted to use their professional judgement. Also, they might have too little 'say' in how a case is investigated. I hope that these problems will not occur, as the appointment of case examiners provides potential for real improvement over the old procedures. It is essential that standards and criteria should be set and guidance given but, within those parameters, case examiners should be able to exercise their professional judgement.

Lay Involvement in Decision-Making

The 2003 Proposals

25.101 One striking feature of the 2003 proposals was that they would have allowed a single, medically qualified case examiner to close a case without consultation with – or the agreement of – a lay colleague. That arrangement represented an important departure from the principle – which had been accepted by the GMC in 1990 – that no case which raised a question of SPM (or, from 1997, SDP) should be closed by a medically qualified screener without the agreement of a lay screener. Before the introduction of lay screeners in 1990, there had been concern on the part of many about the lack of lay involvement in the screening process.

25.102 During the initial consultation on the new FTP procedures, concern was expressed about the absence, under the proposals then being considered, of any requirement that a lay person should confirm a preliminary decision to close a case taken by a single medically qualified case examiner. Concern was also expressed by some individuals and organisations that the proposed model would place too much responsibility in the hands of one individual. Despite those concerns, the GMC did not change its position. The FTP Review Group's paper, which was considered by the Council at its November 2001 meeting, pointed out that 'double-handling' of cases (whereby cases which a medically qualified screener had made a preliminary decision to close were also considered by a lay case examiner) would require significant additional resources. It was estimated that case examiners would close 2000 cases a year. The effect of double-handling cases where there had been a preliminary decision to close the case would, it was said, be to produce 2000 extra screener transactions a year and almost to double the number of case examiners required. Case examiners are an expensive resource and the appointment of an increased number of case examiners would represent a significant additional cost to the GMC. It was also suggested that double-handling of cases by case examiners would cause delay. The paper suggested that no decision should be taken on the point at that time. Instead, the FTP Review Group concluded that the **'best approach'** would be not to make a decision about lay involvement then but instead to **'allow the detailed processes**

to evolve with experience'. That suggestion was adopted and the issue was shelved for the time being.

25.103 The GMC's internal paper, 'Review of Fitness to Practise: The New Model', of October 2002 (the version dated 22nd November 2002) did not directly address the issue of lay input into decisions by case examiners to close cases. Instead, it referred to the **'important principle'** that all cases, save those closed by the GMC office staff, should be considered by **'two experienced people'**. The implicit suggestion appeared to be that the objections both to a lack of lay involvement and to the involvement of only one person in the decision-making process could be met by the fact that most cases would be considered by an **'experienced and appropriately senior member of staff'** in addition to a case examiner. The paper proposed that, if the member of staff and the case examiner disagreed, the case should be referred to another case examiner (not necessarily one of the lay case examiners). The paper went on to propose that the IC might wish to **'insist'** that it should see any case where there was disagreement or doubt. These proposed arrangements for cases where a member of staff and a case examiner disagreed about the way to dispose of a case were not set out in the 2003 draft Rules. Nor were they mentioned in the draft Guidance accompanying the 2003 draft Rules or in the draft Guidance for case examiners, 'Investigation Stage Test – Guidance for Case Examiners', produced by the GMC in late 2003 (the 2003 draft Case Examiner Guidance). It seems, in fact, that the arrangements proposed in November 2002 (whereby a case could be referred to the IC for a 'second opinion') had been dropped by that time and that a decision had been taken that a single medically qualified case examiner was to be permitted, in a case delegated by the IC, to take a decision to close a case without first securing the agreement of any other person. Similarly, a single lay case examiner was to be permitted to take a decision without any input from a medically qualified person.

Comment

25.104 I find it depressing to observe that, over the period of more than two years during which the new procedures were being developed, the GMC did not appear to recognise or accept the fundamental requirement for lay involvement in all cases that might be closed without referral to a FTP panel. Of course, one is sympathetic to problems of money and resources but there are some things that are so obviously necessary that they simply have to be done, whatever the cost. First, there was a shelving of the problem and then, a year later, an attempt to find a solution that was plainly unsatisfactory. Later still, that attempt was abandoned and the lack of lay involvement was ignored. Given the GMC's earlier commitment to greater lay involvement, it seems to me extraordinary that the removal of lay input into such important decisions could ever have been contemplated.

25.105 At the Inquiry's hearings in December, Sir Graeme Catto and Mr Scott were asked about the absence of any lay input into a decision by a medically qualified case examiner to close a case. Sir Graeme said that one of the factors which had influenced the decision had been the delay that had in the past been caused by passing cases between different people within the GMC. However, case examiners will be working in the GMC's offices, so it is hard to see why it should have been thought that delay would arise. Sir Graeme also said that it had been thought that case examiners, who would be contracted to work for

the GMC in dedicated time, would be more professional and focussed than the existing screeners, who had to fit in their screening activities between their other commitments. That hardly meets the point that a medically qualified case examiner will bring a medical perspective to the case and that a lay perspective is also needed. Nor does it meet the point that more than one person should be involved in a decision to close a case. However, in the course of their evidence, both Sir Graeme and Mr Scott indicated that the GMC was prepared to look again at the issue. This it has now done and it appears that its members have belatedly recognised that the proposed arrangements were unacceptable and would not have commanded the confidence of the public.

The 2004 Position

25.106 The May 2004 draft Rules provided (as the November 2004 Rules provide) that all cases which survive the preliminary sift by the GMC staff will be considered by two case examiners, one medical and one lay. This is a most welcome move and, in fact, provides greater lay involvement than under the old procedures. The involvement of a second case examiner is not confined to, as previously, cases where a medically qualified case examiner had taken a decision to close the case or was contemplating such a decision. Instead, lay case examiners are to be involved in the consideration of every case that reaches the stage of being referred to a case examiner. Thus, the arrangement has even greater resource implications than the arrangement that had been contemplated in November 2001, when it was thought that the double-handling of the cases where a preliminary decision to close had been taken would almost double the number of case examiners required. If all other aspects of the new FTP procedures had remained the same as had been proposed in 2003, significantly more case examiners would have been needed. However, as I shall explain, changes to other aspects of the new procedures were also introduced in the May 2004 draft Rules (most notably to the arrangements for dealing with cases with a health or performance element and, at the adjudication stage, for preparing cases for review and restoration hearings). These changes appear likely to have the effect of reducing significantly the workload of the case examiners in relation to those aspects.

25.107 The changes in the role of the IC that I have already mentioned will also have a significant impact on the role of the case examiners. Under the November 2004 Rules, a case will be referred to the IC only if the two case examiners who consider it cannot agree or in the event of an oral hearing being necessary before a decision is taken whether or not to issue a warning. As a consequence, in the vast majority of cases (certainly in the vast majority of cases involving allegations of misconduct), the case examiners will take the decision whether or not to refer a case to a FTP panel. The case examiners will, therefore, have a central and most important role.

Comment

25.108 As I have said, the current provision for the involvement of lay case examiners in all decisions (save in those cases closed by staff) provide for much greater lay involvement than under the old procedures. I recognise that the resource implications must be

considerable. In my view, lay involvement in all decisions is likely to result in improved quality of decision-making. My understanding is that the lay case examiners will play a full and equal part in decision-making and that their scrutiny of a case will not necessarily take place after that of the medically qualified case examiner. I hope that that will be so. If a lay person examines a case file in the knowledge that a medical person has already reached the conclusion that the case should be closed, his/her thought processes may be distorted. There is a danger that the lay person will subconsciously defer to the view of the medical person. If the lay person examines the case without any preconceptions, his/her decisions are likely to be of greater value in the drive towards public protection. In my view, this increase in lay involvement is likely to engender a greater degree of public confidence.

The Investigation Stage

25.109 I shall now examine the various processes involved in the investigation stage. In particular, I shall consider the activities undertaken by the GMC staff, by the case examiners and by the IC.

The Purpose of the Investigation Stage

25.110 It is important to note at the outset that, as I have previously explained, the term 'investigation' in this context is not intended to mean a process of evidence gathering. The 'investigation' to be undertaken during the investigation stage of the FTP procedures is the determination of whether a case should be referred to a FTP panel. However, the process of evidence gathering may be one of the activities carried out during the investigation stage.

The Preliminary Sift of Cases by Administrative Staff

25.111 Under the old procedures, members of the GMC staff (exercising the legal powers of the Registrar) carried out an initial filtering exercise. They closed cases that fell into certain categories which had been identified by the GMC as not giving rise to an issue falling within its remit. Under the new procedures, the first step in the process of dealing with allegations reported or referred to the GMC will be a similar initial sifting exercise.

25.112 Under rule 4 of the November 2004 Rules, the staff will be required to refer for consideration by a medical and a lay case examiner an **'allegation'** which they consider **'falls within'** section 35C(2) of the 1983 Act. Section 35C(2), to which I have previously referred, states that:

> **'A person's fitness to practise shall be regarded as ''impaired'' for the purposes of this Act by reason only of –**
>
> **(a) misconduct;**
>
> **(b) deficient professional performance;**
>
> **(c) a conviction or caution in the British Islands for a criminal offence, or a conviction elsewhere for an offence which, if committed in England and Wales, would constitute a criminal offence;**

(d) adverse physical or mental health; or

(e) a determination by a body in the United Kingdom responsible under any enactment for the regulation of a health or social care profession to the effect that his fitness to practise as a member of that profession is impaired, or a determination by a regulatory body elsewhere to the same effect.'

25.113 Whether or not the staff consider that a case **'falls within'** section 35C(2) seems a rather odd 'test' to apply. From the words of the rule itself, it is not clear to what extent the staff are to be required to consider whether the allegation is capable of amounting to an 'impairment'. If they are, the test would impose a much higher threshold than was imposed under the old conduct procedures, when the Registrar (or member of staff) had to refer a case to a medical screener if it raised a question of SPM. If the staff are required only to consider whether the information contains an **'allegation'** of the types listed in sub-paragraphs (a) to (e), the threshold will be similar to that under the old procedures, and would be appropriate.

25.114 The draft Investigation Manual Version 2, dated November 2004 (the November 2004 draft Investigation Manual), produced for the guidance of the GMC staff, shows the intended scope of the Registrar's discretion (or that of the staff exercising his legal powers). A staff member should close a case only on specific grounds. Broadly speaking, the staff members should have concluded that the allegation does not raise a question of any of the factors listed at paragraphs (a) to (e) of section 35C(2) of the 1983 Act.

Comment

25.115 It appears that the GMC intends that the 'test' at this initial stage should be similar to the test under the old procedures. It is to be hoped that a form of words might be found so that the Rules more clearly express the GMC's intention. I suggest that the rule might be amended to state: '... where the Registrar considers that the allegation raises a question whether the doctor has been guilty of misconduct, his/her professional performance has been deficient, s/he has been subject to a conviction, caution or determination or has suffered or is suffering adverse physical or mental health (i.e. the factors listed at paragraphs (a) to (e) of section 35C(2) of the 1983 Act)'. The public would then know what test the GMC was applying at this stage.

The Diversion of Cases to Local Complaints Procedures

25.116 At this point, it is necessary to consider what, if any, steps will be taken by staff at this stage of the new procedures to direct cases into local complaints procedures. In the past, as I explain in Chapter 18, many cases have been closed by GMC staff because the complaint related to treatment under the NHS or in the private sector and it appeared that local complaints procedures either had not been used at all or had not been pursued to their conclusion. Before closing a case and advising a complainant to direct his/her complaint to local complaints procedures, the staff did not consider (as the Rules required them to do) whether the case raised a question of SPM. The GMC staff would advise a complainant

to pursue his/her complaint through local complaints procedures and would close the case, unless the staff had reason to believe that the doctor was dangerous or the complainant insisted on the complaint being considered by the GMC.

25.117 Two concerns arose out of this practice. The first was that it put the onus onto the complainant to take matters forward. Second, the GMC did not follow matters up and seek to find out whether the complaint had been pursued locally; there was therefore a danger that some complaints that might have amounted to SPM were lost to the regulatory system. Those concerns were put to the witnesses from the GMC who gave evidence to the Inquiry. They were asked why the GMC did not take responsibility, in an appropriate case, for passing the case to the relevant complaints body, instead of leaving it to the complainant. They were also asked why the GMC did not follow up such cases to ensure that they were not lost. In evidence to the Inquiry, Sir Graeme Catto said that the issue was 'rising to the top of our (*i.e. the GMC's*) agenda'.

25.118 These issues are not expressly dealt with in the November 2004 Rules, the Guidance accompanying them, the November 2004 draft Investigation Manual or the initial processing and assessment form (IPA). The IPA sets out every step of the investigation stage and, if it were the intention of the GMC to close cases because local procedures had not been exhausted, I would have expected the IPA to identify the stage at which that should be done and to specify the criteria to be applied. The Guidance accompanying the November 2004 Rules states:

> **'... the Registrar may ... advise the maker of the allegation about other means of resolution (such as the NHS complaints procedure) or refer the allegation directly to another body for consideration'**.

25.119 However, the context of this passage suggests that this advice is only to be given if the member of staff has already decided that the case does not fall within the jurisdiction of the GMC. To give such advice in those circumstances would be entirely appropriate. The criteria set out in the IPA for making the decision as to closure seem to me to have been drafted so as to ensure that all matters that do fall within the GMC's jurisdiction are accepted into the system. It looks as though the GMC has accepted that the old practice about which the Inquiry expressed concern is to be discontinued under the new procedures. I recognise that that will lead to an increased workload for the GMC but it is clearly the right decision.

25.120 It might be said that it would be reasonable for the GMC to advise the makers of allegations about the existence of alternative means of resolution even in cases where the allegation did fall within the GMC's jurisdiction. Provided that the maker of the allegation was not put under pressure and freely consented to take his/her allegation to a local NHS body, what could be the harm in that? In my view, it would not be a good idea to offer such advice. At the present time, local NHS complaints procedures are not appropriate for many cases in which patient protection issues arise; for example, there are at present no adequate facilities for investigating a complaint about a general practitioner (GP) at the first stage of the NHS complaints procedures. Now that the Commission for Healthcare Audit and Inspection (known as the Healthcare Commission) is responsible for the second stage,

such facilities are available then, but I do not think it would be right to suggest that a complainant take that route in order for the allegation to be investigated.

25.121 The November 2004 draft Investigation Manual describes a procedure by which cases which have been referred to the GMC by a public body may be referred into a local procedure. The GMC staff should contact the referring body to discuss the best way forward. This is entirely appropriate.

Informal Dialogue

25.122 During the Inquiry hearings, there was discussion about the need for the GMC, on receipt of a complaint (particularly one coming from a private individual), to contact the doctor's employer or primary care organisation (PCO) in order to ascertain whether there were any local concerns about the doctor. This had never been the GMC's practice in the past. As I explained in Chapter 18, some GMC members thought that such a practice would be unfair to doctors. However, Mr Scott told the Inquiry that the GMC intended to consider introducing such a practice.

25.123 After the Inquiry hearings, the GMC announced that, from May 2004, it would henceforth be operating a new policy for handling complaints at the initial stages of the FTP procedures. The intention was to discuss most complaints with the doctor's employers (which term I understand to include PCOs and others with whom the doctor is contracted to provide medical services). The purpose of these discussions would be, first, to discover whether the complaint was an isolated matter or an example of a wider concern about the doctor which had been recognised locally and, second, to inform those with local clinical governance responsibilities that the GMC was considering a complaint about the doctor. I understand that this change was put into effect under the old procedures and that it yielded useful information. The GMC has informed the Inquiry that, between May 2004 and September 2004, early disclosure to doctors' employers was made in 87% of cases. The remaining 13% were cases where the complaints made could not raise an issue for the GMC.

25.124 The position under the new procedures appears in the November 2004 draft Investigation Manual. In Stream 1 cases (those that will definitely require full investigation), the staff member will not enter into informal dialogue with the doctor's employer; in Stream 2 cases (those where it is not immediately clear whether or not a full investigation will be needed), dialogue will take place. The consent of the complainant to that disclosure will be required and the doctor will be informed. At a later stage, there will be formal disclosure of the allegation to the employer or PCO in both Stream 1 and Stream 2 cases, although this will be by letter and it is recognised that the employer or PCO might not respond.

25.125 Reports in the medical press have suggested that the new arrangements have been greeted with dismay by doctors. It has been said that the informal disclosure to employers and PCOs of the fact that a complaint has been made is 'unfair to doctors' since employers will be liable to draw adverse conclusions from the fact that a complaint has been made. At the time of writing, it had been reported that at least two medical defence organisations were challenging the right of the GMC to request a doctor's employment details for the

purpose of contacting his/her employers to discuss a complaint made against him/her at a stage earlier than the time for formal disclosure to employers.

25.126 I do hope that the GMC will not be deflected from making these enquiries. The obtaining of information from an employer or PCO is an essential part of the investigation. Moreover, I do not think that the fears voiced in the medical press have real foundation. I very much doubt that an employer or PCO will draw an adverse conclusion from the fact that an allegation has been made, unless it tends to confirm concerns that the employer or PCO already feels. If that is the position, it is right that the employer or PCO is made aware of the new allegation, in the interests of patient safety, and that the GMC is aware of the other pre-existing concerns. In Chapter 27, I recommend that this procedure should be enshrined in the Rules and that the GMC should have the power to require the doctor to provide any information necessary to permit these communications to take place.

Evidence Gathering

25.127 I shall now consider what, under the new procedures, the GMC proposes to do by way of evidence gathering. I have described in earlier Chapters how, under the old procedures, the GMC generally did little in the way of evidence gathering unless and until a decision had been taken to refer a case to the PCC for a hearing. As a consequence, a decision whether or not to refer a case to the PPC or the PCC would sometimes be taken on the basis of insufficient evidence and was in the past usually made without information about any previous concerns which might have arisen locally about the doctor's conduct or performance. I have already mentioned that, in its 2001 Consultation Paper, the GMC identified one of the weaknesses of the old FTP procedures as the limited investigation (in the sense of evidence gathering) carried out before a decision was made about what to do with a case. Mr Scott acknowledged this weakness in his evidence to the Inquiry when he observed that the old procedures put 'the cart before the horse' in that a decision was taken whether a case should be referred to the PCC before the necessary evidence had been gathered.

The 2003 Proposals

25.128 The 2003 draft Rules gave the Registrar the power, before referring a case to the IC or to a case examiner, to carry out such further investigations as in his opinion were appropriate. The Guidance that accompanied the 2003 draft Rules stated that these investigations might include writing to the doctor's employers and obtaining witness statements. Under the 2003 draft Rules, case examiners and the IC were also to have the power to carry out, or to direct the staff to carry out, further enquiries into cases, over and above the investigations already carried out by staff.

25.129 Despite the powers contained in the 2003 draft Rules, there was little in the other documents which the Inquiry had seen, before the GMC witnesses gave evidence in November and December 2003, to suggest that the GMC intended significantly to increase its evidence gathering activities at the investigation stage. Nevertheless, Mr Scott was adamant that, under the new FTP procedures, the approach would be quite different from that previously adopted. The GMC staff would, he said, undertake evidence

gathering. Mr Scott referred to the fact that the GMC was in the process of assembling a team of in-house lawyers, who would undertake evidence gathering. However, it was clear that the intention at the time he gave evidence was for the in-house lawyers to undertake investigations after a case had been referred to a FTP panel and not before; Mr Scott did not seek to say otherwise. He pointed out that some members of the existing office staff also had the potential to undertake investigative work. Mr Scott said that the case examiners would have a key role in directing what evidence gathering should be undertaken and in judging whether the evidence that had been collected was sufficient to enable them to reach a decision. The case examiners (unlike screeners in the old procedures) were to have powers to undertake and direct evidence gathering. Mr Scott emphasised to the Inquiry the 'profound nature' of this change which, he said, would ensure that **'the mindset'** of those operating the procedures would be 'fundamentally different' as a result.

The 2004 Position

25.130 Under the November 2004 Rules, the Registrar may, before deciding whether to refer a case to the case examiners, carry out such investigations as in his opinion are appropriate to the consideration of whether or not the allegation falls within section 35C(2) of the 1983 Act or of the doctor's fitness to practise. The Guidance that accompanies the November 2004 Rules suggests, by way of example, that the Registrar (personally or by his staff) may make enquiries of the doctor's employer in order to investigate whether the doctor's fitness to practise is impaired. The draft document 'Making decisions on cases at the end of the investigation stage: Guidance for Case Examiners and the Investigation Committee', produced by the GMC in September 2004 (the September 2004 draft CE/IC Guidance), states that initial investigations will be carried out by staff (with the assistance of lawyers where required), for example, in cases where there is insufficient evidence to establish whether the allegation falls within the GMC's jurisdiction or where further information is required to see if a pattern of behaviour may be established. It is said that such investigations may include making enquiries of the doctor's employer, colleagues or others, or obtaining medical reports or other documentation. I refer at paragraphs 25.153–25.154 to the arrangements for evidence gathering which are now envisaged.

25.131 After a decision has been taken to refer a case to the case examiners, the November 2004 Rules require the Registrar to carry out any investigations which, in his opinion, are appropriate to the consideration of the allegation by the case examiners. Such investigations may be carried out whether or not any investigations have been conducted prior to that stage. Surprisingly, in the light of what was said at the Inquiry's hearings about the key role which case examiners were to play in directing the process of evidence gathering and the fundamental change which would result, the May 2004 draft Rules omitted the power included in the 2003 draft Rules for case examiners to make enquiries into a case, or to direct the staff to make such enquiries. That power has not been restored by subsequent versions of the Rules. I do not know the reason for this omission.

25.132 The November 2004 draft Investigation Manual says that case examiners will be asked to approve an investigation plan and may wish to give instructions as to further forms of investigation to be carried out. It appears therefore that the investigations will be instigated

and carried out by the staff, but that case examiners should be able to give instructions, at least from the time when a case has been referred to them. That power is not reflected in the Rules. It should be; the case examiners should have the power to direct investigations.

Disclosure to the Doctor's Employer or Primary Care Organisation of the Fact that a Complaint Has Been Made

25.133 I shall now consider the point in the investigation stage process where the GMC is obliged to give formal notice to a doctor's employer or PCO that an allegation has been made about him/her.

Mandatory Disclosure: the 2003 Position

25.134 I have already explained in Chapter 18 that, after 2000, the GMC was required, in certain circumstances, to disclose the fact that it was investigating a complaint against a doctor to the Department of Health (DoH), and to any person or body by whom the doctor was employed or by whom s/he was contracted to provide services. Those circumstances arose once the GMC had made a decision to refer the doctor to the PPC, to invite him/her to agree to an assessment of his/her professional performance or to invite him/her to agree to undergo medical examination. In other words, disclosure took place after screening of a complaint and then only if the complaint was to go forward. Although referral of a case to the IOC was not included in the list of triggers for disclosure, the Inquiry was told that it was treated as such.

25.135 With the impending introduction of the new FTP procedures, the GMC had to consider at what point in the new procedures it would be appropriate for disclosure to take place. Under the 2003 draft Rules, disclosure would have been mandatory when the earliest of the following events occurred: referral of a case to an IOC for decision, referral of an allegation to a FTP panel, the making of a direction that a performance assessment should be carried out, the issuing of an invitation to a doctor to enter into voluntary undertakings or the issuing of a warning to a doctor. The inclusion of the last of these events as a trigger for disclosure suggests that it was contemplated at that time that the decision to issue a warning (rather than to refer a case to a FTP panel) might be taken before notifying (and, presumably, before obtaining background information from) the doctor's employer or PCO. That would seem to be another example of 'putting the cart before the horse', because the information available from an employer might have been such that a warning was insufficient to meet the seriousness of the case. It should be noted that, in a 'health case', the invitation to undergo a medical examination would not, under the 2003 draft Rules, have triggered disclosure; instead, the relevant trigger would have been the invitation to enter into voluntary undertakings under the equivalent of the old voluntary health procedures.

25.136 The effect of these new provisions would have been that, in many instances, disclosure would have taken place later under the new FTP procedures than had been the case since 2000 under the old procedures. It is not clear whether the GMC had intended this to be the consequence of the proposed changes or whether the effect was accidental. It would certainly have been an unfortunate retreat from the post-2000 position. It would have

meant that the GMC could have been in possession of relevant information for several weeks or months without disclosing that information to the relevant person or body.

25.137 As a result of evidence given to the Inquiry which indicated that the proposals would not command public confidence or support, of reservations expressed by the DoH and of an apparent recognition of its own obligation to provide timely information for the purposes of clinical governance, the GMC reconsidered its original proposals which, it was conceded, were **'clearly flawed'**. At a Council meeting held in November 2003, it was decided that disclosure should be brought forward to the point under the new procedures where the Registrar (in practice, a member of staff) or a case examiner took a decision that the complaint or other concern justified investigation.

Mandatory Disclosure: the 2004 Position

25.138 The May 2004 draft Rules therefore provided that a further event which would trigger disclosure should be a decision by the Registrar (in practice, a member of staff) to carry out or direct investigations before or after making the decision to refer a case to the case examiners. This would still have been unsatisfactory. This trigger would have been dependent entirely on whether or not any investigations were undertaken. If (as was invariably the case in the past) they were not, the doctor's employer or PCO would not be informed of the complaint at that stage. Even assuming that, in the future, the staff were to carry out investigations in most cases, there would almost certainly remain some cases in which there would be none. For example, when the fact that a doctor has been convicted of a criminal offence is reported, it will be open to the Registrar (or the staff, exercising his legal powers) to refer the conviction direct to a FTP panel. However, in some cases, he may not do so and will instead refer it to a case examiner. If, as he well might, he does so without carrying out any investigations, the duty to disclose would not have arisen, under the May 2004 draft Rules, until after the case examiner had made his/her decision.

25.139 Another change was that, under the May 2004 draft Rules, an invitation to undergo a health assessment was also to trigger disclosure. The issuing of an invitation to enter into voluntary undertakings remained in the list of triggering events although, since this would always be preceded by a health or performance assessment, it could never be the earliest event.

25.140 The July 2004 draft Rules contained further changes to the list of events that would trigger disclosure. These were reproduced in the November 2004 Rules. The issuing of a warning has been removed from the list. Instead, disclosure will have to take place at the earlier stage of referral of an allegation for consideration by the case examiners. This is a welcome change. It gives greater certainty and means that disclosure will, in general, take place earlier than would have been the case under the old procedures. Referral to case examiners is a step that will always happen in a case which is not closed by the staff at the initial stage, save when a conviction case is referred direct to a FTP panel, and such referral is also a triggering event. If pre-referral investigation takes place, this will bring forward the disclosure process. The issuing of an invitation to a doctor to enter into voluntary undertakings has been removed from the list of triggering events.

The Treatment of Convictions

25.141 I have described in earlier Chapters the treatment of conviction cases under the old FTP procedures. Convictions for minor motoring offences were not referred to the medical screeners and did not proceed beyond the office staff. In November 2002, the Registrar was given power to refer convictions for offences in respect of which an immediate sentence of imprisonment had been imposed directly to the PCC unless, in his opinion, such direct referral would not be in the public interest. All other conviction cases were referred to a medical screener and most of those cases were referred by the medical screeners to the PPC. In 2003, the PPC referred to the PCC less than a third of the doctors convicted of criminal offences whose cases had been referred to it. In Chapter 20, I mentioned the need, recognised by Mr Scott when he gave evidence to the Inquiry, for the GMC to make its treatment of conviction cases more consistent.

The 2003 Proposals

25.142 The 2003 draft Rules contained what amounted to a retreat from the post-November 2002 position. They provided that, in a case where a conviction had resulted in the imposition of a sentence of imprisonment, the Registrar **'may'** refer the allegation directly to a FTP panel. The Guidance which accompanied the 2003 draft Rules said that the Registrar was required to refer a conviction directly to a FTP panel where the doctor had received an immediate custodial sentence and where he **'considers it in the public interest to do so'**. This would have reversed the presumption which had existed since November 2002 that all convictions resulting in an immediate sentence of imprisonment would be referred to a FTP panel unless such a referral would not be in the public interest.

The 2004 Position

25.143 The May 2004 draft Rules (the provisions remain virtually unchanged in the November 2004 Rules) altered the position once again. The Registrar will now be required to refer directly to a FTP panel any conviction case which results in the imposition of a custodial sentence, whether immediate or suspended. This is a welcome change. It makes for greater certainty in that limited class of case. So far as any other conviction is concerned, the Registrar will be required to refer it direct to a FTP panel **'unless he is of the opinion that it ought to be referred to a medical and a lay Case Examiner for consideration'**. Although this latter provision creates a presumption in favour of referral, it gives a very wide discretion to the Registrar.

25.144 In September 2004, the GMC produced guidance (which was annexed to the September 2004 draft CE/IC Guidance) to members of staff and case examiners as to how they should deal with police cautions and with convictions which had not resulted in the imposition of a sentence of imprisonment. Members of staff are advised that they should refer direct to a FTP panel any case where the doctor has been convicted of a 'serious arrestable offence' within the meaning of the Police and Criminal Evidence Act 1984, of a racially motivated offence, of an offence involving child pornography, of an offence under the Misuse of Drugs Act 1971 (as amended) and of any offence involving an element of dishonesty. The guidance states that there is **'a presumption that the nature of these**

convictions means that the case will automatically reach the investigation stage test'.

25.145 At the other end of the scale, members of staff are advised that they may, unless the case has any exceptional aggravating factors, close cases which involve only a conviction for fixed penalty motoring offences, offences committed in the UK which are dealt with by substantially similar procedures, equivalent offences committed abroad and for offences whose **'main ingredient'** is the unlawful parking of a motor vehicle.

25.146 The guidance to staff states that all convictions (and, it seems also to be intended although it is not expressly stated, police cautions) not falling within any of the categories that I have previously described should be referred to case examiners. Case examiners should apply the investigation stage test in the same way as when dealing with non-conviction cases. They are advised that they must consider the seriousness of the case and that they are entitled to consider the doctor's fitness to practise **'in the round'**. Where there has been an assessment of the doctor's health (e.g. following a drink driving conviction), case examiners may authorise the staff to invite the doctor to agree voluntary undertakings. However, case examiners are reminded that, where there is a realistic prospect of erasure, the case must be referred to a FTP panel.

Comment

25.147 It appears to me that this guidance is clear and appropriate. I particularly welcome the guidance that all offences involving an element of dishonesty should be referred to a FTP panel. Case examiners may need guidance as to the kind of case in which there is a realistic prospect of erasure. Also, the guidance ought perhaps to make it plain that cautions are always to be dealt with in the same way as convictions. In my view, it should also be made plain that convictions resulting in a conditional discharge should be treated in the same way.

25.148 In my view, this guidance should be placed in the public domain. The question of whether a doctor convicted of a criminal offence should face a FTP panel is one in which members of the public have a legitimate interest. They should have the opportunity of contributing to a debate about which cases should be referred to a FTP panel and which should not. Moreover, the way in which the system operates in future should be transparent. The GMC should publish statistics showing a breakdown of the types of criminal offence and caution reported to the GMC and the outcomes of the decisions whether or not to refer such cases to a FTP panel and the reasons for the decisions taken. I suggest that the statistics should also show the final decisions taken by FTP panels in conviction and caution cases, so that it is possible to see clearly how the GMC deals with conviction and caution cases from beginning to end.

Closure of Cases by the Office Staff

25.149 When the Registrar decides not to refer an allegation to the case examiners, he (in practice, the staff exercising his powers) must notify the doctor, together with any person who brought the allegation to the attention of the GMC, of his decision and of the reasons for it.

Notification of the Doctor

25.150 The Guidance accompanying the November 2004 Rules states that the GMC will disclose to the doctor **'all complaints that are not wholly frivolous'**. Whether or not there has been prior disclosure of the allegation to the doctor, the November 2004 Rules require the Registrar, as soon as is reasonably practicable after referral of an allegation for consideration by the case examiners (or referral to a FTP panel in the case of a conviction which the Registrar refers direct to the adjudication stage), to write to the doctor, informing him/her of the allegation made against him/her and stating the matters which appear to raise a question as to whether his/her fitness to practise is impaired. The Guidance states that, if the Registrar intends to disclose the allegation to the doctor's employer or PCO before taking a decision whether to refer it to the case examiners, the doctor must be told of that intention. The doctor should also be sent copies of any documents received by the GMC in support of the allegation. The doctor will be invited to respond to the allegation by written representations within 28 days and will be informed that any representations received from him/her will be disclosed, where appropriate, to the maker of the allegation (if any) for comment. The July 2004 draft Rules provided (and the November 2004 Rules also provide) that disclosure of the doctor's representations to the maker of the allegation will be made only **'where appropriate'**. It is not clear in what circumstances it is envisaged that it would not be appropriate to make such disclosure.

25.151 There is no provision in the Rules requiring that the maker of an allegation should be shown the doctor's response and, if so, at what point in the proceedings. In evidence to the Inquiry, Mr Scott said that, in some cases, it would be evident from the first that an allegation should proceed. If the Rules required that the maker of the allegation should be invited to provide comments before referral of the case to a case examiner or to a FTP panel, this might cause delay. He said that it was better to leave the decision whether to invite comments from the maker of the allegation in the hands of the Registrar or case examiners. I can see that that would be sensible where it was clear that the case was to proceed, whatever the response of the maker of the allegation were to be. However, if there were any doubt about whether the case should proceed, it seems to me to be necessary to obtain the comments of the maker of the allegation before a decision is made. When giving evidence, Mr Scott gave an undertaking that comments would be invited from the maker of the allegation in any case where there might be doubt about whether to send the case to a FTP panel. I note that the November 2004 draft Investigation Manual instructs caseworkers to disclose to the maker of the allegation the doctor's comments on those parts of the allegations that have come from him/her. This appears to give effect to Mr Scott's undertaking to the Inquiry. However, as I have said, the requirement to make disclosure to the maker of the allegation has not been incorporated into the Rules. I think it would be preferable for this to be done. Mr Scott said that it would be too difficult to include this provision in the Rules without tying the GMC to seeking the complainant's comments in every case; that, he said, would cause unnecessary delay. However, I think that, with a little ingenuity, it could be managed.

Further Evidence Gathering

25.152 I have already said that, under the November 2004 Rules, after a decision has been taken to refer a case to a case examiner, the Registrar will be required to carry out such investigations as in his/her opinion are appropriate to the consideration of the allegation by the case examiners. In particular, the Registrar (or the staff, exercising his powers) will at this point be able to direct that an assessment of a doctor's performance or health should be carried out. This provision first appeared in the May 2004 draft Rules. Previously, and at the time of the Inquiry hearings, it had been intended that the power to direct a health assessment should be exercised only by a medically qualified case examiner or the IC. It had been suggested that the IC might not wish to delegate (at least in the short term) even to a medically qualified case examiner the decision whether to direct a performance assessment. I shall discuss this new power conferred on the Registrar when I deal with the arrangements for dealing with cases involving issues of health and performance.

25.153 The September 2004 draft CE/IC Guidance states that cases will be allocated to 'investigation teams' (each comprising a lawyer, an investigation manager, a number of investigation officers and case examiners). The draft Guidance says that regular team meetings will be held, at which decisions will be taken about the investigations required and progress will be reviewed. Lawyers (both in-house and external) will carry out certain investigations and will advise on those required. In a letter to the Inquiry, the GMC has said that the investigation of cases will be **'a lawyer-led process'**. The September 2004 draft CE/IC Guidance says that such investigations may include obtaining witness statements and expert reports, as well as directing health or performance assessments.

Comment

25.154 The GMC says that it intends to employ staff, both legal and non-legal, to carry out evidence gathering at the investigation stage. Since the Inquiry's hearings, I have seen advertisements in the newspapers seeking staff to carry out investigative work. This is a most welcome development. I do hope that a culture will be established within the GMC of proactive investigation, carried out with real determination and inquisitiveness – rather than by following a set protocol, at the end of which the investigation is regarded as complete, regardless of whether the issues have been 'bottomed'. I would hope also that an early opportunity will be taken to restore to the case examiners the power, which was proposed under the 2003 draft Rules, to direct that any investigations which they deem necessary should be carried out.

Consideration of Cases by Case Examiners

25.155 I shall now turn to examine the process by which the case examiners will consider cases and make decisions upon them.

25.156 During 2003 and 2004, the GMC was engaged in devising guidance for the use of case examiners and (latterly) of IC panels. The Inquiry has seen three drafts of such guidance.

These are the 2003 draft Case Examiner Guidance and the September 2004 draft CE/IC Guidance, to which I have already referred, together with the draft document, 'The Investigation Stage Test – Guidance on Criteria and Thresholds', produced by the GMC in June 2004 (the June 2004 draft Case Examiner Guidance).

25.157 The Inquiry has also seen drafts, produced in 2003 and in June and September 2004, of the case examiner decision forms (CEDFs) to be used by case examiners when recording their decisions.

25.158 The GMC told the Inquiry that it intended to pilot the Guidance and CEDFs during a trial period in October 2004, after which they will be amended further as necessary.

The Test to Be Applied

25.159 The test to be applied at the end of the investigation stage will, as I have said, be whether there is a realistic prospect of establishing that a doctor's fitness to practise is impaired to a degree justifying action on registration. The impairment might arise by reason of misconduct, deficient professional performance or adverse health, or as a result of a conviction or caution or as a result of a determination by another professional regulatory body. I have already discussed the problems that arise in connection with this test and my ideas as to how these problems might be rectified and I shall not repeat my observations here.

Guidance on the Approach to Be Applied

25.160 The November 2004 Rules contain no criteria to be used by case examiners when applying the investigation stage test. However, some insight into the approach that case examiners are expected to adopt can be gleaned from the 2003 draft Case Examiner Guidance, the June 2004 draft Case Examiner Guidance and the September 2004 draft CE/IC Guidance.

Cases Which Give Rise to a Presumption of Impaired Fitness to Practise

25.161 Case examiners will first of all have to evaluate whether an allegation is serious enough to indicate that the doctor's fitness to practise may be impaired to a degree justifying action on the doctor's registration. The September 2004 draft CE/IC Guidance advises that certain categories of conduct, namely sexual assault or indecency, violence, improper sexual/emotional relationships and dishonesty, should be referred by case examiners to a FTP panel unless there are **'exceptional reasons'** for not doing so. These categories of conduct are the categories which had previously constituted 'SPM by definition', save that 'dysfunctional conduct' has now been replaced by the narrower category of 'improper sexual/emotional relationships'. In such cases, there will be a presumption of impaired fitness to practise and, therefore, no need to consider the issue of seriousness.

25.162 The September 2004 draft CE/IC Guidance advises that, where case examiners consider that there is no realistic prospect of establishing a case evidentially, they should not **'normally'** close the case without first obtaining legal advice. Case examiners are advised

to record on the CEDF the reasons for their decision, referring specifically to any legal advice received.

25.163 The June 2004 draft Case Examiner Guidance had advised case examiners that they should not **'normally'** consider any arguments in mitigation raised by the doctor when considering whether to refer a case involving these categories of conduct to a FTP panel. However, that advice was omitted from the September 2004 draft CE/IC Guidance. I am concerned about that omission because I think the advice is important. It is clear from cases examined under the old procedures that the screeners often used to take mitigating factors into account quite inappropriately.

Considerations of Seriousness

25.164 The September 2004 draft CE/IC Guidance then sets out the approach to be adopted in other cases (usually involving complaints about a doctor's clinical practice), where there may be serious or persistent failures to meet the standards in 'Good Medical Practice' which raise an issue of impaired fitness to practise. It advises that not all failures to meet standards will involve an impairment of fitness to practise of a degree sufficient to justify action on the doctor's registration. When considering whether the impairment is of such a degree, case examiners are advised that they should consider both the nature and the seriousness of the allegations. They will need to consider also the persistent and serious nature of any failures to meet the standards in 'Good Medical Practice'. The September 2004 draft CE/IC Guidance then sets out a number of circumstances in which a question of fitness to practise is likely to arise. These are:

- **'A doctor's performance has harmed patients or put patients at risk of harm'**
- **'A doctor has shown a deliberate or reckless disregard of clinical responsibilities towards patients'**
- **'A doctor has abused a patient's trust or violated a patient's autonomy or other fundamental rights'**
- **'A doctor has behaved dishonestly, fraudulently or in a way designed to mislead or harm others'**
- **'The doctor's behaviour was such that public confidence in doctors generally might be undermined if the GMC did not take action'**
- **'A doctor's health is compromising patient safety.'**

25.165 This list of circumstances is helpful. However, it seems to me that case examiners need some specific examples by which to gauge whether the threshold is crossed in the particular case under consideration. What is required is a comprehensive set of case examples showing where the threshold should lie.

25.166 If the case examiners consider (taking into account all the above) that the allegation is of sufficient seriousness to have the potential to justify action on registration, they must then consider whether there is a realistic prospect of establishing the case evidentially.

Consideration of the Evidence

25.167 The September 2004 draft CE/IC Guidance sets out advice on how case examiners should approach the question of whether there is a 'realistic prospect' of establishing, in an individual case, that a doctor's fitness to practise is impaired to the required degree. The advice is in terms almost identical to those in the *aide memoire* which was first produced in January 2001 for the guidance of the PPC (although the *aide memoire* spoke of a **'real'**, rather than a **'realistic'** prospect). The September 2004 draft CE/IC Guidance includes a reminder that the criminal standard of proof applies in cases heard by a FTP panel.

25.168 The advice contained in the September 2004 draft CE/IC Guidance that case examiners should not **'normally'** close a case for evidential reasons without obtaining legal advice appears to extend only to cases which carry a presumption of impaired fitness to practise. It seems that, in all other cases (most of which will be cases involving allegations about clinical practice), case examiners will be free to form their own views about evidential issues, guided by the modified *aide memoire*.

Comment

25.169 Assessing the weight of evidence is essentially a legal process and can be quite difficult for non-lawyers. It may be that, in cases involving evidential issues, case examiners will seek the advice of the lawyers in their investigation teams. However, I find it worrying that they are not specifically advised to do so. It seems to me also that the modified *aide memo*ire may be unhelpful in some respects. The reminder that the standard of proof is the criminal standard is likely to create the impression that, if the evidence is disputed by the doctor, the allegation will not be capable of proof, whereas, in fact, if the FTP panel believes the account given by the maker of the allegation, it might find the allegation proved.

25.170 The September 2004 draft CE/IC Guidance also offers advice about the circumstances in which case examiners should consider whether a warning might be appropriate. I shall refer to that advice later in this Chapter.

The Possible Outcomes of the Consideration of a Case by the Case Examiners

25.171 The November 2004 Rules provide that medical and lay case examiners will have a number of options when deciding how to dispose of a case which is referred to them. First, they may direct that the case should not proceed further. It seems that, if the case examiners direct that a case should not proceed further, it will be open to them also to direct that a letter of advice should be sent to the doctor. This option is not mentioned in the Rules or in the September 2004 draft CE/IC Guidance. I shall consider this issue further below.

25.172 Second, the case examiners may decide to issue a warning to the doctor or to refer the allegation to the IC for an oral hearing, with a view to a warning being issued. I shall discuss that option further below. Third, the case examiners may refer the allegation for determination by a FTP panel. I shall deal with the procedure following such a referral later in this Chapter. Finally, the case examiners may recommend that the doctor should be

invited to comply with undertakings following an assessment of his/her performance or health directed by a member of the GMC staff. If such an invitation is issued and if the doctor confirms that s/he is prepared to comply with such undertakings, the case examiners will cease consideration of the case and the case will then be dealt with by way of voluntary undertakings. I shall deal with this option later in this Chapter.

25.173 Both case examiners must agree on how the case should be dealt with. In the absence of agreement, the case will automatically be referred to the IC.

Letters of Advice

25.174 I have explained in Chapter 19 how, under the old FTP procedures, it was open to a medical screener, having taken a decision not to refer a case to the PPC, to send a letter of advice to a doctor under Chapter XV of GMC Standing Orders. The PPC also sent warning letters and letters of advice in some cases which it had decided not to refer to the PCC for a hearing.

The 2003 Proposals

25.175 The 2003 draft Rules contained no specific provision for the sending of a letter of advice in a case which a case examiner had decided should not proceed further. Nevertheless, the Guidance which accompanied the 2003 draft Rules stated:

> **'Where a case is concluded with no further action, the Committee** (*the IC*) **or Case Examiner may issue advice about the practitioner's future practice or behaviour in such terms as they see fit.'**

25.176 The 2003 draft CEDF contained a section in which a case examiner was to record his/her decision whether or not to issue a letter of advice, together with reasons for the decision. The 2003 draft CEDF suggested that a letter of advice would probably be appropriate where a case examiner was **'satisfied that the case does not meet the investigation stage test and does not warrant a warning'**. Three examples were suggested of circumstances in which it might be appropriate to send a letter of advice. The first example was where there had been a **'minor breach in professional standards'**, such as unreasonable delay in sending a promised medical report. The second example was where the doctor had been convicted of a **'minor criminal offence (such as breach of the peace)'**. The third example was where the **'issues'** had **'been resolved locally to the satisfaction of the parties'** and **'confirmation of any advice given locally would be useful'**. The FPPC's paper which was considered by the Council at its meeting in November 2002 had suggested that the terms of any letter of advice sent to a doctor should be disclosed only to the doctor and to the complainant. The letter would not be disclosed to the doctor's employer or PCO. Nor would it be disclosed to anyone who subsequently enquired about the doctor's registration status. It was, however, intended that a letter of advice (together with any complaints against the doctor received locally) would be considered as part of the appraisal process.

The 2004 Position

25.177 The May and July 2004 draft Rules also contained no provision for the sending of letters of advice. Nor do the November 2004 Rules. The June 2004 draft Case Examiner Guidance and the September 2004 draft CE/IC Guidance make no mention of letters of advice. All references to letters of advice have also been removed from the June and September 2004 drafts of the CEDF. The June 2004 draft CEDF did request a case examiner, if s/he had decided that a case should not proceed further, to note the main points to be covered in the letter to be sent to the doctor. It seemed possible that case examiners would be instructed by the GMC that they might include in those points some form of advice to the doctor as to his/her future conduct. That section has been omitted from the September 2004 draft CEDF, which is much shorter than previous versions.

25.178 In a letter to the Inquiry, the GMC has stated:

> **'... it will of course remain open to the GMC to provide advice to a doctor in any terms that it considers appropriate when no formal action (including a warning) is required, but to do so is considered desirable in the interests of maintaining good professional standards. It is anticipated that this power will be used only very sparingly and the GMC is considering how best to reflect this in its internal guidance to staff including Case Examiners.'**

25.179 It appears, therefore, that, despite the fact that all reference to letters of advice has been removed from the draft CEDFs and Guidance, it is contemplated that, on occasion, cases will be dealt with by sending a letter of advice. Whether this power will be used sparingly in future remains to be seen. Under the old procedures, many such letters were sent.

Comment

25.180 There is nothing intrinsically wrong with the sending of a letter of advice; indeed, it may be a good idea, provided that it is not allowed to become a 'soft option' and an alternative to referring a case which, in reality, satisfies the investigation stage test and should therefore be referred to a FTP panel. But, if it is thought to be of value to retain letters of advice, the option should be written into the Rules and proper criteria should be agreed and established for the sending of such letters. Their use should be audited, so as to ensure that they are being used appropriately. It is not acceptable to start the new procedures with part of the process going on outside the Rules. If letters of advice are to be retained, they may – indeed should – be of relevance to the process of revalidation. It would be unfair to doctors if there were inconsistency of treatment in the sending of letters of advice. In the 2001 Consultation Paper, the GMC singled out the lack of transparency in relation to letters of advice as one of the weaknesses of the old system. The present uncertainty has done nothing to remove the obscurity of the old arrangements.

Warnings

25.181 A novel feature of the new FTP procedures is the mechanism for issuing formal warnings to doctors at the investigation stage. Section 35C(6) of the 1983 Act provides that, if the

IC decides that a case ought not to be considered by a FTP panel, it may issue a warning to the practitioner about his/her future conduct or performance. Because there is no express statutory test to be applied to the question of whether a case **'ought not'** to be considered by a FTP panel, the circumstances in which a warning may lawfully be given are not clear from the statute.

The Circumstances in Which a Warning May Be Issued

25.182 The GMC's intention is that a warning will be available where an allegation does not, in the view of the case examiners or the IC, warrant referral to a FTP panel, but where there is evidence to suggest that the doctor's behaviour or performance has fallen below acceptable standards to a degree warranting formal censure by the GMC. The September 2004 draft CE/IC Guidance states:

> **'There will also be cases that demonstrate significant departures from *Good Medical Practice* not so serious as to warrant action on a doctor's registration but requiring a formal response from the GMC in the interests of maintaining good professional standards and public confidence in doctors. The appropriate response in these types of cases will be a warning.'**

25.183 A warning will **'remain valid'** for a period of five years. No decision has yet been made by the GMC about whether a warning should ever be regarded as 'spent' (and, therefore, not discloseable) after five years. The fact that a warning has been issued will be disclosed to the doctor's current employer or PCO and to the person or body who brought the allegation to the attention of the GMC. In addition, it will be disclosed to any prospective employer. It will also be disclosed to any enquirer during the period of the warning's validity. As I understand the position, an 'enquirer' would have to make a specific enquiry about whether a doctor had a FTP history (not just whether s/he was registered or whether there were restrictions on his/her registration) before the fact of the warning would be revealed. At a meeting of the Council in July 2004, Mr Scott told members how office staff provide such information. They answer only each question specifically asked and do not volunteer any additional information.

The 2003 Guidance

25.184 The 2003 draft Case Examiner Guidance advised case examiners to consider four questions when deciding whether a warning was appropriate. These were:

> **'a. Was the doctor's conduct incompatible with his standing as a doctor?'** The 2003 draft Case Examiner Guidance suggested that a warning might be appropriate following conviction for certain categories of criminal offence (e.g. an isolated incident of shoplifting), where the offence had not taken place in a professional context.
>
> **'b. Has the doctor failed to address concerns raised by local management?'** It was suggested that a warning might be **'a means of**

underlying (*sic*) **the seriousness of the concerns and stressing that any misconduct must not be repeated'**.

'c. Is there a need to flag up our concerns with the doctor's employer(s)?' The 2003 draft Case Examiner Guidance suggested that the fact that a warning would be disclosed to the doctor's employer(s) would have the effect of **'ensuring that employers are aware that aspects of the doctor's practice may need to be monitored'**.

'd. Are there any identifiable areas of a doctor's practice in need of assessment or retraining?'

25.185 The 2003 draft Case Examiner Guidance went on to state:

> **'A departure from Good Medical Practice may be viewed as sufficiently significant to justify a warning where it is serious enough for us to mark the fact that the doctor's behaviour was unacceptable and must not happen again, but that it would be disproportionate to take action against the doctor's registration.'**

25.186 At the Inquiry's hearings, it was suggested to witnesses from the GMC (in particular, Sir Graeme Catto and Mr Scott) by Leading Counsel to the Inquiry that the new power to issue formal warnings might make it tempting for case examiners or the IC, in a case where they were uncertain whether a FTP panel would find the facts proved, to opt for the 'bird in the hand' and to issue a warning in a case that ought really to be referred to a FTP panel. This possibility did not appear to have occurred to any of the witnesses previously, although it did appear to the Inquiry to be an obvious danger.

The 2004 Guidance

25.187 The September 2004 draft CE/IC Guidance makes clear that a warning should be considered only where the case examiners have already decided that the investigation stage test has not been met. Moreover, case examiners are advised that, where they consider that allegations are **'borderline between action on registration and a warning'**, the presumption should be that the allegations should be referred to a FTP panel. It seems to me that this draft Guidance, if adhered to, satisfactorily deals with the Inquiry's concern.

25.188 The June 2004 draft Case Examiner Guidance advised also that, where case examiners had decided that the allegations met the investigation stage test, they should not permit any mitigating factors to persuade them to issue a warning, instead of referring the case to a FTP panel. Rather, it should be left to the FTP panel to consider any mitigating factors and the appropriate circumstances. I considered that to be a welcome change in the advice because, as I mentioned earlier, the Inquiry's examination of cases under the old procedures showed that screeners and the PPC often took mitigation into account when they should not have done. However, the advice has been omitted from the September 2004 draft CE/IC Guidance. Indeed, the only reference to mitigation occurs when case examiners are advised that, once it has been established that the investigation stage test has not been met, they should consider all the evidence (including mitigation) when

deciding whether or not to issue a warning. In my view, the advice on mitigation given in the June 2004 Guidance should be reinstated. The GMC must be alert to the potential problem that the case examiners may take mitigating factors into account inappropriately. They should monitor case examiners' decisions to ensure that they are not mistakenly taking mitigating factors into account and issuing warnings in cases that should have gone to a FTP panel. This is important in the interests of protecting patients.

25.189 The September 2004 draft CE/IC Guidance makes no reference to the four questions which the 2003 draft Guidance had suggested the case examiners should consider when deciding whether a warning was appropriate. Nor does it give any further guidance on how a decision whether or not to issue a warning should be approached. The June 2004 draft Case Examiner Guidance had included a few examples of the types of case which might attract a warning. These were brief and contained no detail. They have been omitted from the September 2004 draft CE/IC Guidance. In my view, they should be reinstated because the provision of examples is always helpful. However, what is really needed is not these brief examples but more detailed case studies, covering a much wider range of topics and demonstrating, by the use of more than one case of a similar nature, where the dividing line has been – properly – drawn and why.

Procedure: Notice to the Doctor: the 2003 Proposals

25.190 The 2003 draft Rules set out an elaborate procedure for the issuing of warnings. Where the IC or a case examiner considered that a warning might be appropriate, the doctor would be given notice that a warning was being considered and would be informed of his/her right to make representations in writing. Although the 2003 draft Rules were silent on the point, it appeared that, if no representations were received, or if the doctor indicated that s/he was prepared to accept the warning, a written warning would be issued. If the doctor contended that a warning should not be issued, his/her representations would be considered by an IC panel or a case examiner, and a decision would then be taken as to whether an oral hearing, to determine whether the warning should be issued, was desirable. The question of whether there should be an oral hearing was a matter for a case examiner or the IC panel; there was no right to such a hearing.

Procedures: Notice to the Doctor: the 2004 Position

25.191 Under the May 2004 draft Rules, the provisions for the issuing of warnings were simplified. There was to be no opportunity for the doctor to make written representations specifically on the question of whether a warning should be issued. Presumably, it was intended that the case examiners would take into account, when making their decision, any written representations which had been submitted by the doctor when s/he had first been invited to comment on the allegation made against him/her. Doctors still had no right to insist on an oral hearing.

25.192 The July 2004 draft Rules (which are reproduced in this respect by the November 2004 Rules) reinstated the opportunity for a doctor to make written representations once the case examiners have indicated that they are considering issuing a warning. The case examiners must consider those written representations when deciding how to deal with

the case. The July 2004 draft Rules conferred for the first time a right on a doctor to an oral hearing if s/he chose. This change was intended to meet the concerns of doctors about the new warning procedures. The right to a hearing has been retained in the November 2004 Rules.

The Case Examiners' Decision

25.193 Once the doctor's written representations have been received (or if s/he does not respond to the invitation to provide representations), the case examiners have three options for dealing with the case. The first option is to issue a warning to the doctor. The November 2004 Rules provide that, if the case examiners are satisfied that the allegation **'ought not to be considered by a FTP Panel'** and if the doctor does not make any representations, or if it appears from his/her representations that s/he has not contested the facts upon which the allegation is based, the case examiners may, if they think fit, issue a warning to the doctor.

25.194 The second option is to refer the doctor for an oral hearing before the IC. Case examiners must exercise this option if the doctor requests an oral hearing before the IC, or if they consider it appropriate for some other reason to refer the case for an oral hearing. The third option (which is not explicitly set out in the relevant rule but must, I think, be open to case examiners) is to direct that the case should not proceed further. A direction that a case should not proceed further may be made if it is clear that the doctor is disputing the facts and if the case examiners do not consider, having taken into account the doctor's representations, that it is appropriate to refer the case to the IC for an oral hearing.

25.195 It should be noted that there is no provision for the maker of the allegation to be notified of the fact that a warning is being considered. Nor is there any provision for the maker of the allegation to be shown, or asked to comment on, the doctor's written representations as to whether a warning should be issued.

Comment

25.196 The process by which a warning may be issued following the decision by a case examiner that that would be an appropriate course is potentially complex, time-consuming and expensive. It may result in a hearing before an IC panel which is virtually as resource-intensive as a full hearing before a FTP panel. It may even result in a FTP panel hearing, if new evidence emerges at the IC panel hearing. I shall make some comments and suggestions about this procedure when I have completed my description of all the processes by which a warning may be given during the investigation stage.

Cases Dealt with by the Investigation Committee

25.197 I have explained that, under the November 2004 Rules, IC panels will deal with only two categories of case. The first category consists of cases where the two case examiners have been unable to agree. The second consists of oral hearings for the purpose of deciding whether a warning should be issued.

25.198 The GMC will maintain a list of medical and lay associates, who will be eligible to act as IC panellists. As I have already explained at paragraph 25.90, although, under the Constitution Rules 2004, GMC members will be eligible to sit on IC panels, it is not yet certain whether they will in fact do so. There is a division of opinion among Council members about whether this is appropriate. Whatever the long-term outcome of that debate, IC panels will be chaired by panellists who have undergone assessment and have been appointed for the purpose. Chairmen of panels may be medical or lay. The legal quorum of an IC panel will be three, including a medical and a lay panellist.

25.199 Decisions of IC panels are to be reached by a simple majority. If the votes are equal, the decision will go in favour of the doctor. IC panels will sit with a legal assessor when considering warnings.

Cases Where the Case Examiners Have Disagreed

25.200 In cases where the case examiners have been unable to agree, an IC panel will decide the case in private and on paper. Neither the maker of the allegation nor the doctor will have the right to attend or to be represented. The panel may adopt one of five courses of action.

25.201 First, the panel may determine that the allegation should not proceed further. It seems that, if it makes such a determination, it will have the option of sending a letter of advice to the doctor in the same way as the PPC frequently did under the old procedures. I have already expressed concern that there is no mention in the Rules about letters of advice. If they are to be sent, the circumstances in which this will happen should be set out in the Rules and there should be clear criteria for the circumstances in which this will be done.

25.202 The second option open to the IC panel will be to issue a warning to the doctor without an oral hearing. Where a warning is being considered, the doctor will be given the same opportunity to provide written representations about the issue as if the case examiners had initiated the warning process. The IC panel will then have the option, where the doctor has made no representations or has not contested the facts, of issuing a written warning without a hearing. The third option that the IC panel will have is to decide that an oral hearing should be held in front of a differently constituted panel of the IC. That panel would then decide whether a warning should be issued. Fourth, the IC panel may refer the allegation for determination by a FTP panel. The fifth option arises where the case examiners have failed to agree whether to recommend that a doctor should be invited to comply with undertakings following a performance or health assessment. In that event, the IC panel may determine that the doctor should be invited to comply with such undertakings as the panel thinks fit.

25.203 The November 2004 Rules give the IC no power to direct that any investigations should be carried out, or to adjourn for investigations to be carried out, when dealing with a case where the case examiners have disagreed. Under the old procedures, the PPC had the power to adjourn for further investigations. Furthermore, an IC panel has no power to direct a health or performance assessment in such cases. In my view, the IC should have these powers and I shall recommend that they be provided.

Oral Hearings for the Purpose of Deciding Whether to Issue a Warning

25.204 The 2003 draft Rules provided that an oral hearing held by an IC panel for the purpose of deciding whether to issue a formal warning was to be conducted in private. As for the procedure to be adopted at such a hearing, the 2003 draft Rules would have permitted the Presenting Officer (i.e. the person presenting the case for the GMC, usually a solicitor or counsel) to outline the allegations against the doctor, but not to adduce any evidence. By contrast, the doctor or his/her representative was to have the right to adduce oral or documentary evidence and to address the panel on the appropriate outcome. The 2003 draft Rules provided no opportunity for the Presenting Officer to make further submissions about the evidence adduced by the doctor or about any representations that had been made on the doctor's behalf. The draft 2003 Rules specifically stated that the maker of an allegation had no right to appear before the IC panel and, indeed, the relevant person or body would almost certainly have been unaware that the oral hearing was being held or, indeed, that the possibility of issuing a warning was being contemplated. The IC panel was to be required to give only **'brief reasons'** for its decision, which would have been communicated subsequently to the maker of the allegation.

25.205 At the time of the Inquiry's hearings, I had some concern about the proposal to hold these oral hearings in private. A significant – and very welcome – change introduced by the May 2004 draft Rules (and reproduced in the November 2004 Rules) is that oral hearings in relation to warnings are now to be held in public. I was also concerned at the proposed procedure at such hearings, which was to be wholly one-sided, with only the doctor being permitted to adduce evidence. This arrangement was changed by the May 2004 draft Rules, which would have permitted the Presenting Officer to adduce any relevant oral or documentary evidence and to make further submissions after the doctor had given his/her evidence. This would have disposed of most of the concerns I had about the one-sided nature of the process. If there had been provision for the maker of the allegation to attend the hearing, to give evidence if appropriate and otherwise to provide information to the Presenting Officer, my concerns on that score would have been completely allayed.

25.206 The July 2004 draft Rules (reproduced in the November 2004 Rules) introduced yet further changes. Now, the Rules provide that, once the Presenting Officer has outlined the allegation and the facts upon which it is based, the doctor may respond to the allegation. Both the Presenting Officer and the doctor may adduce any relevant oral or documentary evidence only **'where the Committee considers such evidence is desirable to enable it to discharge its functions'**. The Presenting Officer may then make such further submissions as the IC panel shall allow.

25.207 The effect of these changes is that it is now wholly within the discretion of an IC panel to decide whether or not oral evidence is called or documentary evidence is admitted. The nature and extent of the evidence to be admitted or called is also within the panel's discretion. The Guidance which accompanies the November 2004 Rules states that:

> **'... there is a presumption that evidence will not be received, and this is at the discretion of the Committee** (*i.e. the IC panel*) **considering the case. As the Committee has no power to impose a sanction which will affect the practitioner's registration, it will generally be the case that the**

practitioner's rights, and the public interest, will adequately be served by a summary hearing of this kind.'

25.208 The maker of the allegation will have no right to be notified of the hearing although it is possible that s/he will be called by the GMC to give evidence, if the IC panel permits this.

25.209 In contrast with the position where the IC panel is seized of a case because the case examiners have disagreed, the IC panel may, before reaching its decision, adjourn for further investigations to be carried out, including an assessment of a doctor's health or performance.

25.210 At the conclusion of the oral hearing, the panel can issue a warning or determine that the case should not proceed further. A third option, which arises where new information adduced into evidence at the hearing indicates that to do so would be appropriate, is to refer the allegation for determination by a FTP panel. However, it seems likely that that would be a rare occurrence if it is not intended that evidence should usually be called.

25.211 The Guidance accompanying the November 2004 Rules states that any disputes of fact at an oral hearing relating to a warning will be decided on the basis of the civil standard of proof. Once it has reached its decision, the IC panel must announce the decision and give its reasons (the November 2004 Rules require **'reasons'**, rather than **'brief reasons'**) for that decision.

25.212 At the moment, it is impossible to know how these procedures will work in practice. If disputes of fact are to be resolved, the IC panel will have to receive oral and documentary evidence. It is to be hoped that panels will not make findings of fact on the basis of representations alone. If evidence is to be heard, it must be heard from both sides. The presumption that evidence will not be received gives rise to practical problems. If it is not expected that evidence will be heard, witnesses will not be warned to attend the hearing. Of course, the doctor is likely to be there, but it would be quite wrong for the IC panel to allow the doctor to give evidence when the GMC had not even arranged for its witnesses to attend. On the other hand, it would obviously be unsatisfactory if witnesses were to be required to attend, only to find that the IC panel would not permit them to give evidence. It may be that there will have to be a preliminary hearing before the same IC panel to determine what the issues are and whether oral and documentary evidence will be received. It seems to me that, even if oral evidence is not to be heard, the maker of the allegation ought to be entitled to attend. Without the presence of that person, the Presenting Officer may have no one from whom to obtain information in relation to the representations made on the doctor's behalf and the procedure will inevitably be one-sided. Such a process would not, in my view, provide adequate protection for patients and the public interest.

Comment

25.213 These proposed arrangements for the giving of warnings create a potentially complex, time-consuming and expensive procedure. Although it is said that the oral hearing will be more **'summary'** than that which takes place before a FTP panel, that will not necessarily be so. If evidence is to be admitted, there will be very little difference. It is said that this

more **'summary'** procedure is appropriate and not unfair because the sanction that might be applied does not affect the doctor's registration. That is true, but a warning is a serious matter, will be disclosed to enquirers and in effect goes into the public domain. The GMC says that warnings will 'feed into' the revalidation process, although it is not clear to me at what stage that will happen or what effect a warning would have on whether or not a doctor was revalidated. I note, as a matter of interest, that the 2003 draft Case Examiner Guidance and the June 2004 draft Case Examiner Guidance advised case examiners that a warning should be regarded as a **'serious sanction'** or a **'serious matter'**. The more recent Guidance omits that advice. Nonetheless, it seems to me that the issue of a warning that is disclosed to anyone who enquires is a serious matter and the fact that the GMC wishes to give doctors the right to an oral hearing shows that it recognises that. The giving of a warning is also an important matter from the public point of view. The GMC has recognised that, by deciding that oral hearings in connection with warnings should take place in public.

25.214 I mentioned in paragraphs 25.56–25.58 above that, in my view, the GMC's investigation stage test has been set at the wrong level. Errors of principle such as this usually give rise to practical problems. In my view, the GMC's present difficulties with the issue of warnings within the investigation stage illustrate that problem. If the GMC were to adopt the investigation stage test that I have proposed at paragraph 25.63, all cases that might warrant a warning would automatically go through to a FTP panel. The case examiners and IC would be applying their minds to objective criteria and not trying to guess what sanction might be imposed. If the case did not pass the investigation stage test, the case would be closed, with or without a letter of advice. There would be no warnings at the investigation stage and no need to devise a special **'summary'** procedure with discretion to admit evidence and all the practical problems that will create.

25.215 It seems to me that the practical problems of the proposed oral hearings are very significant. If the discretionary question of whether evidence is to be received is to be decided by the IC panel in every individual case, there will have to be a preliminary hearing in every case. This will have to take place before the same IC panel as will sit on the substantive hearing; a discretionary decision on the admissibility of evidence cannot be taken by a case manager. The expense will be considerable. The only other option is to have a full hearing in every case. I quite understand the disadvantages in that, especially since there is (theoretically at least) the possibility that, at the end of such a hearing, the case might be referred by the IC panel to a FTP panel, which might involve a rehearing of the same evidence.

25.216 If the GMC decides to maintain its present position, a number of problems arise, apart from the ones I have already mentioned. I fear that the complexity of the procedure will result in a lot of borderline cases foundering with no action being taken. Case examiners may be tempted not to send cases for an oral hearing if there is a significant dispute of fact, particularly if it is known that the IC has a lot of work.

25.217 If the present provisions are to be implemented, it is essential that their operation be properly audited. It will be necessary to collect statistics to show how many cases are closed after the invitation for written representations on the giving of a warning has been

issued, i.e. without any action being taken. The GMC should analyse which types of case are being dealt with by way of warning and whether this is appropriate. Under the old procedures, letters of advice and warnings were often issued in cases which should have proceeded to a hearing.

25.218 I do hope that the GMC will consider these observations about the giving of warnings within the investigation stage, together with my concerns about the investigation stage test. The two are closely related and both problems could be resolved in the way I have suggested.

Cases Where the Doctor's Fitness to Practise Is or Might Be Impaired by Adverse Health

25.219 At present, it is envisaged that arrangements which are in many respects similar to the old voluntary health procedures will continue under the new procedures. However, Mr Scott told the Inquiry that the treatment of some health cases would be very different. He said that cases where the issues were only about impairment of health might be dealt with separately under a procedure akin to the old voluntary health procedures. However, health cases with 'complicating factors' would not. If, for example, a doctor had convictions for drug offences, then, despite the fact that the case involved health issues, it would have to go to a FTP panel. It would then be open to the FTP panel to direct that the doctor be referred back to the investigation stage to be dealt with by way of voluntary undertakings. When asked how he envisaged that a case such as that of Shipman in 1976 would be dealt with under the new procedures, Mr Scott said that the case would go to a FTP panel. The doctor might thereafter be invited to give voluntary undertakings. I shall comment on this proposed procedure shortly.

The 2003 Proposals

25.220 The 2003 draft Rules provided that the power to direct that an assessment of a doctor's health should be carried out would lie with the IC or a case examiner. They would exercise the power in a case where a question arose as to whether a doctor's fitness to practise might be impaired by adverse health.

25.221 The 2003 draft Rules provided that, if the assessment(s) showed that the doctor was (or might be expected in the future to be) not fit to practise, or not fit to practise save on a limited basis or under supervision, or both, the IC panel or a case examiner might then direct the Registrar to invite the doctor voluntarily to undertake to comply with certain conditions, which might include limitations on his/her practice. If the doctor gave the necessary undertakings, the IC panel or case examiner (if satisfied that the undertakings were being observed) would postpone further action on the case. The 2003 draft Rules would have given the IC panel or case examiner power to appoint one or more medical practitioners to supervise the doctor and to provide reports as necessary. The IC panel or case examiner would also have had power under the 2003 draft Rules to direct a further health assessment in order to determine whether it was necessary for the doctor to remain under the supervision of the IC panel or case examiner. The IC panel or a case examiner would also have been given power to invite the doctor to agree to the variation of the conditions with which s/he had undertaken to comply and, when appropriate, to release

the doctor from his/her undertakings. If the doctor refused to co-operate, or failed to comply with his/her undertakings or if his/her health deteriorated, the 2003 draft Rules would have given the IC panel or case examiner the power to refer him/her to a FTP panel.

25.222 All these arrangements would have been very similar to the arrangements under the old voluntary health procedures. The 2003 draft Rules gave the powers previously exercised by health screeners to both the IC and case examiners. In practice, however, it seems likely that the IC would have delegated one or more medically qualified case examiners to assume the role filled, under the old procedures, by the health screeners.

The 2004 Position

25.223 The May 2004 draft Rules removed the power to direct a health assessment from both the IC and the case examiners and placed it instead with the Registrar (in practice, the GMC staff). The only exception is that an IC panel may order a health assessment before taking a decision at an oral hearing relating to the issue of a warning. No explanation for this very important change (which has been retained in the November 2004 Rules) is apparent from the documents the Inquiry has seen and it appears that its objective must have been to reduce the workload of the case examiners and, thus, to reduce the number of additional case examiners who would be required to deal with the new arrangements for the double-handling of cases by both a medical and a lay case examiner. Another possible objective was to bring decisions to direct health assessments under staff control so that they could be subjected to financial restraints and service targets. With great respect to the staff – and I entirely accept that they are competent and hardworking and that some of them are very experienced – I cannot think that anyone could have reached a positive conclusion that the quality of decision-making by staff would be better than that by case examiners. Certainly, I am not aware of any evidence upon which such a view might be founded. In short, I cannot think of any reason of principle for making this change.

25.224 The sequence of events contemplated under the November 2004 Rules appears to be that the staff will direct a health assessment after a decision has been taken to refer a case to a case examiner. The staff may or may not confer with a case examiner before doing so. There is no requirement that they should. Presumably, if a case examiner thinks that there should be a health assessment, s/he will be able to request that one should be directed but s/he will not be able to insist. In my view, this rule should be changed so that case examiners (and an IC panel) can direct that a health assessment should be carried out. Indeed, it seems to me that, except in a case where an issue of health obviously arises and where it is clear from what branch of medicine the practitioner who is to carry out an assessment should come, the decision whether to order a health assessment and by whom it should be carried out should always be taken by a medically qualified case examiner rather than by a member of staff who is not medically qualified.

25.225 If the doctor fails to submit to or comply with an assessment of his/her health, the Registrar (or the staff exercising his legal powers) may refer the allegation for determination by a FTP panel. There is no requirement to consult with a case examiner before this is done. The FTP panel may then determine whether the doctor's fitness to practise is impaired and, if it is, may take appropriate action.

25.226 The May 2004 draft Rules implied (although they did not specifically provide) that, once the report of a health assessment had been received, the staff would, as a matter of course, refer the report to the case examiners. Under the July 2004 draft Rules (and now the November 2004 Rules), however, the Registrar (in practice, the staff) is given a discretion whether or not to refer an assessment report to a medical and a lay case examiner and need do so only if s/he considers it **'appropriate'** to do so.

25.227 I assume that the fact that the staff will have a discretion whether or not to refer an assessment report to the case examiners means that they can close the case if it appears to them that the assessment report discloses no evidence that the doctor's fitness to practise is impaired. The staff never made this kind of decision before. I am concerned about it. In my view, if a case warrants a health assessment, it also warrants a decision by a medically qualified case examiner. It may be that the July 2004 draft Rules and the November 2004 Rules have created a situation that was not intended. The Rules also suggest that the Registrar (or member of staff) can direct an assessment only after s/he has decided to refer the case to the case examiners. If, when the assessment report is available, it is not shown to the case examiners, it is difficult to see how the latter can conclude the case. In my view, this rule should be changed. If a case is to be closed on the basis of a health assessment received, the decision should be taken by case examiners, one of whom will be medically qualified, or by an IC panel.

25.228 If the staff refer the assessment report to the case examiners and the case examiners take the view that the doctor is not fit to practise, or is not fit to practise except on a limited basis or under supervision or both, or that the doctor has some condition which (though in remission at the time of assessment) may be expected to make him/her unfit to practise in the future, the case examiners may recommend that the doctor should be invited to comply with undertakings. The November 2004 Rules provide for case examiners – not the staff – to make the decision that undertakings should be offered. If the case examiners recommend that undertakings are appropriate, the Registrar (in practice, the staff) will write to the doctor, inviting him/her to agree to comply with the undertakings specified by the case examiners. If the doctor confirms that s/he is prepared to comply with undertakings, the case examiners must **'cease consideration'** of the allegation.

25.229 If, when they consider the assessment report, the case examiners agree that undertakings are inappropriate or inadequate for the protection of the public, they have power under the November 2004 Rules to refer the case to a FTP panel. The July 2004 draft Rules provided (and the provision has been retained in the November 2004 Rules) that a doctor should not be offered the opportunity to give voluntary undertakings where there is a realistic prospect that, if the allegation were referred to a FTP panel, his/her name would be erased from the register. This provision is designed to give effect to the observations of the Judicial Committee of the Privy Council in the case of Crabbie v General Medical Council[1], to which I referred in Chapters 21 and 23. If the case examiners cannot agree between themselves whether the case should be dealt with by way of voluntary undertakings, it will automatically be referred to an IC panel.

[1] [2002] 1 WLR 3104.

25.230 The May 2004 draft Rules provided (as do the November 2004 Rules) that it should be the Registrar (in practice, the GMC staff), and not the case examiners, who is responsible, in a case where medical supervision is required, for selecting the medical practitioners to act as supervisors and for requesting progress reports as necessary. There is no indication that those progress reports will have to be referred to case examiners. The staff will also assume responsibility for directing that further assessments should be carried out as and when necessary. The November 2004 Rules (like the July 2004 draft Rules) do not provide for any input from the case examiners into that decision. Again, it would appear that these changes in the arrangements are intended to reduce the workload of the case examiners.

25.231 Moreover, if a doctor fails to give the undertakings sought, or if his/her health deteriorates, or if information is received that otherwise gives rise to further concern regarding the doctor's fitness to practise, it is the Registrar (in practice, the GMC staff) who will have a discretion to refer the allegation for determination by a FTP panel. There is no requirement to consult with the case examiners before doing so. Decisions as to whether undertakings should be varied or should cease to apply will, however, be taken by case examiners.

Comment

25.232 I am very concerned about these arrangements. It is entirely appropriate that the staff should undertake the making of the practical arrangements for the medical and professional supervision of a doctor who is subject of voluntary undertakings, but it cannot be right that the overall responsibility for the doctor's progress should remain with a staff member. Under the old health procedures, a health screener was responsible for all decisions and provided professional expertise and continuity of attention. In Chapter 22, I reported the evidence of Dr Sheila Mann, who was a health screener from 1996 to 2004. I described the improvements to the health procedures that had been effected within the last few years. I thought (and I think that Dr Mann thought) that the new procedures would operate much as they had done in the past. Dr Mann said that it had been intended that one of the first batch of case examiners appointed should be a psychiatrist, in order to maintain continuity within the health procedures. However, as at December 2003, it had not been possible to recruit a suitable candidate. As a consequence, Dr Mann was concerned that there would not be a sufficient period of overlap to enable her to pass on the benefit of her experience to the new appointee. In March 2004, two of the recently appointed case examiners (one a professor of psychiatry) were appointed health screeners pending the introduction of the new FTP procedures. It is to be hoped that there was an opportunity for them to learn from Dr Mann's experience. However, as I have said, their future role will be very different from that of a former health screener. It is profoundly disappointing that the GMC should have abandoned its original plans, not, so far as I can see, for reasons of principle but for reasons of expediency. I hope that the GMC will think again. From what I heard from the evidence of Dr Mann, I am quite satisfied that a considerable degree of professional expertise is required in the interpretation of assessment reports. Also, some of the decisions to be taken are of a difficult and delicate nature. They affect the safety of patients and of the public. With all due respect to the staff members, whose competence I do not in any way seek to impugn, these decisions must be taken by appropriately qualified medical practitioners.

Cases with a Performance Element

25.233 The new procedures for dealing with cases where an allegation suggests that a doctor's professional performance is deficient are essentially very similar to those for dealing with health cases. In December 2003, Mr Scott told the Inquiry that he could not imagine that what were then termed the 'performance procedures' would operate in anything like the same way in the future as they had in the past. He said that, following a challenge to a doctor's fitness to practise, a case examiner would consider whether it was necessary or appropriate to order a review of the doctor's performance. If a performance assessment were undertaken and if the assessment report showed deficiencies in performance and the doctor accepted a statement of requirements, the case would go into 'consensual disposal' and would not go to a FTP panel unless the doctor was uncooperative. The arrangements for 'consensual disposal' would be very similar to the old voluntary performance procedures. It appears that what Mr Scott had in mind when he said that the performance procedures would be different in the future was not that the practical arrangements would be different but that the underlying philosophy would change. During their evidence to the Inquiry, both Mr Scott and Sir Graeme Catto voiced the intention that the GMC should move away from focussing on the remediation of doctors referred to it and should instead direct its attention towards 'cases where restriction on registration was appropriate'.

25.234 As with health cases, the power to take a decision to direct an assessment of a doctor's performance will, under the November 2004 Rules, lie with the Registrar (in practice, GMC staff) and not, as it would have done under the 2003 draft Rules, with the case examiners or the IC. This is a particularly significant change since, at the time when the new FTP procedures were being formulated, there was doubt about whether the IC would delegate the power to make that decision even to a medically qualified case examiner. It was anticipated that the IC would retain for itself the power to decide whether a performance assessment should be undertaken, at least in some cases. It was intended, however, that, in time, the IC would delegate such decisions to one or more case examiners. That was the situation which appears to have been envisaged by Mr Scott, when he gave evidence to the Inquiry. He spoke as if the case examiners would be taking these decisions. However, their job description did not mention this function.

25.235 Prior to the May 2004 draft Rules, it was the intention that the IC would assign medically qualified case examiners to take over the role played by the performance case co-ordinators in the old performance procedures. Once a performance assessment had been undertaken and had concluded that a doctor was not fit to practise or not fit to practise save on a limited basis or under supervision or both, a case examiner would have taken over the management of the case. Under the 2003 proposals, the voluntary performance procedures would have remained much the same as under the old procedures, save for some simplification of the procedures by eliminating referrals to, and hearings by, the Assessment Referral Committee.

25.236 This approach has now been changed and, under the November 2004 Rules, the power to direct a performance assessment will lie with the Registrar (in practice, the GMC staff). Indeed, neither case examiners nor the IC will have any power to order such an

assessment save only that an IC panel may order a performance assessment before taking a decision at an oral hearing relating to the issuing of a warning. The powers and function of the staff and case examiners are virtually the same where a performance assessment has been undertaken as when an assessment of health has been carried out. The only difference is that, where a doctor fails to comply with the reasonable requirements of the performance assessment team, the staff will have the power (without consultation with case examiners) to refer the case to a FTP panel for consideration of suspension of the doctor's registration or of the imposition of conditions on his/her registration.

25.237 One possible outcome of a case where a performance assessment has been carried out will be the issuing of a warning. A warning is likely to be considered by the case examiners in a case where an assessment report raises a significant cause for concern about a doctor's practice but not concerns of such magnitude as to warrant referral to a FTP panel. I am concerned about this proposal. Logically, if there is significant cause for concern, the case will have passed the investigation stage test that I have proposed and will warrant referral to a FTP panel. The case examiners or IC could, as an alternative to referral to a FTP panel, invite the doctor to agree to voluntary undertakings. Such a course would be preferable to the issue of a warning. If a warning is issued, there will be no one to follow up the cause for concern and to see whether the doctor has done anything to rectify his/her shortcomings. It may be said that the warning will be communicated to the employer or PCO who will then be responsible for supervision. That may be so and it may be well done or not. However, the GMC will have relinquished responsibility, notwithstanding the existence of 'significant cause for concern'.

Comment

25.238 Under the November 2004 Rules, in cases where a performance assessment has been carried out and where voluntary undertakings are given, the GMC staff will take over many of the functions which, under the old procedures, were exercised by medically qualified performance case co-ordinators. This is a very significant departure from the old arrangements and from those proposed in 2003. It is likely to have a considerable impact on the future operation of the performance procedures.

25.239 I have already expressed my concern about the changes to the health procedures which I believe will be detrimental to the quality of supervision provided by the GMC. The same concerns arise, for much the same reasons, in respect of the changes to the performance procedures. The professional expertise applied and the continuity of case management by medically qualified case co-ordinators, which were good features under the old procedures, will be lost. I am particularly concerned at the prospect that the staff will be able to close a case without referring it to case examiners. But that is not the only problem. I see from the November 2004 draft Investigation Manual that it is intended that there should be a team of staff dedicated to the provision of performance assessments. So be it. Arranging an assessment is an appropriate function for the staff. Deciding whether there should be one is another matter. Assessments are expensive and a staff member might be put under pressure not to order an assessment for financial reasons. Indeed, there are real reasons to fear that that might be so. The November 2004 draft Investigation Manual

refers to **'performance against service targets'** in respect of both health and performance assessments.

Disclosure of an Assessment Report to a Doctor's Employer or Primary Care Organisation

25.240 One very welcome development that was introduced in the May 2004 draft Rules was a requirement that, on receipt of the report of an assessment of a doctor's performance, the Registrar should send a copy, not only to the doctor him/herself but also to any person by whom the doctor was employed to provide medical services or with whom s/he had an arrangement to do so. Concern had been expressed at the Inquiry's hearings (and by the Performance Procedures Review Group, chaired by Dame Deirdre Hine, which reported to the GMC in April 2004) that this information was not given to those persons and bodies with local responsibility for doctors. The report of the Review Group had observed that a performance assessment report **'cannot be regarded as a private document between the GMC and the doctor'**. Receipt of the assessment report would have enabled employers and PCOs to have a better understanding of the nature and extent of the doctor's problems and to make an informed decision about the steps they should take to deal with those problems.

25.241 However, this provision was omitted from the July 2004 draft Rules and does not appear in the November 2004 Rules. In its place is a much more limited provision, whereby details of any relevant undertaking (save any relating exclusively to the doctor's health) will be disclosed to employers and PCOs and to any enquirer. This was done under the old procedures. There is now no mention of disclosure of assessment reports to employers and others. The proposal appears to have been dropped.

Comment

25.242 This is extremely disappointing. It is difficult to see how local NHS bodies can properly discharge their clinical governance obligations if they do not have access to this kind of information about the doctors for whom they are responsible. I have found no reference to this change of direction in the briefing papers distributed to Council members prior to the meeting in July 2004 at which the July 2004 draft Rules were approved. I know of no explanation for the change. I can see that information about undertakings is of some value but it cannot compare with the usefulness of the assessment report itself.

Cancellations of Referrals to a Fitness to Practise Panel

25.243 As I have explained in Chapter 20, in 2002, 20% of all referrals by the PPC to the PCC were subsequently cancelled by the PPC. Under the old FTP procedures, a decision to cancel required the agreement of the PPC. The complainant had to be consulted about the proposal to cancel; however, this was done only if the complainant was a private individual and not if the case had been referred to the GMC by a public body.

25.244 It is obviously important that cases that have been properly referred for a disciplinary hearing should not be cancelled without good reason.

The 2003 Proposals

25.245 Under the 2003 draft Rules, where the Presenting Officer (usually a solicitor or counsel instructed by the GMC to present the case before the FTP panel) considered, in the light of any evidence which had become available to him/her, that the fitness to practise of a doctor whose case had been referred to a FTP panel or an IOP was not impaired or that, for some other reason, the proceedings before the panel should not be held, s/he could have asked the IC or a case examiner to reconsider the case with a view to cancelling the referral to a FTP panel. It would have been open to the IC, had it wished, to delegate to a case examiner the task of deciding whether the referral of a case should be cancelled. No notice of the request to cancel a referral had to be given, either to the doctor or to the maker of the allegation. Nor was any guidance given as to how the task should be undertaken.

The 2004 Position

25.246 The May and July draft 2004 Rules contained significant changes to the proposed arrangements for the cancellation of a referral to a FTP panel or an IOP and these have been retained (with some further alteration) in rule 28 of the November 2004 Rules. A decision to cancel a referral is now to be initiated, not by the Presenting Officer, but by the Registrar (in practice, a member of the GMC staff). That member of staff may refer the case for a decision to any member of the IC (i.e. presumably, under the new arrangements for the composition of the IC, any person whose name appears on the list of persons eligible to sit on an IC panel, including some members of the GMC) or to the President. Those persons will be able to act alone and without consultation with others. The discretion given to them will be very wide. The November 2004 Rules permit a decision to cancel a hearing to be made, *inter alia*, if evidence becomes available (the May 2004 draft Rules would have required that the evidence be **'new'** but the July 2004 draft Rules and the November 2004 Rules removed that requirement) that suggests that a doctor's fitness to practise is not impaired or **'if it appears that for some other reason, the hearing before the Panel should not be held'**. There is still no requirement to notify the maker of an allegation that a cancellation is being considered, still less to consult him/her on whether this should be done. Once the decision has been made, rule 28 requires the Registrar to serve notice of the decision, together with the reasons for it, on the doctor and the maker of the allegation.

Comment

25.247 I am very concerned about this new rule for several reasons. First, the grounds on which the discretion exists to cancel a case are extremely wide. They could cover almost any eventuality. For that reason, the power of cancellation is open to abuse. It might be used where somebody (either a member of the administrative staff or a GMC member or another case examiner) is of the opinion that the case examiners' decision to refer a particular case to a FTP panel was wrong. Provided that a member of staff is willing to initiate the request (and it might be difficult for him/her to refuse if asked), any IC panellist will be able to cancel a referral with no formality whatsoever, without consulting any other member and without even notifying the maker of the allegation. I am concerned that GMC staff, worried about a backlog of FTP panel hearings or about some difficulty in arranging a hearing date

or the attendance of witnesses, might invite an IC panellist to cancel a hearing. It is even more worrying to think that it might become known which panellists were prepared to comply with such requests so that they could be 'hand-picked'.

25.248 In a recent letter to the Inquiry, the GMC said that the power of cancellation would be used **'in a small proportion of cases'** where the GMC's lawyers had advised that the case had no merit and that the hearing should not proceed. However, the Rules, as currently drafted, do not provide that the initiative to cancel a hearing should come from a lawyer, as the 2003 draft Rules did. It seems, therefore, that it must now be envisaged that a cancellation could be initiated by a non-legal member of staff. I am unsure what was meant by the assurance that the power of cancellation would be used in only a small proportion of cases. It was used in as many as 20% in 2002. I can see that improved investigation in the early stages should result in there being fewer cases where evidential problems arise after referral to a FTP panel. However, it remains to be seen how many cancellations will occur under the new procedures.

25.249 In my view, this rule should be changed. Cancellation of the hearing of a case that has been properly referred should not be undertaken lightly; nor should it be done in obscurity. Such decisions should be taken by a panel of the IC after careful consideration and the reasons for the decision should be formally recorded. The reasons given should be specific to the case and should not be general or formulaic. Both the doctor and the person making the allegation should be notified some time before the meeting at which the matter is to be considered and should be told why cancellation is to be considered. They should have the opportunity to make representations.

25.250 Whether the GMC adopts the changes I have suggested or resolves to continue with the arrangements it has currently made, there must be very careful monitoring and audit of the numbers of cancellations applied for and granted and the reasons for the decisions. These numbers and the reasons (anonymised as appropriate) should be placed in the public domain on an annual basis. In the past, the number of cases cancelled after referral did not usually feature in the GMC's annual FTP statistics. That was not acceptable as it provided an incomplete picture of what was actually happening.

Consensual Disposal of All Categories of Case

25.251 At its meeting in May 2004, the Council agreed that the GMC should request legislation to enable it to deal with all categories of case by means of 'consensual disposal arrangements', i.e. by the doctor giving voluntary undertakings about his/her future conduct or practice. Under the existing Rules governing the new procedures, such consensual disposal will be available only in cases involving a health or performance element. However, if the new proposal is brought into effect, conviction, caution and determination cases – as well as allegations of misconduct – could be disposed of by means of voluntary undertakings. The GMC is to ask the DoH to effect the necessary amendment to the legislation by way of an order under section 60 of the Health Act 1999. Meanwhile, there is to be consultation and detailed work is to be carried out on how such consensual disposal might operate.

Comment

25.252 It may be premature for me to comment but I think it would be helpful if I expressed my concerns about this proposal. My first concern is that cases dependent upon reports of convictions, determinations by another regulatory body and allegations of misconduct must, in my view, be dealt with in the public domain. I fear that 'consensual disposal' may take place in private. Second, I am concerned, particularly in respect of allegations of misconduct, that there may be no adequate resolution of the issues in dispute. In health and performance cases, there will be assessment reports which set out the nature and extent of the doctor's impairment of fitness to practise. This will not be so in a case of misconduct. Insofar as there is a dispute about the facts, there is a real danger that the factual issues will be 'fudged' by the GMC accepting the doctor's account of events, including all the mitigation. It may do so in order to avoid the cost and effort of a contested hearing. It may accept proffered undertakings – much as happened in some cases under the voluntary health procedures – on the ground that it is better for the public to be protected by voluntary undertakings than to take the risk that a FTP panel might find that the doctor's fitness to practise was not impaired or not sufficiently impaired to warrant the imposition of conditions on his/her registration. In my view, the GMC should proceed with extreme caution down the route to consensual disposal in all types of case, at least if the intention is, as I understand it to be, to operate such procedures in the investigation stage.

25.253 If there is to be consensual disposal in cases of misconduct, conviction and determination, there must be a hearing before a FTP panel sitting in public. In effect, such disposal must take place at the adjudication stage and not as part of the investigation stage. In conviction and determination cases, the FTP panel should be made fully aware of the underlying circumstances. The way in which this could be done might vary according to the nature of the proceedings. There might be a transcript of the previous proceedings. A police officer might give evidence of the circumstances of a conviction. In misconduct cases, there should be an agreed statement of facts on which the maker of the allegation should be entitled to comment in writing. The FTP panel should see both the statement and the representations so that, if it appeared that there was a significant dispute of fact, a full hearing could be held. The agreed statement should be put in the public domain. The FTP panel should have all relevant facts in the GMC's possession, including of course any previous FTP record. The FTP panel should satisfy itself that the proposed undertakings are sufficient to protect the public and to reflect the gravity of any offence. Afterwards, the doctor's compliance with his/her undertakings should be monitored and there should be provision for returning the case to the FTP panel in the event of a breach. However, this procedure would differ very little from the procedure now followed, where the doctor makes admissions and conditions are imposed.

Revival of Allegations

25.254 Under the old procedures, conviction cases and cases involving complaints about a doctor's conduct which had been closed by the screeners or by the PPC could be 'revived' if the GMC subsequently received notice of another conviction or complaint

about the same doctor. The Rules provided for a 'limitation period' of two years, after which an earlier report or complaint could not be revived. In Chapter 20, I questioned whether such a comparatively short period adequately protected patients. Cases involving complaints about performance could also be revived; no limitation period was specified in the Rules but, in practice, the GMC operated a 'cut-off' after three years.

25.255 In November 2001, when the new procedures were being developed, it was agreed by Council that it should be possible for a complaint closed at the initial stages of the procedures to be revived in the event of a new complaint being received. However, no such a provision appeared in the 2003 draft Rules, or in any subsequent draft. The November 2004 Rules make no specific provision for revival of allegations.

25.256 It seems to me that there should be proper provision for the revival of allegations previously closed. One can readily imagine circumstances in which an allegation which seemed relatively minor at the time it was considered assumes greater significance when another similar complaint is received subsequently. This is particularly so in cases involving allegations of deficient performance. It is important in the interests of patient protection that the GMC should, in those circumstances, be able to look at the picture as a whole, rather than being artificially limited to consideration of the subsequent allegation only. If there is to be revival of closed allegations in certain circumstances, it is important that the relevant provisions are contained in the Rules – not least so that doctors may be aware of the possibility of an allegation against them being reopened and of the circumstances in which this might be done. It is, in my view, entirely appropriate that there should be a limitation period after which it should not, save in wholly exceptional circumstances and in the interests of patient protection, be appropriate to reopen a previous complaint. I would suggest that that period should be significantly greater than the two or three years previously operated. I would suggest a period of five years.

Review of Investigation Stage Decisions

The 2003 Draft Rules

25.257 Under the 2003 draft Rules, IC panels and case examiners were to have the power to review one of their own decisions to refer or not to refer a case to a FTP panel or to dispose of the case by means of a warning. Such a review was to take place only where new evidence or information had become available which made such a review desirable for the protection of members of the public or otherwise in the public interest. The doctor was to be consulted and the IC panel or the case examiner was to take into account the doctor's interests, in addition to the public interest. There was no provision in the 2003 draft Rules for the maker of the allegation to be consulted about the proposal to review a decision – not even a previous decision to refer the case to a FTP panel – even though that person might have been in a position to comment on the new evidence or information and would plainly have had an interest in knowing that a review was to take place.

Discussion at the Inquiry

25.258 There was some discussion at the Inquiry seminars in January 2004 about the need for a speedy means of review of decisions taken at the investigation stage. In the past, the great

majority of cases reported to the GMC have been closed at a preliminary stage and in private, and it is anticipated that that will continue under the new procedures. It was thought, therefore, that, if public dissatisfaction were to be avoided, there should be some means of reviewing decisions to close cases taken at a preliminary stage. There was a large measure of agreement that such a review should be available both to the maker of the allegation and to the doctor concerned. However, most participants were of the view that the right of a doctor or maker of an allegation to seek a review should be circumscribed in some way. It was feared that, if doctors and complainants had an automatic right of appeal, the GMC would be inundated with unmeritorious applications. I can see the force of that. However, the Inquiry heard that, in the Canadian Province of Québec, any complainant who is dissatisfied with the preliminary decision of the body performing the equivalent 'screening' function to that of the investigation stage of the new procedures (the Inquiry Division of the Collège des Médecins du Québec) is entitled to a review by a review panel. Apparently, there is no problem with inundation there. It appears that, if a decision is taken at the 'screening' stage not to refer a case to a disciplinary hearing, the complainant receives a letter setting out the reasons for the decision in detail. I suspect that it is because the complainant receives a full and detailed explanation of the reasons for the decision that there are not too many unmeritorious applications for review.

The 2004 Position

25.259 The proposed provisions governing reviews changed in 2004. The July 2004 draft Rules removed the power of review from IC panels and case examiners and limited the decisions that will be susceptible to review. This remains the position under the November 2004 Rules. They provide that the President (and only the President) may review a decision not to refer an allegation to a FTP panel, a decision to issue a warning, or a decision by the case examiners to accept a doctor's voluntary undertakings following a health or performance assessment. There can be no review of a decision by an IC panel or case examiner to refer a case to a FTP panel. Nor, as I read the Rules, may the President review a decision by the Registrar (or member of staff) not to refer a case to a case examiner.

25.260 There are only two grounds on which a review will be granted. One is that there is information that the GMC has erred in its administrative handling of the case and a review is necessary in the public interest. The second is that there is new evidence or information which makes such review necessary for the protection of the public or for the prevention of injustice to the doctor, or that a review is otherwise necessary in the public interest. It follows that any doctor or maker of an allegation whose request for a review does not fall within those narrow limits but who is nevertheless dissatisfied with the decision will have to apply for judicial review. I am disappointed that the GMC has not felt able to act upon the experience of the Collège des Médecins du Québec, Montreal, and to offer an unfettered right to a review. If, as the GMC intends, makers of allegations which are not going to proceed to a hearing will receive a full letter of explanation of the decision, together with a copy of the CEDF, it would seem that there would be no real danger of an inundation.

25.261 The doctor and the maker of the allegation must be notified of a decision by the President to review a case and must be provided, where appropriate, with copies of any new

evidence received. The November 2004 Rules require that their representations on the proposed review must be sought. Where the President decides to review a decision, he may determine that the original decision should stand or he may refer the allegation to two case examiners for consideration as if it were an allegation being considered by them for the first time.

25.262 The decision on a review must be notified to the doctor concerned and to the maker of the allegation, together with any other person whom the Registrar considers to have an interest in receiving notification.

Comment

25.263 These new arrangements are in some respects a definite improvement on the 2003 proposals. The fact that the maker of the allegation is now involved in this process is a most welcome change. Also, the decision has been taken away from the IC or a case examiner. To have left it in their hands would not have been satisfactory, as there would have been no 'fresh look' at the case. Another improvement is that it is not possible under these provisions to review a decision to refer an allegation to a FTP panel. That is welcome, although it may increase the danger of surreptitious cancellations, about which I expressed my concern in paragraph 25.247. I am, however, concerned about the provision that the President alone should exercise these powers personally. There are two reasons for this: one of principle, one of practicality. There would be much to be said for giving the power of review to someone outside the GMC. It would allay public concern that the GMC is a 'closed shop' and protects doctors. It would also provide a useful means of external audit. The second reason is that the role of President is already extremely demanding and I do wonder whether it is sensible to impose upon him this additional burden. The amount of work that will be involved is, as yet, uncertain. Some case files are several inches thick. If the President is to reach a personal decision in each case, as opposed to ratifying a decision suggested by a member of staff, he will have to read the whole case file, possibly including close examination of medical records or a performance assessment report. He might find himself driven to delegate the task to others.

25.264 As I mentioned above, it appears that the present provisions do not allow for a review to right an error made by a member of staff in rejecting an allegation at the earliest stage, before referral to a case examiner. If so, this *lacuna* should be remedied.

Interim Orders

25.265 As I explained at paragraph 25.23, IOPs will take the place of the old IOC. The November 2004 Rules provide that it will be open to the Registrar at any stage to refer an allegation to an IOP for consideration of the making of an interim order. A single case examiner may direct the Registrar to refer a case to an IOP. The November 2004 Rules do not contain any similar power for the IC. However, the Guidance accompanying the draft Rules suggests that it will be open to the IC to make a **'recommendation'** that a case should be referred.

25.266 Hearings before an IOP will generally be in private, unless the doctor requests otherwise, or the IOP considers it appropriate for one of a number of reasons to hear the case in

public. An IOP may impose an interim order for a period of up to 18 months. Orders will be subject to periodic review.

The Adjudication Stage

25.267 I shall now consider the processes undertaken at the adjudication stage. I shall begin by examining the composition of the FTP panels which will hear allegations that have been referred to the adjudication stage.

Fitness to Practise Panels

The Composition of the Panel

25.268 As I have already said, GMC members will not be eligible to sit on FTP panels. However, the panels will work within an organisational and policy framework established and supported by the GMC. Panels will be composed of associates, some medically qualified and some not. They will be appointed, selected and trained by the GMC, which will also manage, monitor and appraise their performance. Continued service as a member of a FTP panel will depend on performance being satisfactory.

25.269 Panels will be chaired by panellists who have undergone assessment and have been appointed to act as chairmen. Chairmen may be medical or lay. At the Inquiry seminars, there was some discussion about the wisdom of having a legally qualified chairman. I discussed this issue in Chapter 21 and also drew attention to the recommendation of Miss Jean Ritchie QC in her report into the conduct of Rodney Ledward. She expressed the view that the chairmen of PCC panels should be legally qualified. Plainly, FTP panels need legal advice and expertise. In the past, this has been provided by a legal assessor and, in the immediate future at least, it is intended that this should remain the case. Some legal assessors are no doubt very good. I have also seen transcripts of advice given by legal assessors that has been unclear or even frankly wrong. Even if the legal assessor is completely competent, there are limitations on the role s/he can play. He or she cannot direct the course of the FTP panel's deliberations so as to ensure that matters are considered in a logical order and that only evidence relevant to the issue under consideration is taken into account. It is difficult to teach these skills to a non-legal chairman who may sit on a GMC panel only a few times in a year. Also, as I observed in Chapter 21, the GMC has to teach its chairmen how to conduct a hearing and what to say at each stage of the proceedings. Such matters would be second nature to a legally qualified person.

25.270 In November 2001, the Council agreed (by 36 votes to 35) that, under the new procedures, FTP panels hearing conduct cases which met appropriate criteria should have a legally qualified chairman. It was envisaged that a legally qualified chairman would be appointed in long or complex cases, in cases involving many difficult legal or procedural issues and in certain high profile or particularly controversial cases. A decision as to whether a legal chairman should be appointed would be taken at the case management stage. Internal GMC documents show that the November 2001 decision was still extant a year later. In May 2003, Council agreed that, if a legally qualified chairman was appointed to chair a

hearing of a conduct case, a legal assessor should also be appointed. Since May 2003, it appears that the intention to use legally qualified chairmen has been abandoned. Sir Graeme Catto told the Inquiry that the GMC had discussed the idea of using legal chairmen in the recent past and had decided to 'leave that option open'. He said that some associates eligible to sit on PCC panels were legally qualified; he did not know whether any of them have ever chaired a panel.

25.271 My view on this issue is that, if the GMC retains control of the adjudication stage, it should enrol some legally qualified chairmen and should try them out, starting with the more complex cases. If they are found to be a success, the practice could be extended. It seems to me that the new procedures are bound to throw up new legal points. Some of them might well be complex. The presence of a legally qualified chairman might help to ensure that decisions on such points were right, from the start. If the idea were taken up of having a corps of panellists who would sit on cases from all the healthcare regulatory bodies, it would be possible to have full-time legally qualified chairmen.

25.272 In addition to a legal assessor, FTP panels may, in a case involving a health or performance element, receive advice from one or more specialist health advisers or specialist performance advisers selected by the Registrar from a panel maintained for the purpose. A legal quorum for the FTP panel will be three, including at least one lay and one medical panellist. GMC staff will act as secretaries and clerks to the FTP panels. The September 2004 draft Guidance for Panellists suggests that a doctor will be able to apply for a specialist adviser to be appointed in a case including allegations of misconduct. I think this must be intended to provide panellists with advice about the practice and standards to be expected within a particular medical specialty.

Notice of Referral to a Fitness to Practise Panel

25.273 Following a decision to refer a doctor to a FTP panel, s/he will be sent a notice of referral containing certain specified information. The November 2004 Rules provide that the allegation(s) and the facts on which it/they are based must be particularised. The 2003 draft Rules had merely required them to be summarised. It is a fundamental rule of natural justice that a person facing any form of disciplinary process must have adequate notice of the charges s/he is to face. If a doctor is facing a specific allegation of misconduct, it is vital that s/he is told exactly what is alleged. However, it does appear to me that, in some types of case (for example, one that depends to a large extent upon a performance or health assessment), it would be sufficient if the doctor were to be told (adopting the words of the adjudication stage test proposed by the GMC) that it was alleged that his/her fitness to practise was impaired (to a degree justifying action on registration) by reason of the matters contained in the assessment report. Even in conduct cases, I doubt that the degree of particularity that appears to have been given in the past is necessary for the giving of proper notice to the doctor. Reading some PCC decisions, it appears that the proceedings have been broken down into the consideration of every single element which must be proved in order to support the allegation of SPM. I do wonder whether this is really necessary; it fosters the impression that these are criminal proceedings, whereas they are not.

25.274 The Guidance accompanying the July 2004 draft Rules stated (and the passage appears also in the Guidance accompanying the November 2004 Rules):

> **'Where appropriate, the GMC will also notify the practitioner of the outcome it will be seeking at the relevant hearing.'**

25.275 This process is not provided for in the Rules. The thinking is that it will be helpful and fair to doctors. In effect it lets them know the worst that could happen to them. I can see that an indication that the GMC is not seeking erasure or suspension might encourage a doctor to make admissions, secure in the knowledge that the worst that can happen is the imposition of conditions or restrictions. He or she might even be able to negotiate a set of conditions which could be entered into voluntarily. However, it does seem to me that there are real disadvantages in such a practice. In the first place, once the GMC has pitched its desired outcome at a certain level – say, the imposition of conditions – it will be extremely difficult for a FTP panel to impose a more serious sanction. The effect will be to tie the panel's hands. Second, an early indication of the desired outcome is likely to colour preparations for the hearing by both the doctor and the GMC. If the FTP panel were determined to take a different view, there would be the potential for unfairness to the doctor. Third, I remind the reader that, when the GMC was thinking about the form of its new procedures, it wished to create some real separation between the adjudication and investigation functions. It chose to keep the investigation function in-house and the FTP panels were supposed to have some real independence. In fact, they have precious little. Panellists are to be selected, appointed, trained, issued with guidance, appraised and possibly dismissed by the GMC. If, in addition, the GMC seeks effectively to impose an upper limit on the sanction available in an individual case, the independence of FTP panels will be further reduced.

25.276 Moreover, it appears that the present proposals may go beyond the giving of an indication as to what sanction the GMC will seek. **'Outcome'** could include the giving of undertakings which might be accepted without any findings of fact or decision about impairment of fitness to practise. I have already expressed my views about the need, in the public interest, for clarity in the resolution of cases involving misconduct, convictions and determinations.

25.277 I think that the GMC should think again about this whole idea. I do not think that any indication of the GMC's preferred outcome should be given in advance of the hearing. It would create an expectation on the part of the doctor which, if not fulfilled, would be unfair to him/her and which, if fulfilled, may not provide adequate protection for patients. Moreover, it may be that, if the case is contested, it becomes more serious as the evidence unfolds. If the GMC is to put forward its views on the appropriate outcome, this should, in my view, be done, as it has been done in the recent past, at the hearing before the FTP panel. If this course is followed, it should be made clear to all that the GMC is only making a submission and that the FTP panel is under no obligation to heed it.

25.278 The Guidance accompanying the November 2004 Rules is silent on the question of who at the GMC is to decide what outcome the GMC will be seeking in any individual case (although the Registrar is given responsibility for serving the notice of referral). I do not know who it is intended should decide where the desired outcome is to be pitched. I am

not aware of any provision in the Rules relating to the old or the new procedures that entitles any particular person or panel or committee to make such decisions. If a decision of this importance is to be made, the person or body making it should be formally authorised to do so on the GMC's behalf and proper criteria for such decisions should be agreed and published.

25.279 The September 2004 draft Guidance for Panellists gives no advice about how FTP panellists should approach cases where the GMC has given an indication of the desired outcome. Indeed, it does not mention the fact that such an indication might be given. These are important matters on which guidance should surely be given.

Evidence Gathering

25.280 The November 2004 Rules do not appear to contain any specific provision for further investigation of a case after referral to a FTP panel. The Guidance which accompanies the November 2004 Rules says that, before sending out a notice of referral, the Registrar will undertake such further investigations (including instructing solicitors to procure witness statements and other documentary evidence) as are necessary for the satisfactory presentation of the GMC's case at the hearing. In my view, there should be enshrined in the Rules a specific power to investigate further. This should empower the GMC to require the production of any evidence, documentary or otherwise, in the event that anyone might seek to impede such investigations.

Case Management

25.281 In the past, considerable problems arose with the arrangements for hearings before PCC panels. There was no formal mechanism for case management. As a consequence, there were no proper arrangements for disclosure of evidence and no reliable means of ascertaining the likely length of cases or of scheduling them at times when the parties and witnesses were available. This led to the frequent adjournment of cases, with consequent inconvenience, delay, expense and, no doubt, distress both to witnesses and to the doctors concerned. In the recent past, some informal management of cases referred to a PCC panel was undertaken. However, participation was entirely voluntary. A very welcome aspect of the new procedures is the introduction of a formal system of case management with pre-hearing case management reviews.

25.282 The case management provisions apply to initial referrals to a FTP panel and also to subsequent hearings to review a case (where a doctor's registration has been suspended or made subject to conditions) and to applications for restoration of a doctor's registration. The case management reviews will be conducted by a legally qualified Case Manager. The November 2004 Rules provide that the Case Manager should act independently of the parties. He or she is to be a quasi-judicial figure, who will be contracted part-time by the GMC to deal with case management reviews. Case management reviews will usually take place by telephone conference. The Case Manager will give directions to secure the **'just, expeditious and effective'** running of the hearing before the FTP panel.

25.283 The November 2004 Rules set out detailed provisions for one or more case management reviews in advance of a FTP panel hearing. The provisions (which have been extensively

revised since they first appeared in the 2003 draft Rules) cover such matters as the disclosure of documents, exchange of witness statements, exchange of expert evidence, and exchange of skeleton arguments. They also cover the provision of time estimates and suggested dates for hearings. They provide for the parties to state whether the health of the doctor is to be raised as an issue and for the doctor to give prior notification of the extent to which facts and evidence are admitted. There is provision for the Case Manager to direct the parties to provide a statement of agreed facts in a case where an allegation is admitted. In short, the case management provisions should enable the parties and members of the FTP panel to prepare properly for hearings, should avoid the unnecessary attendance of witnesses and should reduce to a minimum the frequent adjournments which were in the past made necessary by the late disclosure of important evidence.

25.284 The November 2004 Rules also provide for certain 'automatic' directions to take effect in the absence of any direction by a Case Manager or of agreement by the parties to the contrary. These are applicable to hearings by both FTP and IC panels. These directions require each party not less than 28 days before the date of the hearing to provide to the other party a list of every document which s/he proposes to introduce as evidence, together with a copy of every document which the other party has not previously received. They also require each party to notify the other, within 14 days of receiving the list, whether or not s/he requires any person to attend to give oral evidence in relation to the subject matter or making of any document. Even where one party notifies the other that s/he requires a person to attend, the IC or FTP panel has discretion to dispense with the need for oral evidence in certain circumstances.

25.285 The November 2004 Rules provide that a FTP panel may draw such inferences as it considers appropriate in respect of the failure by a party to comply with directions issued by the Case Manager. There had been concern that the case management provisions would have no 'teeth', since there was no sanction available if directions were not complied with. It was suggested that the risk that adverse inferences might be drawn from the result of non-compliance should be a deterrent. It was also suggested that a party who failed to comply might be penalised in costs. However, it appears that the idea of imposing a penalty on costs has not been adopted; instead, the drawing of adverse inferences is to be allowed. The Guidance which accompanies the November 2004 Rules states that failure to comply with the directions of the Case Manager might lead, not only to the drawing of adverse inferences, but also to evidence not being admitted at the FTP panel hearing. That provision is not in the Rules, although I suppose it might be said that an IC or FTP panel has a discretion to refuse to admit any evidence for good reason. I am rather concerned about the provision that an adverse inference may be drawn against a party who has failed to comply with a case management order. I would have thought that it would be proper to do that only in a most exceptional case, where a flagrant refusal to comply is consistent only with the desire to conceal a particular piece of evidence. In general, I would have thought it dangerous to draw adverse inferences from what may be no more than a failure to comply due to incompetence and disorganisation. One must not lose sight of the objective of the proceedings, which is to arrive at the truth. I think that a penalty in costs would usually be more appropriate. That can sometimes teach an incompetent solicitor to do better in future. If such a penalty were available against a doctor, it would have also to be available against the GMC.

Comment

25.286 Taken as a whole, I regard these new case management provisions as a very good idea. However, their effectiveness will be directly related to the amount of effort that is put into them by the Case Managers. In the course of my work as a judge, I have seen many case management orders which simply follow a standard form and are not adequately tailored to the specific circumstances of the case. That is a danger where automatic directions are allowed to operate or where the parties are allowed to agree an order. Good case management requires that the judge (or Case Manager) has the time and inclination to read the papers thoroughly, to get a clear grasp of the issues, to ask a lot of questions about the way in which the case is to be presented and to make orders that will ensure that the parties are ready with their evidence and that no one is taken by surprise. I hope that these provisions will have the desired effect. The work of Case Managers should be audited to ascertain the extent to which they achieve their objective of avoiding adjournments, disrupted hearings and the unnecessary attendance of witnesses.

25.287 The Guidance accompanying the November 2004 Rules suggests that case management reviews may not be necessary for cases which rely to a large extent on health or performance assessments. I recognise that the GMC has a good deal of experience of such cases. However, I must say that the impression I have, from reading the transcripts of one or two performance cases, is that a case management review would have been most helpful. Miss Jackie Smith, Head of the Performance Section, told the Inquiry about one performance case in which the doctor had called 36 witnesses. I would have thought that robust case management might have helped to avoid such a situation.

The Hearing: the Parties

25.288 The November 2004 Rules state that the 'parties' to a hearing before a FTP panel are the GMC and the doctor, or their respective representatives. Under the new procedures, it will no longer be open to the maker of an allegation to present the 'prosecution case'. Doctors are expected to attend hearings. They are entitled to be represented by counsel or a solicitor, or by a representative of their professional organisation, or, in certain circumstances, by a member of their family or another person. The GMC will be represented by the Presenting Officer. If the doctor does not appear, the FTP panel may, in certain circumstances, proceed to hear the case in his/her absence.

The Hearing: Public or Private

The 2003 Proposals

25.289 The 2003 draft Rules provided that, except where considering a health allegation (and in certain other special circumstances), a FTP panel must sit in public. The Guidance which accompanied the 2003 draft Rules, however, stated that, where a FTP panel was considering an allegation of adverse health or of deficient performance, the presumption was that the case should be heard in private. The proposals at that stage, therefore, created uncertainty as to whether it was intended that a case involving an allegation of deficient performance should be heard in public or in private. This topic had been the subject of debate within the GMC for some time.

The 2004 Position

25.290 The November 2004 Rules provide that hearings before a FTP panel should in general take place in public. They provide that a hearing before a FTP panel should be in private when the panel is considering a doctor's physical or mental health. They also provide that it should be open to a FTP panel, in certain circumstances, to hold a public hearing in a health case. Such public hearings are likely to be unusual.

25.291 A FTP panel may, of course, engage in private deliberations (i.e. discussions about the decisions it has to make or about other issues relevant to a case) at any stage of a hearing.

The Hearing: Standard of Proof

25.292 The November 2004 Rules are silent on the standard of proof to be applied by FTP panels. The Guidance accompanying the November 2004 Rules states:

> **'Where it is making a finding on disputed facts, the panel must be sure of its decision.** (*That means that the criminal standard of proof is applied to findings of fact.*) **The issue of whether the practitioner's fitness to practise is impaired, and the imposition of a sanction, or warning, are matters of professional judgment.'**

25.293 The Guidance goes on to deal with decisions relating to sanction:

> **'The panel must be sure that any proposed action (whether to close a case with or without a warning, or to impose a sanction on the doctor's registration) is sufficient to protect patients and the public interest, failing which it must consider taking action against the practitioner's registration or imposing a more severe sanction, as appropriate.'**

25.294 Both IC and FTP panels may, where it would be just to do so, consider and determine together two or more allegations against the same doctor within the same category or the separate categories of impairment listed in section 35C(2)(a)–(e). They may also consider and determine together allegations against two or more doctors. The Guidance accompanying the November 2004 Rules states:

> **'Hearings will, therefore, be holistic, in that allegations will be brought forward based on the totality of the evidence obtained during the investigation stage (including, where appropriate, health and performance assessment reports) and may comprise a combination of allegations relating to a doctor's health, performance or conduct, or based on a caution, conviction or determination.'**

25.295 In a recent letter to the Inquiry, the GMC observed that it would not be possible to approach the issue of standard of proof, as in the past, on the basis that it was determined by the category of case being heard. The letter stated:

> **'... the GMC appreciates that there are practical issues to be resolved and is therefore in discussion regarding its approach to the standard of proof and the way in which hearings will operate in this respect.'**

25.296 Mr Scott told the Inquiry that hearings would not be labelled 'health', 'conduct', 'performance', 'conviction' or 'determination'. Instead, hearings will deal with allegations of various kinds, side by side. There will not be different processes according to the nature of the allegation made. Mr Scott gave the example of a performance case where a complaint had been made about a specific incident or incidents. He said that, if evidence could be adduced to support the complaint, then the subject matter of the complaint could be asserted as a fact and the criminal standard of proof would apply to the making of a decision as to the truth or otherwise of that fact. If, however, the evidence to support the complaint was not available, the subject matter of the complaint could be used merely as a 'trigger' to carry out a performance assessment and would not feature in the list of charges. The relevant evidence before the FTP panel would then be the assessment report and the criminal standard of proof would not apply.

Comment

25.297 The issue of what standard of proof should be applied in GMC proceedings is a thorny problem. The GMC has always maintained that, out of fairness to the doctor, the criminal standard of proof must be applied to findings of fact in conduct cases. In Chapter 21, I observed that it seems something of a paradox that the GMC should insist on the criminal standard of proof and yet allow findings of fact to be made on a bare majority decision. I suggested that the civil standard was more appropriate in proceedings which had the protection of patients and the public interest as their primary objectives. In the case of Sadler v General Medical Council[2], the Court observed that the appropriate standard of proof in a performance case was the civil standard. Under the new procedures, a FTP panel may have to decide issues of conduct, performance and possibly health during the same hearing. It would be quite a tall order for them to direct themselves properly as to the different standards of proof, especially without the guidance of a legally qualified chairman. In my view, the appropriate standard of proof within a protective jurisdiction is the civil standard. In proceedings affecting the welfare and safety of children, the civil standard of proof is applied, notwithstanding the facts that the allegation considered might also amount to a criminal offence and the consequence of an adverse finding might well be the loss of contact with a child. I shall recommend that the GMC adopts the civil standard of proof for all cases, except, perhaps, those allegations of misconduct which also amount to a serious criminal offence, for which cases the criminal standard of proof would arguably be appropriate.

The Hearing: Procedure

25.298 The procedure to be followed at a hearing of a FTP panel was set out in the 2003 draft Rules but has been extensively revised since. I do not propose to set out the procedure in detail. Its main elements, as they appear in the November 2004 Rules, can be summarised briefly.

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[2] [2003] 1 WLR 2259.

Evidence about the Facts

25.299 Following any preliminary legal arguments, the doctor will indicate whether s/he wishes to make any admissions. Where facts are in dispute, the Presenting Officer will open the case for the GMC and may adduce evidence and call witnesses in support of the case. As at present, witnesses will give evidence on oath or will affirm. They can be compelled to attend.

The Admission of Hearsay and Other Inadmissible Evidence

25.300 There is no significant change to the rule governing the admissibility of evidence. The November 2004 Rules provide that an IC panel or FTP panel may:

> **'... admit any evidence they consider fair and relevant to the case before them, whether or not such evidence would be admissible in a court of law'**.

That provision is subject to a proviso:

> **'Where evidence would not be admissible in criminal proceedings in England, the Committee or Panel shall not admit such evidence unless, on the advice of the Legal Assessor, they are satisfied that their duty of making due inquiry into the case before them makes its admission desirable.'**

This provision is very similar to the equivalent rule under the old procedures. I hope that, in the future, FTP panels will be more ready to admit hearsay evidence than they have been in the past.

Vulnerable Witnesses

25.301 A welcome development is the rule providing for the treatment of vulnerable witnesses, including young people and witnesses who claim to have been the victim of a doctor's sexual misconduct. The rule enables an IC or FTP panel to use such measures as video links, pre-recorded evidence, interpreters or intermediaries, screens and the hearing of evidence in private to assist such witnesses. A doctor who is unrepresented will not be permitted to cross-examine a witness who claims to have been a victim of sexual misconduct by him/her without the written consent of the witness. Instead, the doctor (or, failing that, the GMC) must appoint a legally qualified person to cross-examine on his/her behalf. The FTP or IC panel must take into account the advice of the legal assessor and any representations from the parties in relation to the treatment of vulnerable witnesses.

Inquisitorial or Adversarial Proceedings

25.302 Historically, proceedings before the PCC panel were adversarial in nature. Recently, there has been some discussion about the possibility of adopting a more inquisitorial procedure, whereby it would be open to panellists to explore areas of evidence not covered by the parties' advocates.

25.303 In its 2001 Consultation Paper, the GMC said:

> **'There is a concern that PCC hearings are oppressive and upsetting, particularly to witnesses. Although a move to a more inquisitorial procedure would not negate the need for the evidence of witnesses to be thoroughly tested, it is arguable that a less adversarial approach would create a greater sense of an impartial investigation of the facts and achieve the same results, while causing less distress to those questioned. Any changes would have to safeguard the rights of doctors to defend themselves fully. The GMC's preferred direction is towards a more inquisitorial model, and it intends to commission work, drawing, where appropriate, on best practice elsewhere, to explore the possibility of developing an inquisitorial process for the PCC which would not compromise the doctor's right to a fair hearing.'**

25.304 The proposed move to a more inquisitorial process was supported by a large majority of respondents to the 2001 Consultation Paper, both medical and lay.

25.305 Following the consultation process, the GMC examined some examples of inquisitorial processes, but concluded that the existing style of PCC hearings should be retained. In coming to that conclusion, the GMC emphasised the extent to which members of the PCC were involved in questioning witnesses. Indeed, it suggested that the process before the GMC was not (as it appeared to have accepted in its 2001 Consultation Paper) purely adversarial, but was instead **'hybrid'**, in that it incorporated both adversarial and inquisitorial elements.

25.306 In fact, while FTP panellists are able to ask some questions, they are not encouraged to allow their questions to range too widely. The September 2004 draft Guidance for Panellists advises that **'the purpose of the Panel's questions is to seek clarification, not to cross-examine the doctor or witness'**. The intention seems to be that panellists should ask questions only to clarify issues that have already been raised. In my view, this is a pity. I have seen examples of cases before PCC panels in which the advocates on both sides had failed to explore an issue which was of real importance. An example was the case of Council for the Regulation of Healthcare Professionals v General Medical Council and Solanke[3], in which the doctor had admitted to the PCC having an improper relationship with a vulnerable patient and that he was, therefore, guilty of SPM. Neither counsel had sought to explore the circumstances in which the relationship had begun. This was plainly an important issue. The outcome of the case was the imposition of a sanction that appeared to the CRHP/CHRE, to be unduly lenient. It appealed to the High Court. The Judge held that, on the basis of the information available, the decision was at the lenient end of the spectrum but not unduly lenient. He pointed out, however, that the case had not been properly investigated and that no questions had been asked at the hearing about how the relationship had begun. This was, the Judge said, 'a serious failing'. Had it been regarded as acceptable for panellists to explore issues for themselves, this might have occurred in the case of Solanke and all the relevant facts might well have emerged.

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[3] [2004] EWHC 944 (Admin).

25.307 In my view, there should be a change of policy on this issue. I do not suggest that GMC proceedings should become purely inquisitorial. However, I do think that they should become more inquisitorial in that panellists should be encouraged to ask questions and to explore issues which they think are of relevance, even if it appears that the parties do not intend to do so. The objective of the hearing is, after all, to enable the panel to reach the right decision for the protection of patients and the public.

Submissions Made and Evidence Adduced by the Doctor

25.308 At the conclusion of the GMC's evidence, the doctor may submit to the FTP panel that the evidence which has been adduced is insufficient to enable the panel to find the facts proved, or to support a finding of impairment of fitness to practise. If such a submission of 'no case' is made, the FTP panel must consider and announce its decision whether to uphold the doctor's submissions. If no submission is made, or if a submission fails, the doctor may then open his/her case and may adduce evidence and call witnesses in support of it. The chairman of the FTP panel will then ask the specialist adviser(s), if any, to give any advice on the medical issues. The legal assessor may be invited to give advice on points of law.

The Panel's Findings of Fact

25.309 The FTP panel will then consider the evidence and announce its findings on the facts. The May 2004 draft Rules provided that, save in exceptional circumstances, a FTP panel should not be required to give reasons for its findings of fact. That provision did not appear in the July 2004 draft Rules, nor does it appear in the November 2004 Rules. It was not at first clear to me whether this change in the Rules meant that FTP panels would always give reasons or whether it merely indicated that the GMC no longer considered that the issue needed to be covered by the Rules. I hoped that the former was the case because it is important, in the interests of transparency, that the parties and the public understand why a FTP panel has decided as it has at all stages of the proceedings. However, the September 2004 draft Guidance for Panellists says that panels will not normally be required to give reasons for findings of fact unless it is necessary to do so. Examples given are when it is necessary to **'clarify the finding of fact'** or **'in other exceptional circumstances'**. I do not think this is at all satisfactory. It is important, as I have just said, that the parties and the public should understand why decisions have been reached. I do not suggest that elaborate explanations should be given. Nor should it be necessary for the panel to deal with every single disputed fact. However, panels ought to explain their findings on the crucial factual issues and it should be possible for this to be done in a few sentences. I can see that this would be easier for a legally qualified chairman than for one who is not.

Evidence and Findings on the Issue of Fitness to Practise

25.310 A FTP panel will have the power, under rule 17(4), before making a determination whether a doctor's fitness to practise is impaired, to direct a health or performance assessment. This is a welcome development and means that a FTP panel will be able to get a more

rounded picture of the doctor than at present. On receipt of the assessment report, the FTP panel may then proceed to consider and determine the allegation or may, under rule 17(5)(b), refer the allegation back to the Registrar for referral to the case examiners so that they can consider whether it would be appropriate for the doctor to be dealt with by way of voluntary undertakings.

25.311 This latter provision causes me some concern. It is obviously useful that a FTP panel should be able to obtain the assessment but it would be thoroughly unsatisfactory if, having received the assessment, the panel could avoid making findings of fact or a decision whether the doctor's fitness to practise is impaired. That appears to be the effect of the provision I have just mentioned. So, for example, in a case where a doctor has been convicted of offences of dishonesty in the context of drug addiction, there will be a referral to a FTP panel but the panel, on receiving a health assessment, might send the case back for voluntary undertakings without there being any finding of impaired fitness to practise. This really will not do. If the GMC is to regain the confidence of the public, it must be seen to be taking appropriate action. Once seized of a case, a FTP panel must reach a decision. It could still send the case for voluntary undertakings if it thought that that was appropriate after deciding that there was impairment of a degree justifying action on registration. However, in my view, the better course would be for the FTP panel to impose conditions itself and to have the same supervisory arrangements for conditions imposed by a FTP panel as for voluntary undertakings.

25.312 Apart from exercising its power to order a health or performance assessment, the FTP may also receive any further evidence and hear any further submissions from the parties as to whether, on the basis of any facts found proved, the doctor's fitness to practise is impaired.

25.313 The 2003 draft Rules specifically provided for FTP panels to receive evidence about a doctor's past history before making a finding in relation to impairment of his/her fitness to practise. The Guidance which accompanied the 2003 draft Rules stated that the Presenting Officer would be able to adduce evidence about previous warnings issued by the IC and findings by a FTP panel that the doctor's fitness to practise was impaired. This was at the stage after the FTP panel had made its findings of fact and before it made a decision as to the doctor's fitness to practise.

25.314 By contrast, there is no explicit provision in the November 2004 Rules which requires a FTP panel to take into account a doctor's FTP history. The Guidance which accompanies the November 2004 Rules is silent on this point, as is also the September 2004 draft Guidance for Panellists. This omission is puzzling as it surely cannot be intended that FTP panels should not consider this information. It may be that the GMC had concluded that there is no need to make provision for it in the Rules. There was such a provision in the General Medical Council Preliminary Proceedings Committee and Professional Conduct Committee (Procedure) Rules Order of Council 1988, under the old procedures, and there is a provision in the November 2004 Rules governing the procedure of IC panels when considering warnings. Why is there no such provision for FTP panels? It might have been omitted by mistake, but then one would have expected to see reference to consideration of the doctor's past history in the September 2004 draft Guidance for Panellists. But it is

not there either. I think it should be spelled out exactly what previous history (if any) the FTP panel will look at and at what stage.

25.315 In Chapter 21, I mentioned my concern that PCC panels often took purely personal mitigation into account when deciding whether a case of SPM had been proved. I explained my view that such personal mitigation was quite irrelevant to the issues of SPM, but that PPC panels might have been misled by the decision of the Judicial Committee of the Privy Council in the case of Rao v General Medical Council[4], which was based upon a misunderstanding of what had been said in the case of Preiss v General Dental Council[5]. This problem should not arise under the new procedures because purely personal mitigation will be relevant to the issue of whether a doctor's fitness to practise is impaired. The whole picture will be relevant including past misconduct, past problems of health or performance and personal mitigation.

The Test to Be Applied

25.316 When it has received the further relevant evidence, the FTP panel will deliberate and will announce its findings on impairment of fitness to practise. It must give reasons for its decision. Rule 17(2)(k) of the November 2004 Rules requires a finding as to whether the doctor's fitness to practise is 'impaired'. The rule does not add the words 'to a degree justifying action on registration'. The rule correctly reflects the statutory test in section 35D of the 1983 Act. Inconsistently with that, the September 2004 draft Guidance for Panellists says that FTP panels will decide whether fitness to practise is impaired **'to a degree justifying action on registration'**. This kind of inconsistency is very confusing. The position is this. The first task of the FTP panel is to decide whether the doctor's fitness to practise is impaired. I have suggested a test that it should apply. If it finds that the doctor's fitness to practise is not impaired, the panel will usually take no further action although it may, under section 35D(3), give the doctor a warning as to his/her future conduct or performance. If the FTP panel decides that the doctor's fitness to practise is impaired, it should then go on to decide (under rule 17(2)(l)) what sanction to impose. It is at that stage that the panel must decide whether the impairment is such as to justify action on registration. Although the draft Guidance advises panellists that they may (in wholly exceptional circumstances) decide that fitness to practise is impaired and yet take no action, I find it hard to imagine circumstances in which that would be appropriate if the FTP panel found that the impairment of fitness to practise was of a degree justifying action on registration. What the FTP panel can do if it finds that the doctor's fitness to practise is impaired, but not to a degree such as to justify action on registration, is not entirely clear. I will return to this point very shortly.

The Hearing: Consideration of Sanctions or Other Action

25.317 If the FTP panel finds that the doctor's fitness to practise is impaired, it will then receive further evidence and will hear any further submissions from the parties about the appropriate sanction, if any, to be imposed. At any stage before making its decision as

[4] [2003] Lloyd's Rep Med 62.
[5] [2001] 1 WLR 1926.

to sanction or warning, the FTP panel may adjourn for further information or reports to be obtained in order to assist it in exercising its function. The Presenting Officer and the doctor's representative are expected to refer to the relevant part(s) of the GMC's Indicative Sanctions Guidance for Fitness to Practise Panels. The FTP panel chairman will again invite the specialist adviser(s), if any, and the legal assessor, to provide advice on the medical and legal issues.

25.318 The FTP panel will then consider and announce its decision whether to impose a sanction or a warning or to **'take into account'** undertakings that have been offered. It must give reasons for its decision. Decisions of the FTP panel are taken by a simple majority. No abstentions are permitted and there is no casting vote. Where the votes are equal, the FTP panel must decide the issue under consideration in the doctor's favour. The only exceptions to this latter rule occur when a FTP panel is considering a submission of 'no case' or where a FTP panel is considering an application to restore a doctor's name to the register, in which case the issue must be resolved against the doctor where the votes are equal.

Sanctions

25.319 Section 35D(2) of the 1983 Act provides that, where a FTP panel finds that a person's fitness to practise is impaired, it may if it thinks fit:

> **'(a) except in a health case, direct that the person's name shall be erased from the register;**
>
> **(b) direct that his registration in the register shall be suspended ... during such period not exceeding twelve months as may be specified in the direction; or**
>
> **(c) direct that his registration shall be conditional on his compliance, during such period not exceeding three years as may be specified in the direction, with such requirements so specified as the Panel think fit to impose for the protection of members of the public or in his interests'**.

25.320 These sanctions are the same as those that were available to the PCC. In addition, the PCC had a specific additional power to admonish a doctor in a case where it had found the doctor guilty of SPM but had decided to take no action. After 1999, the term 'reprimand' was used instead of the rather old-fashioned 'admonishment'. A significant change from the past is that, whereas erasure was not available as a sanction to the CPP in a performance case (although indefinite suspension was, in certain circumstances), it will be possible for a FTP panel to direct that the name of a doctor should be erased from the register if it finds his/her fitness to practise impaired by reason of deficient professional performance. The power to impose a sanction is discretionary and it is therefore open to a FTP panel to take no action even after a finding that a doctor's fitness to practise is impaired to a degree justifying action on registration. As I have said, I find it difficult to imagine circumstances in which that would be appropriate.

25.321 A doctor is entitled to appeal to the High Court against a decision of a FTP panel. The FTP panel's determination will not usually take effect until the period for an appeal to be lodged (28 days) expires, or until the appeal itself has been determined. Where a FTP panel considers it necessary for the protection of members of the public, or in the interests of the public or the doctor, it may impose an order of suspension or conditions that will take effect immediately. The power to impose immediate conditions on a doctor's registration is new and welcome.

Warnings

25.322 As I have noted earlier, section 35D(3) provides that, where a FTP panel finds that the doctor's fitness to practise is not impaired, it may nevertheless issue a warning about his/her future conduct or performance. I can understand why this provision has been inserted. It would be appropriate in a case in which the doctor had done something wrong, possibly making a prescribing error or missing a diagnosis (so that his/her fitness to practise had at the relevant time been impaired), but had taken immediate steps to rectify his/her shortcomings so that, by the time the case came before the FTP panel, his/her fitness to practise was no longer impaired. The September 2004 draft Guidance for Panellists suggests that a warning may be given where there is significant cause for concern after a performance assessment. I have already expressed my reservations about the usefulness of that procedure, if there is to be no form of follow-up.

25.323 Strangely, section 35D does not give the FTP panel the power to issue a warning where it has found an impairment. This *lacuna* must surely be unintentional and must be remedied. It is absurd that the FTP panel may find that the doctor's fitness to practise is impaired, although not to a degree justifying action on registration, but that it could not then issue a warning. I think that the GMC has become confused because it forgets that the statutory test is 'impairment of fitness to practise' not 'impairment to a degree justifying action on registration'. For the avoidance of doubt, I repeat that, in my view the scheme should be as follows:

- if the panel finds no impairment it will either take no action or may give a warning under section 35D(3)
- if the panel finds impairment falling short of that justifying action on registration, it should be able to issue a warning and may exceptionally take no action
- if the panel finds an impairment justifying action on registration, it should impose one of the three sanctions in the statute.

Written Undertakings

25.324 Rule 17(2)(m) of the July 2004 draft Rules introduced a new provision which has been reproduced in the November 2004 Rules. A FTP panel may **'take into account'** any written undertakings (including undertakings relating to limitations on his/her practice) entered into by the doctor which the FTP panel considers to be sufficient to protect patients and the public interest. The doctor must expressly agree that the undertakings (save any relating

exclusively to his/her health) should be disclosed to his/her employer or PCO, to any prospective employer or PCO and to any enquirer.

25.325 It is not quite clear to me what is meant by **'take into account'**. Does it mean that, when considering what sanction to impose after a finding of impairment of fitness to practise has been made, the FTP panel may decide that the undertakings offered would provide an adequate degree of protection and that no other action is necessary? If so, that would be reasonable, provided that there were adequate supervision of compliance with the conditions and that a breach of them were to be regarded as every bit as seriously as a breach of conditions imposed by the FTP panel itself. At present, there is no provision in the 1983 Act or the November 2004 Rules for the supervision of a doctor who is subject to such undertakings or for cases where undertakings have been given to be brought back to the FTP panel for routine review or for reconsideration in the event of a breach of undertaking. Nor does it appear that the GMC would have any 'teeth' with which to deal with a breach. No doubt those matters could be rectified and, if this procedure is to be used, they must be. However, I cannot see any real reason why a FTP panel should ever need to **'take into account'** undertakings when considering sanction. If the FTP panel has heard the evidence, it can impose appropriate conditions itself and the existing Rules make provision for review and for action in the event of any breach.

25.326 It is not clear from the Rules whether this provision is intended to have the limited application that I have just described. The positioning of the relevant provision within the November 2004 Rules and the contents of the September 2004 draft Guidance for Panellists suggests that this will be the case. However, the possibility occurs to me that it might be intended to **'take into account'** or accept undertakings from a doctor at an earlier stage in the proceedings. The provision is wide enough to permit that. If that were done, the FTP panel might never reach the stage of making findings of fact or deciding whether there was an impairment of fitness to practise. That would not be at all satisfactory. I have already explained why essential findings should not be 'fudged'. There must be a clear basis on which the GMC acts. Otherwise there can be no proper protection of the public interest.

Publication of Panel Decisions

25.327 A decision reached by a FTP panel, together with reasons, will be notified to the doctor, to his/her employer or PCO and to any person or body which brought the allegation to the GMC's attention. In addition, it will be published on the GMC's website. The only exception is that confidential information about a doctor's health will not be made public.

Review Hearings

25.328 The Guidance which accompanied the July 2004 draft Rules stated that an order for suspension or for the imposition of conditions would be reviewed by a FTP panel prior to the end of the period for which the suspension or conditions were imposed. The Guidance accompanying the November 2004 Rules states that such an order will **'generally'** be reviewed. In my view, there should have to be quite exceptional reasons for not holding a review hearing. There is no provision in the Rules for the date of a review hearing to be

fixed at the original FTP panel hearing, as was the practice under the old procedures in a health or performance case. Review hearings are extremely important, as they are the 'teeth' behind the sanctions other than erasure. If a doctor thinks that a period of suspension or conditional registration will simply expire and that s/he will automatically be allowed to return to unrestricted practice, there will be cases in which the remediation objective behind the imposition of suspension or conditions will not be achieved and patients will be put at risk.

The 2003 Proposals

25.329 The 2003 draft Rules provided for the appointment of a case examiner to assist the FTP panel in carrying out its investigations and with preparing evidence for a review hearing. The appointed case examiner was to be responsible, *inter alia*, for procuring evidence and for inviting the doctor to undergo a health assessment or directing a performance assessment as appropriate.

The 2004 Position

25.330 These arrangements were changed by the May 2004 draft Rules (reproduced in the November 2004 Rules), with the result that all these functions are now to be undertaken by the GMC staff, not by case examiners. I assume that this change was made as part of the attempt by the GMC to mitigate the effect of the significant increase to the workload of case examiners caused by the introduction, in the May 2004 draft Rules, of the double-handling of cases by case examiners. In my view, the 2003 proposals were better and should be reinstated.

25.331 It seems to me that what is required is that someone should be responsible for keeping a watchful eye on the progress of any doctor subject to conditions during the operative period. When examining the old procedures, I came across cases in which conditions had been imposed, including supervised practice and a package of remedial measures, but in which nothing at all had happened for several months. Someone in the GMC should be keeping watch to ensure that the doctor adheres to the conditions imposed and, where appropriate, should request regular progress reports. When the end of the period of suspension or conditional registration approaches and preparations are to be made for a review hearing, it seems to me that, in virtually every case, there should be some sort of independent assessment of those aspects of the doctor's performance or health that had given rise to the original finding of impairment of fitness to practise. In the past, the GMC has often released a doctor from conditions on the basis of a report from someone involved in his/her remediation. I am by no means convinced of the adequacy of some of these reports as a basis for ending supervision. Those who have been involved in facilitating a doctor's remediation are not always best placed to assess its results. We all like to think that we have done a good job and there is a grave danger that a report from someone who has been involved will present an unduly sanguine view of the doctor's progress. In any event, such a person is unlikely to have undertaken any objective, measurable assessment of the doctor's performance or competence. In my view, there should be something more patently independent and objective.

Early Review Hearings

25.332 There is also provision for an 'early review hearing'. The 2003 draft Rules provided that such a hearing could be held on the application of the doctor, if a case examiner so directed. In addition, the 2003 draft Rules provided that a case examiner should be able to direct an early review hearing where information was received that suggested that such a hearing was **'necessary'** or **'desirable'**. The May 2004 draft Rules gave the power to direct an early hearing to the Registrar (i.e. the GMC staff) rather than to a case examiner. A direction for an early review hearing was to be made when the Registrar was of the opinion that it was **'desirable'** to do so. This remains the case under the November 2004 Rules. The right of the doctor to request an early review was retained. However, the July 2004 draft Rules omitted the reference to an application by the doctor for an early review and it was not restored in the November 2004 Rules.

25.333 The provision that there should be an early review when the Registrar (in practice a member of staff) thinks it **'desirable'** is very vague. There is no requirement that there must be an early review in the event of a breach of a condition or undertaking. Also, it appears that the whole system will be reactive; it will depend upon someone reporting to the GMC that a problem has arisen. It does not appear that anyone in the GMC will be 'keeping watch'. There is no provision even for a supervisor to submit a regular report.

The Procedure on a Review Hearing

25.334 The doctor must be given at least 28 days' notice of a review hearing and must be provided with certain specified information, including any new evidence. The doctor will be required to indicate whether s/he wishes to attend the hearing. If s/he does not attend, s/he will have an opportunity to make written representations.

25.335 At the review hearing, the Presenting Officer representing the GMC will inform the FTP panel of the background to the case and of the sanction previously imposed. He or she will direct the FTP panel's attention to any relevant evidence, including transcripts of previous hearings. The 2003 draft Rules provided that both the GMC and the doctor should be permitted to call or produce evidence. However, the May 2004 draft Rules would have permitted only the doctor to adduce evidence and call witnesses, making the hearing a one-sided process. The July 2004 draft Rules contained a provision permitting the GMC to adduce evidence also and to call witnesses in relation to the doctor's fitness to practise. The November 2004 Rules also permit evidence to be called by the GMC about any failure on the part of the doctor to comply with a condition previously imposed upon his/her registration. That is most welcome. After the GMC's evidence, the doctor may present his/her case, may adduce evidence and call witnesses in support of it. The FTP panel will then receive further evidence and hear submissions as to whether the doctor's fitness to practise is impaired or whether s/he has failed to comply with any condition imposed on his/her registration.

25.336 The FTP panel must then consider and announce its finding on the question of the doctor's fitness to practise and in relation to any alleged breaches of conditions. This procedure is good in principle although, as I have said, in my view, there ought to be some up-to-date independent objective evidence about the doctor's fitness to practise.

25.337 The FTP panel may then receive further evidence and hear any further submissions from the parties about its disposition of the case and must then consider and announce its decision as to the appropriate direction. It will be open to the FTP panel at this point to **'take into account'** any written undertakings entered into by the doctor in the same circumstances as I have described previously.

25.338 The various courses of action open to a FTP panel at this point are set out in section 35D of the 1983 Act and vary according to the direction that was originally made by the panel. Where a FTP panel has given a direction that a doctor's registration should be suspended, it is open to the FTP panel at a review hearing to direct that the period of suspension should be extended for a specified period not exceeding 12 months at a time. It is also open to the FTP panel, except in a health case, to direct erasure of the doctor's name from the register. The FTP panel may also direct that the doctor's registration should, from the expiry of the current period of suspension, be conditional upon compliance with specified requirements for a period not exceeding three years.

25.339 In Chapter 21, I discussed the problems that could be created by a period of suspension. If the suspension had been ordered as a 'sharp rap on the knuckles' for a doctor who had been guilty of some form of misconduct which did not affect his/her clinical practice, it might not have been inappropriate for the doctor to be permitted automatically to resume practice when the period of suspension expired. However, if suspension were imposed on account of poor performance, ill health or a form of misconduct which did affect clinical practice, the effect of suspension might be that the doctor was even more unfit to practise at the end of the period than at the beginning. He or she would have been 'out of practice' in both senses of the expression. Sometimes, the panel imposing the suspension would advise the doctor as to what remedial steps s/he should take while suspended. But it was thought, rightly in my view, that no conditions could lawfully be imposed during a period of suspension so supervision was not appropriate.

25.340 Under the new procedures, it seems unlikely that suspension will be ordered in any case unless there is quite a serious degree of impairment of fitness to practise. It is not possible to impose conditions during the period of suspension, although FTP panels might sensibly advise doctors as to the remediation they think it appropriate that they should undertake while suspended. It seems to me that no doctor who has been suspended should ever be allowed to resume practice without undergoing some form of assessment. In my view, it is not sufficient to impose conditions at the expiration of the period of suspension. Conditions will almost certainly be required, but they should be imposed after the doctor has successfully passed an assessment of basic competence.

25.341 Where the original direction was for conditional registration, the FTP panel at a review hearing may direct erasure (except in a health case), direct that the doctor's registration should be suspended, for a maximum period of 12 months, or direct that the period of conditional registration should be extended for a period of not more than three years. It is also open to the FTP panel to revoke its original direction or to revoke or vary any of the conditions imposed by the direction for the remainder of the current period of conditional registration. Where a doctor has failed to comply with a condition on registration, a FTP panel may, except in a health case, only direct erasure of the doctor's name from the register or direct that the doctor's registration should be suspended.

Comment

25.342 I have already mentioned some of my concerns about what might be described as the 'business end' of the new FTP procedures. The mere imposition of conditions or suspension is not enough to protect the public from a doctor whose fitness to practise is impaired. There must be proper supervision and adequate assessment of the doctor before s/he is allowed to return to unrestricted practice. I do not think it is satisfactory for a long period of conditions to be imposed, as this means that the doctor can disappear from sight and practise under very little supervision. The GMC might think that a doctor will be supervised locally by his/her PCO. However, in my view, the GMC should take responsibility. Also, a relatively early date for a review hearing before a FTP panel might well have the effect of focussing the doctor's mind on his/her remediation. In my view, periods of conditional registration should not usually exceed 12 months initially. A renewed period may well be necessary but the shorter initial period will at least mean that the doctor is brought back for review within a reasonable time.

25.343 I have already expressed my concern also that there is no provision in the Rules for the regular monitoring or surveillance of a doctor who is subject to a direction for conditional registration imposed by a FTP panel. In other words, the doctor is less well supervised than s/he would have been under the old voluntary health or performance procedures. This is a serious gap and means that conditions imposed by a FTP panel may well be significantly less onerous than for a doctor in voluntary procedures. (Of course, I recognise that the new arrangements for voluntary undertakings in cases with a health or performance element may be rather more lax in future, when they will be under the control of staff rather than the health screeners and performance case co-ordinators who were able to bring expertise and continuity to their work. That remains to be seen.) However, there seems to be no sense in devising a system which is manifestly less stringent in cases where conditions are imposed by a FTP panel than when undertakings are entered into voluntarily. In my view, a professional supervisor should be appointed in every case where a doctor is practising under conditions, and that professional supervisor should provide regular feedback to the GMC. There should be a medical supervisor in all health cases and s/he should be expected to operate to the standards that were required under the old voluntary health procedures. Also, in my view, some form of independent assessment must be made before conditions are lifted.

Applications to Restore a Doctor's Registration

25.344 The 2003 draft Rules set out the procedure to be adopted when a doctor whose name has been erased from the register applies for restoration. They provided for a case examiner to be appointed to consider and prepare the evidence to be placed before the FTP panel at a restoration hearing. He or she was to have the same powers to procure expert and other evidence as in relation to a review hearing. These arrangements were changed by the May 2004 draft Rules and the changed regime is reflected in the November 2004 Rules. The staff – and not case examiners – will carry out the functions that were previously to be carried out by the case examiners. I think that that is a retrograde step. I can see no reason of principle why case examiners should not be required to undertake this work;

they are manifestly better qualified to do so than GMC staff. I can only conclude that the reason for the change was to reduce the workload of case examiners.

25.345 The November 2004 Rules contain no requirement that a performance or health assessment should be carried out automatically in the case of every application to restore. The staff may direct an assessment of performance or health; it is open also to the FTP panel which hears the application to direct an assessment before making its decision. In my view, it should be mandatory for a doctor to undergo an assessment of every aspect of his/her fitness to practise before his/her application to restore is heard. Since the amendment to the 1983 Act effected in 2000, the doctor will inevitably have been off the register and away from clinical practice for an appreciable time – five years if the erasure was not voluntary.

25.346 The procedure at a restoration hearing is similar to that at a review hearing, save that the decision to be taken by the FTP panel is whether to grant or refuse the application to restore. The FTP panel must give reasons for its decision. In an appropriate case, it may make a direction suspending indefinitely the applicant's right to make further applications for restoration. It is not open to the FTP panel to restore the doctor to the register subject to conditions. I understand that the GMC believes that FTP panels might restore applicants too readily if the option to restore with conditions is available. It also takes the view that, if there are doubts about a doctor's fitness to practise, the decision should be to refuse restoration. I understand that point of view. But the time must come where a panel thinks it appropriate to restore but where a period of supervision would be a wise safeguard. I recommend that every doctor restored to the register after erasure should have a mentor, who undertakes to monitor his/her progress and to report to the GMC.

Appeals

25.347 Decisions of FTP panels will be subject to appeal by a doctor and to judicial review on the application of a complainant. In addition, the CRHP/CHRE will be able to refer a decision of a FTP panel to the High Court in certain circumstances. The GMC has pointed out that it has no power to appeal decisions made by FTP panels. The GMC says that it wishes to have the ability to question those decisions that do not appear adequately to protect the public interest. In a briefing paper for the May 2004 Council meeting, it was pointed out that the GMC could invite the CRHP/CHRE to mount an appeal on its behalf; however, it was suggested that that was not a satisfactory alternative to being able to act itself.

25.348 As a consequence, the GMC agreed at its May 2004 meeting that, subject to further work on mechanisms and to consultation, it should request further legislation to enable the GMC to appeal to the High Court against decisions of FTP panels which it considered unduly lenient, either as to sanction or as to whether the doctor's fitness to practise was impaired on the facts found. In my view, such a power would be inappropriate and is in any event quite unnecessary. It would be inappropriate because the GMC continues to exercise a very close degree of control over FTP panels. It is unnecessary because the CRHP/CHRE has the power and the resources to mount an appeal. If the GMC is concerned about a decision being unduly lenient, it can invite the CRHP/CHRE to take action; indeed, it has already adopted this course in a recent case. The GMC is under a

duty to co-operate with the CRHP/CHRE and this seems to me to be an obvious area for such co-operation.

Conclusions

25.349 In the course of this long Chapter, I have expressed my views about the GMC's proposals for its new FTP procedures. It is clear that, in some areas, the new procedures will be a significant improvement on the old and, in other areas, the reverse appears to me to be the case. I do not propose, at this stage, to repeat the detailed observations that I have made as I have gone along. Instead, I want to stand back and examine the new procedures in the round.

25.350 In Chapter 15, I reported at some length the opening submissions to the Inquiry of Mr Roger Henderson QC on the GMC's behalf. I shall not repeat them here. Their gist was an acceptance that there was much that had been unsatisfactory under the old procedures. However, I was urged to accept, those were the 'bad old days' and it would all be different in the future. This was also the message to the Inquiry from the GMC witnesses, in particular from the President and the Chief Executive. I have no hesitation in accepting the sincerity of their expressions of intention. However, I have grave reservations about the willingness and ability of the GMC as presently constituted to change its ways.

25.351 I regret to say that my overall reaction to the way in which the new procedures have been developed is one of disappointment. Although, in the early days, at the time of the 2001 Consultation Paper, there was every indication that the GMC had a vision of what it wanted to achieve, that vision has been lost. I do not believe that that vision, or the purpose or principles that underpinned it, have been translated into the new procedures.

25.352 The GMC knows what the fundamental purpose of its FTP procedures is or should be. It was clearly set out in the 2001 Consultation Paper. The fundamental purpose was said to be to promote and safeguard the public interest, which involved individual patient protection, the maintenance of public confidence in the profession and declaring and upholding proper standards of conduct. In my view, if that fundamental purpose is to be met, there are some basic principles that should be applied; for example, subject to the requirements of medical confidentiality, everything that the GMC does must be capable of scrutiny; it must be transparent. The work that the GMC does must be thorough, careful and of high quality. That means that every aspect of the FTP procedures must be properly resourced. Each process must be undertaken by persons who are suitably qualified and properly trained to carry it out. In the interests of fairness and of the proper maintenance of standards, procedures must be followed and decisions made in a consistent, transparent manner. Those are the broad principles that should have been followed in developing the GMC's approach to its new procedures. They should not have been forgotten right to the end.

25.353 The criteria for evaluating the proposals that were enunciated in the 2001 Consultation Paper reflect those principles but they have not been met. By way of illustration, one such criterion was compliance with the Human Rights Act 1998, and the GMC said that it was

'in no doubt' that it was necessary, in order to demonstrate that its procedures were fair, to separate the investigation and adjudication functions. Not only would this ensure compliance with the Human Rights Act 1998, but it would foster public confidence and it would satisfy those doctors who felt that it was unfair that they should be prosecuted and judged by the same body. The GMC talked about this idea and then decided – in effect – to abandon it. Members could not bring themselves to relinquish part of the process. It seems that their justification for this was that they believed that no one else could undertake either of the functions as well as they could. And yet, this was a body that had been the subject of severe public criticism on many grounds and which had embarked on reform, apparently because it had recognised the force of that criticism.

25.354 There is one issue of importance that was present in the minds of GMC members at an early stage and from which they have not resiled. That was the need to abolish the separate procedures for conduct, health and performance and to create a unified set of procedures for all types of case. That they have done and I do not think that anyone doubts that this was the right thing to do. The appropriate legislative changes went through in 2002. Since then, there has been no real sign of an overall plan carried through to fruition. There was the publication of the 2003 draft Rules, which contained some improvements on the old procedures and the retention or introduction of many unsatisfactory features. Since then, the GMC has responded to criticism from a variety of quarters, including this Inquiry. It has made some improvements. Many of the criticisms related to matters that the GMC might have been expected to have seen for itself, if it had formulated an overall vision of how it wanted its new procedures to operate. For example, it is amazing to me that the GMC should have resiled from its commitment, under the old procedures, to the involvement of lay persons in the preliminary processes for sifting complaints.

25.355 Such improvements as have come about since 2003 have been made in a piecemeal fashion and in response to criticism. But, unfortunately, not all the changes that have been made since the 2003 draft Rules have been for the better. Some provisions of the 2003 draft Rules have been changed for the worse. I have in mind in particular the changes to the role of the case examiners. In 2003, it was intended that they should fulfil a variety of functions, mainly during the investigation stage, but also including involvement in the supervision of doctors subject to voluntary undertakings and in the preparation of the cases of doctors subject to conditions, suspension and erasure who were coming up for a review or restoration hearing before a FTP panel. I am unaware of any criticism of the proposals that case examiners should fulfil those functions; indeed, I personally thought them satisfactory. Many of these functions have now been taken away from case examiners and have been given to members of staff who are not well qualified to carry them out. As I have said earlier in this Chapter, I cannot think of any reason of principle for those changes and am driven to the conclusion that they have been made for reasons of expediency. Another example of a change for the worse is the new provision for the cancellation of referrals to a FTP panel; the new arrangements are open to abuse and are not even remotely transparent. A third example is the arrangements for the issue of letters of advice. The lack of any clear criteria for their issue was identified as a defect under the old procedures. Yet, after an initial proposed improvement, the informal arrangements proposed have all the defects of the previous system.

25.356 One particular concern that I must mention is the lack of transparency in the way in which the new procedures have been developed. The draft Rules have been changed from time to time and new guidance has been issued to accompany new sets of Rules. There is, of course, nothing wrong with that. It is understandable that the GMC's thinking has developed over time and as a result of consultation. Yet, there has been very little public discussion at the GMC about the thinking behind the changes; nor are the reasons apparent from briefing papers prepared for the use of members at Council meetings. I have no doubt that the changing proposals have been fully discussed by the Fitness to Practise Committee and I accept that it is entirely proper that it should meet in private. However, it must have been very difficult for doctors, medical defence organisations, health administrators and the public (as it has been for the Inquiry), to trace the development of the procedures and to understand what has been decided and why. Indeed, even now that the new procedures are in operation, it is still difficult to find out exactly how they are going to operate. It must be apparent from this Chapter that it has not been easy for the Inquiry to piece the picture together. In my view, there is an urgent need for a handbook containing all the Rules, all the guidance currently in operation and any standards, criteria and thresholds to be applied when making decisions. The handbook should also give a clear and complete account of what can happen at each stage of the procedures. Moreover, the GMC must ensure that the guidance it issues is in conformity with the Rules and the underlying provisions of the 1983 Act. The handbook should be readily available and should be accessible on the GMC website.

25.357 The result of all the changes to the draft Rules is that the new procedures are much like a curate's egg: they are good in parts and not good in others. I have made a lot of suggestions about alterations that would, in my view, be for the better. I make them in a constructive spirit. I hope that some – if not all – of them will be adopted. But the process of change has been tortuous and piecemeal. It is discouraging, as it indicates to me that, even now, at the start of the new era, there is no real commitment to the underlying principles of good regulation. In short, I am not convinced that the leopard has changed its spots or ever will.

CHAPTER TWENTY SIX

Revalidation

Introduction

26.1 As I explained in Chapter 15, once a doctor qualifies to have his/her name entered on the medical register, s/he is entitled to practise medicine and to remain on the register unless and until such time as his/her name is suspended or erased from it. For many years, doctors have been under a professional duty to maintain their professional competence. However, there has been no means of ensuring that they do so and no sanction for failing to do so, unless and until the doctor's fitness to practise is called into question as a result of a complaint to the General Medical Council (GMC). In 1998, in the wake of at least two high profile cases in which doctors were seen to have been practising at unacceptably low standards over a period of time, there was a move within the GMC to introduce a requirement for some form of periodic assessment by which a doctor's fitness to remain on the medical register could be reviewed. This concept was developed and the GMC now proposes to introduce, in 2005, a requirement that all doctors wishing to retain a licence to practise must, every five years, undergo a process by which their entitlement to practise is 'revalidated'. It is said that the process of revalidation will require doctors to demonstrate on a regular basis that they are 'up to date and fit to practise'.

26.2 Revalidation is of considerable interest to the Inquiry. I have explained in this Report how the systems by which the NHS monitored the practice of general practitioners (GPs) during the period of more than 20 years in which Shipman worked as a GP failed to detect that he was obtaining large amounts of diamorphine illicitly and killing his patients. The GMC, as regulator of the medical profession, did not at that time undertake any routine monitoring of doctors; its role in the monitoring process was confined to reacting to complaints. It received no complaints that could have led it to suspect that Shipman might be killing his patients. Since 1998, there have been many changes within the NHS. I have described some of them in Chapter 5. In 1999, the NHS introduced clinical governance, which I described in Chapter 12. When these changes have had time to settle down and to develop to their full potential, they should result in much-improved monitoring of doctors' performance, with the twin benefits of detecting the development of substandard performance and the raising of standards generally. The GMC is now to introduce revalidation, which, as I have said, should involve a periodic demonstration of the individual's fitness to practise.

26.3 In this Chapter, I propose to examine the GMC's proposals for revalidation, the way in which revalidation will be linked to clinical governance and the potential that the two processes will have for the detection of poor or aberrant clinical performance. I am in no doubt that the problems caused by poorly performing doctors are significant. As Professor Dame Lesley Southgate, Professor of Primary Care and Medical Education, University College London, said at the Inquiry seminars: 'There are poorly performing doctors out there who are harming patients'. Professor Sir Graeme Catto, President of the GMC, speaking of the purposes for which revalidation was to be introduced, said that the performance of at least 90% of doctors gave rise to no concerns; that suggests that there

is or could be a problem of poor performance with as many as 10%. That estimate may be on the high side; others mentioned a figure of 5% or even 3% of doctors whose performance gives rise to problems. Whichever figure is the more accurate, the problem is not insignificant. As I explained in Chapter 12, the methods of identifying poor performance through local clinical governance procedures are limited. Revalidation could provide a significant additional means of achieving that end.

26.4 Plainly, any system of revalidation of registration must have wider aims than merely the detection of the activities of a mass murderer practising as a GP. However, as a broad brush test, it is pertinent to consider whether, if revalidation as currently proposed had been in force during the 1980s and 1990s, it would have brought Shipman's activities to light. My overall objective in the Inquiry is to make recommendations for change to bring about the provision of interlinking systems of monitoring and regulation which will detect not only doctors who deliberately harm their patients but also those who harm them for other reasons such as incompetence, ill health or an unwillingness to keep up to date. I have already made recommendations for the reform of death certification and coroners' investigations. I have also made recommendations for the strengthening of the rules relating to the use of controlled drugs. I believe that those recommendations, if implemented, could help in the detection of dysfunctionality. Now, I wish to examine the part that could be played by revalidation. If revalidation were to consist of a periodic assessment of a doctor's competence and fitness to practise, it could make a huge contribution to safeguarding the public against the incompetent and out of date doctor. Whether it would catch another Shipman may be a different matter. It might make a contribution, as one part of the interlinked systems. As well as considering its potential benefits, I wish to examine whether revalidation, as currently proposed, will in fact achieve the purpose for which it is intended.

Evidence

26.5 The GMC's principal witness on the issues relating to revalidation was Mr Stephen Brearley, a consultant general and vascular surgeon, a GMC member and the Chairman of the Registration Committee. Sir Graeme, and Mr Finlay Scott, Chief Executive of the GMC, also gave evidence about revalidation. Sir Donald Irvine, immediate past President, spoke on the subject during his evidence and made contributions at the Inquiry seminars. Dr Malcolm Lewis, a GP and Chair, Welsh Branch of the GMC, represented the GMC at the seminars. Other important contributions to the debate about revalidation came from Dame Lesley, Dr John Grenville (a GP, who represented the British Medical Association (BMA) at the seminars), Dr William Reith (a GP, on behalf of the Royal College of General Practitioners (RCGP)) and Dr John Chisholm (a GP and Chairman of the General Practitioners Committee (GPC) of the BMA).

The Development of the General Medical Council's Proposals for Revalidation up to the End of 2002

26.6 The possibility of requiring doctors to undergo some sort of periodic reassessment of their fitness to practise was first raised in the 1970s. In 1975, the Merrison Committee, whose

Report I mentioned in Chapter 15, referred to a growing interest in linking continued registration with periodic tests of competence. However, the Committee took the view that the issue lay outside its Terms of Reference. It passed on the evidence that it had received on the topic to another committee, which had been set up by the medical profession under the Chairmanship of Sir Anthony Ament, to review, *inter alia*, the existing methods of ensuring the maintenance of standards of continuing competence to practise. The Report of the Ament Committee, entitled 'Competence to Practise', published in 1976, stressed the importance of doctors keeping their practice up to date and accepted that there might be considerable value in some form of re-licensure. However, it concluded that there was no evidence to justify the introduction of re-licensure as a compulsory requirement. It was thought that **'a system of licensing for all could not be based upon measurements satisfactory enough to justify it'**. The Report recommended that, instead, doctors should be encouraged to keep up to date voluntarily. In short, the Ament Report concluded that there were insuperable practical difficulties in the way of any form of revalidation. Those members of the GMC who are currently charged with the responsibility of developing proposals for revalidation might be forgiven for thinking that perhaps the Ament Committee was right.

26.7 Proposals for re-licensure surfaced again in 1998 in the immediate aftermath of the GMC hearings of allegations of serious professional misconduct against three doctors, arising out of concerns about the paediatric cardiac service at the Bristol Royal Infirmary. Sir Donald, then President of the GMC, describes in his book, 'The Doctors' Tale'[1], how the idea developed. He said that, by June 1998, there was a growing awareness of **'the clear public expectation that medical regulation should include measures to assure patients that consultants, and general practitioners, continue to perform effectively throughout their working lives'**.

26.8 At that time, Sir Donald had in mind the introduction of some form of revalidation only for those doctors who practised unsupervised, i.e. consultants and GP principals. He envisaged that revalidation would operate in conjunction with the basic strategies for securing and maintaining good medical practice, which included the setting of clear general and specific standards, effective local clinical governance and effective local and central arrangements for dealing with poor practice. He suggested that the current specialist register (which contained the names of those doctors entitled to practise in unsupervised positions in the various secondary care specialisms) was not 'fit for purpose' if there was no check on the doctors' continuing fitness to practise over many years. He suggested that revalidation should take place at five-year intervals. At a meeting of the leaders of the profession, held in August 1998, there was general agreement that the idea was sound in principle; however, reservations were expressed about how revalidation was to be achieved in practice.

26.9 In the ensuing months, the debate about revalidation got underway within the profession at large. Support was not universal. There was perhaps a further stimulus towards action – at least within the GMC – when Rodney Ledward was struck off the medical register at the end of September 1998. He had been practising as a consultant gynaecologist in

[1] Irvine, Donald (2003) 'The Doctors' Tale'. Oxford: Radcliffe Medical Press.

Kent. His incompetence (manifested by an unusually high complication rate following operative procedures) had been evident to some for many years, but no action had been taken to prevent him from practising. As it happens, September 1998 was also the month in which Shipman was arrested on suspicion of the murder of Mrs Kathleen Grundy.

26.10 Revalidation was discussed at a meeting of the GMC in November 1998 but no firm decision was taken about what should be done. However, at a special conference held in February 1999, the GMC decided, by a very substantial majority, to introduce revalidation. It also decided that revalidation should apply to all doctors, not only to consultants and GP principals. It was further decided that revalidation should be linked directly with registration; in other words, no revalidation would mean no licence to practise. However, the GMC also decided that no doctor would be refused a licence to practise unless and until s/he had been through the GMC's performance procedures and had been found unfit to practise by a panel of the Committee on Professional Performance (CPP). I described the operation of the performance procedures in Chapter 24. In February 1999, these procedures were still relatively new, having been introduced in July 1997.

26.11 There was discussion at the special conference in February 1999 about how revalidation was to be carried out. It was expected that most would achieve revalidation without difficulty and that only a tiny proportion would fall to be dealt with under the performance procedures. According to Sir Donald, in 'The Doctors' Tale', the original proposal, set out in the paper prepared for discussion at the conference, **'introduced the idea of a staged model – local profiling, regular review, assessment and external quality assurance'**. Powerful voices spoke against any form of 'examination' as the basis of revalidation. There was general agreement that revalidation should dovetail with local clinical governance procedures. The Chief Medical Officer (CMO) for England, Professor (later Sir) Liam Donaldson, made an important contribution to the debate and was supportive of the principles behind revalidation. He was at that time closely involved with the development of clinical governance within the NHS. He said that he saw revalidation as **'an important piece of the overall framework of quality in the NHS which ... must be put in place'**. Sir Donald described how Professor Donaldson spoke of **'the strong interdependence between professional self-regulation – of which this** (*revalidation*) **was an important part – and clinical governance and the statutory duty of quality within the NHS'**. He also spoke of the potential of revalidation for improving quality of practice. It was envisaged that revalidation, properly implemented, would achieve two objectives: the weeding out of poorly performing doctors so as to protect patients, and the enhancement of performance in others.

26.12 There was another aspirational contribution to this debate that I particularly wish to mention. Professor David Hatch, Consultant Anaesthetist at the Great Ormond Street Hospital for Sick Children, said that, in his 30 years of practice:

> **'... nobody has given me an opportunity to demonstrate that I am fit to practise and up to date. I would welcome the opportunity to try to show that to the parents of the children I anaesthetise and the children themselves in some cases. I would hope that the Register, available 24 hours a day, seven days a week, would be the instrument for doing that.**

I hope that people will look up the Register, and the fact that I am on it will indicate that I am safe to anaesthetise their children.'

It appears that not all members of the GMC shared this positive approach to revalidation. But those who did not were in the minority and, as I have said, the proposals were carried and revalidation was on its way.

Developing the Practical Arrangements

26.13 A Revalidation Steering Group (RSG) was formed by the GMC to devise plans for the implementation of revalidation. Its aim was to produce fully developed proposals for discussion within two years. The target date for implementation was 2002. The RSG first reported to the GMC at a Council meeting in May 1999. The RSG recommended that revalidation should be based on the principles set out in the GMC publication 'Good Medical Practice'. As I understand the outline proposals at that time, it was intended that work would be done to compile a 'local profile' of a doctor's performance. Although the term 'profiling' was not explained, I take it to mean that the essential requirements for doctors of each particular type would be analysed, standards would be set and a means devised of assessing the individual doctor against the essential requirements. In that way, each doctor would be subjected to an individual judgement, based on material or evidence that s/he would produce. The precise way in which this was to be achieved was not at that time specified in any detail. More detailed development work was to take place. Meanwhile in May 1999, it was also envisaged that if, during the process of revalidation, any concerns arose about a doctor's performance, there should be an opportunity for local remedial action, followed, if necessary, by referral to the GMC's fitness to practise (FTP) procedures and action on registration (i.e. the imposition of conditions on or suspension of registration). The RSG stressed that the development of revalidation must be co-ordinated with that of clinical governance, which was then still in its infancy. At the same meeting, Council agreed that there should be full public consultation about the development of revalidation, based on the RSG proposals.

26.14 The RSG continued its work. It sought the advice of Dame Lesley, who had led the team responsible for developing the assessment instruments used by the GMC in its performance procedures. Dame Lesley provided advice and, together with Professor Mike Pringle (then Chairman, RCGP), set out their ideas in a paper published in the British Medical Journal (BMJ) in October 1999[2]. Dame Lesley and Professor Pringle envisaged that doctors would have to be revalidated in each aspect of the work they undertook. For each large specialty, there would be a number of local or regional revalidation groups. A small specialty might need only one revalidation group to serve the whole country. The membership of the groups would include representatives of the specialty concerned, the local professional organisation, the public and doctors in health service management. Members of the groups would be trained by national professional organisations, usually the medical Royal Colleges. These organisations would be recognised by the GMC for that purpose and also for the purpose of setting the standards that the doctors in each

[2] Southgate, Lesley, Pringle, Mike (1999) 'Revalidation in the United Kingdom: general principles based on experience in general practice', BMJ, Vol 319.

specialty would have to meet. A doctor would apply for revalidation to the revalidation group appropriate to his/her specialty. The group would examine the evidence submitted and would make a decision whether or not to recommend revalidation. The group would seek evidence of a safe standard of practice. The work of the revalidation groups would be monitored and quality assured by the relevant Royal College. Work would have to be done to ensure that consistent standards were applied nationally.

26.15 The BMJ paper also set out in some detail the kind of material that might have to be submitted with the application. This, it was said, would vary from specialty to specialty. The requirements must not place too great a burden on doctors. In all cases, there should be **'an extended curriculum vitae'**, in which the doctor would describe the nature of his/her education, experience and clinical practice. This document would set out details of the continuing medical education undertaken by the doctor. Dame Lesley and Professor Pringle also discussed the possibility of using material collected for clinical governance purposes but stressed that much development work would have to be done before this could be used. The BMJ paper also suggested that some doctors might wish to take a different route to revalidation, for example, by submitting themselves to the peer review accreditation schemes operated by some of the Royal Colleges. The RCGP's schemes for gaining Fellowship or Membership of the College by assessment of performance were mentioned as particular examples. These programmes set a higher standard than the basic standard of competence which it was envisaged would apply to the revalidation process. It was suggested that doctors who were able to demonstrate that they had achieved and were maintaining those higher standards should be entitled to rely upon them for revalidation.

26.16 In November 1999, the RSG reported again to Council. Broadly speaking, its recommendations reflected the ideas described by Dame Lesley and Professor Pringle in their BMJ paper. The RSG recommended that revalidation should be based initially on the 'profiling' of the doctor's practice, based on evidence collected in the locality where the doctor worked. That evidence would be scrutinised by the doctor's peers and by **'informed lay people'** who would then make a judgement whether to recommend revalidation or referral into the GMC's FTP procedures. The RSG recommended that the local processes upon which revalidation was to be founded should be supportive of continuous improvement and should not be restricted to identifying unacceptable practice.

The General Medical Council Consultation Paper of June 2000

26.17 In June 2000, the GMC published a Consultation Paper, 'Revalidating Doctors, ensuring standards, securing the future'. The Consultation Paper set out the philosophy behind revalidation and drew attention to the benefits it would bring. It would benefit patients by protecting them from poorly performing doctors, by promoting good medical practice and by making the register a valid indicator of current fitness to practise. It would also increase patients' confidence in doctors by giving them the assurance that doctors were regularly submitting evidence of competence. Revalidation would also benefit doctors; it would help good doctors to be even better; it would help doctors with weaknesses to correct them and it would enable doctors to defend themselves better against unfounded

criticisms about their fitness to practise. Finally, it would benefit the employers of doctors by providing an assurance that the doctors they employed were fit to practise and by providing an additional mechanism to identify and deal with poor performance. The Consultation Paper described the wider context of reform of which revalidation was a part. It mentioned a gradual change in culture that had taken place in the recent past, including the promotion of quality improvement and of openness and honesty about mistakes and poor performance. There was reference to the development of explicit standards of practice by the GMC and to the introduction of clinical governance arrangements. There was particular reference to appraisal as a means by which employers could monitor whether doctors were complying with their contractual obligations. It was said that revalidation of doctors' registration and appraisal were **'complementary professional and managerial functions'**, which required a common core of information about professional performance. The GMC's proposals on revalidation were, it was said, designed to make the best use of this common core of information.

26.18 Before describing the process by which revalidation was to be carried out, the Consultation Paper described the **'Principles of Revalidation'**. In summary, these were that it must be effective (i.e. it must sort out those who were fit to practise from those who were not); it must be locally based whilst reflecting the doctor's practice by reference to national standards; it must be transparent, comprehensive, thorough, proportionate to the risks posed by poorly performing doctors, fair, non-discriminatory, consistent and verifiable. By 'verifiable' was meant that the information used for making a judgement about a doctor's fitness to practise must be susceptible to audit. It was also said that revalidation must be as simple as was consistent with effectiveness and must build on, not duplicate, existing and planned arrangements; it must also be flexible, supportive and developmental, predictable (in the sense that it must not contain traps or ambushes) and properly resourced. The Consultation Paper also described the standards of good practice upon which revalidation would be based. The starting point for all doctors was to be 'Good Medical Practice', but more detailed standards were to be worked out for each of the specialties.

26.19 The Consultation Paper described the process of revalidation as it was then envisaged. The process would have three stages. The first stage consisted of the collection of the evidence on which the profiling of the doctor's performance was to be based. Every doctor was to maintain a revalidation folder, which should contain current information from several sources to show how well s/he was practising. The information was likely to include results of audit, a record of continuing professional development, the views of a sample of patients and the views of a sample of working colleagues, including those who referred patients to the doctor or received referrals from him/her. It was said that the revalidation folder would usually be reviewed annually; any deficiencies would be identified by the reviewer and advice given about how the doctor might remedy those deficiencies. It was envisaged that, in the NHS – at least within the hospital setting – the annual review would be conducted through employers' appraisal systems.

26.20 The second stage of the revalidation process would be an **'assessment'** which would take place every five years, when the doctor's revalidation folder would be assessed independently by a small revalidation group of doctors and lay people. The assessment

would be made against standards laid down by the GMC and the medical Royal College of the relevant specialty. The revalidation group would have to satisfy itself that the doctor was fit to practise and, if so satisfied, would recommend revalidation to the GMC. The third stage of the revalidation process was the action to be taken by the GMC. Usually, that action would consist of revalidating the doctor's register entry in accordance with the recommendation of the revalidation group. However, if the revalidation group considered that action on the doctor's registration was necessary, the GMC would have to decide whether to invoke one of its FTP procedures, which might result in the doctor's erasure or suspension or in conditions being imposed on his/her registration. It was made plain that if, at any stage in the five-year cycle, information came to light – as the result of clinical governance mechanisms or in any other way – which gave rise to serious concerns, these should be addressed immediately, usually by means of referring the doctor to local performance procedures but, in a bad case, by immediate referral to the GMC. The first and second stages of the revalidation process would be subject to external quality assurance. This was to ensure consistency, fairness and public safety.

26.21 In an important passage at paragraphs 20 and 21, the Consultation Paper explained that the quality assurance of medical care must involve several different bodies working together, of which the GMC was only one. The Consultation Paper stressed also that the intention was that clinical governance and revalidation would complement each other since **'neither on its own would be sufficient to protect patients'**. It said that there was broad agreement between the various bodies involved that revalidation should use existing and proposed local systems (for example, appraisal in the NHS), rather than devising new arrangements that would have the effect of taking doctors away from their patients.

26.22 In later sections, the Consultation Paper set out in greater detail how the revalidation process would work in practice. The type of evidence which it was expected would appear in the revalidation folders was described and comments were invited. It was expected that much of the information required should be **'generated as a by-product of quality assurance at their** (*i.e. doctors'*) **place of work'**. One suggestion was that information about patient complaints should be included. The Consultation Paper indicated that the GMC was working with other organisations to ensure that its requirements for the contents of the revalidation folder would be compatible with, *inter alia*, the emerging arrangements for the appraisal of doctors within the NHS. The medical Royal Colleges were to provide more detailed guidance as to what would be expected for each specialty.

26.23 The Consultation Paper contained a substantial section dealing with the link between appraisal and revalidation. Views were sought on this issue. At that time, appraisal for doctors within the NHS was in an early stage of development. The appraiser was to be another doctor. The Consultation Paper stated that appraisal was to be a formative process in that it was intended to support doctors in maintaining and improving their professional performance. Appraisal would include, but would not be limited to, a review of the contents of the doctor's revalidation folder. Any gaps in the revalidation folder should be identified and any deficiencies within the doctor's practice which were identified should be addressed by the appraiser arranging for any necessary

developmental or remedial action. That would give an opportunity for the deficiencies to be rectified before revalidation was due. One outcome of each annual appraisal should be a statement, which would go into the doctor's revalidation folder, confirming that a satisfactory appraisal had taken place and identifying any developmental needs. In this way, revalidation, when it came, ought to be straightforward.

26.24 The detail of the appraisal discussion was to be confidential as between the appraiser and the appraisee. This was considered necessary since it would be damaging to the appraisal process if appraisees felt unwilling to raise issues for fear that to do so might damage their prospects of revalidation. The revalidation folder used for appraisal would not be confidential. The revalidation group would examine the information contained in the revalidation folder, together with any other information about the doctor available to it from other sources, and would assess the accuracy, significance and sufficiency of that information before reaching a decision whether the doctor had demonstrated his/her fitness to practise. The Consultation Paper observed that the relationship between appraisal and the five-year revalidation assessment would need to be reviewed as the processes of appraisal and revalidation evolved.

26.25 The Government supported the GMC's proposals. Understandably, it was particularly anxious that those proposals should dovetail with NHS clinical governance arrangements and would not give rise to a lot of extra work for doctors. On 6th July 2000, Mr John Denham MP, Minister of State at the Department of Health (DoH), told a Parliamentary Standing Committee:

> **'We want to ensure that the system of revalidation on which the GMC has been working for some time fits well with the system of annual appraisal of doctors in the NHS and wider systems of clinical governance that we are putting in place. The systems must be seamless without duplication of time and effort in collecting information. I believe that the system that we are putting in place in the NHS will, if we get the details right, work effectively with the new measures from the GMC to introduce revalidation, which I welcome.'**

26.26 The GMC received many responses to its Consultation Paper. Most respondents were supportive of the principles of revalidation and approved the proposed methods of collecting of information, the proposed content of the revalidation folders and the method of scrutiny. Various concerns were expressed. In particular, it was felt that doctors would need a good deal of guidance. Almost all respondents approved the idea of a link between appraisal and revalidation. Many stressed the need to ensure that the formative nature of appraisal was not lost. Many respondents were concerned about what revalidation was going to cost the GMC. It was suggested that the GMC should undertake a cost benefit analysis. There was also a suggestion that, before the GMC adopted the proposals, they should be tried out in pilot studies.

26.27 In short, the public consultation revealed no concerted opposition to the proposals. There was, however, some opposition from within the medical profession. Sir Donald said, in

'The Doctors' Tale', that sections of the BMA were strongly opposed to the proposals. The opposition came particularly from the hospital consultants.

The First Pilot Study

26.28 The GMC decided to undertake a pilot study and this took place between February and April 2001 (the 2001 pilot study). It was conducted by a Revalidation Technical Group (RTG) which had been formed by the GMC. Its objective was to test the feasibility of using the revalidation folder as a means of evaluating a doctor's fitness to practise. Volunteer doctors were asked to assemble and submit revalidation folders. The folders were considered and assessed by mock revalidation groups, each of which was designated to deal with the revalidation folders submitted by doctors of a specified specialty. The groups had three options open to them. The first was to state that they were of the opinion that the doctor was up to date and fit to practise and to recommend that s/he should be revalidated. The second was to state that they could not certify that s/he was up to date and fit to practise and did not, therefore, recommend revalidation. The third was to request further information from the doctor before making any recommendation.

26.29 Five of the mock revalidation groups looked at all the 20 revalidation folders which had been submitted by GPs. It was found that there was great variability in the depth of information provided by different doctors and also in the time they had taken to prepare their material. It took group members an average of 21 minutes each to read the contents of a revalidation folder and an average of 13 minutes for a group to consider it together and reach a decision. There was a substantial degree of consistency between the decisions of the five groups; indeed, if the decisions of one of the five groups were excluded altogether, there was a remarkable degree of consistency between the results of the remaining four. The results for the GPs' groups showed that 86% of the recommendations were for revalidation; in only 11% of cases was further information requested and in only 3% was there a recommendation that the doctor should not be revalidated. I would have thought that those results were rather encouraging, especially as everyone involved was participating in a completely unfamiliar process. One might reasonably expect the process to improve and become quicker with repetition. The quality of material in the revalidation folders would improve as doctors gained a better idea of what was expected of them. More verifiable information would become available from clinical governance processes. Also, group members would gain in experience.

26.30 The RTG's report of the pilot study was generally optimistic for the future. It included the following observation:

> **'It is clear from the information generated by each panel** (*i.e. mock revalidation group*) **that there is a close correlation between positive recommendations for revalidation and those doctors who have been through appraisal. There are a number of reasons for this. Firstly, such doctors tended to have to hand the kind of information required by revalidation and were therefore able to supply the data needed to make a positive recommendation despite the short timescale of the piloting programme. Secondly, revalidation groups expressed greater**

confidence in making a positive recommendation where they knew that the doctor had already been subject to a review and documentation from that review had been made available. Thirdly, groups were in general reluctant to make positive revalidation recommendations where there was no third party verification of the data presented by the doctor. Third party verification is not limited to appraisal but clearly having an appraisal is helpful in this respect.'

26.31 In the light of subsequent events, that passage merits further attention. First, at the time of this pilot study, GPs were not subject to appraisal; appraisal for consultants was introduced very shortly afterwards. The observation that the revalidation groups had been more confident to recommend revalidation for doctors who had been appraised must, therefore, have related to hospital doctors below consultant grade – in other words, doctors in training grades, who could truly be said to be working in a 'managed environment'. All or most of the information used in their appraisals would have been provided by their employers and would be verifiable. Second, it appears that it was not only the fact that appraisal had taken place, but also the availability of the documentation from that appraisal, that gave confidence to the revalidation group. However, the statement that revalidation groups were reluctant to recommend revalidation unless the data presented by the doctor had been verified in some way is interesting and slightly puzzling. The revalidation groups had recommended revalidation in 86% of cases relating to GPs. It is difficult to see how much of the GPs' data could have been verified. They had not yet been appraised and there was – and still is – very little clinical governance data emanating from primary care organisations (PCOs) that relates to an individual doctor. However, apart from being slightly puzzled, I am not at all surprised that a revalidation group would find comfort in the knowledge that at least some of the data it was considering had been verified in some way. It seems likely that another factor would be that doctors who had undergone appraisal would have a better idea of how to assemble a revalidation folder that gave a good picture of their practice.

The Cost Benefit Analysis

26.32 Following the 2001 pilot study, the GMC undertook a cost benefit analysis or, at least, did its best to do so. It found, not surprisingly, that it was relatively easy to assess the costs of implementing its proposals for the revalidation process. However, it was almost impossible to assess the benefits of revalidation. The benefits were not assessable in the short term; they would accrue over a long period of time. In any event, revalidation was only one aspect of the drive for improved quality and it would be impossible to ascribe any particular improvement to revalidation, as opposed to any other measure. The exercise enabled the GMC to find out how much it would cost to implement the proposals but was otherwise inconclusive.

26.33 The cost analysis showed that, following the introduction of revalidation, the total annual financial deficit to the GMC which would result from the introduction of revalidation could be as much as £14 million. First, there would be the annual operational cost of £9 million. Then there would be a sum of nearly £5 million which would result from the loss to the GMC of the annual retention fees (ARFs) paid by a substantial number of retired or

non-practising doctors who, it was expected, would not choose to seek revalidation but would instead allow their registration to lapse. If some of those doctors transferred onto the supplementary list, for which a reduced ARF was payable, that £5 million loss would be reduced to some extent. So, the overall cost to the GMC would lie somewhere between £9 million and £14 million.

26.34 In addition, the human resource implications were assessed. Doctors would have to spend time preparing their revalidation folders; some would be taken away from clinical work to sit on revalidation groups; some would be involved with assessment of those found to be performing poorly. In all, it was thought that the revalidation proposals would require the annual full-time equivalent of 204 doctors.

Developments during 2001

26.35 During 2001, the GMC's thinking moved in the direction of making a closer linkage between revalidation and appraisal. This closer linkage developed from discussions and correspondence that took place between Sir Donald, then President of the GMC, and representatives of the BMA. The relevant correspondence did not become available to the Inquiry until May 2004, about five months after the GMC witnesses had given evidence. It is welcome as it allows me to fill in a gap in the history.

26.36 The disclosed correspondence shows that, from some time before May 2001, Sir Donald had been in correspondence with the BMA about the revalidation of hospital consultants. I mentioned earlier that Sir Donald had described in his book, 'The Doctors' Tale', how the hospital consultants were opposed to the idea of revalidation. The opposition was channelled through the Central Consultants' and Specialists' Committee (CCSC) of the BMA. At this time, the GPC of the BMA was strongly supportive of the proposals, as was the RCGP.

26.37 On 4th May 2001, Sir Donald wrote to the then Chairman of the BMA, Dr Ian Bogle. It is clear that the letter was written against the background of the recent successful conclusion of the negotiations between the CCSC and the Government about the introduction of a requirement that all consultants working in the NHS should undergo annual appraisal. The Government had been determined to introduce this requirement and the consultants had not been enthusiastic about the idea. However, a deal had been struck, the details of which are of no concern to the Inquiry. Appraisal was to be based upon the principles of 'Good Medical Practice'. At this time, there had not as yet been any agreement about the appraisal of GPs. Sir Donald's letter was about revalidation. He expressed his pleasure that the BMA was committed to the principle of revalidation. He went on to stress the importance of the Government's investment in clinical governance, in particular the collection of data, audit and appraisal. He stressed that the GMC wanted to ensure that revalidation was built on clinical governance. The GMC wanted revalidation to be as simple as possible, consistent with effectiveness. The more effective the NHS's clinical governance arrangements, he said, **'the lighter the GMC's touch can be'**. He then referred to the conclusion of the negotiations on appraisal for consultants and said:

> **'Provided that this agreement is robustly and effectively implemented, NHS appraisal documentation will be the vehicle for revalidation for the**

great majority of NHS consultants. We would take the same approach with other groups of doctors who have appraisal systems. In particular, we look forward to receiving details, when they are agreed, of the outcome of negotiations in relation to appraisal for GPs, academic clinicians, doctors in training and locum doctors working in an institutional setting.

Once these arrangements are in place, which should be soon, it will be possible to put revalidation for the vast majority of doctors in the country on a sound operational footing.'

26.38 That letter does not suggest that the idea of assessment by local revalidation groups was to be abandoned and replaced by NHS appraisal. What Sir Donald was suggesting was that the material to be assessed should be the documents resulting from the appraisal (i.e. the forms completed by the appraiser and the appraisee, which I shall refer to as the 'appraisal forms'), rather than the entire contents of the doctor's revalidation folder.

26.39 Later in that same letter, Sir Donald spoke of the GMC's intention to provide quality assurance of revalidation decisions by calling for a sample of doctors' revalidation folders and having their contents scrutinised by GMC assessors. The purpose of this scrutiny would be to check on a random basis that the outcomes of appraisal were consistent with, and fully supported by, the underlying evidence on which they were based. Sir Donald also outlined the programme for the implementation of the revalidation proposals. At the meeting to take place later that month (May 2001), Council members were to be invited to agree that the Government should be approached about the legislative amendment that would be necessary in order to implement the proposals. It was hoped that the necessary legislation would be in force by about May 2002 and that revalidation would actually begin in 2004.

26.40 At its May 2001 Council meeting, the GMC considered a detailed description of the revalidation process and duly resolved to request the Government to put the necessary legislative framework in place, on the understanding that much detailed work remained to be done.

26.41 On 27th June 2001, Sir Donald wrote to Dr Peter Hawker, Chairman of the CCSC, in reply to a letter from Dr Hawker, which I have not seen. In this letter, Sir Donald repeated the undertaking he had given to Dr Bogle about the use of appraisal documentation as a vehicle for revalidation of NHS consultants. He said that it had not been possible to pilot the use of appraisal documentation in the 2001 pilot study because there had been no such documentation available. This was a reference to the fact that, at the time of the 2001 pilot study, only hospital doctors below consultant grades had undergone appraisal and no standardised forms had been produced for completion by appraisers and appraisees in the course of the appraisal process. Consultant appraisal was launched in April 2001 and appraisal documentation was to be considered in a further pilot study.

26.42 In October 2001, Mr Scott, Chief Executive of the GMC, wrote to Dr Bogle. He repeated the GMC's assurance that, provided appraisal was **'robustly and effectively'** implemented, appraisal documentation would be the vehicle for revalidation of the great majority of NHS

consultants. Later in the same letter, Mr Scott clarified what written material would have to be produced by a doctor wishing to be revalidated. Each consultant would have to produce Forms 1 to 4 of the consultant appraisal documentation for each year of the revalidation period. I described these forms in Chapter 12 and specimen forms for use in GP appraisal are at Appendix D. Consultants would not be required routinely to produce the underlying documentation (i.e. the contents of their revalidation folders) but would have to do so on request. This might occur as part of the quality control sampling or if the revalidation group or the GMC needed **'for other reasons to look in more depth before a decision on revalidation can be made'**. I infer from this letter that it was the intention of the GMC to receive a full set (i.e. Forms 1 to 4) of the completed appraisal forms, which would then be scrutinised by the revalidation group. If the revalidation group was in doubt about whether to recommend revalidation, it would call for the underlying documentation, i.e. the contents of the doctor's revalidation folder.

26.43 The briefing papers circulated prior to the Council meeting in November 2001 contained a progress report, setting out the current position, as described above. The intention was to use for the purposes of the revalidation process the completed appraisal forms for all doctors who had undergone appraisal. Annex A to the briefing paper set out the state of development of the appraisal arrangements for various groups of doctors. In relation to NHS consultants, it was said that NHS appraisal would be the vehicle for revalidation provided that it was robustly and effectively implemented. The briefing paper described other ongoing work, including that with the medical Royal Colleges and their Faculties (i.e. sections dealing with small specialties), which were to develop the standards and criteria that would be imposed and the specific evidence that would be required to be produced by doctors within each specialty. A further pilot study was to be carried out. On a different topic, it was suggested that those doctors who were not in clinical practice (or not in full-time practice) should be eligible for revalidation if they were to submit the results of an assessment carried out at their own expense.

Taking Stock of the Position in 2001

26.44 It seems to me that the practical proposals for the revalidation process set out in the Consultation Paper had been well thought out. They were consistent with the underlying principles of revalidation. The 2001 pilot study had shown that revalidation by the review of folders was feasible, although the proposal for reviewing appraisal forms had not yet been tested. The methods envisaged for revalidation would be quite expensive to put into operation, in terms of both money and human resources. They would also impose a very substantial administrative burden on the GMC, a point to which I shall later return. The proposals complied with the requirements of the Government that there should be as little duplication of effort as possible between appraisal and revalidation. The doctor would prepare his/her folder of evidence for use in appraisal; that appraisal would be carried out either by an employer or under arrangements to be agreed for GPs, for which PCOs were to be responsible. The information within the doctor's folder would, where possible, be drawn from that gathered in the process of clinical governance. The folder or the appraisal forms would be used again in revalidation although, in the majority of cases, the folder would not have to be produced.

26.45 It is true that there were some obvious imperfections and uncertainties. In 2001, consultant appraisal was in its early days, so it was not known how much information would be contained in appraisal forms and how reliable it would be. Clinical governance processes throughout the NHS were in their infancy and the amount of information available from such sources was small; but it might reasonably have been expected to improve in the future. Those who were aware of the position in general practice would have known that there was, at that time, very little 'hard' information available about an individual GP's performance, unless s/he was a single-handed practitioner. Information was collected about GP practices, not about individual practitioners. Moreover, appraisal of GPs had not yet begun; it was scheduled to begin in 2002 but, in 2001, it was not known how it would work in practice. There was also a major concern as to whether appraisal would achieve its formative purpose if the same appraisal forms and folder of information were also to be used for revalidation purposes. Concerns of this nature were discussed within the profession and within the GMC.

26.46 One concern which does not appear to have been raised at this period was whether the standards of performance applied by the CPP in making findings on the issue of seriously deficient performance (SDP) were high enough to provide a satisfactory baseline for revalidation. It will be recalled that the GMC had decided at an early stage that any doctor who was not granted revalidation through the usual revalidation process would not be deprived of his/her licence to practise save as the result of a decision of one of its FTP committees. It must, I think, have been anticipated that the most likely form of FTP procedure that might result in the loss of a licence following an unsuccessful attempt to obtain revalidation would be the performance procedures. There was no discussion of whether the fact that a doctor's performance had been found by the CPP not to be seriously deficient could properly be equated with the assurance to be given to the public that revalidation would mean that their doctor was 'up to date and fit to practise'.

26.47 However, with the *caveats* mentioned above, it appears to me that the foundation for a system of revalidation that would command public confidence had been well laid.

Observations in the Report of the Bristol Inquiry

26.48 The Report of the Public Inquiry into children's heart surgery at the Bristol Royal Infirmary between 1984 and 1995, 'Learning from Bristol', was published in July 2001. The GMC had given evidence to that Inquiry and had explained its proposals for revalidation. These met with the warm approval of the Inquiry Panel, chaired by Professor (now Sir) Ian Kennedy. The Report noted that revalidation involved **'the submission of evidence to external assessors of continuing competence'**. If the doctor could not demonstrate continuing competence, his/her licence to practise would be called into question and ultimately withdrawn. It observed that the GMC's proposals were at an advanced stage of development. The potential value of revalidation was already coming to be widely recognised by the public, as well as within most (although not all) of the healthcare professions. The Report recommended that revalidation should become mandatory for all healthcare professionals and that the necessary processes should be developed as soon as possible. The Report stressed the importance of external assessment in the revalidation process. The fact that there was some resistance within the healthcare

professions must not, it was said, be allowed to stand in the way of progress. The Report observed that the public was entitled to the protection of an assurance that all healthcare professionals had reached agreed levels of competence.

26.49 The Report also discussed ways in which public confidence in the process of revalidation could be gained and retained. The Inquiry Panel plainly understood that the revalidation of doctors was to be carried out by revalidation groups or 'revalidation teams'. The Report recommended that the revalidation team should include **'an external presence'**, i.e. a person or member of an organisation external to the profession and to the employer. This was to be someone with an understanding of the public interest. The Report also suggested that there should be a mechanism for ensuring that the systems for revalidating healthcare professionals were integrated into other initiatives for protecting patients. It proposed that the task of co-ordinating these various systems should be a priority for the Council for the Regulation of Healthcare Professionals (now known as the Council for Healthcare Regulatory Excellence) which was to be established shortly.

The Second Pilot Study

26.50 The GMC's second revalidation pilot study took place in April 2002. Again it was conducted by the RTG. The report setting out the results of the study was issued in September 2002. The purpose of the second study was to examine the quality of the linkage between the **'outputs of appraisal systems'** and the information needed for the revalidation process. It was hoped that a better understanding would be gained of the documentation that would emerge from appraisal (i.e. the completed appraisal forms) and its capacity to demonstrate fitness to practise in accordance with 'Good Medical Practice'. The study also sought to compare the capacity of the completed appraisal forms to demonstrate fitness to practise with the capacity of the underpinning evidence contained in the doctors' folders to do so.

26.51 As I have said, consultant appraisal was introduced in April 2001 and, by April 2002, the process of appraising consultants was well underway. It is clear from the report of the second pilot study that the consultants' appraisal forms were similar to those which were just coming into use for GPs. GP appraisal officially began in April 2002. However, at the time of preparation for the second pilot study, GP appraisal had not yet begun and it appears that the detail of the appraisal forms to be used had not yet been finally agreed. The pilot study comprised consideration by mock revalidation groups of appraisal forms submitted by hospital doctors who had recently undergone appraisal. A few GPs were also included, using appraisal forms that had been developed in Wales as part of a GP appraisal pilot project.

26.52 Some of the mock revalidation groups examined the underpinning evidence contained in the doctors' folders, as well as the appraisal forms. Other groups just considered the appraisal forms. There were four forms. Form 1 provided factual background information about the doctor's career and professional status. Form 2 described the doctor's current professional activities. Form 3 comprised a list of the documents that were held in the doctor's folder and a statement about any continuing professional development that the doctor had undergone in the previous year. Form 4 contained an agreed summary of the discussion that had taken place during the appraisal interview.

26.53 The findings of the pilot study were that, when the evidence contained in doctors' folders was scrutinised by the revalidation group, it would have been sufficient to allow a positive revalidation decision in 69% of cases; in the remaining cases, more information would have been required. However, when only the appraisal forms were considered, the conclusions were that, although the forms were capable in some cases of providing sufficient insight into the doctor's practice to form a sound basis for revalidation, they did not do so in the majority of cases. Only in 32% of cases could a positive revalidation decision have been made; in the remainder, more information would have been required. In particular, there were four specific areas of 'Good Medical Practice' in which there was often a shortage of information. These were 'Working with colleagues', 'Relationships with patients', 'Health' and 'Probity'. Nevertheless, the overall conclusion of the report was that, if all four forms were completed and if Form 4 contained a summary of a **'robust appraisal discussion'**, it could be adequate for the purposes of revalidation. In other words, provided that those conditions were satisfied, there would be no need for a revalidation group to examine the underpinning evidence from the doctor's folder.

26.54 The report explained the RTG's plans for further work. It intended first to work on ways in which the provision of information could be improved, particularly in the four areas of 'Good Medical Practice' that had been identified as giving rise to difficulties. Its work would include the development of a patient questionnaire and of a questionnaire dealing with relationships with colleagues. Then, it was proposed to conduct further pilot studies, using those improved types of information. After that, the RTG intended to focus on the internal GMC procedures for handling the different aspects of the revalidation process. These plans for further work were never taken forward because a halt was called and the RTG was disbanded – I am not sure when.

The Amending Legislation

26.55 In December 2002, the Medical Act 1983 (the 1983 Act) was amended by the addition of new sections 29A to 29J. These were to come into force on a date which has still to be appointed. Section 29A imposed a duty on the GMC to make regulations with respect to **'licences to practise'**. The regulations were to cover the granting, refusal or withdrawal of a licence to practise and the **'revalidation of a medical practitioner of a prescribed description as a condition of his continuing to hold a licence to practise'**. Revalidation was defined in the Act as an **'evaluation of a medical practitioner's fitness to practise'**. The new provisions appear to me to impose on the GMC a duty to make regulations empowering it to revalidate doctors, in the sense of carrying out an evaluation of a doctor's fitness to practise. The legislation gave the GMC very wide powers to require the production of documents and the supply of information for the purpose of revalidation and, if a doctor failed to co-operate with the revalidation process, the GMC could withdraw his/her licence to practise. In the event that a doctor's fitness to practise was thought to be impaired, s/he could be referred into the FTP procedures. The legislation was therefore in place for revalidation to be implemented in accordance with the arrangements described in the Consultation Paper of 2000.

A Change of Direction

26.56 Until April 2003, an informed member of the general public who had been following the development of the GMC's proposals for revalidation would have thought that the GMC intended to be directly responsible for the revalidation of all doctors and that the process would involve an evaluation of the individual doctor's fitness to practise, undertaken by a revalidation group (usually a local revalidation group), of which at least one member would be a lay person. The perception would have been that the twin purposes of revalidation were to be to protect patients and the public from under-performing doctors and to improve the quality of health care generally. However, in April 2003, that informed member of the public would have discovered that the GMC's plans had changed, that it had abandoned the idea of evaluation of individual doctors by revalidation groups and that it now intended to revalidate, in most cases without further scrutiny, all doctors who had undergone five consecutive annual appraisals – or, in fact, fewer than five at the beginning of the revalidation cycle.

The Prospectus of April 2003

26.57 In April 2003, the GMC issued a document which it has since termed a 'Prospectus', but which was in fact a booklet issued to all doctors on the medical register. The Prospectus was entitled 'A Licence to Practise & Revalidation' and it was intended to inform doctors how revalidation was going to work in practice. The Prospectus was designed to enable doctors to start making preparations for revalidation. The purpose of revalidation was explained; it was to modernise the system of regulation and to increase public confidence. The aim was to ensure that doctors were up to date and fit to practise throughout their careers. Doctors were advised to **'start thinking now'** about how they would collect the information that would demonstrate to the GMC that they were fit to practise. The GMC said that, during 2004, it would ask all doctors on the register whether they wanted a licence to practise. If they did, a licence would be granted by the end of 2004, after which time it would be unlawful to practise without a licence. The licence granted would be a general one, not related to any particular specialty. The register, which is a public document, would state whether the doctor held a licence to practise.

26.58 The Prospectus said that revalidation of those doctors who had been granted licences to practise would begin in April 2005 and that, in order to retain his/her licence to practise, every doctor would have to be revalidated at some stage over the following five years. Revalidation would require the doctor personally to show the GMC that s/he had been practising medicine in accordance with the principles of 'Good Medical Practice', as applied to the doctor's specialty. The Prospectus stated that the GMC would not seek to prescribe exactly what information a doctor should collect for this purpose. Indeed, the GMC had formed the view (apparently on the basis of legal advice which it had received) that it did not have the legal powers to do so. I interpose to say that I find that surprising in view of the powers that it will have when sections 29A to 29J of the 1983 Act (as amended) come into force; but that is what was said. The information the doctor was to provide would have to cover all headings in 'Good Medical Practice'. It would be up to each individual doctor to decide how s/he would demonstrate to the GMC that s/he was fit to practise.

26.59 The Prospectus explained that there were to be two possible routes to revalidation: the **'appraisal route'** and the **'independent route'**. In order to take the **'appraisal route'**, the doctor would have to show the GMC that s/he worked in a **'managed environment'** and had **'participated in an annual appraisal system'**. For an appraisal to be acceptable to the GMC, it would have to be based on the principles of 'Good Medical Practice' and **'be operated within a quality assurance system'**. It was said that the GMC believed that **'full participation in annual appraisal'**, with **'completed supporting documentation'**, during the revalidation cycle was **'a powerful indicator of a doctor's current fitness to practise'**.

26.60 It seems that the GMC had arrived at this state of belief despite the fact that the second pilot study had shown that in only 32% of cases had the perusal of the completed appraisal forms been sufficient to allow a decision to be made that the doctor was fit to practise. Yet the Prospectus asserted that the GMC believed that merely taking part in annual appraisal (for the purpose of which appraisal forms were completed) would provide a powerful indicator that the doctor was fit to practise. It is not clear on what evidence this belief was based.

26.61 The Prospectus explained that doctors working in a variety of NHS settings, including GPs working under a General Medical Services (GMS) Contract, would be able to consider themselves as working within a **'managed environment'** for the purpose of revalidation. The justification for that was that GPs were participating in a scheme of annual appraisal with quality assurance. However, it does not seem to me that GP principals, who are independent contractors, can be said to work in a **'managed environment'** within the ordinary meaning of that term. The Prospectus said that, for those doctors who were already subject to appraisal, there was nothing additional that they needed to do to prepare for revalidation. They should not have to collect any data for revalidation over and above that which they would be required to record and keep for appraisal and other local systems. Provided doctors were confident that, by the time they came to be revalidated, they would have had at least one appraisal, they need do nothing more. The Prospectus made clear that the GMC would not usually ask to see the folder of evidence that a doctor had prepared for appraisal. However, the GMC might wish to examine a sample of such folders.

26.62 The Prospectus then outlined the independent route to revalidation. This might apply to doctors working outside mainstream health care, those with 'portfolio' practices or those taking a career break or working overseas. For such doctors, the onus would be on them to produce evidence to show that they were adopting the principles of 'Good Medical Practice' and were undertaking appropriate continuing professional development. Acceptable evidence would include **'appropriate quality indicators'**, where necessary supported by other data and information. The Prospectus explained that the GMC was developing a range of tools to help doctors who wanted to provide independent evidence for use in the revalidation process. These would include self-declaration forms to cover the 'Probity' and 'Health' headings of 'Good Medical Practice'. Also, there would be a patient satisfaction questionnaire to cover the heading 'Relationships with patients' and a professional colleague survey which could be used for the heading 'Working with colleagues'. The Prospectus said that the evidence would be reviewed in a way which

would be **'as efficient, effective and proportionate to the aims of the process as possible'**. The GMC did say that it would not normally ask the doctor to provide all the information used to support evidence of practice quality.

26.63 The Prospectus advised doctors that they would be given notice in due course of what was required of them and when. It also indicated that the GMC intended to carry out **'appropriate testing'** before revalidation began in 2005. It was not made clear to what this **'testing'** referred.

26.64 The Prospectus also provided an explanation of the processes which would follow if the doctor failed to provide sufficient or adequate information, and described the circumstances in which a doctor's licence to practise might be withdrawn. It explained that, if the information initially provided by the doctor was thought to be insufficient, the GMC would ask for further information. If, thereafter, it was considered that the information was **'inadequate'** the GMC would assess the doctor's case to see if there was:

> **'. . . positive evidence that you** (*the doctor*) **are not fit to practise.**
>
> **If there is not we will revalidate you and your licence to practise will remain valid. If there is we will refer you to the appropriate fitness to practise procedure. The process will be bound by statutory rules and you will have the right to appeal against our decision.'**

And later:

> **'We will only withdraw your licence if ... a fitness to practise panel directs that your registration should be suspended or erased.'**

26.65 The Prospectus did not explain how the stage between the initial consideration of information and the final stage of referral into the FTP procedures would be carried out. I feel bound to draw attention to the difference between the language used to address doctors and that later used to explain revalidation to the public. Doctors were told that they would be revalidated unless there was positive evidence that they were unfit to practise. The public was told that, to secure revalidation, a doctor would have to demonstrate that s/he was up to date and fit to practise.

26.66 This explanation was followed by a section headed **'Questions and Answers'**. One question asked how the proposed system of revalidation compared with assurance systems outside medicine. In the answer, the Prospectus stated that there was a **'good professional comparison'** with the periodic formal reassessment that airline pilots must undergo if they wish to retain their licence. It was said that this process was analogous in several ways to the new arrangements for doctors. First, it promoted the idea of regular confirmation of fitness to practise. Second, the purpose of reassessing pilots is, it was said, to ensure that they have remained good pilots, not to find out if they are bad pilots. There were more appropriate local and rapid ways of identifying bad pilots. Third, it was said that no airline would rely only on periodic reassessments; airlines have their own local management procedures to assess their pilots' suitability for specific work. In one respect, this comparison between doctors and pilots is particularly apposite; both doctors and airline pilots take our lives in their hands when working. I can see also that there may be

other similarities between the revalidation of doctors and the formal assessments undergone by pilots. However, the answer in the Prospectus did not mention an important distinction between the two processes, namely that pilots have to undergo a series of competence tests in the course of periodic assessment, whereas revalidation, as proposed in the prospectus, would not involve any such testing.

26.67 Another question and answer dealt with the role of lay persons. It will be recalled that, under the arrangements envisaged up to the end of the second pilot study, undertaken in April 2002, at least one member of the local revalidation group was to be a lay person. The Prospectus of April 2003 explained that lay people would be involved at two levels, **'in both the design of the systems and their operation'**. It appears that the reference to lay input to the design was a reference to the fact that lay people had been involved in the development of 'Good Medical Practice' and in **'shaping policy on revalidation'**. It was clear that lay involvement in the appraisal route to revalidation was to be limited to the fact that **'Appraisal systems based on *Good Medical Practice* require doctors to reflect on the quality of their relationship with patients.'** It was said that **'Doctors may use questionnaires completed by patients as a means of giving us information about the quality of their professional practice.'** Presumably, this related to doctors who were seeking revalidation via the independent route. Third, it was noted that **'The quality of doctors' relationships with patients will also be considered as part of clinical governance systems.'** Finally, it was said that lay people would monitor the GMC's processes; how they would do so was not explained. It was said that decision panels considering individual cases would have a lay member. I think that these would be the panels which were to hear appeals against licensing decisions. It was said that the GMC's Patients' Reference Group would **'regularly consider the revalidation process'**. What seems clear is that there was to be no routine lay involvement in the decision whether to revalidate an individual doctor. In short, there had been a retreat from the earlier commitment to active lay involvement in that process.

26.68 Thus it appeared that, by early 2003, not only had the GMC rejected the idea that revalidation should, for most doctors, be based on evaluation by local revalidation groups, it had also moved to a position where, as it was put in the medical press at the time, for doctors working in the NHS, **'five satisfactory appraisals equals revalidation'**. Indeed, in the early years, only one appraisal might equal revalidation. How and why the GMC had moved to this position was not made clear.

26.69 The implications of the change must be understood. The GMC had moved from evaluation by a revalidation group of an individual doctor's fitness to practise by means of examination of evidence (be it the contents of his/her folder or the completed set of appraisal forms) to a position where there was to be no individual evaluation at all but, instead, an assumption that, if the doctor had been through the appraisal process, s/he must be up to date and fit to practise.

Reactions to the New Proposals

26.70 Between April 2003 and the time when the GMC was due to give evidence to the Inquiry, there was considerable discussion in the medical press about the new proposals. By and

large, doctors seemed content with the proposals although some objections were raised from within the profession. For example, an article which appeared in the periodical 'Doctor', on 17th July 2003, reported that Professor Pringle, then Chairman of the RCGP and a member of the GMC, had warned that revalidation under the current proposals would not achieve what it purported to achieve. He said that it would not offer the public protection from poor or under-performing doctors. It would only **'create an illusion'** of protection.

26.71 During the second half of 2003, the Inquiry received a good deal of evidence about the appraisal of GPs, which had been introduced in the spring of 2002. By the time of the Inquiry hearings, one cycle of appraisal of GP principals should have been completed. The Inquiry heard evidence from a number of witnesses, in particular from Dr Chisholm, and also from Dr Reith, who gave evidence and attended the Inquiry seminars on behalf of the RCGP. I have referred to their evidence in Chapter 12. Both were enthusiasts for the concept of the appraisal of GPs – indeed of all doctors – but they expressed concern about the use of appraisal as the foundation for revalidation. The more I heard, the more concerned I became at the prospect that revalidation was to depend so heavily on appraisal.

26.72 The main concern that the witnesses expressed, the validity of which I came to accept, was that the appraisal of GPs had been designed for purely formative purposes; it was intended that it would provide for doctors an opportunity, in dedicated time, to think and talk about their practice and, by means of this process, to improve it. It had not been intended to provide any form of assessment or evaluation of the doctor. Appraisers were not intended to, and had not been trained to, form any judgement about an appraisee's fitness to practise. Appraisal was to be based upon (although not limited to) a confidential discussion based on a folder of documents produced by the doctor. The appraiser's role was to stimulate self-examination by the appraisee in circumstances of complete confidentiality and to help the appraisee to plan his/her future professional development. GPs being appraised were to feel free to raise concerns about themselves or their practices without any fear that they would be 'judged' upon them, let alone that they would be reported. Only if serious concerns arose would the appraiser stop the appraisal and report his/her concerns to the PCO. That was the only circumstance in which a GP could 'fail' an appraisal. If appraisal were now to be used for the purposes of assessment or evaluation, GPs might not be frank and open with their appraiser and the formative value of appraisal would be lost. GPs had initially been suspicious about the whole idea of appraisal and had accepted it only when satisfied of its formative nature.

26.73 The second concern was that the arrangements for the appraisal of GPs were consistent with its formative purpose and were not appropriate for an assessment or evaluation. The contents of the folder of information upon which the appraisal was based were selected entirely by the doctor being appraised. There was no list of documents that the doctor had to produce. Nor was there, in any of the areas examined by the Inquiry, any direct input by the PCO into the appraisal process of data collected from clinical governance activity. A doctor could submit such data if s/he had it and wanted to submit it but, if s/he preferred not to, there was no obligation to do so. In any event, as I explained in Chapter 12, PCOs have very little clinical governance data that relates to an individual doctor; in the main, it

relates to the GP practice as a whole. A further problem was that PCOs would not necessarily tell an appraiser if they had any particular concern about a doctor. As a result, a PCO might be aware of a serious complaint against the appraisee; the appraisee might or might not raise it for discussion with the appraiser but, if s/he did not, the appraiser would remain in ignorance of it.

26.74 During the hearings, I had the opportunity to examine some anonymised completed appraisal forms provided by the Tameside and Glossop Primary Care Trust (PCT). The amount and type of information contained on the forms produced was very variable but, in some cases, it was sparse and could never have provided a basis for an evaluation of fitness to practise, even if the appraiser had been qualified and trained to carry out that task. A further concern was that, apart from the section of Form 4 on which were set out the doctor's training needs for the coming year, some PCOs (including the Tameside PCT) did not receive any of the appraisal forms. It had apparently been intended that they should receive copies of Form 4 (which should contain a summary of the appraisal discussion) but it became clear in the course of the Inquiry's evidence that this was not happening in some areas. Moreover, it had never been envisaged that PCOs would see the contents of the doctor's folder and the evidence to the Inquiry was that they did not do so. Thus, although appraisal was said to be a part of clinical governance, many PCOs had no input and received very little output.

26.75 Yet another concern related to the variable arrangements made by different PCTs when introducing appraisal. In some places, many GPs had not yet been appraised; in others, they had been appraised, but the quality of appraisal as between PCTs appeared to be variable. Selection processes for appraisers were also variable; in some places, PCTs had insisted that only accredited GP trainers could act as appraisers; in others the PCT had simply called for volunteers. Appraisers underwent training but it was very brief and often provided little more than an introduction to the documentation. Some PCTs provided additional support and training; others did not. Certainly, there had been no attempt at teaching appraisers how to evaluate a doctor's fitness to practise. Indeed, this is hardly surprising as that was not the purpose of the exercise. Appraisers were advised that, in the unlikely event that a serious concern arose about a doctor's fitness to practise, the appraisal should be discontinued and the concerns reported to the PCT. How serious the concern would have to be before the appraiser took that action was not clear. Advice issued by the DoH suggests that it would be appropriate to discontinue appraisal if it appeared that the doctor's conduct, health or performance posed a threat to patients. The Inquiry has not heard of any case in which an appraisal has been stopped for that reason.

26.76 I agreed with those witnesses, including Dr Reith, Dr Chisholm and Professor Richard Baker, who told the Inquiry that this process of appraisal would not be an appropriate basis for revalidation. It could not be compared with the kind of appraisal that I know takes place in many employment situations, where an employee is appraised by a senior person who is in possession of a good deal of information about the employee's performance during the previous year. Nor did it appear to me that GP appraisal could be considered a suitable substitute for the scrutiny of a doctor's folder by a local revalidation group. It seemed to me that, under the arrangements described in the Prospectus of April 2003, the GMC had, in effect, delegated responsibility for revalidation of GPs to appraisers, who

were not expected and were not equipped to carry out an evaluation of the doctor's fitness to practise. The GMC was not intending to examine the doctors' folders and it was not clear from the Prospectus whether it would examine the appraisal forms. It subsequently became clear that there was no intention to examine the forms. In short, there was to be no **'evaluation'**, as required by the imminent amendments to the 1983 Act. It appeared to me that, instead, the GMC was going to renew, virtually automatically, the licence to practise of any doctor seeking revalidation provided that his/her appraisal had not been stopped on account of serious concerns having arisen about his/her fitness to practise. I became concerned that such a system would offer no greater protection to patients than that afforded by existing systems and that, therefore, the public could not reasonably have confidence in revalidation as then proposed.

When and Why Did the General Medical Council Change Direction?

26.77 The Inquiry invited the GMC to provide a witness statement dealing with its proposals for revalidation. The GMC submitted a written statement from Mr Brearley. Shortly before the Inquiry hearings reached the stage at which revalidation was to be discussed, the GMC announced an important modification to its previous proposals. This was the addition of a requirement that a doctor seeking revalidation should produce a 'clinical governance certificate', signed by a senior officer of the organisation employing the doctor or, in the case of a GP, by an officer (probably the clinical governance lead) of his/her PCO. The certificate would state that there were no (or no significant) unresolved concerns about the doctor, arising out of clinical governance procedures. There was still left in place the basic proposal that, for doctors working in a **'managed environment'**, revalidation would be based upon appraisal. I shall discuss this modification of the GMC's proposals later in this Chapter. For the moment, I shall attempt to focus upon the course of events in the months preceding April 2003 and the reasons for the change of direction.

26.78 Mr Brearley's witness statement did not explain the events that had led to the publication of the new proposals in April 2003. Accordingly, I examined the briefing papers and minutes of the Council meetings that took place during this period. I could find no paper dealing with proposals for the revalidation process or any reference to a proposal for change during the period between September 2002 and April 2003. The minutes of Council meetings during this period contain no reference to a decision to change the arrangements previously proposed. It seems that the decision may have been taken at a special internal conference in February 2003. I have seen no record of the discussion which took place there.

26.79 Dame Lesley Southgate told the Inquiry that the RTG, of which she was a member, had been disbanded. She did not say when this had happened. She seemed very reticent on this topic and I did not press her about it but she did say that she thought that the group had been disbanded because it had been 'parting company' with the GMC on the direction revalidation was to take. Mr Brearley said that the further work which it had been planned that the RTG should undertake after the second pilot study was not undertaken because of the GMC's increasing interest in using clinical governance processes for revalidation and a 'slight change of direction with regard to evaluation of evidence'.

26.80 Dr Chisholm told the Inquiry that the GPC of the BMA had been extremely supportive of the GMC's early proposals for revalidation based upon scrutiny of the doctor's folder. It had worked with the RCGP to produce the booklet 'Good Medical Practice for General Practitioners', which was to form the basis of the standards to be applied by those undertaking the revalidation evaluation. When asked about appraisal, he said that he and his Committee were strongly supportive of appraisal and were anxious to see it well resourced and implemented. However, he expressed reservations about the nature of the direct linkage between appraisal and revalidation that had been GMC policy since publication of the Prospectus in April 2003. He then volunteered that he thought that there were two reasons why the GMC had changed its policy. First, he thought that the GMC had found the concept of in-depth revalidation to be 'rather daunting in terms of the complexity of the task'. Second, he said that there was 'really quite strong enthusiasm from the BMA representatives of the hospital doctors to go down the route of five satisfactory appraisals being the way to revalidate'. He added that, at the last GMC meeting he had attended (which would have been the last meeting of the 'old' GMC of 104 members on 20th and 21st May 2003), Professor Pringle had 'made a very trenchant attack on the way in which appraisal and revalidation were now to be linked'. Dr Chisholm added that the debate was now over and that the April 2003 proposals were to be the 'way forward'. He accepted that this represented a considerable shift from the GMC's earlier proposals. Later in his evidence, he said that there had been voluble opposition to the original proposals and that the GMC had been concerned at their resource implications. When asked whether the opposition had been less voluble from GPs than from hospital consultants and junior hospital doctors, he said that he thought that it had, although he was more confident in saying that about the leaders of the GPs (who had been strongly supportive of the GMC's original proposals) than about the rank and file. He said that many GPs might not thank the RCGP and the GPC for campaigning for 'a more complex and thoroughgoing system'. When asked whether the leaders of the profession should give a lead to doctors and encourage them to accept the need for a real evaluation as part of the revalidation process, he said that several leaders of the profession had spoken out both in public and in private against the new proposals but that the 'floor' of the GMC had been against them, including the voices of some medical Royal Colleges (but not the RCGP) and of the BMA.

26.81 Mr Brearley gave oral evidence on behalf of the GMC in relation to the question of the change of direction. The thrust of his evidence was that the Prospectus of April 2003 did not represent a major change of direction at all. The underlying principles were exactly as they had been before. There had been a slight change of direction which had been made solely in order to achieve improvements to revalidation. The new arrangements were, he said, better than the old ones would have been.

26.82 In his written statement, dated 5th December 2003, Mr Brearley said that the pilot studies of 2001 and 2002 had revealed certain **'weaknesses'** in the arrangements that were then contemplated. These were that:

- despite regular local review, formal scrutiny of the folders would take place only once every five years
- the scrutiny would normally take place without the doctor being present

- there would be no obvious link to clinical governance
- it was doubtful that the system would be cost-effective.

26.83 With great respect to Mr Brearley, I find the first three of these supposed **'weaknesses'** wholly unconvincing as reasons for abandoning the earlier proposals. I can see that an assessment by a local revalidation group of the doctor's folder or appraisal forms that took place more frequently than once every five years might be better than what had originally been planned, but I cannot see that to remove all formal scrutiny would be an improvement. As to the second 'weakness', I can see that an assessment by a local revalidation group that was attended by the doctor might be better than one from which s/he was absent. But to abandon the assessment by a local revalidation group altogether would not remove that 'weakness'. Instead, it would throw away such benefits as would accrue from an assessment in the absence of the doctor. And it cannot sensibly be suggested that a wholly private and formative appraisal process can replace the objective scrutiny that would have taken place under the original proposals. Nor can I accept the third 'weakness', namely that the original proposals did not involve an **'obvious link to clinical governance'**. Indeed they did, to the extent that it was intended that the folder, on which both appraisal and revalidation were to be based, would contain information which came from clinical governance procedures. However, as I have pointed out, for individual GPs, this link was limited because there was and is not a great deal of 'hard' data from clinical governance. Under the original proposals, at least the contents of the doctor's folder would have been seen by people responsible for making an evaluation whereas, under the new proposals, there was and is to be no evaluation of that material at all.

26.84 As to the fourth 'weakness', I have already mentioned the cost benefit analysis of revalidation as a whole, which had been attempted in 2001 and had shown that it was not possible to evaluate the benefits. So far as I am aware, no analysis has ever been carried out of the 'value' of the use of local revalidation groups, as opposed to the 'value' of any other method of revalidation. I entirely accept that it would be a difficult exercise. The cost of using revalidation groups to examine the folders was known from the analysis carried out in 2001. It might well have been cheaper if appraisal forms only had been looked at. If what this 'weakness' amounted to was that the GMC came to the conclusion that the use of revalidation groups was too expensive, then I could understand that point of view. What I cannot understand or accept is that the abandonment of the local revalidation groups in favour of appraisal could be seen as an improvement in itself and could achieve a greater – or even a similar – degree of protection for patients.

26.85 In oral evidence, Leading Counsel to the Inquiry took Mr Brearley through the Consultation Paper of 2000 and the results of the two pilot studies. Mr Brearley said that the pilot studies had highlighted a number of problems. He mentioned some of those problems. He said that the pilot studies had been small, and that, because of the limited number and range of practice of the doctors involved, it had not been possible to assess the sensitivity of the method of evaluation being used. I see the logic of that and accept that the pilot studies left a degree of uncertainty. However, as I pointed out, further pilot studies could have been carried out. Mr Brearley mentioned that there was no 'gold standard' against which

to measure the effectiveness of the process of scrutiny. I agree, but I think that it would have been possible – although expensive – to devise an objective test, possibly by subjecting a group of doctors to the type of assessment used by the GMC in its performance procedures and comparing the results with an evaluation of their folders or appraisal forms. In short, although I could see that the pilot studies had not demonstrated conclusively that the proposed method would be effective, this was not a reason for abandoning the local revalidation groups at that stage.

26.86 Mr Brearley said that the second pilot study had demonstrated that examination of the appraisal forms alone would not be a sufficient basis for evaluation. Revalidation groups would also have needed to see the underlying documents contained in the doctors' folders. He accepted that the second pilot study had been of value in that it had shown what kind of information was useful for the purposes of making an evaluation of fitness to practise. He made the point, in relation to the current proposals (under which revalidation is based upon the completion of appraisal), that what had been learned from the pilot study could be used to improve appraisal, by ensuring that the right kind of information was included in the appraisal process. However, he accepted that the GMC had never sought to prescribe what information ought to go into appraisal; that, he said, was the role of the medical Royal Colleges. He hoped to see development along those lines and was sure that appraisal would improve over time.

26.87 As I have said, Mr Brearley said that there had been 'a slight change of direction with regard to evaluation of evidence'. He was asked whether there had been any resistance to the original proposals from the profession. He replied that doctors felt under tremendous pressure; medicine was a very stressful occupation and there were high alcoholism and suicide rates. Also there was a high drop-out rate. Any additional burden would make things worse. He added that appraisal had been made a contractual requirement and doctors had been promised dedicated time for it and for the necessary preparations. However, this had not been provided and all the work had to be done in the doctors' own time. Be that as it may, I cannot see that submitting the appraisal forms or the folder – already prepared – to a revalidation group imposes any significant burden additional to that imposed by the requirement to undergo appraisal.

26.88 Mr Brearley then said that the decision to change from revalidation groups to reliance upon appraisal and clinical governance had come about because of the rapid development of clinical governance. He said that clinical governance had been in its infancy when the process using revalidation groups had been designed. He accepted that, in the Consultation Paper of 2000, the GMC had talked about the advent of clinical governance and that it had concluded then that both clinical governance and revalidation as separate entities were necessary for patient protection. The Consultation Paper had said that neither would be sufficient without the other. Leading Counsel to the Inquiry suggested that it was somewhat disingenuous for the GMC to claim that it was the progress of clinical governance and appraisal that had removed the need for separate evaluation for the purposes of revalidation and had allowed the GMC to change its proposals and make revalidation dependent upon appraisal. Mr Brearley rejected that suggestion and asserted that, in 2000, the role of clinical governance had been unclear;

it was only recently that the GMC had seen what part clinical governance could play and would play in the future when it reached its full potential.

26.89 When Leading Counsel suggested that the GMC had made a substantial shift in direction, Mr Brearley suggested that she was making 'terribly heavy weather' of it. He asserted that the system that the GMC now proposed would be better than the one previously planned. When asked in what respects, he said that the new system brought in clinical governance information that would not otherwise have been available. Under the original revalidation plans, he said, some of the information held by the NHS trust or PCO would not have gone into the doctor's folder and would not have been considered by the revalidation group because what went into the folder was a matter for the doctor. However, he agreed that it had been the original intention that someone from the NHS trust or PCO, who would have knowledge of the doctor, should be on the revalidation group. But, he said, it would have been impracticable to arrange that in all cases. I can see that that might have been so. However, it does not seem to me that it would have been difficult to build into the original revalidation group system a requirement that the NHS trust or PCO should provide clinical governance data. In fact, it would also have been possible, had it been thought desirable, to ask the NHS trust or PCO to provide a clinical governance certificate as well.

26.90 When asked whether the GMC was now confident that appraisal and clinical governance were working well all over the country to the extent that it was safe to rely upon them for revalidation, Mr Brearley said that the GMC must assume that they were because the law of the land required it to be so. However, the evidence received by the Inquiry has shown that clinical governance and appraisal are not working well everywhere. I have already referred to the evidence received by the Inquiry in relation to appraisal. Evidence from the Commission for Health Improvement showed that clinical governance was operating patchily and the September 2003 Report of the National Audit Office showed a similar picture. At the Inquiry's seminars, Professor Aidan Halligan, Deputy CMO for England and Director of Clinical Governance for the NHS, said that clinical governance was not yet embedded in primary care. Mr Brearley himself had said in evidence that data collection in hospitals was 'a nightmare'. When reminded of that, he observed that data collection was only a part of clinical governance. That I accept, but it seems to me that no one who has considered the available evidence could conclude that clinical governance and appraisal were working well over the whole country. Indeed, Mr Brearley himself accepted that appraisal and clinical governance were not working perfectly but said that they were much improved and he was confident that they would continue to improve. He may be right, but it is difficult to understand how, at the time when the GMC decided to move away from its plans for evaluation of the doctor's fitness to practise, based on scrutiny of appraisal forms or folders, to a system that relied on taking part in appraisal and the provision of a clinical governance certificate, it could have had confidence in the operation of clinical governance or appraisal. As I shall shortly explain, the GMC was, in fact, well aware of the limitations of appraisal and clinical governance.

26.91 When Mr Brearley was asked to comment on the reasons given by Dr Chisholm for the GMC's change of stance, he repeated that none of those reasons was the principal reason. The principal reason was that the new model was better. Had the GMC found the

prospect of organising individual scrutiny of folders to be daunting? Mr Brearley's answer was 'yes', that it was a big task but that was not a problem. However, there was no point in the GMC doing something separate just so that it could claim ownership of the system. If clinical governance could provide a better system, there was no point in the GMC pursuing its own system. Had there been any opposition from the profession? Mr Brearley said that there had been opposition from some members of the profession because of the demands upon their time. Had cost been a factor? Mr Brearley said that it had to some extent because it is the doctors' money that the GMC spends and revalidation groups would be expensive. But he said that, if revalidation groups had been the only way of doing the job properly, the GMC would have funded them. However, if it was not necessary to spend that money, it was sensible not to do so.

26.92 Sir Graeme Catto and Mr Scott were also asked about the apparent change of stance. They too said that this was not a substantial change but a 'modification' or 'refinement' of the previous plans. There had, they said, been a recognition that reliance on clinical governance would be a better way of achieving the aims and objectives of revalidation. I must say that the move away from an arrangement whereby the evidence relating to the individual doctor seeking revalidation would be assessed by a revalidation group and the doctor's fitness to practise would be evaluated, to an arrangement where the doctor is assumed to be fit to practise if s/he has undergone appraisal and there are said to be no significant unresolved concerns about his/her practice, seems to me to be a major change. Moreover, it seems to me that, provided that the material on which the assessment was based was adequate, the former arrangement would have a much better prospect of ascertaining whether a doctor was or was not fit to practise and would, therefore, afford a greater degree of protection for patients.

Further Evidence after the Inquiry Hearings

26.93 However, further evidence was later discovered which threw light on the GMC's thinking on revalidation in the period between September 2002 and April 2003. In evidence, Mr Brearley mentioned that the GMC had commissioned management consultants (in fact, an organisation known as SHM Productions Ltd (SHM)) to undertake a study of how revalidation and recertification were carried out in other countries. A copy of SHM's study was submitted to the Inquiry in December 2003. On reading it, the Inquiry team found that it contained a reference to earlier reports on revalidation. Those were duly requested. The second (March 2003) report arrived shortly afterwards. A further request was made for the first report and this arrived in February 2004.

The First SHM Report

26.94 SHM's first report was dated December 2002. It was entitled 'GMC revalidation proposal – identifying key issues and alternatives'. The introductory section recorded that, because revalidation had **'far reaching implications both for the organisation and for the profession as a whole ... it is necessary to step back and consider what the potential pitfalls may be'**. This would require detailed evaluation and analysis (phase two) which would be carried out by SHM the following year (2003). For the present, there would be

an overview of the major issues and a discussion of the key areas of contention. The report would address five questions:

> **'• What is the current context for revalidation?**
>
> **• Which models have been used for professional revalidation and regulation elsewhere?**
>
> **• What precisely is the current proposal for revalidation?**
>
> **• What alternative models should be considered?**
>
> **• What are the next steps that constitute the body of the work required in phase two?'**

26.95 Four key **'areas'** of revalidation were identified, by reference to which the SHM analysis was to be carried out. These were:

> **'1. What evidence should doctors provide for review? *The inputs.***
>
> **2. How should the evaluation be carried out? *The review process.***
>
> **3. How can the 'hearts and minds' of doctors be captured? *Doctor buy-in.***
>
> **4. How can the public be reassured and made to feel ''safe''? *Public buy-in.*'**

26.96 The report described the activities undertaken by SHM during the first phase of the project. These included a review of GMC documentation, a review of externally published information about revalidation, telephone interviews with GMC members and staff, and a review of alternative models in operation abroad. These reviews had been followed by a discussion between the SHM team and the GMC revalidation team. I shall summarise the report's conclusions.

26.97 The report concluded that there was general acceptance on all sides that some form of revalidation was required, but there was considerable divergence of opinion among GMC members and staff about the form it should take. Areas of agreement listed were that:

- some form of revalidation was necessary and desirable
- the model adopted must be simple to implement
- the model adopted must be agreed by doctors and patient groups
- reviewing folders of evidence from 100% of doctors was not feasible owing to costs and resources
- the current thinking was that some sort of link with appraisal was inevitable, but there was concern that the **'platform'** offered by appraisal was **'patchy at best and very shaky at worst'**
- the key risks were of trying to do too much too soon or of panicking and doing too little. Either would damage the GMC's credibility

- no model could claim to prevent 'another Shipman'
- communication and understanding were key issues, for both doctors and the public.

26.98 It was reported that there was little agreement about what revalidation could achieve. There were strong views and diverging opinions on almost all aspects of the revalidation proposals from the objectives down to the criteria for success. These were analysed in some detail. For example, in relation to the question of what should be seen as the chief motivation towards revalidation, it was said that some saw revalidation as having emerged from the need to ensure that the public had confidence in doctors; others saw revalidation as having arisen as a result of Government pressure following high profile misconduct cases such as Shipman's; and yet others saw it as part of a worldwide trend towards modernisation of professional regulation. This was followed by a discussion about the advantages of presenting revalidation in a positive rather than a negative light. However, the point was made that to present revalidation as a means of ensuring high professional standards was somewhat undermined by the fact that revalidation would present only a **'very low bar'** for doctors to achieve. The report recorded the comment by one person interviewed that revalidation was **'merely an assessment of basic proficiency'**.

26.99 Another important topic discussed in some detail was the linkage between appraisal and revalidation. It was said that there was general agreement that **'some sort of link'** was necessary. There were two main arguments in support of a link. First, the use of the same material for both processes would minimise the workload for doctors. Second, the link would ensure that appraisal was given **'an edge'**; some of those interviewed expressed disapproval of the idea that appraisal should be purely developmental; one said, **'it is a form of assessment ... if it is purely chatting it is no use at all'**. There then followed a comprehensive list of concerns about using appraisal for the purpose of revalidation. These concerns must have been expressed during the interviews with GMC members and staff. They bear a strong resemblance to the kind of concerns that the Inquiry heard when receiving evidence about appraisal and its proposed link with revalidation. For example, concern was expressed about the **'immaturity'** of appraisal and about the patchy way in which it was operating. Doubts were also expressed about the ability of appraisal to pick up a bad doctor. Also mentioned was the dichotomy between the formative nature of appraisal and its use in the process of revalidation, which should be summative (i.e. pass/fail) in nature. It was said that appraisal had been presented as formative and supportive, while the Government saw it as a means of performance management. Doubts were expressed about the abilities of appraisers and the rigour with which appraisals would be carried out. One interviewee expressed a fear that under-performing doctors would be allowed to continue in practice on the basis of **'anything for a quiet life'**. There was no incentive for an appraiser to report poor performance; such a report would be bound to **'ruffle feathers'** and to damage professional relationships. It was said that, historically, there had been **'a cultural problem of doctors reporting their colleagues'**. One interviewee observed that employers might be unwilling to bring forward doctors who were not performing well, as they might think that it was **'better to ''contain'' a bad doctor than have no doctor at all'**. Also, the issue of consistency of quality of appraisal was raised, and of the materials on which appraisal was based. Some interviewees expressed concern about the lack of lay involvement in appraisal which might lead to a perception

by the public that revalidation would take place inside the **'club'**. Another point was that it might appear that the whole revalidation process was being passed over to employers and that the GMC was **'admitting defeat'**. If the GMC was to rely on employers, it would have to ensure that the employers' systems were **'strong'**. This section of the report concluded with the observation that these objections were a **'significant catalogue'** which could not and should not be **'dismissed lightly'**.

26.100 Another section of the report discussed the process by which the evidence provided by doctors should be reviewed for the purposes of revalidation and who should take part in that review. Some interviewees believed that it was critical that there must be active lay involvement. There was considerable divergence of view as to what the role of the GMC should be in the review; at the extremes, some thought that it should be wholly responsible for the revalidation process and others thought that it should limit itself to the quality assurance of a process to be carried out at local level. The role of employers was also discussed and an interesting range of views recorded. For example, it was suggested that employers could play a useful role in acting as the **'early warning system'** for identifying poorly performing doctors before they were identified through the revalidation process. Also, they could help by providing the GMC with the information which was required from doctors for the purposes of revalidation. However, concern was expressed that employers could not be relied upon to report **'at-risk'** doctors. That would require a **'considerable change of culture'**. Too often, it was said, NHS trusts allowed a poorly performing doctor to move on from post to post without reporting him/her to the GMC.

26.101 The next section of the report discussed various possible 'models' for revalidation. First, approaches in other countries and professions were considered. The mechanisms used were classified as **'soft'** (i.e. those with a developmental focus) and **'hard'** (i.e. those which depended upon assessment or testing). I note that the column relating to pilots in this country records that they are subject to the **'hardest'** mechanism, namely **'testing'**. I mention that because, in its Prospectus published a few months later, in April 2003, the GMC suggested, as I have previously mentioned, that there was **'a good professional comparison'** between its new proposals for the revalidation of doctors and the periodic reassessments undergone by airline pilots.

26.102 The report then listed seven possible models for the revalidation of doctors. These consisted of one model which was said to be **'currently under consideration'**, three possible models which had already been discarded and three more models which had emerged from discussions between SHM and the GMC and which were said to be worthy of further examination. In respect of each model, an attempt was made to describe how it would work in practice, and to assess its potential acceptability to doctors and patients, its feasibility and cost. Assumptions had had to be made but these had been based upon discussions with GMC staff.

26.103 The model **'currently under consideration'** was not one of the models that had been tested in the pilot studies; nor was it the model that was to emerge in April 2003. Under this model, doctors were to provide Form 4 (including their personal development plan) from their appraisal documentation (although not their folders and not Forms 1 to 3). They were also to provide one **'Ramsey-type questionnaire'** during each five-year cycle. The

GMC described a **'Ramsey-type questionnaire'** as a patient satisfaction or peer review questionnaire. The evidence (presumably Form 4 and the questionnaire) was to be **'reviewed'** by the GMC. How that was to be done was not stated. If the evidence was satisfactory, the doctor would be revalidated. If not, the doctor might be asked to provide further information or might be referred to a revalidation group. Revalidation groups (which would be made up of lay people and doctors) could request further information and could refer an **'at-risk'** doctor into the FTP procedures. This model was assessed as having **'medium'** acceptability to doctors, but to be likely to command **'low'** public confidence, since most members of the public would themselves have **'some experience of appraisals themselves which leads them to be cynical about their value as an input to revalidation'**. It was said that the feasibility of this model was **'low'** because of the resource implications for the GMC of a review of all doctors' evidence. Finally, the costs were assessed as **'high'**.

26.104 There then followed consideration of the original model, involving the examination by revalidation groups of the folders compiled by doctors. This had already been discarded. Its acceptability to doctors and the level of public confidence it was likely to command were assessed as **'medium'** but feasibility to the GMC was **'very low'** on account of the resource implications. The costs were assessed as **'high'**.

26.105 The next model (also already discarded) would have involved written and/or practical tests. These were to include a multiple choice test of knowledge. The tests might be supplemented by patient satisfaction and peer assessment questionnaires. Acceptability to doctors was assessed as **'v low'**, as doctors **'generally do not welcome the concept of their knowledge being put to the test'**. On the other hand, public confidence in the model was likely to be **'high'** because **'the public likes the rigour implied by a test (many currently assume that, like pilots, doctors have to take tests on a regular basis)'**. It was said that the GMC would regard feasibility as **'low'** because a very large range of tests would be required to cover a wide range of specialised areas of practice. Costs were assessed as **'medium'**. It appears to me likely that this model was discounted as being too 'hard'.

26.106 Also already discarded was a model that was based upon evidence of continuing professional development. This would have involved spot checks to ensure compliance with agreed plans. Although acceptability to doctors and to the GMC was assessed as **'high'**, it was considered that public confidence would be **'low'** since the public would think it was **'both cosy and ineffective'**. It appears to me that this model must have been discarded as too 'soft'.

26.107 Next came what was called the **'self-revalidation model'**. This was described thus:

> **'Local employers would use an ongoing range of measures including appraisal and peer/patient** (*word omitted but probably questionnaires*) **(working to GMC standards) in order to identify individuals** (*i.e. doctors*) **at risk. These cases would be referred to the GMC annually (and as required throughout the year) who would then employ FTP procedures if necessary. GMC would also exercise quality control on the appraisal process and carry out statistically valid spot checks on individual**

> **doctors. In addition, every five years doctors would be required to put together evidence of having met CPD** (*i.e. continuing professional development*) **requirements along with summaries of their appraisals which would be spot-checked by the GMC. The local systems are primarily focused on detection (via appraisal, observation, working relationships, patient questionnaires, etc.), while the GMC's focus is on action.'**

26.108 It was thought that acceptability to doctors would be **'medium'**, as would be the level of public confidence it was likely to command; the GMC would rate feasibility as **'high'** and the costs would be **'low'**. The main risks identified in this model were the doubts as to whether appraisal would be sufficiently rigorous, and whether local systems would be sufficiently robust and consistent. I note that acceptability to the public was assessed as **'medium'**. This model depended heavily on appraisal and the report had already observed that the public might well be cynical about the value of appraisal. Indeed the other model that depended on appraisal had been given a **'low'** public acceptability rating.

26.109 The sixth option was called the **'questionnaire model'**, under which doctors would have to submit peer and patient questionnaires annually. Doctors identified as being at **'some moderate risk'** would have to submit additional information, similar to the original folders of evidence, or undergo **'structured interviews ... by trained peers'**. Any doctors considered to be at risk would be referred into the FTP procedures. It was considered that this model would have **'medium'** acceptability to doctors but would command a **'high'** degree of public confidence (in particular on account of patient involvement in the questionnaires and the fact that doctors would be assessed by their peers). Feasibility for the GMC would be **'medium'** and costs would be **'low'**. It was noted that this model was used elsewhere but was untried in the UK. I observe that all the models save one were untested in the UK.

26.110 Finally, there was an **'assessment model'**. Doctors would undergo a formal assessment based on **'multiple inputs'** such as peer and patient questionnaires, interview, observation (presumably of clinical practice) and CPD. These would be carried out locally. If additional information were required, it would be submitted to a revalidation group. The GMC's role would be to provide quality assurance through an **'examine the examiner mechanism'**. It was thought that this would have **'low'** acceptability to doctors, who would resist any form of assessment. However, it was noted that there was evidence from other industries that, over time, professionals came to accept, and even welcome, the objectivity of such mechanisms. Public confidence in such a model was likely to be **'high'**. Feasibility for the GMC would be **'medium'**, as most of the responsibility would be carried at local level. Costs would be **'high'**. Risks would include lack of consistency and a doubt about the robustness of local processes. The human resource implications might deter employers and doctors.

26.111 I have set out these options in some detail to demonstrate, first, that this report sought to consider various options in an objective way. However, what is notable is that there was no attempt to assess the efficacy of the various methods in evaluating fitness to practise.

Nor did the report consider which model would afford the best patient protection. The report was about acceptability and public confidence, not efficacy.

26.112 Finally, the report considered what steps should be taken next. In essence, it advocated further and more detailed research and analysis and posed a number of highly pertinent questions for the GMC to consider. It did not point towards any of the possible models as the most appropriate. That was for the future.

26.113 The report shows that, in December 2002, the GMC was considering a wide range of options for revalidation. It does not appear that, at that time, it had a clear view of the way in which it intended to proceed. It is apparent that, by then, the idea of a link between revalidation and appraisal was already under consideration. However, there were those within the GMC who did not regard that link as appropriate or satisfactory – at least if appraisal was to remain a formative and supportive process. There were concerns as to whether appraisal, and local processes in general, were robust enough to form a basis for revalidation. At the heart of these concerns was plainly a doubt as to whether revalidation based on appraisal would provide an adequate indicator of a doctor's fitness to practise and a sufficient protection for patients. The GMC's 2000 Consultation Paper had listed first among the benefits of revalidation that it would protect patients **'from poorly performing doctors – who will be identified as early as possible'**. Clearly, there were doubts on the part of some within the GMC as to whether revalidation based on appraisal would be capable of fulfilling this purpose.

The Second SHM Report

26.114 SHM reported again three months later in March 2003. By that time, the GMC had made the decision that revalidation should, in most cases, be linked to appraisal and the Prospectus of April 2003 was in the course of production. There was no detailed discussion in the report of the model that the GMC had decided to adopt. Instead, the purposes of the report were to identify key issues within revalidation which remained to be resolved, to discuss the role of the GMC within the revalidation process and to advise the GMC on how to communicate its revalidation policy and effectively to get across its **'key messages'** to doctors, partner organisations, the press and the general public. Many of the GMC's subsequent statements on the issue of revalidation appear to have had their origins in the advice contained within this report.

26.115 The report referred to the divergence of opinions which had been expressed at the time of SHM's first report about what revalidation could and should do. It reported that there was now a **'high level of definitive agreement'** within the GMC about the purpose of revalidation, although there was **'considerable uncertainty from other quarters'**. The GMC had now defined revalidation as being designed to **'increase confidence in the Register'** by **'ensuring that doctors are up to date and fit to practise'**. In other words, it was intended to be **'a proportionate system which quality assures the register'**. It was not intended to quality assure individual doctors. The report stated that the production of this definition had led to **'confusion and dispute'** among a minority of stakeholder groups which had believed that revalidation should be designed to detect poorly performing doctors. The report indicated that it was **'one of the key tenets of**

revalidation' that it was not intended to identify poor performance and that it had never been suggested in the GMC's communication about revalidation that this was the case. In fact, as I have said, the detection of poorly performing doctors had been listed in the GMC's 2000 Consultation Paper as the first of a number of benefits that would accrue to patients as a result of revalidation. It was not surprising, therefore, that some people were confused and disappointed by the definition of revalidation which had been disseminated by the GMC in early 2003. The report did not refer to the definition of revalidation contained in the amendment to the 1983 Act which had recently been passed; this stated, as I have said, that revalidation was an **'evaluation of a medical practitioner's fitness to practise'**. This seems very different from the concept of 'quality assurance of the register' which was being propounded by the GMC in March 2003.

26.116 The report recorded greater support for linking appraisal to revalidation than had been the case at the time of SHM's first report, although some people gave their support **'grudgingly'**. There was a feeling that doctors would have to accept that there was an element of performance management in appraisal. Some took a **'more defeatist approach'**, acknowledging that there was **'no realistic alternative'** to appraisal. There was reference to concern about the training of appraisers and the content of the appraisal process, together with the fact that there was no guarantee of independence or lack of bias. The report drew attention to the fact that the precise role to be played by lay people in revalidation had still not been agreed. The GMC's move away from lay involvement in revalidation groups which would scrutinise the evidence of individual doctors had been **'met with some cynicism'**. However, SHM was optimistic that the proposals for lay involvement in the ways currently being considered by the GMC would gain support with time.

26.117 The report went on to discuss quality assurance of the revalidation system, noting that responsibility for the quality assurance of various aspects of the system rested with different organisations. I shall revert to that part of the report later in this Chapter. For the moment, I mention only that the report identified two **'important risks'** of the sharing of responsibility for quality assurance among different organisations. It suggested that it was **'almost inevitable'** that **'gaps'** would **'emerge between the boundaries of different responsibilities'**. It pointed out that the consequences of evidence or judgements falling through these gaps could be very grave indeed. It also referred to the absence of any **'clear overall responsible body or mechanism for providing overarching governance and co-ordination'**.

26.118 I wish to make two observations about the SHM reports and the GMC's decision to change direction. First, it seems clear to me that there was a recognition within the GMC that the new proposal was indeed a significant shift rather than a 'slight change of direction' or a 'refinement' of the earlier proposals. Second, the GMC changed direction notwithstanding the warnings that it had been given (in the first SHM report) about the shortcomings, perceived within the GMC itself, of appraisal as a basis for revalidation and (in the second SHM report) about the **'important risks'** inherent in a system which divided responsibility for quality assurance between so many organisations.

The Revalidation Proposals at the Time of the Inquiry Hearings

The Thinking behind the Proposals

26.119 I mentioned earlier that, shortly before the Inquiry hearings relating to the GMC began, the GMC had modified its plans for the revalidation of doctors working in a **'managed environment'**. In the Prospectus of April 2003, it was said that such doctors could choose the 'appraisal route'. They would have to show that they had successfully completed their annual appraisals. However, by late 2003 (probably as a result of evidence which had been given to the Inquiry), the GMC had recognised that evidence from the doctor alone that s/he had participated in appraisal would not be sufficient to generate the necessary confidence in revalidation. It therefore opened negotiations with the DoH for the provision of direct corroboration of that participation. At that stage, it was intended that the 'corroboration' should consist of a certificate to be signed by the clinical governance lead, chief executive or medical director of the **'managed organisation'** in which the doctor worked. The certification would be to the effect that the doctor had participated in appraisal and that **'no concerns about the doctor's fitness to practise have arisen locally through clinical governance systems'**. These terms were set out in the briefing papers for the Council meeting on 25th November 2003, at which the new arrangements were to be discussed. In the event, the draft of a proposed clinical governance certificate (described by Mr Brearley at the time as 'the bare bones of a deal') was delivered by the DoH to the GMC during the course of that meeting and the proposed terms (which were, as I shall explain, rather different from those referred to above) were agreed then. In future, the appraisal route was to be known as the 'appraisal and clinical governance route'.

26.120 Mr Brearley gave evidence to the Inquiry about the GMC's plans. From the outset, Mr Brearley stressed that it was not possible for the GMC, as keeper of the medical register, to monitor the day-to-day performance of all doctors. It had to work in conjunction with local processes. I think he had in mind local clinical governance processes including appraisal. He said that there had been a change of culture in the medical profession and that doctors were now more prepared to recognise that a colleague might not be performing adequately and to accept responsibility for that, by seeking to help that colleague but also, if necessary, by reporting him/her. As I understood him, Mr Brearley considered that, in this new atmosphere, clinical governance would be more effective at detecting poorly performing and dysfunctional doctors.

26.121 Mr Brearley described revalidation as the 'fulfilment of a professional duty'. He said that everyone readily agreed that there was a professional duty on every doctor 'to maintain one's standard of practice and to keep up to date'. This had led to the need for a formal statement to be made to patients that the doctor was up to date and fit to practise. This was, he said, a way of 'quality assuring the medical register' that would give patients a basis for making an informed choice of doctor. He accepted that, if the register was to contain only the names of people who were up to date and fit to practise, there had to be a means of detecting those doctors who were not fit to practise. That would be done, he said, when the doctor came to revalidation, if the dysfunctional practice had not already been detected and dealt with by the operation of clinical governance measures. It would be hoped and believed that most dysfunctional practice would be picked up well before it had persisted for as long as five years.

The Appraisal Element in Revalidation

26.122 Leading Counsel to the Inquiry wished to explore with Mr Brearley how the GMC thought that the new proposals would meet the objectives of revalidation. She reminded him of the objectives of revalidation as set out in the Consultation Paper of 2000. She was seeking to discover how appraisal could provide the necessary evaluation of fitness to practise that was required, when the appraisal of GPs was a purely formative process, with no specific requirements as to what material the doctor had to provide in his/her folder and no objective tests of any kind. The Inquiry had heard ideas from a number of other witnesses of how appraisal might be made more objective and more effective as a means of detecting dysfunctional practice. Counsel suggested that methods of assessment such as observation of doctors' consultations with patients, reviews of medical records, consideration of audit and of mortality statistics and discussion about complaints might be effective. Mr Brearley observed that many witnesses to the Inquiry had 'hobby horses' to ride and confessed that he had one or two of his own. But, he said, none of these methods of assessment had been validated by research. His personal preference was for patient and peer questionnaires. He described these, as operated by the American Board of Internal Medicine, and explained the results of some research carried out. His enthusiasm was manifest. When Mr Brearley was asked whether the GMC intended that questionnaires would be a part of the revalidation process when it came into force in 2005, he said that they would not be for doctors coming through the 'appraisal and clinical governance route', at least until the stage had been reached when a concern had been raised about the doctor being revalidated. If a concern was raised either as the result of appraisal or on account of the fact that the doctor was unable to obtain the necessary clinical governance certificate, such questionnaires (together with reviews of medical records and observations of consultations) might be used for the purpose of the more detailed examination required at that stage. He thought it highly desirable that questionnaires should be used by all doctors coming through the 'independent route'.

26.123 On the question of whether the GMC could specify what information should be included in the folder that would form the basis of appraisal, Mr Brearley explained that the GMC had taken legal advice in the early days of the discussions about revalidation and had, as I have said, been told that it could not prescribe exactly what type of information should be submitted for the purposes of revalidation. I can see that the GMC cannot prescribe what information must be provided for the purposes of appraisal; that must be a matter for the employer or 'main contractor', the NHS. However, the amendments to the 1983 Act give the GMC very wide powers to require the supply of information or the production of documents for the purposes of revalidation. I hope that the GMC will not hesitate to set out what it thinks is appropriate. It could ask the NHS to ensure that certain categories of information are provided for appraisal purposes. That material would then be available for the GMC if and when it wishes to scrutinise some doctors' folders.

26.124 Leading Counsel then turned to ask Mr Brearley whether, when first planning how the revalidation process should be undertaken, the GMC had thought that GPs might find any particular difficulty in collecting data to put in the folders. At that time, it was expected that the folder would be used for appraisal and revalidation purposes. He said that no such difficulty had been perceived. GP practices already had quite good data collection

systems; indeed, he thought the systems for data collection in general practice were rather better than those available in hospitals, which, as I have said, he described as 'a nightmare'. Now that it was proposed that revalidation should be based on appraisal, Counsel wanted to know whether the GMC was concerned about the robustness of GP appraisal. It was carried out by another GP, who did not require any particular accreditation, and it was based on material selected by the doctor him/herself. These factors did not appear to give rise to any concern in the mind of the GMC. Indeed, Mr Brearley's view was that GPs had gone about appraisal in a very thorough way and its introduction had been rather more successful for GPs than it had been in hospitals. For example, he said, many people carrying out appraisal in hospitals had had no training at all. Yet, despite that, it is apparently intended that doctors working in hospitals should be able to achieve revalidation by means of the appraisal and clinical governance route.

26.125 Mr Brearley said that the GMC was confident that appraisal for GPs could be made into a robust process. It was a rapidly developing and well resourced activity which was a statutory requirement for NHS trusts. He saw no reason why there should not be mandatory elements to appraisal; indeed, he said that the GMC would be in favour of that. Mr Brearley had in mind some of the elements described in the 'Revalidation Toolkit', published by the RCGP in Scotland.

26.126 Mr Brearley said that he believed – and the evidence I have heard leads me also to believe – that the great majority of GPs take appraisal very seriously and put a great deal of effort into it. For such doctors, it is very beneficial. The difficulty is how to deal with the small proportion of doctors who wish to conceal deficiencies in performance, ill health problems or other problems from the appraiser. Appraisers cannot probe into potential problem areas about which they have no information. Mr Brearley agreed that it would be helpful if some types of information had to be produced and if PCOs were entitled and expected to provide clinical governance information (including information about complaints and concerns) direct to the appraiser, as well as to the appraisee.

26.127 It appeared that Mr Brearley and the GMC agreed with the general proposition that the introduction of some mandatory elements and the provision of some mandatory types of information would give structure to appraisal and would make it more effective as a foundation for revalidation. There are several possible elements, including observed or videotaped consultations with patients, patient and peer questionnaires, reviews of medical records and, possibly, knowledge tests (which nowadays can be undertaken on-line). There are several types of information that PCOs could provide to appraisers, such as prescribing data and records of complaints or concerns about the doctor. However, any instructions to change the format of appraisal would have to go from the DoH to the NHS bodies affected.

The Role of the Clinical Governance Certificate

26.128 As I have said, in the briefing papers for the November 2003 Council meeting, GMC members were told that the clinical governance certificate was designed to provide corroboration that appraisal had taken place and that no concerns about the doctor had arisen locally through clinical governance systems. However, it became apparent that that

was not how Mr Brearley saw the certificate. He told the Inquiry that it might even be that PCOs would have sufficient information about the doctors on their lists to enable them to provide a clinical governance certificate that would be capable of standing alone as a basis for revalidation. Under the new GMS Contract, which came into force in April 2004, he said, a PCO is able to go into the practice premises and obtain all sorts of information useful for clinical governance purposes. Mr Brearley said that he would almost go so far as to say that the judgement that a PCO could make about a doctor might be sufficient for revalidation purposes, even without appraisal. If the PCO was not willing to provide the clinical governance certificate, the doctor would not be revalidated and would have to go through more detailed scrutiny by the GMC. In short, to his mind, it might be quite satisfactory for revalidation to be based upon local clinical governance activities. I had difficulty in reconciling that view with the emphasis that the GMC had laid on appraisal as the basis for revalidation since the publication of the April 2003 Prospectus. However, it was not Mr Brearley's view that appraisal should play no part at all in the process of revalidation. He said that it was to play a limited, but important, role in the summative process of revalidation, because appraisers would be required to stop the appraisal if 'important unresolved concerns' about the doctor's practice arose during the process. He also used the expression 'major concerns'. However, in Mr Brearley's view, the main summative tool was to be the clinical governance certificate.

26.129 This 'downgrading' of the importance of appraisal within the revalidation process represented a considerable change of emphasis from the 'appraisal route' which had been described in the April 2003 Prospectus. In that document, the GMC had declared that it believed that **'full participation in annual appraisal, with completed supporting documentation, during the revalidation cycle, is a powerful indicator of the doctor's current fitness to practise'**. As I have observed previously, the reasons for that belief were never explained. It appeared from Mr Brearley's evidence that the GMC no longer regarded appraisal as a powerful indicator of fitness to practise, but believed that the clinical governance certificate was; appraisal was by then regarded as just an additional safety net.

The Terms of the Clinical Governance Certificate

26.130 In the course of Mr Brearley's evidence, Leading Counsel to the Inquiry sought to investigate the adequacy of the terms of the proposed clinical governance certificate. This was not an easy issue for Mr Brearley to deal with, because the idea had arisen very recently and the terms of the certificate had not yet been finalised. Mr Brearley signed his written statement of evidence on 5th December 2003 and gave oral evidence on 17th December. In his written statement, Mr Brearley said that what the GMC wanted was **'confirmation that no concerns about the doctor's fitness to practise have arisen through clinical governance processes'**. At that time, the proposal (which had been received by the GMC at its meeting on 25th November) was that the chief executive, medical director or clinical governance lead of the relevant NHS body would certify that:

'a Appraisal had been carried out and signed off by a trained appraiser

b The appraisal had produced an agreed personal development plan

c The process had included validated data

d The process was robust

e There were no concerns about the doctor's probity or health

f There were no disciplinary processes under way

g There were no relevant disciplinary findings.'

26.131 As Leading Counsel took Mr Brearley through this list, it became apparent that some of the statements were problematical, at least in the context of GP appraisal. Under the existing arrangements, the certifier could not know whether any validated data had been included in the appraisal. The PCO is not entitled to see the folder of documents produced by the doctor for the purposes of appraisal. Nor could the certifier say whether the individual appraisal had been **'robust'**. It would have taken place in private and the discussions which formed the basis of the appraisal would have been confidential to the appraiser and the appraisee. There was some discussion about whether item **'d'** related to the robustness of the whole process of appraisal as operated by the particular NHS trust or PCO, or whether it was intended to refer to the robustness of the individual appraisal. If the former, the fact that (as was at that time the intention) the trust's processes had been quality assured by the new Commission for Healthcare Audit and Inspection (now known as the Healthcare Commission) would have been sufficient to enable the certifier to state that the **'process was robust'**. If the latter, the certifier would have no basis of knowledge on which to rely. The certifier would know whether the appraiser had been trained but little else. The certificate as to probity and health would, Mr Brearley explained, be in addition to the self-declarations that would be required of all doctors when applying for revalidation. Thus, the clinical governance certificate would provide some support for the self-declaration, although, as Mr Brearley observed, the signatory could sign only on the basis that there was no information to the contrary. As for **'f'** and **'g'**, Mr Brearley, who is not a GP, accepted that, if disciplinary processes were almost unknown in primary care (as has been the case since 1996, although there are now the new list management powers), then no information would be available in respect of these items. He stressed that what the GMC wanted to know was whether there were any concerns about the doctor's fitness to practise.

26.132 As I have explained, the briefing papers for the Council meeting on 25th November 2003 had recommended that the GMC should seek a certificate **'to the effect that the doctor has indeed participated in appraisal, and that no concerns about the doctor's fitness to practise have arisen locally through clinical governance systems'**, although, elsewhere in the briefing paper, there was a reference to **'significant unresolved concerns'**. When asked to look at the briefing papers, Mr Brearley immediately recognised that there was not a good match between what the GMC had wanted and what had actually been proposed by the DoH (see paragraphs 26.130–26.131). The minutes of the meeting recorded that the GMC should seek a certificate declaring that there were **'no**

significant unresolved concerns' about the doctor. Mr Brearley was puzzled as he could not remember there being any discussion about the introduction of the phrase **'significant unresolved'**. He did not know how those words had come to be introduced. He said that he thought that the GMC ought to be told about *any* concerns about the doctor's fitness to practise and that the GMC would then want to know how, if at all, they had been resolved. He said that the Registration Committee, of which he is Chairman, would not feel inhibited from putting forward proposals to reflect the original intention that the GMC should be told about *any* concerns. The Inquiry heard nothing more about this until November 2004 although the draft Guidance which the GMC published in September 2004 (see paragraph 26.142) states, at different points, that the clinical governance certificate is to certify that there are **'no significant unresolved concerns'** and **'no unresolved local concerns'** about the doctor's fitness to practise. Neither wording contained in the Guidance accords with Mr Brearley's wishes.

26.133 Moreover, both wordings could give rise to difficult decisions for the certifier. What does **'significant'** mean in this context? It is not clear; this was one of Mr Brearley's objections. Second, what does **'unresolved'** mean? Does it mean completely unresolved or does it cover cases where a problem has arisen and steps have been taken to resolve it but it is not yet clear whether those steps have been completely successful? One can see immediately the possibility that different thresholds might be applied by different people. I think that Mr Brearley was sensible when he said that he and his Committee wanted the GMC to be told about *any* concerns.

26.134 Quite apart from those difficulties, it appeared to me that reliance on a certificate for which only one person was responsible would be problematical. First, there would be the problem of personal bias, in favour of or against the doctor seeking revalidation. It must be recognised that local medical communities are small; GPs know each other and often have personal and social relationships as well as their professional ties. A clinical governance lead is likely to be a GP who may well have practised in the locality; indeed, s/he may still be doing so on a part-time basis. It is asking a lot to expect such a person to refuse to sign a certificate for a colleague or a friend. Conversely, there would almost certainly be some GPs in the area about whom the clinical governance lead had formed a generally poor impression. Would such a person be treated fairly? It seemed to me that, if reliance were to be placed on a clinical governance certificate, responsibility should be shared by more than one person. If real importance were to be attached to the certificate – and it were not to be just corroboration that appraisal has taken place – the dangers of leaving the process in the hands of one person would be manifest.

26.135 Finally, the value of a clinical governance certificate must depend to a very large extent on the quality of the clinical governance arrangements in the area in which the individual doctor is practising. The evidence I have heard leads me to conclude that there is some way to go before clinical governance is fully implemented in primary care. Put another way, the quality of clinical governance cannot be relied on in all places.

The Effectiveness of the Post-November 2003 Proposals

26.136 The addition of a clinical governance certificate to the requirements for revalidation by the appraisal route was a step in the right direction, although only a modest one. The

post-November 2003 proposals were still dependent upon appraisal. Appraisal in its present form cannot provide an evaluation of fitness to practise. The clinical governance certificate would be of uncertain value because of its terminology, the circumstances in which it would be signed and above all because of the variability of the quality of the clinical governance activities underlying it. In an area with good clinical governance provision, with a clinical governance lead who was objective, conscientious and impartial and who applied a low threshold to the expression **'no significant unresolved concerns'**, the certificate would be of value. However, even then it could provide only a negative assurance. Revalidation is supposed to give positive reassurance based on evaluation of fitness to practise. In effect, under the November 2003 proposals, the overwhelming majority of doctors would be 'revalidated' without having gone through a process of revalidation, within the meaning of that term in the amended Medical Act. For the great majority of doctors, the process would depend upon the operation of local clinical governance procedures which would take place whether or not there was a process of revalidation. For the great majority of doctors and their patients, revalidation would provide very little value over and above the monitoring systems that had been put in place by the NHS. The GMC might provide some added value by quality assuring clinical governance procedures through its scrutiny of a proportion of folders kept by doctors for the purposes of appraisal, to which process I shall refer below. However, that would not give much comfort to the average patient who wants to know whether his/her doctor is up to date and fit to practise.

Further Work of Development

26.137 Since the Inquiry hearings, work on the development of the revalidation process has, of course, continued. The Inquiry has become aware of two different, but related, strands of work. In August 2004, the RCGP produced a consultation document entitled 'Portfolio of Evidence of Professional Standards for General Practitioners: a Tool for Continuing Professional Development, Appraisal and Revalidation'. It sets out proposals for the content of the folders that GPs should keep for these three joint purposes. It seeks to establish the standards for such folders and the evidence they should contain. It is based on the principles of 'Good Medical Practice'. It seems to me to be a very useful document. If adopted it would ensure that the material in the doctor's folder was capable of providing a basis for evaluation of fitness to practise. For example, in section 3, which is concerned with good clinical care, the doctor would be required to produce evidence of clinical audit and significant event audit. The evidence to be produced would be not just a statement that the audit had taken place; it would have to include some actual audit reports and some response to or commentary on what had been learned from the process. I would hope that that would include an explanation of the role that the individual doctor had played in the audit, as audits are often a joint effort. To be of value for revalidation, the content of the reports would have to be read; it would not be sufficient merely to check that an audit had been done.

26.138 The Inquiry has also received a document prepared by the NHS Clinical Governance Support Team Expert Group (NCGST), entitled 'Defining the evidence for Revalidation – supporting the Royal College of General Practitioners'. The purpose of this work was to

identify the minimum evidence that should be regarded as essential to allow a clinical governance lead to sign the clinical governance certificate for a GP. It appears that it was envisaged that the evidence would be assessed and 'signed off' quite independently from the appraisal process. The evidence would then be available for use during appraisal if the doctor wished. The work of the NCGST is also useful although its proposals are rather 'softer' than those of the RCGP. For example, under the section dealing with clinical audit, this document recommends that the doctor should provide a **'resume of his/her engagement with audit, giving examples'**. It is made clear that this would not require the doctor to generate his/her own audits but would require that s/he be able to describe how his/her practice has developed as a result of audit outcomes. In short, there is no need to produce an audit report. For significant event audit, the doctor is to produce **'evidence of meaningful participation'**. It is not clear to me whether that would require production of the reports. So, the requirements in respect of audit would be less demanding than under the RCGP proposals. Another example of the difference between the two sets of proposals is that, in the section dealing with relationships with patients, the RCGP proposes that the doctor should submit the practice's complaints procedures, copies of all complaints involving the doctor and evidence that any learning needs have been met. The corresponding section of the NCGST document suggests production of the complaints procedure and a list of complaints received and subsequent action taken. The RCGP proposal provides evidence that, if scrutinised, is much more revealing of the doctor's actual standard of performance. A third example of the difference relates to the way in which patient records should be reviewed. The RCGP calls for a standardised audit conducted by an independent colleague to demonstrate the appropriate quality of the doctor's clinical records. The NCGST suggests (at least initially) self-audit of records for legibility and accuracy to standards set by the RCGP. Here again, the evidence suggested by the RCGP would be more useful for the purpose of evaluation of fitness to practise than that suggested by the NCGST.

26.139 The work of these two groups represented a major advance on the stage that had been reached at the time of the Inquiry hearings. It appeared that the issue of a NHS clinical governance certificate might involve some positive evaluation of fitness to practise. I would welcome a positive process of evaluation of a doctor's folder. However, I was concerned about two aspects of the proposals as they seemed to be envisaged. First, the minimum content of the folder as suggested by the NCGST would not be very demanding or very revealing of the quality of the doctor's practice. It is, as I have said, far less revealing than the contents as proposed by the RCGP would be. Second, I did not think it either fair or appropriate to expect a clinical governance lead to carry out the scrutiny of folders alone. It would put an intolerable burden on that individual, both in terms of workload and responsibility and, ultimately, in terms of accountability, in the event that a decision to sign a certificate turned out to be wrong. He or she could not be expected to exercise the necessary degree of independence of judgement about doctors whom s/he might well know personally as friends or colleagues. There would be a real danger of bias and inconsistency. If such an assessment is to be carried out it should, in my view, be carried out by a small group, which should include (as well as the clinical governance lead) a lay person and a GP who is not from the same area and has no personal knowledge of the doctor to be assessed.

General Medical Council Internal Procedures

The First Stage of Revalidation

26.140 At the time of the Inquiry's hearings in December 2003, the proposed procedure to be followed by the GMC when handling applications for revalidation was this. The doctor would be expected to submit a completed application form, providing some basic information about him/herself. He or she would have to provide a description of his/her practice during the last five years, or since the last revalidation, if revalidation had been granted for a period shorter than five years. If seeking revalidation by the clinical governance and appraisal route, s/he would have to aver that s/he had undergone appraisal within a system based on the principles of 'Good Medical Practice' and would have had to enclose a completed Form 4 from appraisal. He or she would have to provide self-certification of his/her health and probity.

26.141 The GMC would examine all applications for the purpose of identifying the doctor as being one who had been called for revalidation. The contents of the application would be checked to ensure that each requirement had been fulfilled. That would not entail reading the content. Mr Scott said that it was anticipated that there would be some electronic scrutiny of the documents designed to pick up unexpected answers. So, for example, in the certificate of probity, if a 'yes' answer appeared where a 'no' answer was expected, the system would draw attention to that doctor and the matter would be looked into in more depth. It had not yet been finally decided whether electronic means would be used. In the second SHM report of March 2003, which contained advice to the GMC about scrutiny and quality assurance, it had been anticipated that this initial scrutiny (which would be done in all cases) would be carried out by junior office staff. When asked how the doctor's appraisal Form 4 was to be examined, Mr Scott told the Inquiry that the GMC had not yet made up its mind about these processes and that it intended to conduct further pilot studies because the original pilot studies had related to a different process entirely. The Inquiry has not been told of any further studies, although, of course, some may have taken place.

26.142 These proposed arrangements have now been modified, although only slightly. In a document entitled 'Licensing and Revalidation Formal Guidance for Doctors (draft)', dated September 2004 (the 2004 draft Revalidation Guidance), it is explained that doctors should normally make their applications via a secure internet connection direct to the GMC. Doctors working in a **'GMC approved environment'** must provide a description of their practice, demonstrate participation in appraisal **'mapped against the headings of *Good Medical Practice* and completion of an agreed Personal Development Plan'**, provide a statement declaring eligibility for local certification and provide evidence of health and probity. The statement of eligibility will require the doctor to identify the employer or PCO who will be responsible for the clinical governance certificate. The declaration as to health will be signed by the doctor him/herself and must be countersigned by another licensed doctor. It appears that the doctor will not be required to submit appraisal Form 4 although the Guidance is not wholly clear on this point. In evidence to the Inquiry, Sir Graeme Catto described Form 4 as the 'absolute minimum' that the GMC would expect to receive.

26.143 The 2004 draft Revalidation Guidance states that the information submitted must be **'capable of independent verification'**. The application will be examined to see that it is complete and that it demonstrates that the doctor is working in an approved environment. If the application is in order, the GMC will apply for a clinical governance certificate from the employer or PCO. If the certificate is satisfactory, most doctors will be revalidated at this stage. Doctors are warned that they may be required to submit a folder of information **'relating to the headings of *Good Medical Practice*'**. This could be either because the GMC wishes to scrutinise the doctor's folder for quality control purposes or because some doubts have arisen as to the doctor's fitness to practise, presumably as the result of the health or probity declarations or the request for a clinical governance certificate.

The Second Stage of Revalidation

26.144 The 2004 draft Revalidation Guidance contains some information about what will happen at the second stage of the revalidation process if the evidence that the doctor has submitted is **'insufficient or raises a question about fitness to practise'**. It is said that one or more actions might be taken. The doctor might be asked to provide further specific information or evidence. Further evidence might be sought through the use of secondary tools, such as peer and patient questionnaires or observation of practice. The doctor's evidence could be referred to a Registration Decisions Panel for advice. Finally, the doctor could be referred to the GMC's FTP procedures for investigation. It is also said that if a doctor is **'required or permitted'** to submit his/her folder, **'specially trained experts will review the folder, taking into account any relevant specialty-specific standards defined by the medical Royal Colleges or other authoritative bodies'**. The **'experts'** will prepare a summary report, which will be considered by a Registrations Decisions Panel, which will recommend to the Registrar what action should be taken.

26.145 I must express some concern about the imprecision of these arrangements. It is not clear whether action will be taken in every case. That is left open; action might or might not be taken. I can see that it would be difficult to be precise about exactly what further information might be required; that must depend upon the nature of the insufficiency identified or the question that has arisen about the doctor's fitness to practise. However, if further evidence is submitted, it is not clear who is to examine it and to judge its adequacy or what standards are to be applied. Not in every case will evidence be referred to a Registration Decisions Panel for advice. If a doctor's evidence is to be submitted to a Registration Decisions Panel, by what standards is the Panel to advise? As I understand the position, only doctors' folders (and not other evidence), are to be reviewed by the **'experts'**. It is not clear whether these will be experts who are medically qualified and practising in the specialty to which the doctor belongs or whether they are to be 'expert' in scrutinising folders. It is possible that these second stage procedures will be robust but it is not clear that they will be. The robustness of the second stage is crucial to the revalidation process. If a doctor who fails at the first stage is revalidated at the second stage without careful individual evaluation of his/her fitness to practise, the whole process will be without value.

The Third Stage of Revalidation

26.146 The third stage will apply only to those doctors who have been referred into the FTP procedures as the result of their failure to satisfy a Registration Decisions Panel. I anticipate that most of those cases will be doctors whose performance has given rise to concern. I can see that there might be a few cases who are referred for health reasons or because concerns have arisen about some aspect of the doctor's conduct. However, as I say, in the main, poor performance will more usually be the reason.

26.147 When a doctor is referred into the FTP procedures on account of concerns about performance, s/he will usually be required to undergo a full GMC performance assessment. I described that process in Chapter 24. Briefly, it comprises two phases. Phase I is a peer review. Phase II comprises three forms of objective assessment: a knowledge test, a simulated surgery and objective structured clinical examinations, placing the doctor in certain clinical situations to which s/he has to react. For GPs, the standard of the objective tests is calibrated at the level required for entry to general practice, known as summative assessment. Sir Donald Irvine told the Inquiry that he thinks that that standard is too low. He would like to see the performance assessment calibrated to the standard required by the RCGP for its Membership by assessment. Dame Lesley Southgate, who is a member of the Postgraduate Medical Education Training Board (PMETB), which is shortly to assume responsibility for overseeing the training of GPs, said that the intention was to devise a common standard for entry to general practice and for Membership of the RCGP. The standard for entry to general practice would be raised to some degree. Under the old FTP procedures, when a performance assessment revealed SDP but it was considered that the standard of the doctor's performance was likely to be improved by remedial action, the doctor would usually be invited to agree to a 'statement of requirements'. In the future, s/he will be invited to agree to voluntary undertakings. The statement of requirements usually comprised some requirements for re-education and they might also contain a requirement for supervision and impose some restrictions on the doctor's practice. My understanding is that, in the future, if the doctor who has failed the performance assessment accepts the proposed voluntary undertakings, s/he will be revalidated on those terms. The revalidation may be for a shorter period than the usual five years. Thus, the revalidated doctor will not be 'up to date and fit to practise' but will be practising under conditions. Mr Brearley said that this would be acceptable because the conditions will ensure that the doctor is not a risk to patients. I have no reason to say that he is not right about that. However, I must observe that a member of the public who understood that his/her doctor had been revalidated (and was therefore up to date and fit to practise) might be surprised to learn that the doctor was practising under restrictions and conditions that had been imposed in the interests of patient safety.

26.148 If a doctor who is offered voluntary undertakings declines to accept them or if the GMC member of staff (probably a case examiner) responsible takes the view that voluntary undertakings are not appropriate, the doctor will be referred to a FTP panel. There will then be a hearing at which it will be decided whether the doctor's fitness to practise is impaired and, if so, whether it is impaired to a degree justifying action on registration. The FTP panel may decide to erase or suspend the doctor from the register, in which case s/he will not

be revalidated, or may decide to impose conditions, in which case the doctor will be revalidated but must practise in accordance with the conditions.

26.149 As I understand the new procedures, a FTP panel in a performance case will operate to the same standards as the former CPP. In theory, that is the standard by which the performance assessment has been conducted, i.e. the standard required for admission to general practice. Sir Donald told the Inquiry that, when the performance procedures were first brought in, that was what happened. If the doctor had 'failed the assessment', the CPP would take action on registration. Quite apart from the fact that he felt that the official standard was too low, he expressed concern, echoed by Dame Lesley, that, over the last few years, there had been some slippage of standards. Doctors were able to attack the findings of the first phase of the assessment (or some of them) and the panels of the CPP had to form a view as to the validity of the criticism in the assessment report. The result, said Sir Donald, was that CPP panels applied their own views as to what was acceptable. This resulted in doctors whose performance was (in Sir Donald's view) quite unacceptable being allowed to continue in practice. Sir Graeme himself described the standards applied in the performance procedures as 'remarkably low'. That view confirmed the impression I myself had gathered from the files that I read. Sir Donald observed that, if such panels were to provide the 'baseline' for revalidation, it was vital to establish appropriate standards of practice and performance. Otherwise, revalidation would be meaningless as a means of protecting the public. I agree with him.

26.150 It seems to me that it is essential that agreed standards are laid down for the use of FTP panels in a form in which they can be readily applied. The GMC is able to establish standards for entry into the profession and the medical Royal Colleges, and the PMETB establishes standards for entry onto specialist registers. Nowadays, examination for these purposes is not limited to a written test. There are various forms of performance assessment, for example in the GPs' summative assessment. In my view, if revalidation is to command public confidence, it must have a 'baseline' which is capable of being objectively applied and within a reasonable period of time. In Chapter 24, I explained how there could sometimes be a delay of several years before performance procedures were completed. Meanwhile the doctor remained in practice unless s/he was obviously unfit. I think that there must be a clear threshold below which a doctor would be 'taken off the road' until s/he had improved and had been reassessed as performing at a satisfactory level.

The Relevance of a Doctor's Fitness to Practise History

26.151 It is not clear from the 2004 draft Revalidation Guidance at what point in the revalidation process it is intended that a doctor's FTP history with the GMC should be considered. Nor is it clear how, if at all, a FTP history will affect the outcome of the revalidation process. The Guidance refers to the introduction under the new FTP procedures of a system of warnings, which will be issued by the GMC where there has been a significant departure from 'Good Medical Practice' which is not so serious as to justify action on a doctor's registration. The Guidance states that the GMC **'will want to see evidence that the problems which gave rise to the warning have been addressed by the time of the doctor's next revalidation'**. The Guidance also indicates that, where necessary, the

doctor's revalidation date will be brought forward to ensure that problems have been addressed promptly. If they have not, it is said, the doctor's registration may be at risk. However, it is not clear at what stage evidence about the doctor's compliance with the terms of a warning will be sought, whether the evidence will be sought from the doctor him/herself or from some other person or body, what the nature of the evidence required is likely to be, by whom it will be scrutinised and against what standard. If a warning is to have any significance at all within the revalidation process, it will be necessary for independent, objective evidence of compliance with the terms of the warning to be sought and for that evidence to be scrutinised to an agreed standard by a competent (probably medically qualified) person or by a group of people, both medically qualified and lay.

26.152 The 2004 draft Revalidation Guidance states that the GMC may also wish to bring forward a doctor's revalidation date if s/he has been practising subject to conditions or undertakings under the FTP procedures or if s/he has resumed practice after a period of suspension or erasure. That said, it is not clear what, if any, effect the doctor's FTP history will have on the outcome of the revalidation process. Nor is it clear whether the doctor will be required to provide additional evidence over and above the basic documentation that must be provided by all doctors. It seems likely that, if additional evidence is to be required from a doctor who has been given a warning, it will also be required from doctors who are or have been subjected to other sanctions and to undertakings. In that event, the same questions arise about the nature and source of that evidence and how it is to be scrutinised. Another uncertainty is whether, when an application to revalidate is received by the GMC, any check will be made to ascertain whether there is any allegation against the doctor that is currently being investigated under the FTP procedures and, if so, what the procedure for dealing with the application to revalidate will be.

Quality Assurance

26.153 I mentioned earlier that the second SHM report contained some proposals in relation to quality assurance. Several areas were identified where quality assurance intervention was required. The first of these was **'setting the specialty-specific standards by which doctors' fitness to practise will be assessed'**. In fact, the model which the GMC had by that time decided upon involved no 'assessment'. However, it was (and still is) intended that the medical Royal Colleges should set standards, evidence and criteria against which the doctors' evidence should be measured. The second area was assuring the standards and planning local systems designed to identify and take action on performance and conduct issues. This was to be the responsibility of NHS trusts. Responsibility for ensuring the quality of appraisal systems and for clinical governance generally (the third area) was to lie with the Healthcare Commission and equivalent bodies in other parts of the UK. The GMC was to be responsible for scrutinising the revalidation evidence produced by doctors. It was envisaged that this would probably consist of a quick check in every case to ensure that doctors had complied with the obligation to submit evidence and that the documentation was complete. In most cases, that would be the only scrutiny. It seems that that advice has been largely accepted. I have already noted, at paragraph 26.117, that the second SHM report warned the GMC about the risks inherent in shared accountability for quality assurance.

26.154 The second SHM report also recommended a more detailed scrutiny of a sample of evidence. In evidence, Sir Graeme and Mr Scott said that the GMC intended to quality assure the first (external) stage of revalidation by taking a small sample of doctors who would otherwise be revalidated and subjecting their applications to detailed scrutiny. The report suggested a sample of 1.4% for doctors working in a 'managed environment'. Mr Scott told the Inquiry that the GMC was 'revisiting the sampling model'; he expected the percentage of cases sampled to be larger than originally suggested. The objective will be to see whether, within that sample, detailed scrutiny produces the same decision as the 'appraisal and clinical governance route'. More recently, the GMC has said that, in addition to taking a sample of cases with no specific risk factors, it intends to scrutinise a larger sample of doctors taken from groups which present known risk factors. The GMC has not said what these risk factors are to be.

26.155 When asked how this detailed scrutiny was to be conducted, Sir Graeme said that the GMC would want to see the original documents in the doctor's folder, which should contain some verifiable information derived from clinical governance activities and collected by the PCO. Other documents might originate from within the doctor's practice, rather than from the PCO. The GMC would want to see them all. At the time of the Inquiry hearings, the GMC had not decided who was to carry out the scrutiny. According to the 2004 draft Revalidation Guidance, the GMC has decided that this scrutiny is to be carried out by **'specially trained experts'**. No further detail has been given.

What Value Is Added by Revalidation?

26.156 In the course of evidence, I made the point to Mr Brearley that, if dysfunctional practice is to be detected by clinical governance procedures which are in continuous operation, and appraisal will provide a formative experience and 'safety net' once a year, there seemed little role left for revalidation as a separate process. What 'added value' did it provide? Mr Brearley's first point was that it would focus the mind of the officer of the NHS trust or PCO who had to decide whether s/he could properly sign a clinical governance certificate, saying that there were no (or no significant) unresolved concerns about the doctor. I could see the force of that, although the extent to which his/her mind would be focussed would depend upon the extent to which that officer were to be held accountable if s/he provided a 'sign-off' and it later transpired that his/her judgement about the nature or seriousness of a known concern was wrong. If the consequences for the officer were to be serious, I could see that having to sign the certificate would focus the mind. But if nothing much were to happen when a judgement to issue the certificate turned out to be wrong, then officers would soon discover that, and the 'mind-focussing' effect might be limited. Later in his evidence, Mr Brearley made a related point about the added value of revalidation, which I think is rather stronger. He said that, if the clinical governance lead of a PCT heard about a concern which did not seem particularly serious, s/he would be more inclined to take action upon it and try to resolve it, if s/he knew that in, say, two years' time, s/he would have to decide whether s/he could sign the clinical governance certificate for that doctor. That, I think, would add some value.

26.157 In relation to the issue of added value, Mr Brearley also suggested that, by undertaking the process of revalidation, the GMC was 'quality assuring' the medical register. This was

a reference to the definition of revalidation which, according to the second SHM report, had been promulgated by the GMC in early 2003. People will be able to look at the register, he said, and know that their doctor has been through a process and is fit to practise. It does not seem to me that, for the patients of NHS doctors, that provides much by way of added value. If revalidation is to be dependent on clinical governance, the real reassurance that patients will want is that clinical governance is working well and is detecting under-performing doctors. The fact of revalidation adds virtually nothing. However, for the patients of doctors who cannot take the 'appraisal and clinical governance route', revalidation could give real reassurance provided that the GMC puts in place an adequate method of scrutiny and evaluation. The same could be said for doctors who, although eligible to undergo revalidation through the 'appraisal and clinical governance route', fail to do so and have to undergo further scrutiny by the GMC. Again, the reassurance is of value only if the methods are good enough.

26.158 Mr Brearley also said that revalidation would have an independent value because, by undertaking quality assurance procedures – by means of the in-depth scrutiny of a sample of doctors who would otherwise be revalidated automatically on receipt of the clinical governance certificate – the GMC would find out whether clinical governance was really working and detecting dysfunctional practice. I could see the force of that point too. Of course, all depends on the thoroughness of the quality assurance mechanisms.

Developments since Early 2004

26.159 Since the conclusion of the hearings in December 2003 and the seminars in January 2004, the GMC has continued to provide the Inquiry with documents relating to a number of issues, including revalidation. As might be expected, there have been developments. I have already referred to work done by the RCGP and the NCGST.

26.160 In March 2004, there took place the first meeting of a joint working group set up between the GMC, the RCGP, the BMA and the NHS Modernisation Agency, the purpose of which was to consider ways of improving clinical governance in primary care. At this meeting, the joint working group agreed its Terms of Reference, which were to consider how clinical governance mechanisms within primary care can identify emerging poor practice and deal with it in a way that protects patients. Also, the joint working group was to consider how clinical governance mechanisms could support doctors working in primary care in the collection of objective, practice-based data, from which evidence to support revalidation could be drawn. One of the issues discussed at the first meeting was the need for clarification of the various standards and guidance documents currently in existence and for the development of a 'checklist tool' that made clear what practice parameters are not acceptable. It was said that the 'Revalidation Toolkit', developed by the RCGP in Scotland, might provide a useful template for use throughout the UK. There was reference to the need to link clinical governance data in primary care to an individual doctor. As I have indicated before, much data is practice-based and does not provide useful information about an individual. There was also a call for greater consistency of application of clinical governance systems throughout the country. It was thought that PCOs would benefit from the creation of local clinical governance support groups, which would have a role in reviewing information known locally about doctors and in reporting to

the clinical governance lead any concerns about a doctor. The view was expressed that the local clinical governance support groups would benefit from lay input, perhaps through the inclusion of the chairman of the relevant local patient group. It was thought that such groups might advise the clinical governance lead about the position of individual doctors seeking a certificate for the purposes of revalidation. Also, they might advise on remedial action.

26.161 I appreciate that this joint working group was concerned mainly to devise ways of improving clinical governance. However, it seemed to me that it could make a valuable contribution to the process of revalidation. If it could develop some standardised means of collecting and presenting 'hard' clinical governance data, there would be a greater prospect that under-performing and dysfunctional doctors would be detected. The clinical governance certificate could become more of a positive assurance of fitness to practise, rather than a negative statement that 'nothing adverse is known'. The certificate would have far greater value in revalidation, and revalidation could then provide a better reassurance for patients. The process of appraisal would also be enhanced. The joint working group also agreed that detailed criteria, standards and evidence for GPs (and doctors in other specialties) should be developed and could then be used to support the revalidation process. The medical Royal Colleges were to take a leading role in this work.

26.162 Pausing there, these developments seemed to me to be most encouraging. Many of the concerns that I had felt about the current proposals for the revalidation of GPs were to be constructively addressed. The joint working group was to have its second meeting in May or June 2004. The Inquiry has not received a copy of the minutes of a second meeting. However, in November 2004, the Inquiry did receive a note of the first meeting of a sub-group of the joint working group, which had taken place on 26th August 2004. I shall describe its contents shortly.

26.163 Meanwhile, at its Council meeting in May 2004, the GMC was asked to approve a draft for a document to be entitled 'The Policy Framework for Revalidation: a Position Paper' (the draft Position Paper). This was to be published in July 2004. I do not intend to summarise its contents other than to say that it described the GMC's current policy on revalidation broadly as I have described it in this Chapter. At the meeting, there was detailed discussion of the draft Position Paper. Some of the discussion related to concerns about matters that had been omitted from the draft Position Paper. In particular, Professor Pringle drew attention to the issues discussed at the first meeting of the joint working group and expressed regret that those ideas had not been reflected in the draft Position Paper. There was no reference in the draft Position Paper to the development of standardised means of collecting data or to improving the range of clinical governance data relating to individuals rather than GP practices. Nor was there any reference to the idea that a clinical governance support group, including a lay element, might assist and advise the clinical governance lead with decisions on certification and related issues. Professor Pringle proposed that these changes should be mentioned in the Position Paper, when published. The result was a modification of the draft Position Paper so as to presage some scrutiny of evidence at a local level. How or by whom this scrutiny was to be conducted was not made clear.

26.164 At the meeting in May, Professor Pringle pointed out that there was a need for the GMC to 'reactivate' the medical Royal Colleges and to encourage them to get on with the work of preparing detailed standards, criteria and evidence to be used in connection with revalidation. This is painstaking work and cannot be achieved in a short time. Concern was expressed that it would not be completed by the time revalidation was launched in 2005. I have already referred to the progress that has been made by the RCGP in this regard. This work is important as it will underlie not only the decisions taken at the second stage of the revalidation process but also the scrutiny of the small sample of cases that will be scrutinised for quality assurance purposes.

26.165 The Position Paper was published in July and was followed by the publication of draft Rules and Guidance in September. These were accompanied by a letter, inviting comments and suggestions. It appears to me that the draft Rules are uncontroversial. They provide a legal framework for what the GMC intends to do. However, the 2004 Revalidation draft Guidance contained a few new developments. In particular, the GMC has now created the concept of a **'GMC approved environment'**. This concept was mentioned in the April 2003 Prospectus although it was described differently. This is a working environment in which clinical governance procedures are applied and doctors have to undergo periodic appraisal. Doctors working in such an environment will be eligible to revalidate through the clinical governance and appraisal route. The concept of the **'GMC approved environment'** is also to be used in connection with doctors who have a restricted licence to practise (i.e. doctors who are licensed only to work in GMC approved environments). Already there is a long list of private healthcare providers who have been provisionally approved for these purposes and it is said that the list may be extended in future. How rigorous the approval procedures have been, I have no idea. The result of this change is that there will be very few doctors in clinical practice who will have to take the independent route to revalidation.

26.166 On 10th November 2004, very shortly before delivery of this Report was due, the Inquiry received from the GMC a note of a meeting of the sub-group of the joint working group of the GMC, the RCGP, the BMA and the NHS Modernisation Agency which had taken place on 26th August 2004 and to which I have already referred. I have previously reported on the first meeting of the joint working group, which took place in March 2004. The note revealed that the proposals for the provision of a clinical governance certificate had advanced some way. It appears that the discussions at the meeting related to those proposals and that it was not the function of the sub-group to make decisions. However, some points appear to have been agreed. The meaning of the note is not entirely clear to me. It will have been prepared for the benefit of those who attended the meeting and who would understand the context of the discussion. I may have misunderstood it to some extent. In some respects, the content of the note has been clarified by the receipt, on 11th November 2004, of a letter from Sir Liam Donaldson, the CMO.

26.167 The note of the meeting of 26th August 2004 made plain that it would be for the NHS to decide how to **'deliver local certification'**. Further work would be required, but the group (I assume that means the sub-group) and the bodies represented would work together to ensure readiness for the introduction of revalidation. Under the heading **'Local Support Groups'**, it was said that the NHS Modernisation Agency was continuing to work on

'defining the nature of local support groups'. It was also said that **'local certification groups'** would consist of three people drawn from the certifying organisation, such as a PCO. One of the members of the certificating group would be a lay person, presumably an employee or officer or board member of the PCO. The certifying organisation would decide who those individuals would be. I am not sure whether a **'local support group'** is the same as a **'local certification group'**. As I reported in paragraph 26.160, the joint working group, which met in March 2004, discussed the possibility of local clinical governance support groups reviewing information known locally about doctors and reporting any concerns about a doctor to clinical governance leads. This type of group would have some lay input. That seemed to be a different group from a 'local certification group', the name of which suggested that it would be responsible for signing the clinical governance certificate.

26.168 The sub-group welcomed the work being done on tools and guidance and said that it was for the NHS to produce this in conjunction with partners such as the medical Royal Colleges. The need for consistency throughout the UK was stressed. It was stated that the guidance should be generic and potentially applicable to all specialties and all four countries of the UK. It was also stated that the publication of documentation on local certification should be co-ordinated. This paragraph of the note does not appear to relate to the work done by the RCGP and NCGST to which I referred in paragraph 26.138. The RCGP's work was concerned with the evidence that should be produced by GPs for the purposes of CPD, appraisal and revalidation. The NCGST's work sought to identify the minimum items of evidence that a GP would have to produce to allow a clinical governance lead to sign a clinical governance certificate.

26.169 The note recorded that the GMC's formal guidance on licensing and revalidation would state what information about doctors would be required from local certification. The GMC envisaged that local certification would have two components. There would be certification of participation in appraisal and certification of the absence of **'unresolved significant concerns'**. Because those providing the certificates would need to understand the significance of the document they were signing, additional information would be provided. In respect of participation in appraisal, certification would confirm five points, namely, that appraisal had taken place; that the process had produced an agreed personal development plan; that the process had been carried out and signed off by a trained appraiser; that the process had been **'informed by validated data about the doctor's actual practice'**, and that local clinical governance processes including appraisal were quality assured. It is not clear to me what was meant by the process being **'informed by validated data'**; nor am I sure to what extent the clinical governance processes are to be quality assured.

26.170 In respect of the certificate relating to:

> **'unresolved significant concerns, certification would confirm that:**
>
> **i. There are no locally-known concerns about the doctor's health.**
>
> **ii. There are no locally-known concerns about the doctor's probity.**
>
> **iii. There are no local disciplinary procedures in progress.**

iv. There have been no relevant disciplinary findings locally over the specified period.'

These were quite specific requirements and it appeared that the certificate would not provide any general assertion about the doctor's fitness to practise or even the absence of concerns about other matters.

26.171 The note of the meeting recorded that it had been agreed that the information that would **'underpin local certification'** should be **'derived from clinical governance and verifiable data'**. I do not know what that means. If the clinical governance certificate were to deal with only the four specific items listed above, it would not be dependent on information **'derived from clinical governance'** or on **'verifiable data'**. The health and probity certificates could never be more than assertions that the NHS body knew of nothing that would call the doctor's health or probity into question. The third and fourth items were simply matters of record. I cannot see what role **'verifiable data'** could play. The note said that the information (that would underpin local certification) should enable certificating organisations to identify concerns about a doctor's practice. Where such concerns exist, appropriate action should be taken locally and information should be shared with other bodies, such as the GMC, where applicable. It was agreed that the NCGST would produce detailed working specifications on how local certification might work.

26.172 In the light of this document, some matters seemed tolerably clear. The clinical governance certificate would be negative in nature. In effect, it would say only that nothing adverse was known in four specific respects: health, probity, current local disciplinary procedures and local disciplinary findings within the revalidation period, usually five years. Mr Brearley's wish that *any* concern about the doctor should be brought to the GMC's attention had not been addressed. What was meant by **'disciplinary procedures'** in the context of general practice was not clear. As I have said, disciplinary proceedings hardly exist today in general practice; they have been replaced by list management powers. Does the term **'disciplinary procedures'** include the exercise of list management powers? It was however tolerably clear that a complaint from a patient that was under investigation and had, for example, been referred to the Healthcare Commission would not prevent the completion of a clinical governance certificate. Nor, presumably, would the knowledge that the doctor was being sued for damages in respect of the death of a patient, unless there were also local disciplinary procedures in train.

26.173 It seemed to me that, if revalidation were to be reliant on local clinical governance systems, the person or group providing the clinical governance certificate should be required to consider the totality of the clinical governance data available in respect of a doctor before signing the certificate which was to form the basis of revalidation. The certificate should not be based on only a few discrete aspects of that data. A member of the public who was told that a person or group had provided a certificate saying that there were **'no unresolved significant concerns'** about a doctor would not understand that what was being certified was only that there had been and were no disciplinary proceedings against the doctor and no concerns about his/her health or probity. He or she would understand the certificate to mean that there were no concerns about complaints

which had been made about the doctor and were as yet unresolved, no concerns about his/her general prescribing practice or prescribing of controlled drugs, no concerns about his/her lack of participation in audit – indeed that there were **'no unresolved significant concerns'** about the doctor at all. I believe a member of the public would expect – and would be entitled to expect – the person or group to review all the information available before reaching a conclusion as to whether or not to sign this important document. If the effect of the clinical governance certificate is limited to a statement that, so far as is known, the doctor has no health problems, is not dishonest and has had no involvement in disciplinary proceedings, the public should be made aware that this is the case.

26.174 What was not clear to me after reading the note of the sub-group was whether or not it was intended that there would be any local scrutiny of a doctor's evidence by a clinical governance lead (as was contemplated by the NCGST) or by a local clinical governance support group or local certification group. If that was not to take place, it would mean that there was to be no evaluation of the doctor's fitness to practise. That is, as I have observed, a fundamental statutory requirement for revalidation.

26.175 The CMO's letter, dated 10th November 2004, has shed further light on the proposals for revalidation, which now appear to be the joint proposals of the GMC and the DoH. In his letter, the CMO declared that, in his view, **'firstly, the culture and process of clinical governance are now strongly embedded in local NHS organisations and, secondly, appraisal of NHS doctors is now well established'**. I am not sure upon what evidence the CMO has reached these conclusions. They are very different from the views expressed by his deputy, Professor Halligan (and by others), at the Inquiry seminars in January 2004 to which I referred at paragraph 26.90 above. Certainly, the Inquiry has received no evidence from the DoH (or elsewhere) to support this change of view. Of course, it may be that the CMO is speaking about the position in the hospital service. The Inquiry is concerned only with general practice.

26.176 The CMO then explained that, because he had reached these conclusions, the DoH **'would endorse the General Medical Council's principle that local ''certification'' would provide an explicit assurance about the doctor's practice at the point of revalidation'**. He continued:

> **'There must be an explicit and positive confirmation that doctors' practice-based evidence really is being reviewed through annual appraisal, operating within an environment subject to clinical governance. There would be explicit, rather than implicit, local certification (delivered by the clinical governance lead or the medical director or chief executive, as appropriate, for the most senior doctors) covering two components – that the doctor had been appraised and that there were no unresolved local concerns that might call into question the doctor's fitness to practise.**
>
> **In the case of participation in appraisal, explicit certification would confirm that:**

a. **Appraisal had taken place;**

b. **The appraisal process had produced an agreed Personal Development Plan;**

c. **The appraisal process had been carried out, and signed off, by a trained appraiser;**

d. **The appraisal process had been informed by verifiable data about the doctor's actual practice;**

e. **Local clinical governance processes – including appraisal – were quality assured.**

In the case of the absence of significant unresolved concerns, explicit certification would confirm that:

a. **There are no locally-known concerns about the doctor's health;**

b. **There are no locally-known concerns about the doctor's probity;**

c. **There are no local disciplinary procedures in progress;**

d. **There have been no relevant disciplinary findings over the specified period.'**

26.177 It now appears that the position is that the first stage of revalidation, which all doctors will be required to undergo, will comprise the submission of personal information (including declarations as to health and probity) to the GMC and the provision of a clinical governance certificate comprising the listed assertions about the doctor's participation in appraisal as well as those about health, probity and disciplinary proceedings. It does now appear clear that it is the intention of both the GMC and the DoH that revalidation will not comprise an evaluation of the doctor's fitness to practise. As I have said, appraisal as currently carried out for GPs cannot provide such an evaluation.

26.178 It may be that it is intended that appraisal will be 'toughened up'. Indeed, I have read in the periodical 'Doctor' as recently as 5th November 2004 that **'GP appraisals are set to get tougher to ensure problem doctors are flagged up during revalidation'**. It was said that **'a source close to the Department of Health said discussions were going on about how appraisal could be monitored to ensure it was stringent enough to allow revalidation to pick up problem doctors'**. The same article reported differing views from sections of the profession. Some thought that 'toughening up' would be a good idea; others thought that appraisal should not be used as a tool for picking up poor performance. However, it appears from the CMO's letter to me that he is satisfied that appraisal is already an adequate foundation upon which to base revalidation. I regret to say that I cannot agree.

An Important Concern

26.179 Throughout my examination of the GMC's proposals for revalidation, I have felt some concern that the public was being led to expect more from revalidation than it could

reasonably be expected to provide, in terms of reassurance about the competence of an individual doctor. It is important that patients and all other interested parties understand exactly what revalidation means and what its limitations are. Mrs Joyce Robins, who represented Patient Concern at the Inquiry seminars, made a plea that patients should be put fully in the picture and should be told what revalidation involves in practical terms and why it is deserving of public trust. It is important that revalidation is not 'oversold'. There are three different, although related, foundations for my concern.

26.180 The first is that, if a member of the public is told that revalidation will ensure that his/her doctor is 'up to date and fit to practise', s/he will, I believe, have the impression that s/he can expect the doctor to be practising at a level of competence above the basic level of acceptability. The expression 'up to date and fit to practise' will, in the minds of most members of the public, convey the idea that the doctor is 'fully up to speed' – not that s/he has just 'passed muster'. Yet the position is that a doctor will be revalidated unless his/her conduct, performance or health is such that a FTP panel decides that it must take action upon the doctor's registration. Even then, the doctor might be revalidated subject to restrictions and conditions upon his/her practice. In order to be refused revalidation on the grounds of poor performance, the doctor's performance will have to be so seriously deficient that the FTP panel feels obliged to suspend or erase him/her.

26.181 I have already referred to the low standards that are applied in performance cases and have said that that low standard will form the baseline for revalidation. In the course of a discussion at a GMC Council meeting on 12th May 2004, Mr Brearley remarked that doctors know that 'if they participate in revalidation and they are really bad, their registration could be at stake'. The implication is that the doctor will fail to be revalidated only if s/he is 'really bad'. The reality of the 'remarkably low' standard above which doctors will be revalidated does not square with the claim that revalidation gives an assurance that the doctor is 'up to date and fit to practise'. In my view, there is a real danger that the public does not understand this.

26.182 In the course of his evidence, Mr Brearley explained that one of the purposes of revalidation was that patients should be able to make an informed choice about their doctor. They would be able to look at the register and see that their doctor had been revalidated. Yet Mr Brearley had also said that a doctor might be revalidated and yet be subject to restrictions on his practice, imposed by a FTP panel for the safety of patients. He considered that this provided an acceptable safeguard for the public because the conditions would ensure that the doctor could not practise in areas in which s/he might present a risk to patients. However, it seemed to me that, if patients were to be in a position to make an informed choice of doctor, they would need to know more than merely whether their doctor had been revalidated. Patients would need to know whether there were any restrictions upon the doctor's practice and, if there were, they might need to know what they were and why they had been imposed. Mr Brearley's reply to this was that it would not be right to reveal too much information about the doctor because this would lead to a disproportionate loss of confidence in him/her. He considered that, if the fact that a FTP panel had imposed a sanction were to go into the public domain and destroy confidence in the doctor so that s/he could not practise, FTP panels would be reluctant to impose those sanctions. From that evidence, it appeared that the public is to be told that the

doctor, if revalidated, is up to date and fit to practise and they can have confidence in him/her. That would be most unsatisfactory because the reality might be that s/he is on the borderline of being unfit to practise. I was concerned about this. However, I see, from the draft Guidance recently published, that it is the GMC's present intention that the medical register will include the information that the doctor has been revalidated subject to conditions. How much detail will be provided I do not know. The information is 'in the public domain' in that if an enquirer telephones the GMC and asks directly whether the doctor's registration is subject to conditions, s/he will be told. In my view, this information should be readily available to the public from the GMC's website.

26.183 My second concern about the position of the public is that they are told that, in order to secure revalidation, the doctor must demonstrate to the GMC that s/he has been practising in accordance with the principles of 'Good Medical Practice'. In fact, as I have explained, it is not at all clear that s/he will have to do any such thing. He or she will have to provide a description of his/her practice (in the sense of what s/he does, rather than how s/he does it), assert that s/he has undergone appraisal and make a declaration as to his/her health and probity. The GMC will then seek a clinical governance certificate, which may confirm that the doctor has taken part in appraisal and that there are no significant unresolved concerns relating to his/her fitness to practise. If given, the certificate asserts a negative; in effect nothing adverse is known. There has been no positive demonstration of the standard of the doctor's practice. It is important that, if the present arrangements are to continue, the true position is made clear. It may be that it is intended in future to introduce some local scrutiny of the evidence in the doctor's folder. I cannot tell.

26.184 My third concern is that the public is being given the impression that doctors undergoing revalidation have to pass some sort of objective test. This is not positively suggested in official GMC publications, although the GMC came very close to it in the Prospectus of April 2003 when it drew a comparison between revalidation and the periodic assessments that airline pilots have to undergo. However, my real concern on this issue is that the GMC has, on more than one occasion, to my knowledge, made statements that suggest that revalidation will involve either a test or some form of thorough check of fitness to practise. Under the present proposals, it will not. During the GMC's opening statement to the Inquiry, Leading Counsel for the GMC said that, in the process of revalidation, each and every doctor's competence and performance would be 'checked and rechecked' so that the public could have the assurance that doctors were not merely entitled to treat them by virtue of not having been found wanting. Instead, patients would be able to know and have confidence that a positive decision had been made that registered medical practitioners were fit to practise and that the information upon which a judgement had been made to that effect had been objectively verified and corroborated within a quality assured system.

26.185 On another occasion, revalidation was compared with the MOT test for vehicles. The MOT vehicle test is an objective test of the roadworthiness of an individual vehicle. Various features of the vehicle are examined against specified standards. If it fails any part of the test, it fails the whole test. There is no such thing as a pass with conditions. Revalidation for doctors is quite different. The overwhelming majority will be revalidated on the basis of appraisal, which is not a test of fitness to practise and does not incorporate any detailed

standards with thresholds by which it is possible to pass or fail. The only threshold by which the doctor can ultimately fail to be revalidated is, as I have said above, a very low one indeed. The point is that for most doctors the process is not a test at all and bears no resemblance to the MOT vehicle test.

26.186 Revalidation was described by Sir Graeme Catto as 'a sort of MOT test for doctors' in a BBC radio programme, 'Down With ...', broadcast on 12th May 2004. The programme comprised a debate about whether the GMC was doing all it should to safeguard and protect the interests of the public and patients. Sir Graeme said that the standards of practice and care that patients are entitled to get from their doctors are set out in 'Good Medical Practice' and that the GMC aimed to 'maintain and strengthen these high standards with a new system of revalidation – a kind of MOT for doctors'. Another contributor then spoke. This was Mr Alan Hartley, a member of the Patients Association and of the GMC's Patient Reference Group. He said:

> **'Approximately every five years, a doctor will be assessed as to his training and will have to show that he has kept up to date on training on new methods, so, from the public's point of view, what it means is they will know that when a doctor has been revalidated that he is fully up to speed with the latest innovations and the latest treatments. A huge step forward.'**

26.187 I interpose to draw attention to the way in which being 'up to date and fit to practise' was equated with being 'fully up to speed'. A while later, Sir Graeme again referred to revalidation as the 'MOT for doctors'. He expressed pride in the fact that no other country in the world had a system of time-limited licence dependent upon doctors demonstrating that they are up to date and fit to practise. To call revalidation a MOT for doctors is a catchword. It is easy for the listener to remember. I think that many people who heard that programme will have taken away the impression that revalidation is a test for doctors, just like the MOT. That is not a true impression.

Whither Revalidation?

26.188 It is not clear from the documents recently provided by the GMC whether its plans for revalidation are settled. It is fair to say that there has been a recognition that revalidation will evolve over time but it appears, from the 2004 draft Revalidation Guidance that the GMC does not expect to make any significant changes to its proposals in the near future. In my view, that is a pity, because the present proposals do not meet the requirements that were outlined so clearly in the Consultation Paper of 2000. Nor in my view will they satisfy the statutory definition of revalidation, which is an **'evaluation of a medical practitioner's fitness to practise'**.

26.189 It appears that the GMC has set its face against undertaking an individual evaluation of every doctor. However, that is what the statute requires. In the early days, the GMC took the view that it could not delegate that function; it rejected the suggestion that the medical Royal Colleges might offer an alternative route to revalidation. It has now accepted that it can delegate everything other than the final decision to revalidate. The statute does not

appear to forbid delegation. However, it does require an evaluation of an individual doctor's fitness to practise.

26.190 Quite apart from the statute, the GMC has always promised the public an individual evaluation of fitness to practise. In my view, its present proposals do not fulfil that promise. I propose to set out my ideas for how both the statute and the promise could be satisfied – only in the context of general practice, because that is the limit of my remit. My proposals would satisfy the GMC's wish to link revalidation closely with clinical governance. They would also, I believe, avoid doing serious damage to the formative nature of appraisal.

26.191 In my view, the main platform for revalidation should be the preparation by each doctor of a folder of evidence which demonstrates what the doctor has been doing in the last five years. Some of the contents of the folder would have to be specifically laid down and would be compulsory. They would include data derived from clinical governance. These would include, for example, prescribing data and records of complaints or concerns including any report from the Healthcare Commission or a GMC or NCAA assessment. I hope that, in the future, more information of that kind will be available to PCOs. Other compulsory items would originate within the doctor's own practice. These should, in my view, be much along the lines proposed by the RCGP in its consultation paper. For example, there should be a record of the CPD activities the doctor has undertaken. A copy of appraisal Form 4, a patient satisfaction questionnaire, the results of a clinical audit and some significant event audits should all be included. In addition, there could be a video recording of the doctor in consultation with patients. I would also suggest that the folder should include a certificate to show the successful completion of a knowledge test. I shall say a little more about that below. Of course, it would be open to each doctor to include additional material besides the compulsory items. The doctor's NHS contract of employment or contract for services would have to require the production of these compulsory items.

26.192 The preparation of the folder would take place over a five-year period. Its development could be discussed privately and in confidence during the annual appraisal, and advice could be given as to what more needed to be done. The appraiser would be entitled to see all the material, with the result that the appraisal would be of greater value; the doctor would not be able to conceal any problems. It would seem to me to be sensible if appraisers were to encourage doctors to produce one of the specific compulsory elements each year, for example a video recording or a patient satisfaction questionnaire, so that the appraisal could focus on a discussion of that topic.

26.193 At revalidation, the folder would be scrutinised – not by the GMC, but by a local group based within the PCO and probably chaired by the clinical governance lead. I do not claim this idea as mine; it is that suggested by the joint working group. I think it is a very good suggestion. The scrutinising group should, in my view, include a lay person from outside the PCO and a GP from another area, not personally known to the doctor under consideration. That GP should be accredited by the RCGP as an assessor to standards approved by the GMC. Scrutiny should not be undertaken by a single person; nor should a panel be drawn only from members or employees of the PCO. A positive addition could be that the doctor might be invited to attend the meeting. This would overcome one of the

'weaknesses' of the GMC's original plans identified by Mr Brearley. That group would make an individual evaluation of the doctor's fitness to practise, based upon standards to be set by the RCGP and approved by the GMC. If the local group were satisfied, it would recommend revalidation to the GMC; if it were not, the GMC would take over and proceed to the second stage.

26.194 I do not think that these arrangements would impose an undue burden on PCTs. On average, they have about 100 GPs each. That would mean evaluating about 20 GPs per year and some locums; I am not sure how many of those there would be. I would have thought that that would be manageable. However, there are several ways in which the numbers might be reduced by permitting alternative routes to revalidation. For example, the Membership by assessment of performance of the RCGP requires a high standard of performance. Any doctor who achieves that in the five-year period should, in my view, be automatically revalidated. If the RCGP were to devise a 'refresher assessment' (which could no doubt be approved by the GMC as a proxy for revalidation), I would expect that some doctors would take that route. I think, also, that GPs who are approved trainers could properly be automatically revalidated. Trainers have to be reassessed to a high standard of performance every three years. They could not possibly go through that process successfully if they were not fit for revalidation. Another possibility would be to exempt a GP from revalidation during the first five years after passing the summative assessment. That too would reduce the number of doctors that had to be scrutinised by the group. If it were thought that this proposal would still impose too much of a burden, I suggest that consideration should be given to stretching the revalidation period from five years to seven. Another alternative would be to keep the five-year period for GPs over the age of 50 and allow a longer period between revalidations for doctors under that age. In short, I think it is vital that there should be an individual evaluation of each doctor and I think that the burden that this would impose on individual PCOs could be made tolerable. I advance no proposals about the revalidation of doctors in the hospital service or the private sector.

26.195 So far as the second stage is concerned, the GMC must ensure that this is transparent and rigorous. It should ensure that there is adequate lay involvement. Above all, it must not permit a doctor who has failed to be revalidated at the first stage to be revalidated 'by default' at the second stage. At present, the uncertain nature of the steps to be taken makes that a real possibility. The GMC must ensure also that the standards by which second stage decisions are to be taken are clear and understood by all, including doctors and the public.

26.196 I have already expressed my concern about the low standards of the old performance procedures, which would, but for the advent of the new FTP procedures, have generally underpinned revalidation. The GMC has not said that the standards of deficient performance that will justify action on registration under the new procedures will be any higher than those in operation before. These standards are too low and do not provide adequate protection for patients. In my view, they must be raised if revalidation is ever to have credibility.

26.197 I said that I wished to mention the use of knowledge tests. The evidence received by the Inquiry is to the effect that no doctor can function well unless his/her knowledge base is

adequate and kept up to date, but the fact that the knowledge base is satisfactory is not, in itself, a guarantee that the doctor is practising well. This second factor is often used as a reason for not including any form of knowledge test in the revalidation process. In my view, that is not a satisfactory reason for excluding a knowledge test although it is a good reason for not basing revalidation solely upon such a test. I think that the real reason why so many people seem to veer away from the idea of knowledge tests is that they believe that doctors will not accept them. I cannot believe that there could be any rational opposition to what I am proposing. Nowadays, knowledge tests can be taken on-line and in private. The doctor can find out in the privacy of his/her own study whether his/her knowledge base is satisfactory. If it is, that will provide the doctor with a degree of comfort and might also draw attention to any areas in which a gap has been revealed. I am sure that most doctors who do not do well would wish to remedy the situation. Such a doctor can take another test – and yet another if necessary – until s/he reaches a satisfactory standard. If a doctor cannot bring his/her knowledge base up to standard within five years, surely s/he should not be practising. In my view, there should be a mandatory requirement to produce a certificate of satisfactory completion of a knowledge test taken at some time within the five-year period.

26.198 Clearly, the changes that I have proposed are not entirely a matter for the GMC. They call for the close involvement of the DoH. They would require consultation and I dare say that they would give rise to some consternation in the profession. I do not think that they need to. I believe that the profession has accepted that the public is entitled to the reassurance that doctors are up to date and fit to practise and I believe all those who are intellectually honest, which I believe to be the great majority, will recognise that, if that assurance is to be given, it must have a more solid base than that which is currently contemplated.

Could Revalidation Catch 'Another Shipman'?

26.199 Early in this Chapter, I said that it would be instructive to consider whether a system of revalidation would be capable of detecting the severely dysfunctional behaviour of another Shipman. I was not suggesting that 'catching another Shipman' was to be the litmus test of whether revalidation was worthwhile or whether any particular set of proposals was appropriate. Revalidation should detect a far wider range of deficiencies and much less serious deficiencies than those seen in Shipman. If revalidation can pick up a 'poorly performing doctor' it ought, one might think, to be capable of picking up a grossly dysfunctional one. That is not necessarily so, because many under-performing or dysfunctional doctors do not realise that their practice is deficient and do not make any attempt to conceal their shortcomings. Shipman, on the other hand, knew what he was doing. He was quite capable of giving a good standard of care and very adept indeed at concealing the fact that he was killing his patients.

26.200 First, it is clear beyond argument that Shipman would have done well in appraisal, as it currently operates. He would have produced evidence that many aspects of his clinical care were of a high standard. He could have produced the results of audits; the topics would have been chosen by himself and he would not have conducted an audit into the mortality rate among his patients. He might well have produced his prescribing data; the main interest in that would have been his insistence on prescribing proprietary drugs at a

time when doctors were being encouraged to use generic equivalents. Shipman's prescribing of diamorphine was on the high side but he was not an outlier and, if any questions had been asked, he would have produced the records of one or two patients who were being nursed at home during their terminal illness. He would have talked confidently about his reasons for insisting on the freedom to prescribe as he thought best for his patients. He would have explained why he often prescribed statins at a time when many doctors doubted their efficacy. He could have shown that he had been running chronic disease clinics as long, I think, as had almost any other practice in the area. His patient satisfaction questionnaires would have shown, I think, almost 100% satisfaction in all aspects of his practice. A peer questionnaire might have revealed that he was not liked but it would not have revealed concerns about his practice. There were very few complaints about him after 1994 and none of significance. That is remarkable as in the last four years of practice he killed over 100 patients. There is no possibility that he could have 'failed' at appraisal. In fact, it is quite likely that he would have volunteered (and been accepted) as an appraiser.

26.201 There can be no doubt that the clinical governance lead or medical director of Shipman's PCO would have signed his clinical governance certificate without a moment's hesitation. Shipman would have been revalidated without difficulty under the proposals that will come into force in April 2005.

26.202 Could Shipman have been detected by revalidation as the GMC originally proposed to carry it out? I do not think so, unless the RCGP had laid down, and the GMC had approved, specific items of information that had to be included in the doctor's folder and those items had included something that would have detected Shipman's vulnerability. Of course, he would have been detected if there had been a requirement for an analysis of mortality rates, backed by verifiable data, but I think that would have been a very unlikely requirement. A more likely one would have been a requirement that some of his patient records be submitted to independent review. They would have been found to be of a poor quality generally and not capable of conveying an appropriate amount of information to colleagues. However, only if there had been a review of the records of deceased patients could his criminal behaviour have been detected. A careful review of the records of the recently deceased patients should have revealed real cause for concern, as I explained in my Third Report. However, I must say that I think it very unlikely that anyone would have thought it appropriate to require such a review for the purposes of revalidation.

26.203 Would it be possible for 'another Shipman' to be detected by clinical governance activities, as they might be expected to operate in the foreseeable future? I think that is a real possibility. I have referred to that in Chapter 12.

Conclusions

26.204 When the GMC published its Consultation Paper in 2000, it had recognised the need to provide a mechanism to detect poorly performing and dysfunctional doctors without relying on a complaint from an aggrieved patient or a worried employer or PCO. It decided to require every doctor who wanted to practise to undergo a periodic evaluation of his/her fitness to practise. That would identify the doctors who were known to be, in Dame Lesley

Southgate's words, 'out there harming patients' but it was hoped also that the method by which this was to be achieved would raise the standards of medical practice generally. The GMC started out with sound principles, high aspirations and the best of intentions. Initial proposals were devised and tested but, by 2002, I think that the GMC had realised that the task was more difficult than had been expected. The initial proposals would have been expensive and would have imposed a considerable administrative burden on the GMC. Moreover, the proposals were very unpopular with large sections of the profession. The GMC changed direction. It abandoned the principle of evaluation of each individual doctor's fitness to practise. It decided to base revalidation for the great majority of doctors upon the mere fact that they had taken part in an appraisal process conducted either by their employers or, for GPs, by a GP appraiser instructed by the doctor's PCO. For GPs, at least, appraisal was and is a wholly formative process and, in my view, quite incapable of providing a basis for an evaluation of fitness to practise. The GMC made that change without conducting any study of the efficacy of appraisal as a means of identifying deficient performance. When the GMC made that change of direction, it knew, because it had been so advised by its management consultants, SHM, that there were many objections to the idea of linking revalidation to appraisal and that these amounted to a **'significant catalogue'** which should not be **'lightly dismissed'**. The change of direction was not slight; nor could it be described as a 'refinement' of the former proposals. In my view, that change of direction was substantial and it was made for reasons of expediency and not for reasons of principle.

26.205 About six months after this change of direction had been announced, the GMC felt constrained to attempt to improve its proposals. I am satisfied that it did so because of the evidence given to this Inquiry to the effect that appraisal could not provide a satisfactory basis for revalidation. It attempted to negotiate with the DoH an additional element, the clinical governance certificate, which was to provide an assurance to the GMC that there were, to the knowledge of the signatory, no significant unresolved concerns about the doctor's fitness to practise. This, as I have said, was a step in the right direction. However, the clinical governance certificate as it is now to be provided is of very limited value and the GMC's proposals still do not fulfil the essential requirement of revalidation, which is that it should be an evaluation of the doctor's fitness to practise. The public cannot properly have confidence that a doctor who has been revalidated is 'up to date and fit to practise'. That position may change in the future, if clinical governance improves, as everyone hopes that it will, and if the culture of one doctor's reluctance to report another's failings can be altered. Those changes may or may not come about. But if the GMC intends that revalidation should give the public a reassurance of real, as opposed to illusory, value it must accept that its present proposals are not adequate and must develop a system of revalidation which, at its first stage, entails a summative evaluation of each individual doctor's fitness to practise.

CHAPTER TWENTY SEVEN

Proposals for Change

Introduction

27.1 In this Report, I have examined the procedures that were in force within the NHS for the monitoring of general practitioners (GPs) during the whole of Shipman's career. I have also examined the procedures for the handling of complaints against GPs and the way in which concerns raised about a doctor were received and dealt with. My general conclusion has been that those procedures for monitoring were not such as could have been expected to pick up malpractice by a GP in the absence of a complaint drawing direct attention to that malpractice. I have also reported that, until the report made to the Coroner by the late Dr Linda Reynolds in March 1998, no complaints were made or concerns expressed to the authorities about Shipman such as might have given rise to the suspicion that Shipman was killing patients. I have concluded that, even if complaints had been made or concerns raised which might possibly have given rise to such suspicion, it is unlikely that an investigation would have taken place that might have uncovered Shipman's criminality. The system appears to have operated on the assumption that all doctors were essentially decent and strove to do their best for patients; a few would commit some form of misconduct and some might fail to provide an adequate standard of care. Those would be reported to an appropriate authority and would be dealt with. Shipman's was not the only case that demonstrated that these assumptions could not be made. Nor was his the first.

27.2 In the second half of the 1990s, the Government, the General Medical Council (GMC) and the medical profession had to come to terms with the unpalatable truth that the existing systems for monitoring the conduct and performance of doctors had failed to detect a number of severely dysfunctional practitioners. The public had been badly let down. Some realised that it must follow that the existing systems were also failing to detect dysfunctionality which was of a less serious kind but which might nonetheless put patients at risk of harm. Many people recognised that the whole system had to be overhauled.

27.3 The Inquiry's Terms of Reference conclude by requiring me to make such recommendations for change as I consider are necessary for the protection of patients. To that end, the Inquiry has sought to trace the progress of the overhaul of the systems and procedures by which patients should be protected from dysfunctional doctors. Because Shipman was a GP, the Inquiry was required to focus on the systems and procedures in operation in primary care. My general conclusion is that the overhaul has proceeded a long way, although it is not yet complete. The will to achieve change has been variable. In an organisation as huge and complex as the NHS and in a profession as large as medicine, that is not surprising. My overall impression is that there has been considerable will to bring about change within the Government and in some professional organisations, notably the Royal College of General Practitioners (RCGP). There has been substantial change within the GMC since 1998 and there is about to be more. However, in some quarters of the profession, there has been a disappointing reluctance to recognise the need for change. The view is too often heard that there is no point in change designed to

'catch another Shipman' because there will never be another one. Some within the profession have not recognised that the need for change goes far wider than that.

27.4 In this Chapter, I propose to consider how far the overhaul has proceeded and to make recommendations for its further progress in the interests of patient protection. Some of these proposals will be quite detailed while others will be of a more general nature, as I have already made a number of detailed recommendations in the preceding Chapters.

Proposals for Change Affecting NHS Arrangements for Primary Care

Changes and Reforms to Date

27.5 In 1997, the Government embarked upon a fundamental review of the operation of the NHS. One of the main aims underlying that review was to place a greater emphasis on quality of care. The corollary of that aim was that patients should not be exposed to avoidable risk at the hands of healthcare professionals. In the course of this Report, I have referred to several of the initiatives considered and the changes which have been brought about. I shall not describe those in detail here. It seems to me that, in the long term, the development of clinical governance, which I described in Chapter 12, could, if carried through with determination and adequate resources, have the greatest beneficial effect of all the changes I have examined.

27.6 Another notable development was the change in the structure of the bodies with responsibility for the provision of primary care. Primary care trusts (PCTs) are small organisations, small enough to enable their staff and those GPs who are directly involved in their work to develop personal knowledge of the GPs on their list. PCTs have many new powers. They are entitled to require far more information about a doctor before they decide whether to admit him/her to their lists than used to be the case, including information about his/her involvement in criminal or disciplinary proceedings. They have new powers enabling them to deal with dysfunctional doctors themselves, without having to rely on the Family Health Services Appeal Authority (Special Health Authority) or the GMC. They can remove or suspend doctors from their lists or impose conditions upon their continued inclusion. They are required to undertake clinical governance activities and are being encouraged to set up systems for the detection of poor performance and other forms of dysfunctionality in a GP before such shortcomings give rise to a serious risk of harm to patients.

27.7 One aspect of the thinking behind the change from health authorities (HAs) to PCTs was that local practitioners would now be closely involved in the work of the PCT and in making policy decisions affecting local medical services. It is usual for the Chairman of the Professional Executive Committee (PEC) of a PCT to be a GP. The PCT's Clinical Governance Lead is also likely to be a local GP. These arrangements have both advantages and disadvantages. One advantage should be an increased sense of involvement and 'ownership'. As a result, the feelings of tension and division between GPs and the bodies responsible for their monitoring and supervision should be reduced. A significant disadvantage is that there is a potential for conflict of interest for those GPs who are both local practitioners and PCT officers. There is, in any event, an element of conflict

between the roles that the PCT has to fulfil: sometimes offering support, sometimes having to act as an inspectorate.

27.8 PCTs have their problems. They are very new and have not yet had time to develop a corporate memory. Many of their staff have very little experience of the kind of quasi-managerial and supervisory functions that they have to perform. One of the problems inherent in the smallness of PCTs is that staff have to cover a wide range of functions and are unlikely ever to acquire real expertise in some aspects of their work; they will not have the opportunity to learn by regular experience. Some PCTs have found it helpful to band together into groups for some purposes. Another problem is that, because there are a lot of PCTs (over 300 in England alone), there are many different ways of doing things; standards are variable. Some PCTs appear to have difficulty in making their resources cover all the functions they are supposed to perform. My overall impression is that there is a real determination to make the new systems work well. I hope that PCTs will be given the chance to settle down; there was a period of almost constant change in primary care organisation for several years before the millennium and for a couple of years after. In my view, further structural change should be avoided for a while at least. PCTs need the opportunity to develop expertise and confidence in using their new powers. I think also that the exchange of ideas and the dissemination of good practice could help to ensure that high standards are developed uniformly across the country.

Areas in Which Further Change Is Needed

27.9 I mentioned earlier that clinical governance, if carried through with determination and adequately resourced, could make a very substantial difference to patient safety and to the quality of patient care. There are five particular aspects of clinical governance in its widest sense in respect of which I propose to make recommendations. These are the handling of patient complaints against GPs and of concerns expressed by medical colleagues, fellow healthcare professionals and others, disciplinary proceedings, the use of prescribing information, the use of mortality statistics and appraisal. The other main area in which I wish to make recommendations for change is in the provision of information, both for internal NHS purposes and to patients. I shall also make a number of miscellaneous recommendations about ways in which PCTs might improve patient protection and bring about an improvement in the quality of care provided by GPs.

27.10 Ideas for change covering these broad areas of interest were included in a Consultation Paper issued by the Inquiry in October 2003, entitled 'Safeguarding Patients: Topics for Consideration at the Stage Four Seminars'. These topics were the subject of discussion at the Inquiry's seminars held in January 2004. Details of these seminars are given in Chapter 2 and I shall refer to some of the discussions which took place at the seminars, and the points raised by respondents to the Inquiry's Consultation Paper, in the course of this Chapter.

Handling Complaints and Concerns

27.11 Several issues relating to complaints were raised in the Inquiry's Consultation Paper. Many organisations and individuals responded. By the time of the seminars, several more

issues had been raised, some by respondents to the Consultation Paper, others by the Inquiry itself as the result of evidence recently received. In this section of this Chapter, I shall discuss a number of these issues. In this discussion, I shall assume that the reader has read Chapters 6, 7 and 11 of this Report and is familiar with the systems in operation at the present time.

27.12 As I explained in Chapter 7, the Government has consulted extensively about the reform of the NHS complaints procedures. By the time the Inquiry seminars took place, draft Complaints Regulations had been circulated for consultation purposes. These draft Complaints Regulations proposed changes to both the first and the second stages of the procedures. In general, I considered that the arrangements set out in the draft Complaints Regulations were sensible and helpful and would lead to a substantial improvement in the complaints process as it operates in primary care.

27.13 One of the main provisions in the draft Complaints Regulations was the transfer of responsibility for the second stage of the complaints procedures from independent review panels (IRPs) to the Commission for Healthcare Audit and Inspection (now known as the Healthcare Commission). That proposal met with general support and the Government was anxious to implement the change. Accordingly, in July 2004, a new set of Regulations, the National Health Service (Complaints) Regulations 2004 (the 2004 Complaints Regulations), came into operation. These effected changes to the second stage of the complaints procedures but, so far as GP practices were concerned, left the first stage of the procedures as it was. The Inquiry was advised that it was the Government's intention to reform the first stage of the complaints procedures insofar as it affected GP practices after receipt of the Reports of this Inquiry and of the Neale and Ayling Inquiries. I was content with that arrangement. However, as a result of the separation of the new arrangements for the two stages of the complaints procedures, the present position and the interconnection between the two stages is perhaps a little confusing. I am confident that that situation will be remedied in the near future.

27.14 I will now deal with a number of different issues that arise in connection with the reform of the complaints procedures.

Who Should Receive Complaints?

27.15 At present, a person wishing to make a complaint about a GP has to make it, in the first instance, to the practice within which the GP works. Evidence received by the Inquiry and published research suggests that many people who wish to make a complaint are discouraged from doing so by the prospect of having to 'face' a member of staff or a doctor at the practice about which the complaint is to be made. In its Consultation Paper, the Inquiry asked whether such complainants should have the option of lodging their complaints with the PCT, rather than with the GP practice. Some respondents said that a choice would be welcomed by patients for the reason mentioned above. Those who were not in favour of choice preferred to keep the *status quo*, whereby all complaints relating to primary care are handled in the first instance by the practice. Two main reasons were advanced in favour of that arrangement. First, it was said that, if a practice is allowed to handle the complaint, there is a better prospect that the relationship of trust and

confidence between patient and doctor will be maintained. Second, it was said that many complaints in primary care relate to purely administrative matters and/or are extremely trivial; most can be satisfactorily resolved by the practice. It would overwhelm PCTs if they had to deal with large numbers of such complaints. However, by the time of the seminars, the Government had indicated, in the draft Complaints Regulations, its intention to allow patients to choose whether to complain to the GP practice or to the PCT.

27.16 It seems to me that the need for patient choice in this respect has been demonstrated by the findings in the research undertaken by the Public Law Project and in the York Report, to which I referred in Chapter 7. Those findings were that many patients were unwilling to complain directly to the doctor's practice. If confirmation of that is needed, it is to be found in evidence given to the Inquiry. I recognise the importance of retaining the relationship of trust and confidence between doctor and patient where possible, and I also accept that many minor complaints can be dealt with quickly and satisfactorily by a practice manager. However, if patients are being discouraged from making a complaint by the requirement to make it directly to the practice, they must be given an alternative. Those who are prepared to make their complaints directly to the practice will continue to do so and it is to be hoped that many such complaints will be resolved quickly and easily without damage to the relationship of trust and confidence between doctor and patient. However, those patients who do not wish to do so – for whatever reason – should, in my view, be able to lodge their complaint with the PCT and, if they wish, to avoid being obliged to enter into direct correspondence or discussion with the practice concerned. I think it likely that it will be the rather more serious complaints – those involving personal criticism of the doctor and/or the clinical care provided – which will be lodged with the PCT. I am not suggesting that this will always occur but I think this is the way in which most patients will behave. Accordingly, I do not think that the result of this change will be that PCTs will be swamped by trivial complaints. Nor do I think that this arrangement will be damaging to the relationship between doctor and patient. If the complaint relates to an administrative matter or some other minor problem, I would expect the PCT to facilitate a solution with a view to maintaining or restoring that relationship.

27.17 It is, in my view, desirable that, at the first stage of the procedures, GP practices should continue to deal with most of the complaints that patients bring directly to them. Steps should be taken to improve the standards by which such complaints are handled. The research suggests that the quality of complaints handling within general practice is very variable. GP practices should be helped to adopt a positive attitude towards complaints and to train their staff to handle complaints in an appropriate way.

When Must a Complaint Be Made?

27.18 Under the 1996 complaints procedures, a complaint had to be made within six months of the events complained about. Under the draft Complaints Regulations, this period would be extended to 12 months, with the possibility of further extension in some circumstances. In my view, that proposal was sensible. It effectively recognised that complainants may be ill or bereaved and may not be in a fit state to contemplate lodging a complaint until a considerable time after the events in question. Doctors should have good contemporaneous notes of all consultations and, thus, should not be seriously

disadvantaged by the extension of the period. Although one does not wish to encourage delay, 12 months seems to me a more reasonable period to allow. I hope that that change will be incorporated into the next set of Complaints Regulations.

The Reporting of Complaints to Primary Care Trusts

27.19 One of the issues raised in the Inquiry's Consultation Paper concerned the lack of information available to PCTs about the nature of complaints received by a GP practice and about the way in which they are handled and resolved. This type of information is important for several reasons connected with the PCT's responsibilities for clinical governance. First, the way in which complaints are handled by GP practices is or should be a matter of interest and concern to the PCT. It is an important indicator of the quality of the relationship that the doctors within the practice have with their patients. Second, as Professor Alastair Scotland, Chief Executive and Medical Director of the National Clinical Assessment Authority (NCAA), said at the seminars, the number and nature of the complaints received by a GP practice is likely to be an indicator of the quality of service it is providing. If either a practice or a particular doctor attracts a number of complaints – especially if those complaints are of a similar nature – alarm bells should begin to ring. At present, as I explained in Chapter 7, PCTs find out only how many complaints are lodged at a practice and know nothing of the content of those complaints unless the complainant proceeds to the second stage. Moreover, the PCT receives information about complaints by way of an annual return, not in 'real time' as the complaints are made. Many respondents to the Consultation Paper favoured the provision of more information to the PCT at more regular intervals.

27.20 By the time the issue was discussed at the seminars, it was known that the Government proposed to make changes that would give PCTs improved information about complaints and a discretion to decide how frequently they would require it to be provided. The draft Complaints Regulations would require primary care providers (i.e. GP practices) to provide PCTs with information about complaints at intervals to be specified by the individual PCT. The information would have to include the number of complaints received and their subject matter and would have to specify how the complaints had been handled, including the outcome. The PCT would be required to prepare a quarterly report containing this information for consideration by the PCT Board. At the seminars, there was discussion about the frequency with which GP practices should have to supply the information to their PCT. Some seminar participants thought that complaints should be reported to PCTs as they were made and should not be 'saved up' for periodic reports. Also, the view was expressed that the actual letter of complaint (if the complaint was a written one) or the practice's record of it (if it had been made orally) should be sent to the PCT. Mrs Pauline Webdale, representing the Association of Medical Secretaries, Practice Managers, Administrators and Receptionists (AMSPAR), told the seminars that, at the GP practice where she worked, all complaints were copied to the PCT soon after receipt. This gave rise to very little extra work. The practice did not receive many complaints in a year. My understanding is that the average figure over the whole country is about one complaint per GP per year.

27.21 I am impressed by the arguments in favour of the immediate reporting to the PCT of complaints received by a GP practice. I can see that, for some clinical governance purposes, a periodic report (say, quarterly) would be adequate. However, in one respect, immediate reporting would offer a distinct advantage. If the complaint were of a serious nature, the PCT would be able to intervene and to take over the handling of the complaint. I think that it must be recognised that, where a complaint is handled within a GP practice, the prime objective will usually be to 'satisfy' the complainant, in the sense of resolving the complaint in such a way that s/he will not be disposed to take the matter further. Seen in a positive light, that might be described as 'maintaining the doctor/patient relationship'. Seen from another angle, it might amount to 'back covering'. It is asking a lot to expect the complaints manager or a member of a GP practice with responsibility for handling complaints to deal objectively with serious allegations relating to misconduct or incompetence made against a member of a small practice team. In my view, in the unlikely event that a potentially serious complaint will, in future, be made directly to a GP practice (rather than to the PCT), it would be preferable for the PCT to 'call the complaint in' and to take it over from the practice. That could be done only if complaints are reported immediately and if the PCT sees the actual complaint or, if it has been made orally, a full account of it, as recorded by the practice.

27.22 Such a proposal could give rise to issues of patient confidentiality. However, in my view, these could be resolved. The patient could be asked to consent to the disclosure to the PCT of the letter or record of complaint. In the unlikely event of a refusal to consent, the letter of complaint could be anonymised and, if the PCT thought it desirable to call the complaint in, it could write to the complainant through the practice, to explain why it wished to investigate the complaint. If the patient refused, which I think would be unlikely, the PCT might well be unable to proceed with its investigation. However, depending on the subject matter of the complaint, it might wish to examine other information which was available about the doctor or to institute its own enquiries to ascertain whether there had been any other incidents of a similar nature reported in respect of the doctor. At least, the PCT would be aware of the fact that a complaint had been made and would be alert to any further complaint of a similar nature. Thus, it would be assisted in its clinical governance role.

27.23 Accordingly, I recommend that draft regulation 30 of the draft Complaints Regulations should be amended to require primary care providers to report all complaints to the PCT within, say, two working days of their receipt. The report should comprise the original letter or record of the complaint. It should also be open to a PCT to require delivery of a copy of any correspondence between the practice and the complainant, including the practice's letter of explanation. The PCT should then log the complaint for clinical governance purposes and, if it considers that clinical governance issues arise, the complaint should be 'called in' for investigation by the PCT.

Primary Care Trusts' Responsibility for the Investigation of Complaints

27.24 As I have said, I envisage that, in future, most complaints of any gravity will be made direct to the PCT, rather than to the GP practice concerned. The investigation and attempted resolution of complaints will be a new function for PCTs. Until now, they have handled

complaints only administratively. Complaints managers have 'smoothed the way' for patients making a complaint to a GP practice; they have arranged conciliation and, when necessary, they have made the arrangements for independent review. If the draft Complaints Regulations are enacted (as I hope they will be, with some amendment), PCTs will be responsible for some investigations at the first stage of the complaints procedures. If those investigations are not done thoroughly and objectively, the changes currently proposed will not bring the improvements hoped for. Indeed, in relation to complaints received in the hospital service, the Department of Health (DoH) has recognised that good investigation is essential, both out of fairness to both parties to the complaint and for the purpose of learning from experience. In the DoH's framework document, 'Maintaining High Professional Standards in the NHS', published in December 2003, the importance of prompt, thorough investigation of complaints against, and concerns about, hospital doctors is recognised. In each case, a case manager and a case investigator are to be appointed. It is obvious that comparable arrangements must be made for the prompt and thorough investigation of complaints received by PCTs. In my view, the provision of such arrangements is the single most important issue to be tackled in the reform of the complaints procedures.

The Purpose of Investigation

27.25 I ought perhaps to explain what I mean by the investigation of a complaint. By 'investigation', I mean the gathering of information and evidence relating to the circumstances giving rise to the complaint. Such an investigation might involve asking questions of the complainant and obtaining a statement from him/her, discovering from the complainant the identity of any potential witnesses and taking statements from them, obtaining a statement from the doctor complained of and from any witnesses whom s/he may put forward, obtaining the comments of the complainant (and possibly of other witnesses) about the account given by the doctor and *vice versa*, and initiating other enquiries (e.g. checking assertions made by the complainant or the doctor with third parties and/or with existing documentation). In the case of a complaint about clinical treatment, an investigation might also involve obtaining any relevant medical records, test results and other documents and obtaining evidence from an expert in the relevant specialty.

27.26 Regulation 20 of the draft Complaints Regulations requires the complaints manager of a PCT to investigate a complaint **'to the extent necessary and in the manner which appears to him most appropriate to resolve it speedily and efficiently'**. The complaints manager may request the production of information or documents to enable him/her to consider the complaint properly. No doubt it is intended that guidance will be made available to PCTs and their complaints managers as to how to go about the investigation of complaints. However, I am concerned to see that the words of the draft regulation mention only one purpose behind the investigation, namely the 'resolution' of the complaint. Nothing is said about the need to find out what happened and to establish the facts. Nor is there any reference to using the investigation of a complaint as a learning exercise, for the detection of misconduct or poor practice, or for the improvement of services. I would like to see statutory recognition of the importance of the proper

investigation of complaints to the processes of clinical governance and of monitoring the quality of health care. I also believe that, if PCTs were to approach their new duties in a spirit of learning through investigation, the outcome would be greater patient satisfaction. At present, many complainants feel that they must fight to have their complaint investigated properly. They want to feel that they can tell the NHS that something has gone wrong, in the knowledge that the matter will be fully looked into. I am sure that the Government recognises that the NHS should be able to provide a complaints procedure that does not require the patient to 'do battle'. If the new arrangements are to provide improved patient satisfaction and better learning processes, there must be thorough investigation.

The First Triage

27.27 The Inquiry was concerned to discover how complaints might best be approached so as to satisfy patients and detect poor practice. It appeared to the Inquiry that not all complaints would give rise to issues of misconduct or poor practice or to other issues which have a bearing on the quality of care or patient safety; some complaints might arise from a purely private grievance. I envisage that many 'private grievance complaints' will be of a fairly minor nature and will be made directly to the practice. However, it is likely that, under the new arrangements, some will be made to the PCT. The Inquiry invited discussion about whether it would be possible for a PCT to sort out which complaints it should investigate thoroughly for 'clinical governance' reasons and to differentiate them from ('private grievance') complaints which could properly be handled only with a view to providing 'resolution' for the complainant.

27.28 There was general agreement at the Inquiry's seminars that some sort of 'triage' of complaints would be helpful, although some participants felt that the line between the two types of complaint would not be easy to draw and that a complaint about a 'private grievance' matter might, on further examination, turn out to be indicative of more serious problems within the practice. For example, a complaint that the doctor had been late in arriving at the surgery and had kept the complainant (and possibly others) waiting for an unreasonable time is not likely to give rise to patient safety issues. The desired outcome is probably an explanation and an apology, coupled with an assurance that steps have been taken to ensure that the problem will not arise again. However, the point was made that, if complaints of this nature recurred, they might indicate that there was a problem with the doctor. I can see that. Nonetheless, I think that it will not be difficult for a PCT complaints manager to recognise a single complaint that gives rise or might give rise to clinical governance concerns when s/he sees it. 'Private grievance complaints' of the kind I have just described would not fall within this category, unless the complaints manager became aware of repeated complaints of a similar nature against the same doctor, in which case there would be grounds for investigating further. My reference to 'repeated complaints' implies that the complaint should be viewed in the context of any previous complaints or concerns which had been raised about the doctor, and this must be done. Sometimes, those previous complaints or concerns will have been wholly different and will have no relevance to the complaint under consideration. At times, however, previous complaints and concerns might be highly relevant.

27.29 Professor Scotland was of the view that there would have to be clinical input into any triage decisions to be made by a PCT. I think that he felt that complaints managers would not always recognise patient safety issues. My own impression of, say, Miss Andrea Horsfall (Complaints Service Manager, Oldham PCT) and Mrs Janet Parkinson (Consumer Liaison Manager, former West Pennine Health Authority (WPHA)), both of whom gave oral evidence to the Inquiry, is that they would be perfectly capable of recognising when a complaint raised a clinical governance issue or, at the very least, would recognise when they needed clinical advice before taking a decision. I think that, with appropriate training, they could undertake the first triage quite safely and with the assistance of advice when needed. However, I accept that Professor Scotland has greater experience of complaints managers than I have. In any event, I agree with him that the process of triage would be important and that whoever undertook it would have to be appropriately experienced and to have access to relevant clinical advice.

27.30 The first triage process would therefore result in the division of complaints into those involving purely 'private grievances' and those which required investigation by the PCT.

Investigation and Handling of 'Private Grievance Complaints'

27.31 At present, complaints managers have no experience in the investigation of complaints. However, I think that, with some training, PCT staff who have been accustomed to dealing with complaints administratively could be equipped to handle those types of complaint which do not give rise to patient safety or clinical governance issues. Complaints which give rise to purely private grievances will, in general, require only liaison with the GP practice or, if that fails, conciliation. The objectives should be the satisfaction of the patient and, where possible, restoration of the relationship of trust and confidence between doctor and patient.

Investigation and Handling of 'Clinical Governance Complaints'

The Second Triage

27.32 'Clinical governance complaints' must be investigated with the twin objectives of patient protection and satisfaction and fairness to doctors. PCTs will also wish to ensure that they have a full understanding of the events underlying the complaint in order to comply with their duty in respect of the quality of care provided within their areas. Such complaints will vary greatly in their complexity and potential seriousness. They should not be handled by a complaints manager, but should be referred to a small group formed for the purpose of handling complaints and concerns which raise clinical governance issues. The group might comprise two or three people – for example, the Medical Director or Clinical Governance Lead, a senior non-medical officer of the PCT and a lay member of the PCT Board. The group will have to consider the case (the 'second triage') and decide how it is to be handled. There should be accountability for this process at a high level.

27.33 The first decision will have to be whether the complaint is to be investigated by or on behalf of the PCT itself or whether it would be appropriate for it to be referred immediately to some other body, such as the police, the GMC or the NCAA. If the police decide to investigate,

the PCT should put its own investigation 'on hold'. It might be necessary for the PCT to take immediate action for the protection of patients (e.g. by suspending the doctor from its list) or to ask the GMC to take such action. Discussion with the GMC might result in the GMC taking the case over or it might be decided that the complaint should be investigated by or on behalf of the PCT in the first instance. Similarly, with a case that clearly raised issues of poor performance, the NCAA might decide to carry out an assessment of the doctor or it might advise the PCT how to carry out its own assessment. If the complaint or concern suggests that the doctor may have a health problem, the PCT may wish to invite the doctor to be medically examined. Each of these courses of action should result in clarification of the way in which the PCT is to take the complaint forward. As at the first triage, the complaint must be considered in the context of any previous complaints or concerns about the doctor and in the context of the clinical governance information held by the PCT about him/her.

27.34 There is, however, a very important class of complaint, where the first priority must be to establish what actually happened. It is in dealing with this type of case that PCTs will face their greatest challenge.

Who Should Investigate a 'Clinical Governance Complaint'?

27.35 In evidence to the Inquiry, in responses to the Consultation Paper and at the seminars, there was a significant body of opinion expressing the view that, at present, most PCTs lack the resources and the expertise to carry out an effective investigation of a complex or potentially serious complaint.

27.36 Ms Linda Charlton, Director of Investigations, Office of the Health Service Ombudsman for England, said that her experience in the Ombudsman's office suggested that such investigative work as was currently carried out by PCTs was of very variable quality. Dr Malcolm Lewis, representing the GMC at the seminars, agreed with that view and said that cases reaching the GMC from PCTs showed a wide variation in depth of analysis.

27.37 There was a general view that, being small organisations, PCTs would not have a sufficiently frequent need for a skilled investigator to justify employing anyone in that capacity. It would not be satisfactory to assign the task to someone with many other duties to perform, as s/he would not acquire sufficient experience to carry out the task effectively. However, the contrary view was also expressed. Some PCTs felt that they were able to carry out effective investigation. It appears that, on the occasions when the need arises, such investigation would be carried out by the Medical Director or a Medical Adviser. My clear impression is that most Medical Directors and Advisers do not have the necessary skills. But, in any event, these officers have a very wide range of duties and it would not be feasible to expect them to focus on an investigation to the extent that is necessary once an investigation is underway.

27.38 During the hearings, several PCT employees and officers were asked to consider how they would go about investigating a hypothetical case, based broadly on the concerns that might have been reported (if any had been) about the circumstances of the admission to hospital of Mrs Renate Overton; I wrote about Mrs Overton's death in both the First and Third Reports, as well as in Chapter 10 of this Report. The reported concern would have

been that a GP had administered to a 46 year old asthmatic patient 20mg morphine, by injection, as a result of which the patient was deeply unconscious and unlikely to recover. A consultant at the hospital was of the view that the administration of such a quantity of morphine had been **'highly unusual, even dangerous'**. A complaint or expression of concern of this nature would not be easy to investigate well. It is not necessary here to discuss the suggestions that were made by the witnesses as to how they would have approached the task; suffice it to say that it is plain to me that such an investigation should be undertaken by an investigator who is not only trained in the techniques of investigation and case analysis but is also independent to the extent that his/her view of the GP concerned is not coloured by knowledge of the GP's reputation. It is vital that the investigator should adopt an objective and analytical approach and should not automatically accept the account of any witness, including the GP concerned, without testing its reliability against all the other available evidence.

27.39 The need for independence was demonstrated in my Second Report, where I described the approach of Dr Alan Banks, then Medical Adviser to the WPHA, to the task of examining the medical records of some of Shipman's deceased patients, with a view to ascertaining whether or not there was a pattern of 'common features' in the deaths. Dr Banks knew Shipman and held him in high regard. As a consequence, he failed to see the unusual features which characterised the deaths and which were evident from the medical records. He could not open his mind to the possibility that Shipman might have deliberately harmed a patient or even that he might have given him/her substandard care. A good investigator must have his/her mind open to all possibilities.

27.40 In some PCTs, such investigative work as must occasionally be done is carried out by the committee or group with responsibility for considering how to deal with concerns about a doctor's poor performance. It seems to me that these committees or groups may be well fitted for deciding whether an assessment of a doctor's performance should be undertaken (possibly by or under the guidance of the NCAA), and for considering what should be done when an assessment has been undertaken. However, the functions of assessment and investigation are different. If a PCT seeks advice from the NCAA about how to investigate, say, an adverse incident, the NCAA will do what it can to help by making suggestions. There is, at present, no NHS body with comparable functions in respect of investigation to those of the NCAA in respect of assessment. It does not seem to me that it would be satisfactory to assign the duty of investigating 'clinical governance complaints' of any potential gravity to a committee or group within the PCT, even if there were a suitable advisory body available.

27.41 I do not think that the staff of an individual PCT are likely to be satisfactory as investigators of complaints involving disputes of fact, issues of clinical judgement or potentially serious medical errors. At the seminars, there was a general consensus that the investigation of a complaint of any potential seriousness should be undertaken by a person or small team that was dedicated to the task. There was almost universal acceptance that individual PCTs were too small, and that their need for the service would arise too infrequently, to justify the employment of such a team.

Involving Other Bodies in the Investigation of a 'Clinical Governance Complaint'

27.42 Respondents to the Consultation Paper had been asked to consider whether there should be an outside body which would have responsibility for advising PCTs on investigations and which could, in particularly difficult cases, take over the investigation itself. Various bodies were suggested for consideration: strategic health authorities (SHAs), the NCAA, the Healthcare Commission and the medical Royal College rapid response teams. Views were also sought on whether a new body, independent of the NHS, should be established to receive and investigate complaints.

27.43 A number of respondents suggested that complex complaints should be dealt with outside the PCT. Some said that complaints should be investigated at SHA level, although others said that SHAs did not yet have sufficient investigative experience. Yet others thought that SHAs would not have the necessary independence. At the seminars, Mrs Flora Goldhill, representing the DoH, said that, although SHAs might be able to offer advice, it would not be in keeping with their functions to have responsibility for the direct conduct of an investigation.

27.44 Some respondents, including the Consumers' Association (now known as Which?), suggested that the Health Service Ombudsman might investigate complaints. The Ombudsman's office was perceived as being completely independent and its investigative work was recognised to be of a high quality. Ms Charlton said that, although it might be appropriate for some complaints to go directly to the Health Service Ombudsman, the great majority of complaints should be investigated at local level.

27.45 Some respondents thought that it might be appropriate for the Healthcare Commission to be involved in the investigation of complaints. However, by the time of the seminars, the Government had announced its intention that the Healthcare Commission should be responsible for the second stage of the NHS complaints procedures. Accordingly, it seems inappropriate that it should be involved at the first stage. I shall return to the role of the Healthcare Commission later in this Chapter.

How Should Specialised Investigative Skills Be Provided for Primary Care Trusts?

27.46 Ms Charlton suggested that proper investigative procedures could be put in place at local level, but only if PCTs were to join together, possibly across the area covered by each SHA, to pool investigative resources. She agreed that, if there was a high turnover of staff in a PCT, this would result in a lack of continuity of expertise. The pooling of resources would lessen the impact of this. Professor Richard Baker, Director, Clinical Governance Research and Development Unit, University of Leicester, also supported the idea of pooling resources and suggested that the ideal team might consist of a manager, a nurse or physician assistant and a doctor. The team should be able to call on external advisers when necessary. He thought that PCTs would need to be in groups of at least six to provide those resources. It emerged that the Health Service Ombudsman's investigative team (which is of course much larger than would be required for a group of PCTs) comprises lay investigators. Ms Charlton said that, in recruiting for the team, the Health Service Ombudsman looks for people with experience in dealing with large quantities of

information, with good analytical skills and with the ability to speak confidently to doctors and complainants about the issues involved. The investigators have access to independent clinical advice as and when necessary. The investigators collect and analyse the evidence and write a report setting out conclusions and recommendations. Ms Charlton thought that it would be preferable for the investigation of complaints on behalf of PCTs to be carried out by lay persons with access to clinical advice, rather than by clinicians. She stressed that it was important from the public's point of view that the investigation of doctors should not be carried out by doctors. Dr John Grenville, who represented the British Medical Association (BMA) at the seminars, agreed that investigations should be carried out by lay persons, but said that the provision of expert clinical advice, specifically relevant to the area(s) of complaint, was vitally important. Mrs Goldhill, for the DoH, agreed that it was essential that PCTs should have access to high quality investigative skills and said that the pooling of resources by individual PCTs might be a sensible solution.

27.47 There was general agreement that investigators must be properly trained. Mrs Goldhill spoke of the steps to be taken by the DoH to develop such training and mentioned a programme run by Middlesex University. She also said that the DoH was working on a good practice toolkit for the handling of primary care complaints.

27.48 Another reason advanced in support of the idea that PCTs should band together to provide an investigation team was that it would reduce the problem created by the perceived conflict of interest if a PCT were to investigate (as it would otherwise have to do) a complaint against a GP on its own list. The potential conflict was said to arise out of the dual role of providing support and assistance to GPs on the one hand and investigating or 'policing' GPs on the other. However, the problem could be more acute than that. The Inquiry has become aware of instances when the GP under investigation has been a member of the PCT's PEC – even the Chairman – or of the PCT's performance group. There is plainly a direct conflict there. Professor Scotland said that the pooling of investigative resources by groups of PCTs would reduce any potential problem of a conflict of interest. I agree, and add that it would also increase the independence and objectivity of the investigation.

27.49 I think that the best course will be for groups of PCTs to set up joint investigative teams. I express no view as to how many PCTs should band together; much will depend on the size of the PCTs and the geographical configuration of the group. I say nothing about the constitution of the team, save that it appears to me that it would be sensible for the DoH to take advice from persons such as the Health Service Ombudsman who have experience of this function and to disseminate that advice to PCTs.

The Conduct of the Investigation of a 'Clinical Governance Complaint'

27.50 In my view, where it appears to the person or group responsible for carrying out the second triage within the PCT that there is uncertainty about the events giving rise to the complaint, because there is a conflict between the account of events given by the doctor and the complainant, or for some other reason, the complaint should be referred to the inter-PCT investigation team. It should be the task of that team to carry out an investigation

along the lines described at paragraph 27.25. Its objective should be to reach a conclusion as to what happened and to set out the evidence and conclusions in a report which should be delivered to the PCT on whose list the doctor's name is included. There may be cases in which it is quite impossible for the investigators to reach a conclusion about what happened because there is a conflict of evidence. In that event, they must say so in their report.

Deciding Where the Truth Lies in a 'Clinical Governance Complaint'

27.51 At the seminars, there was discussion about how disputed facts should be resolved once an investigation had been carried out by or under the auspices of the PCT. One option was that an oral hearing should be held locally and a panel should decide where the truth lay and make the necessary findings of fact. As I explained in Chapter 6, that is what used to happen before 1996. All complaints that appeared to amount to a breach of the GP's terms of service were heard by a medical service committee (MSC) of the family practitioner committee (FPC) or, later, the family health services authority (FHSA). The MSC was able to resolve any factual disputes. Since 1996, there has been no facility to resolve disputes of fact at the first stage of the complaints procedures. This may well account for at least some of the dissatisfaction felt by complainants. If the doctor gives a different account of events from that of the complainant, it is likely that the practice complaints manager or another member of the practice will accept the doctor's version and will seek to 'resolve' the complaint on that basis. When such complaints are investigated by an inter-PCT team as I have suggested, it is to be hoped that the investigators will be less likely to display any such bias. Indeed, a team of investigators serving a group of PCTs might be expected to approach a complaint with a greater degree of independence than would an officer of an individual PCT. However, there may be circumstances in which a dispute of fact is crucial to the resolution of the complaint and where it is impossible to make a fair determination of the issue without hearing oral evidence.

Acting on the Investigation Report Where There Are Unresolved Factual Disputes

27.52 At the seminars, the view was expressed that it would not be appropriate to convene an oral hearing locally during the first stage of the complaints procedures. It was said that the experience was too stressful. Others favoured oral hearings because they enabled those involved to hear all the evidence. It was said that, if a hearing was held, the PCT should present the complaint to the hearing, rather than leave the complainant to 'prosecute' the complaint. However, I have come to the conclusion that there should not be an oral hearing locally at the first stage. If the report of the investigating team is inconclusive because of a dispute of evidence, the case should, in my view, be referred to the Healthcare Commission, under the power which will, I hope, be included in the amended draft Complaints Regulations which the Government intends to implement in the near future. Later in this Chapter, I shall discuss a provision in the draft Complaints Regulations whereby a PCT would be able to refer a complaint to the Healthcare Commission at any point in the first stage of the complaints procedures.

Acting on the Investigation Report Where All Factual Disputes Have Been Resolved

27.53 When the investigation report is complete, it should be considered by the PCT at a high level. I suggest that it would be appropriate for this to be done by the same group that carried out the second triage. The report should be viewed in the context of the doctor's past history. The PCT may wish to take action. It may be appropriate at that stage to refer the matter to the GMC. Referral to the NCAA may be appropriate. If a systems failure has been revealed, referral to the Healthcare Commission might be the best course. On the other hand, the report may reveal misconduct or deficient performance, but not of a sufficiently serious nature as to warrant referral to another body. The PCT might feel able to deal with the matter itself, either through its performance panel or by invoking its list management powers or the disciplinary powers that I shall recommend that PCTs be given. It might wish to liaise with the local deanery about the provision of supervision or retraining for the doctor. The point was made that there was a need for clearer standards to be established for onward referral and it was suggested that protocols should be devised for the guidance of the PCT.

27.54 Meanwhile, it is, of course, important that the complainant is kept fully informed about the progress of the investigation and, save to the extent that disclosure would breach the doctor's medical confidentiality, that s/he should be fully informed of the outcome of the investigation and the steps to be taken as a result. If the investigation and decision as to how to proceed could be carried out thoroughly and with a reasonable degree of expedition, it would, in my view, remove many of the causes for dissatisfaction inherent in the present arrangements for the handling of complaints. It would also enable prompt steps to be taken in those cases which raise patient protection issues.

Refusal to Proceed with the Investigation of a Clinical Governance Complaint If There Are to Be Concurrent Proceedings

27.55 The draft Complaints Regulations provide for the circumstances in which a NHS body might refuse to proceed with the investigation of a complaint where other forms of proceedings are or might be taking place at the same time. One such other form of proceeding is a civil action for damages.

27.56 In Chapter 7, I mentioned that, under the 1996 complaints procedures, a complaint could not be accepted for independent review if the complainant intended to institute legal proceedings or, presumably, if s/he had already done so. In evidence to the Inquiry, Miss Horsfall said that she felt this was sometimes unfair. In my view, not only is it unfair but it is inappropriate.

27.57 Although one of the purposes of a complaints procedure is to 'satisfy the complainant', a much more important purpose is to find out what has happened and to decide whether there is a need to take any steps necessary for the protection of patients. Whenever an adverse event has occurred which raises issues of patient safety, the responsible organisation should conduct an internal investigation for that purpose. I cannot see that the position should be different just because a complaint has been made. If a PCT becomes aware of an adverse event affecting a patient, it should investigate the event

whether or not a complaint is made by or on behalf of the patient. That should be done whether or not any person has expressed an intention to take legal proceedings.

27.58 Under the draft Complaints Regulations, it was provided that concurrent legal proceedings would not be a complete bar to the investigation of a NHS complaint at the first stage of the complaints procedures. However, NHS bodies would, in certain circumstances, be able to decide not to begin or continue with an investigation. A complaint which was also to be the subject of a civil action was to be designated a **'complex complaint'**. Draft regulation 18 allowed the relevant NHS body to investigate a **'complex complaint'** if it considered that to do so would not **'compromise or prejudice the concurrent investigation'**. Also, a NHS body could discontinue the investigation of a **'complex complaint'** if it considered that **'to continue would compromise or prejudice the concurrent investigation'**. That meant, for example, that if the widow of a patient of a GP intended to sue the GP in respect of the death of her husband, the PCT would be able to refuse to investigate a complaint lodged by the widow in connection with the death. In my view, that is not entirely satisfactory because it might prevent the PCT from carrying out its clinical governance duties. I am aware that, so far as complaints about secondary care are concerned, the 2004 Complaints Regulations (to which I referred in Chapter 7) prevent a NHS body from investigating any complaint if there are any concurrent legal proceedings. For the same reason, that seems to me to be quite unsatisfactory.

27.59 If a PCT learns of an adverse incident (either because a complaint is received or in any other way), it should investigate and it should offer to disclose the substance of the report of the investigation to the patient or next of kin, whether or not a complaint has been made and whether or not the doctor is to be sued. The PCT should investigate for clinical governance reasons and should take whatever action is necessary in the interests of patient safety. It should not bow to any pressure not to investigate from the medical defence organisation which indemnifies the GP and which might have an interest in suppressing the information that would come out in an investigation. I hope that the Government will think again about this issue and will decide that a complaint should always be investigated, even where legal proceedings are intimated or underway. I strongly recommend that the fact that such proceedings are proposed or have begun should not be a bar to the investigation of a complaint.

27.60 As I explained in Chapter 7, the fact that a NHS body was taking disciplinary proceedings against a doctor would not, under the draft Complaints Regulations, have precluded the furtherance of a complaint brought by a patient. However, the existence of proposed or actual disciplinary proceedings in relation to the substance of the complaint will, under the 2004 Complaints Regulations, now cause a complaint (in relation to secondary care) to be excluded from the operation of the Regulations. In my view, neither the provision in the draft Complaints Regulations nor that in the 2004 Complaints Regulations is satisfactory. If disciplinary proceedings relating to the subject matter of the complaint are contemplated, that presupposes that the event in question has already been investigated. In my view, the complainant should see the substance of the report of the investigation on which the disciplinary proceedings are to be based.

27.61 The draft Complaints Regulations also provide that the NHS body receiving the complaint may defer or discontinue the investigation of a complaint if the matter is being investigated by the police, a regulatory body, a statutory inquiry or some other process. I would accept that, sometimes, in such situations, a NHS body may have to defer its own investigation into a complaint or concern, but it should never lose sight of its duty to find out what has happened and to take whatever action is necessary for the protection of the patients of the doctor concerned. It should also, in my view, provide such information to a complainant as is consistent with the need, if any, for confidentiality in the public interest. I hope that the DoH will redraft these provisions to reflect the principles I have enunciated.

The Role of the Healthcare Commission in the Investigation and Determination of 'Clinical Governance Complaints'

27.62 As I have said, in its Consultation Paper, the Inquiry raised the possibility of complaints being investigated by or with the advice of the Healthcare Commission. From December 2003, it became known that the Healthcare Commission would be responsible for the second stage of the complaints procedure, and it took over that role with effect from 30th July 2004. How these procedures are working in practice, it is too early to say. The Healthcare Commission is a new organisation with many wide-ranging responsibilities, which are designed to encourage improvement in the provision of health care. In order to fulfil its responsibilities for the second stage review, the Healthcare Commission has set up a Complaints Department employing about 70 investigators.

27.63 The view was expressed at the Inquiry's seminars that the resolution of purely 'private grievance complaints' might be a waste of the Healthcare Commission's resources. Mrs Elizabeth Dimond, who had been appointed as Complaints Lead of the Healthcare Commission in advance of the implementation of the reform of the second stage of the complaints procedures, was asked about this. She said that, under what was then draft regulation 23, the Healthcare Commission would not be bound to accept all complaints and, if it appeared that the complaint had been properly handled at the first stage, the request for a review might be refused. I understood from this that, if the complaint was of a minor 'private grievance' nature, the Healthcare Commission might well decline to consider it. On the other hand, if it appeared that the complaint had not been properly handled at the first stage by the GP practice and/or the PCT, the Healthcare Commission might well accept the case with a view to correcting the complaints handling procedures. In those circumstances, it might be appropriate for a 'private grievance complaint' to be considered. In any event, the Healthcare Commission should be well placed to ensure that any lessons that can be learned from its part in the resolution of patient complaints are properly disseminated.

27.64 Under regulation 16 of the 2004 Complaints Regulations, the Healthcare Commission can, on receipt of a complaint, follow one of several different courses, including (as I have said) taking no action. It will be able to refer a complaint back to the first stage of the complaints procedure with recommendations for further action, or to investigate the complaint itself (with or without a panel hearing) or to refer the complaint to a regulator. I expect that the power to refer a complaint to a panel will be used mainly in cases where it is necessary to resolve a conflict of fact by hearing oral evidence.

27.65 Under draft regulation 19, it was proposed that PCTs should have the power to refer a complaint (which they were handling at the first stage) to the Healthcare Commission at any time, provided that the complainant and the Healthcare Commission consented. This proposal has not been incorporated into the 2004 Complaints Regulations but I hope that it will be included in the new Regulations. In my view, it is a very good idea, because the Healthcare Commission's investigating facility could be deployed in the first stage of the complaints procedures in difficult cases, as well as (under the arrangements recently introduced) on second stage reviews of less complex cases. It would be particularly appropriate for a case to be referred upwards either if it was necessary to determine a factual dispute or if the complaint was particularly complex, difficult or serious. A referral to the Healthcare Commission should be capable of being made at any point in the first stage of the complaints procedures. That would mean that a complaint could be referred at the time of the second triage, if it was clear that the issues were complex. For example, the complaint might involve issues relating to both primary and secondary care. The referral might also take place later if the inter-PCT investigation team discovered that the complaint raised more complex issues than had been appreciated.

27.66 Alternatively, as I said at paragraph 27.52, referral might take place when the inter-PCT team found that it could not reach a conclusion because there remained unresolved disputes of fact. The Healthcare Commission would have the facility to carry out further investigation to the extent necessary and, if appropriate, to set up a panel to hear oral evidence about the facts in dispute and to decide where the truth lay.

27.67 On the face of it, referral to the Healthcare Commission would seem to be an ideal way of dealing with complex investigations and with those requiring an oral hearing. Not only would the Healthcare Commission have the necessary resources and expertise, it would also be seen to be independent. However, Mrs Dimond told the seminars that the primary purpose of the provision in draft regulation 19 was to allow the PCT to refer a case during the first stage of the complaints procedures where the complainant had 'lost faith' in the local NHS system, rather than to allow it to pass on cases that were beyond the expertise of the PCT. Indeed, she seemed surprised at the suggestion that cases might be referred because of such a lack of expertise. However, she did say that the Healthcare Commission would probably accept referrals from a PCT where the PCT lacked the necessary expertise to investigate. I hope that the Healthcare Commission will be prepared to accept such cases and that it will have the resources necessary to deal with them.

27.68 One potential disadvantage of sending complex complaints and complaints requiring an oral hearing to the Healthcare Commission during the first stage would be that there would then be no second stage or 'appeal' available to the complainant. In my view, that should not matter, because the complainant would already have been able to take advantage of the resources and independence of the Healthcare Commission. Moreover, if s/he remained dissatisfied, recourse to the Health Service Ombudsman would be a possibility. Some complainants might not see matters in that light. Nonetheless, I consider this the best way forward.

27.69 At the seminars, there was some discussion about the form of the oral hearings that should take place during the second stage of the new complaints procedures as they are at

present. The draft Complaints Regulations provided for the Healthcare Commission to refer a complaint for hearing by a panel of lay people in an appropriate case. At the seminars, Mrs Dimond said that a case would be sent for a hearing by a panel only if the complainant was 'comfortable with that option'. I was concerned to hear that. In my view, a decision to convene a panel should be taken by the Healthcare Commission (after consultation with those involved); the complainant should not be allowed to exercise a veto. The Healthcare Commission has a duty to be fair to the doctor as well as to the complainant, and there is a public interest to be served in finding out the truth. I am pleased to see that the 2004 Complaints Regulations now provide for the decision whether to refer a complaint to a panel to be taken by the Healthcare Commission after consultation with the parties.

27.70 Mrs Dimond also said that, if a panel was convened, it would adopt an inquisitorial, rather than an adversarial, approach. That, I think, is sensible. She said that it would be open to the complainant to request that the doctor be excluded whilst s/he was giving evidence. I hope that that does not mean that, if such a request was made, it would necessarily be granted. If so, I would be concerned about that. Such decisions should be for the panel, after hearing the views of both parties. The complainant should not, in my view, have the right to dictate whether the other party is present during the evidence. However, perhaps this problem will not often arise. Mrs Joyce Robins, who represented Patient Concern at the seminars, said that one of the most unsatisfactory aspects of the IRP process was that complainants were not allowed to hear what the doctor had to say. I would favour a general rule that both parties should be permitted to hear the other's evidence and that of the other witnesses. What should, in my view, be avoided is adversarial cross-examination.

27.71 I was also rather concerned to hear from Mrs Dimond that the Healthcare Commission might encourage conciliation in cases in which there was a conflict of fact. Mrs Robins was strongly opposed to such an idea. She said that, where there was a conflict of evidence, a determination of the facts was required. I entirely agree with her. It will be impossible for a PCT to know what, if any, action it should take in order to protect patients unless there has been a hearing in order to determine the factual basis of the events giving rise to a 'clinical governance complaint'.

Private Sector Complaints

27.72 Another issue relating to the Healthcare Commission was raised at the seminars by Ms Beverley Cole, representing the National Care Standards Commission (NCSC). She was concerned about the handling of complaints made in the private sector. The NCSC has now been subsumed into the Healthcare Commission. Although the NCSC has jurisdiction to investigate complaints about service provision in the private sector, its powers are limited to complaints that amount to a breach of the relevant Regulations or a failure to comply with specified minimum standards. As Ms Cole agreed, the only recourse for some patients who have been treated in the private sector is to complain to the GMC. However, as the Inquiry has discovered in the context of its examination of the GMC's old fitness to practise (FTP) procedures, the GMC's attitude to a complaint about treatment in the private sector was, after the establishment of the NCSC in 2002, to advise the complainant to make use of the local complaints procedures if these had not been

exhausted. If the local procedures had not been exhausted, the GMC would accept the complaint only if it appeared that the doctor might be a danger to patients or the public or if the complainant insisted on pursuing his/her complaint through the GMC. I have already made it clear that that was not, in my view, a satisfactory state of affairs. No doubt the large private healthcare organisations have systems for the investigation of complaints. How well they operate, I do not know. However, I have grave doubts whether all small commercial organisations, such as slimming clinics or cosmetic surgery clinics, will have adequate systems for handling patient complaints. It seems to me that it might be difficult for a patient dissatisfied with treatment provided by a small private organisation – or, worse, a single private practitioner – to have his/her complaint adequately investigated. Complainants in the private sector are at another disadvantage; they do not have access to the Health Service Ombudsman.

27.73 What the position will be under the GMC's new FTP procedures is not completely clear. The available guidance relating to the new FTP procedures suggests that all complaints which do not obviously fall outside the GMC's remit will be accepted for investigation. However, that was ostensibly the position under the old FTP procedures, but it was not the practice. I have carefully examined the Rules governing the new procedures and all the related guidance and instruction of which I am aware. It appears to me that the GMC has decided to discontinue its former practice of advising complainants to pursue their complaints through local procedures. I hope that I am right in reaching that conclusion.

27.74 It seems to me that it would be highly desirable for the complaints handling systems in the private sector to be aligned as closely as possible with those in the NHS, so that a complainant who did not receive satisfaction from a private sector body can proceed to a second stage conducted by the Healthcare Commission. Then, the Healthcare Commission could investigate the matter properly, if appropriate. I would also like it to be able to accept and investigate expressions of concern (for example, from colleagues) arising about doctors working in the private sector, other than those concerns which manifestly require the attention of the GMC. I realise that the Healthcare Commission has been charged with a wide range of functions and that it probably has to manage on limited resources. Nonetheless, I hope that, in future, it will be able to develop as an independent centre of expertise in medical investigation.

Should There Be a New Independent Complaints Handling Body?

27.75 Because the Inquiry was aware that there was some dissatisfaction with the way that complaints are handled within the NHS, by private sector providers and at the GMC, the Consultation Paper raised the question whether there should be a new independent complaints handling body to deal with all complaints within the NHS and private sector. Those complaints which, in the view of the complaints body, warranted the attention of the GMC could be referred to it after investigation. There was little support among respondents to the Consultation Paper or participants at the seminars for the idea of creating a new independent complaints handling body. The main reason for the lack of enthusiasm was that there has recently been a great deal of structural change in the NHS and there is a widely held view that there should be fewer bodies and organisations in the healthcare system rather than more. I agree with that view. I also think it preferable that

most complaints should be handled locally so that there can be local investigation and, where appropriate, local corrective measures.

Should There Be a New Independent Inspectorate?

27.76 Two respondents to the Consultation Paper, Dr William Pickering and Mr Patrick Tierney, suggested that an independent inspectorate should be established to investigate poor clinical practice revealed through complaints and monitoring. They envisaged that the inspectorate would cover both the public and private sectors. When this idea was circulated for discussion, it received very little support, particularly because it was perceived that the creation of such a body would entail significant reorganisation, or even the abolition, of existing bodies such as the Healthcare Commission, the NCAA and the GMC. A number of participants at the seminars thought that the Healthcare Commission would develop its inspectorate role and would take on the functions envisaged by Dr Pickering and Mr Tierney. I have already expressed the hope that the Healthcare Commission will be able to develop its investigative functions so as to provide expertise and independence, which are, I think, the qualities that Dr Pickering and Mr Tierney wish to see. Of course, if it should transpire over the next few years that the Healthcare Commission does not provide the thorough and independent investigations that it is hoped it will, then it would, I think, be necessary to consider an alternative solution. But, in my view, the Healthcare Commission must be given the opportunity to develop these important functions.

Handling Concerns

27.77 One of the features of the 1996 system of complaints handling which struck me as anomalous and potentially unsatisfactory was that complaints lodged by a patient or his/her representative were in the past handled differently from concerns expressed about a GP by, for example, a fellow healthcare professional. The subject matter of a complaint and that of a concern might be identical; the only distinction between the two would have been the identities of the people who conveyed the information. But the method of handling was quite different. Whereas a concern would in general be referred straight to the PCT committee or group with responsibility for considering how to deal with concerns about a doctor's poor performance, a patient complaint might not even be known to the PCT if it was 'resolved' at practice level. Until July 2004, it would go to the PCT only if the complainant wished to apply for independent review. Since July 2004, however, it has been possible for a complaint to by-pass the PCT entirely and to go straight from the local resolution first stage directly to the Healthcare Commission. At the Inquiry seminars, there was wide acceptance that it is illogical to treat a patient complaint differently from a concern expressed by someone else.

27.78 If and when PCTs have full information about patient complaints and receive the more serious ones directly, this disparity of treatment should disappear. If PCTs or groups of them have access to a team of investigators, it will be possible to refer both complaints and concerns to them. Also, if it is envisaged that the Healthcare Commission is to play any significant role in the investigation of complex, difficult or potentially serious complaints, it

should also be able to undertake the investigation of concerns that raise difficult or potentially serious issues. At the moment, the draft Complaints Regulations anticipate that a PCT will be able to refer a patient complaint to the Healthcare Commission (with the patient's and Healthcare Commission's consent). However, the Healthcare Commission cannot accept a reference that does not originate as a patient complaint unless the reference comes from the Secretary of State for Health (SoS). If it is to be intended that the Healthcare Commission should develop investigative expertise for the benefit of the whole healthcare system, I would suggest that consideration should be given to amending the legislation to permit the Healthcare Commission to accept a concern referred to it by a PCT (or other healthcare body) without the need for a reference from the SoS.

The Standards by Which Complaints Are to Be Determined

27.79 One of the (probably unforeseen) consequences of the dissociation of disciplinary proceedings from patient complaints in 1996 was the loss of any (even partially) objective standard by which a complaint could be judged. Before 1996, a complaint was upheld if the doctor was found to have breached his/her terms of service. The sanction imposed depended upon the gravity of the breach and the doctor's past record. To some extent, the MSC had to exercise discretion as to whether a breach had occurred, for example when considering whether the doctor had provided all the services reasonably to be expected of a GP in the circumstances. However, at least there was a legal framework within which the decision was taken.

27.80 From 1996, disciplinary proceedings could be taken for alleged breaches of the terms of service but, in fact, they hardly ever were. Complaints could be lodged in respect of all matters, whether or not they were covered by the GP's terms of service. However, there was no framework at all to help the GP practice complaints manager or the IRP to decide whether to 'uphold' the complaint, or to help the convenor to decide whether to convene a IRP. It might be that some IRP members who had formerly sat on MSCs still applied the standards of the terms of service where possible. Since April 2004, when the new General Medical Services (GMS) Contract came into effect, there have not even been terms of service to act as a background framework. In effect, a complaint is upheld if the decision-makers think it should be. At the first stage, the lack of any objective standards or even guidelines must make the task of the practice complaints manager or supervising partner in a GP practice extremely difficult. It is always hard to be objective when judging a close colleague but it must be much more difficult in the absence of any standards.

27.81 Now that many decisions about complaints will be taken by PCTs and by the Healthcare Commission, it is to be expected that decision-makers will have greater independence of mind than practice managers and, possibly, than local IRPs. However, in my view, they will need standards by which to decide whether or not a complaint should be upheld. In the past, I suspect that this issue has sometimes been 'fudged' because it has not always been necessary to make a positive decision to uphold or reject the complaint; it has sometimes been sufficient to 'satisfy' the complainant. If, as is contemplated in the DoH publication 'Making Amends', there is to be provision for financial redress, a definite decision will have to be made. It ought to be made whether or not redress is available.

27.82 It is disappointing that the draft Complaints Regulations and the 2004 Complaints Regulations have not attempted to grapple with this issue. In my view, it must be tackled. There must be, at the very least, a standard against which a complaint can be judged. Patients should know what their reasonable expectations are and should be entitled to have their complaints upheld when those reasonable expectations have not been met. I have mentioned elsewhere in this Report the need for standards by which the GMC can decide whether and, if so, how it should take action against a doctor. There is also a need for standards by which PCTs and other NHS bodies can decide whether they should invoke their list management or disciplinary powers or whether they ought to refer the doctor to the GMC. At the moment, all the people who take these important decisions have to do so simply on the basis of what they think is right. There is an urgent need for standards to be established for all these purposes. It seems to me that this should be a task for the Healthcare Commission, in conjunction with the GMC and the DoH, after consultation with patient groups and the wider public. The standards pertaining to patient complaints and those by which PCTs and other NHS trusts should make their decisions should not be set in isolation. They must fit together with the threshold by reference to which the GMC will accept and act upon allegations so as to form a comprehensive framework. I shall return to the issue of standards later in this Chapter.

Support for Complainants: the 'Single Portal'

27.83 It seems to be generally acknowledged that there is some confusion in the public mind as to how to go about making a complaint about a healthcare matter. Many people are under the impression that any complaint about a doctor should properly be addressed to the GMC. In fact, under its old FTP procedures, the GMC would accept only complaints that were (broadly speaking) sufficiently serious to raise a question of serious professional misconduct (SPM), seriously deficient performance (SDP) or seriously impaired fitness to practise due to ill health. Even then, as I have said, if there were local complaints procedures available, the complainant would be advised to pursue the complaint by means of those, unless the doctor was thought to be dangerous or the complainant insisted on his/her complaint being dealt with by the GMC. In future, under its new FTP procedures, the GMC will have a single criterion for acceptance of a complaint or concern, namely that an allegation has been made that a doctor's fitness to practise is impaired. Fitness to practise is to be regarded as impaired only by reason of misconduct, deficient professional performance, a conviction or caution, adverse physical or mental health or an adverse determination by another regulatory body. I think that many people will have difficulty in making up their minds whether the matters of which they wish to complain will fall within the GMC's remit. I think that, unless this remit is explained in ordinary language, it will be difficult for healthcare professionals and healthcare managers – let alone members of the public – to decide whether a case should be sent to the GMC. The fact is that the GMC is not the appropriate recipient for many minor complaints about a doctor.

27.84 It is clear that there is a good deal of confusion about the right place to direct a complaint about a doctor. The Inquiry was told that the NCAA and the Health Service Ombudsman both receive complaints about doctors direct from the public. No doubt there are many other organisations that do so. A patient who asks advice from either

the NCAA or the Health Service Ombudsman about where and how to complain will be directed to the appropriate destination, although the question is not always an easy one to answer, particularly where the complaint involves more than one aspect of a patient's treatment. However, many complainants who think that they know where to lodge their complaints in fact send them to the wrong places. A similar problem exists for persons who wish to make a confidential report relating to some sort of suspected malpractice about which they are concerned. I described the problems they face in Chapter 11. No doubt a sustained programme of public education could improve the position for complainants and those who wish to report a concern, but the problem is bound to persist to some extent.

27.85 In the course of the Inquiry, the GMC suggested a possible solution to this problem. It proposed that there should be a 'single portal' or gateway to which anyone who was in doubt about where to lodge a complaint could direct his/her complaint. Any complaint that was directed to the wrong quarter could be referred to the 'single portal'. Advice could be given as to the appropriate destination for the complaint to be received and handled. In other words, the 'single portal' would act as a signpost indicating the appropriate direction of a complaint. Although concerns were expressed about the practicalities of this idea, there was virtually universal acceptance at the seminars that, if it could be made to work, it would be a great improvement on the present position.

27.86 Miss Isabel Nisbet was seconded from the GMC to carry out a project on behalf of the Healthcare Commission and the GMC, namely to examine the feasibility of establishing a means of directing patients and others with concerns or complaints about health care towards the most appropriate route to pursue them. In November 2004, Miss Nisbet presented various options to the Healthcare Commission's Commissioners for the provision of such a service. Briefly, the main options outlined were these:

(a) a website (or single web-based source), giving up-to-date information about complaints procedures in a form that would enable the enquirer to be guided to the most suitable route by a series of questions

(b) a website, as in (a), but with a facility to pass the enquirer to the right place by means of email or customised links to the relevant complaints handling bodies (both local and national) and to potential sources of advice and support

(c) a website with links, as in (a) and (b), but also with an interactive link to answer enquiries by advisers and intermediaries

(d) a website with links, as in (a) and (b), but also with an interactive link to answer enquiries by members of the general public

(e) an arrangement as in (d), but expanded to provide advice to complainants, as well as information to help them to select the appropriate route for their complaint.

27.87 While (a) provided the cheapest of the available options, Miss Nisbet acknowledged that it had the obvious disadvantage that about half the population do not have access to the internet and would not, therefore, be able to avail themselves of this facility. Miss Nisbet recognised that some patients' organisations would be disappointed if a website of this

kind were the only outcome of the project. She observed that most of the patients' organisations which she had contacted had favoured option (d), in addition to web-based information. They had said that patients, many of whom are elderly, valued contact with a human voice – for example, through a telephone helpline – rather than with a website or an automated message system. When discussing option (e), Miss Nisbet observed that the Independent Complaints Advocacy Service in England (ICAS) provides information and advice and she questioned what would be gained by replicating or replacing the services provided by ICAS. She suggested that options (a) and (b) should be developed. She also suggested that options (c) and (d) should be considered further, with a view to providing a service in conjunction with a patients' organisation or by strengthening an existing helpline facility. The Healthcare Commission has informed the Inquiry that it does not propose to take any decisions on the various options until after the publication of the Inquiry's Report.

27.88 In my view, no solution which depends, in the first instance, upon access to a website will be satisfactory. As Miss Nisbet observed, only half the population would have access to it. In addition to any web-based information, with or without interactive links to answer enquiries, there must, in my view, be a telephone helpline with a live human voice to speak to. Otherwise, half the population is unlikely to receive the help it needs. The group without access is likely to include a large proportion of elderly or vulnerable people – the very group most in need of help. I am not opposed to the idea of a website providing information; that might suffice for some purposes. However, in my view, there must be a helpline as well. Miss Nisbet raised the question whether, as ICAS provides information and advice, there is any need to provide advice as well as information about the right destination for a complaint. In my view there is. Very few people who have a problem on their minds about something that has happened at hospital or at their GP's surgery are likely to think that they need an advocacy service. What is needed is a service that not only advises people who have already decided to complain or to raise a concern where to lodge their complaint or concern, but also gives information to people who are uncertain whether or not they wish to complain or raise a concern about where to find the advice that they need. I do not suggest that the single portal service should provide the latter kind of advice but it should be able to refer the caller to, for example, a patients' organisation, an organisation such as Public Concern at Work (which can provide legal advice about the consequences of raising a concern) or possibly to ICAS. I think it would be helpful if, in addition to providing advice about the right destination for a complaint, the single portal service were prepared to forward the complaint to the appropriate body. Whatever form the single portal takes, it must be extensively advertised. It needs to be as well known as NHS Direct and the Samaritans.

Support for Complainants: after the Community Health Councils

27.89 As I explained in Chapters 6 and 7, for many years until 2003, Community Health Councils (CHCs) provided advice and support for persons wishing to pursue a complaint. Before 1996, the CHC would correspond with the FPC or FHSA on the complainant's behalf, would advise on the preparation of the complaint for a MSC hearing and would accompany the complainant at the hearing, acting as adviser throughout. From 1996, the

CHC would, on request, assist in lodging a complaint or requesting an independent review. It would also correspond with the HA/PCT making the arrangements for an IRP hearing and would attend and support the complainant at the hearing. Evidence received by the Inquiry suggests that many CHCs did this work well and that their work was greatly appreciated.

27.90 In Chapter 7, I also described the provisions that have more recently been made for advising and supporting patients who wish to make a complaint. I said that I did not know how well those arrangements were working. I suggest that an independent review be commissioned into the operation of these arrangements about two years after the new Complaints Regulations come into force in their entirety with a view to ascertaining whether patients are receiving appropriate advice and support and correcting any deficiencies that may be revealed.

Disciplinary Procedures in the Context of Clinical Governance

27.91 In Chapter 7, I explained that disciplinary proceedings against GPs at local level fell largely into disuse soon after the introduction, in 1996, of the new complaints procedures. In some places, they were still occasionally used. Their operation depended upon establishing a breach of the GP's terms of service. With the introduction of the new GMS Contract in April 2004, terms of service have ceased to exist. They have been replaced by contractual arrangements. However, as I explained in Chapter 5, from December 2001, PCTs have had new powers of list management. A PCT can remove or suspend a GP from its medical performers' list or impose conditions upon his/her inclusion on the list. There is no power to order a withholding of remuneration; nor is there an official power to administer warnings or reprimands.

27.92 Respondents to the Inquiry's Consultation Paper were asked whether they thought it was appropriate that PCTs should be able to deal with misconduct, deficient practice or poor performance falling below the threshold operated by the GMC or below the threshold at which the PCT would exercise its list management powers. They were invited to consider whether disciplinary procedures should be developed at local level to deal with such cases. Views were also sought on the categories of case in which it would be appropriate for local disciplinary proceedings to be invoked and, in particular, whether there should be a code of conduct or code of patients' rights, breach of which might give rise to disciplinary proceedings.

27.93 The majority of respondents to the Consultation Paper thought that there was a gap in the powers available to PCTs. There was a substantial degree of support for the idea that PCTs should have a wide range of sanctions available to them. A number of respondents to the Consultation Paper and participants at the seminars suggested that the range of penalties available to the PCT should include 'constructive penalties' (e.g. a requirement that the doctor undergo specific retraining), rather than punitive measures. The Royal Pharmaceutical Society of Great Britain suggested that a wide range of options should be made available to PCTs. Examples given were the issuing to GPs of advice letters containing good practice guidance, advice visits, mentoring, retraining and obtaining written undertakings from doctors. It was suggested that early intervention might serve to prevent a more serious outcome.

27.94 In its response to the Consultation Paper, the GMC said that the gap that had been identified in the regulatory system would be narrowed under the GMC's new FTP procedures, which will provide for the issuing of a warning to a doctor where there has been a significant departure from the principles contained in the GMC publication 'Good Medical Practice' or where a GMC performance assessment has indicated cause for concern, but where the GMC does not consider that action on registration is warranted. However, there would still remain a category of cases which might not reach the GMC or which might fall below the threshold for the issuing of a warning. Those cases, the GMC said, should be addressed by PCTs at local level. Mrs Robins, representing Patient Concern, thought that the PCTs' powers should be extended and that the most central and significant problem with the current system was that the PCT does not have the power to impose sanctions to deal with minor matters.

27.95 At the seminars, a hypothetical example was considered in order to allow examination of the adequacy of the PCT's powers. It was supposed that the Healthcare Commission had investigated a patient complaint and had made a recommendation to the PCT that it should require the doctor to undergo retraining. If the doctor failed to co-operate with the PCT's request that s/he should retrain, the only sanction available to the PCT would be to direct the removal of the doctor from the list, contingent upon his/her continuing refusal to retrain. It was suggested that, in the case of a failure to co-operate with a recommendation for retraining, the exercising of list management powers might be somewhat draconian and that, in practice, the PCT's list management powers would be imposed only in serious cases. I do not think it would be draconian to impose contingent removal on a doctor who was refusing to co-operate in retraining. It would be an effective means of persuasion as well as protection for patients. However, I can envisage cases in which the gravity of the circumstances would fall below the 'list management' threshold and where a lesser sanction might be appropriate.

27.96 Professor Scotland said that there was a need for an extension of the PCTs' powers and stressed that there was a need in particular for a less 'long-winded' disciplinary process to be used in the case of less serious matters. It was acknowledged that procedural complexity was one reason why formal disciplinary hearings had largely fallen into disuse after 1996. Professor Scotland suggested that a system of warnings could be implemented by PCTs along similar lines to the system of warnings which exists in the context of an employer/employee relationship. He suggested that there could be gradations of warning, starting initially with advice given off the record, followed by the giving of oral advice, which would be recorded, and finally written advice. He thought that the PCT list should be able to record information on warnings.

27.97 The idea of introducing a system of warnings received widespread support at the seminars. Dr Grenville, for the BMA, welcomed the proposal. He made the point that the complaints system, prior to 1996, permitted PCOs to issue warnings and that the medical profession had been content with that system. Sir Donald Irvine, former President of the GMC, also supported the proposal. He said that the nature of the relationship between PCTs and contracting GPs had been a longstanding problem. By that, I think he meant that PCTs were responsible for GPs but did not have the disciplinary powers of an employer. However, he said that he had known of PCTs which had struck the right balance in the

relationship and had been able to give warnings about matters requiring attention. Mr Martin Staniforth, Deputy Director of Human Resources at the DoH, was also aware of instances of PCTs acting informally to warn GPs about their behaviour and he supported the proposal for a system of warnings to be introduced.

27.98 Professor Scotland emphasised that there would still be a need for a thorough investigation and that, where there was a conflict in the evidence, it would be necessary to make findings of fact. There was general agreement among participants that that would be necessary. According to Professor Scotland, the worst thing that can happen is that concerns are not 'bottomed out'.

27.99 Mrs Robins suggested that, if a warning system were introduced, the more serious level of warning ought to be made public and should even be posted in the surgery. Dr Grenville did not agree with that. He said that the effect upon the doctor might be very serious. He said that the medical profession has a high suicide rate and that it would be necessary to carry out research into the impact on doctors of publishing such warnings. Dr William Reith, who represented the RCGP at the seminars, said that it was important that the individual patient complainant should be made aware of the outcome of the disciplinary proceedings, whether or not the wider public was made aware.

27.100 A number of participants at the seminars said that it would be appropriate for PCTs to have the power to impose financial penalties on contracting GPs. Professor Baker thought that the imposition of financial penalties would be of particular use in dealing with dysfunctional practices as well as with individual GPs. Mrs Robins agreed with that view and said that the imposition of a financial penalty would act as an enormous incentive for a practice to ensure that the problem, whatever it was, was addressed. Dr Grenville said that the imposition of financial penalties would not necessarily lead to a service improvement and that, in his experience, the imposition of financial penalties under the pre-1996 complaints system had not influenced the behaviour of 'problem' doctors. He thought that the most important goal was proper service delivery and that, where problems were identified, it was more important to focus on putting that right. Professor Scotland thought that the imposition of financial penalties might be appropriate in the case of administrative failings but that other forms of sanction (for example warnings, linked to a requirement to undergo retraining) would be a more appropriate way of dealing with performance. He also said that the imposition of a financial penalty should be recorded on the PCT list.

27.101 It was suggested by one respondent to the Consultation Paper that involvement in disciplinary procedures should be reported as part of GP appraisal and that the cause of the problem should be addressed in the doctor's personal development plan. A number of participants at the seminars agreed that the disciplinary procedures should be linked with the appraisal system, but that that process should not replace the taking of action at local level by the PCT.

27.102 I can see advantages in PCTs having a wide range of sanctions available to them once they have conducted an investigation into a complaint or concern and found that it was justified, although not so serious as to merit the use of their list management powers or referral to the GMC or some other body. It seems wrong that a PCT should not have

the widest range of sanctions available to deal with the situation as it has found it to be. I would favour the extension of the PCTs' powers to include both warnings and financial penalties. That is not to say that I think that PCTs should spend their time conducting disciplinary or list management proceedings if they can deal with matters in a simpler way which is both constructive and effective. I agree with Dr Grenville that the most important aim is to improve clinical performance. I think that PCTs should concentrate on bringing about improvement through the giving of advice – probably by the Clinical Governance Lead – rather than by seeking to punish minor shortcomings. If a doctor will not respond to advice about a matter that needs correction (for example, by undergoing some remedial training) then, in my view, the PCT should use its list management powers to 'persuade' him/her to do so. If s/he is still uncooperative, the PCT should use its stronger powers. I hope that PCTs will gain confidence in using their list management powers. Parliament has bestowed them and it must have intended that they should be used.

The Use of Prescribing Information as a Clinical Governance Tool

27.103 In my Fourth Report, I made a number of recommendations about the ways in which the accuracy and completeness of prescribing information could be improved so as to provide a more valuable tool for the purposes of clinical governance. I shall not repeat those recommendations in detail here. I suggested that every doctor working in general practice should use his/her own prescription pad and that the practice of allowing trainees and locums to use the pad of one of the GP principals in the practice should be stopped. In that way, each prescription could accurately be attributed to an individual doctor. I also suggested ways in which the 'blurring' of prescribing data by the issuing of repeat prescriptions could be avoided. In respect of controlled drugs prescribing, I made recommendations that a special prescription form should be introduced and that private prescribing should also be done on the special form so that it could be included in the analysis carried out by the Prescription Pricing Authority. If those measures are adopted, it should be possible for a PCT to obtain a complete and accurate picture of each doctor's prescribing practice; thus, the PCT will be better able to detect abnormal prescribing. Also, the data available to individual doctors will enable them to undertake a more satisfactory audit of their own prescribing practice.

27.104 In my view, special attention should also be paid to the prescribing of controlled drugs by all doctors. Doctors who have had a problem of drug misuse in the past or who are suspected to have a current problem should be subjected to particularly close scrutiny. Not only should their prescribing data be examined carefully but attention should be paid to information held in the controlled drugs registers (CDRs) kept by pharmacies. In the Fourth Report, I recommended the establishment of a controlled drugs inspectorate. One of its functions would be the scrutiny of CDRs to detect abnormal prescribing of controlled drugs and abnormal conduct by doctors, such as collecting from a pharmacy controlled drugs which have been prescribed for patients. The inspectorate and the PCT would be able to liaise if either had a concern about an individual doctor's prescribing of controlled drugs. I hope that the Government will act upon these recommendations.

The Use of Mortality Data as a Clinical Governance Tool

A National System of Monitoring

27.105 In Chapter 14, I described how the Inquiry commissioned a study of the feasibility of using mortality statistics to detect abnormalities which might indicate that a doctor was failing to provide an adequate standard of clinical care for his/her patients or even that s/he was deliberately harming them. I also described the discussion that took place at a special seminar held by the Inquiry in October 2003. The conclusion reached at the end of that seminar was that it would be desirable to operate a national system for the monitoring of mortality rates in general practice. I agree with that view. It seems to me that such a system (particularly if coupled with the reform of the systems of death certification and investigation that I have recommended in my Third Report) would be likely to deter a doctor from criminal activities such as those of Shipman. Even if it did not, it would greatly improve the chances of detecting those activities. Apart from those potential benefits, however, I believe that the collection and analysis of GP patient mortality data are necessary parts of the clinical governance process and that a greater understanding of that data can only have a beneficial effect on the quality of patient care.

27.106 I recognise that there are practical difficulties in the way of setting up a satisfactory system, in particular the difficulty of linking an individual patient death with an individual GP. However, I recommend that work should be undertaken to find ways of doing this. The DoH will have to take the lead. Some ideas were suggested at the seminar and I am optimistic that, with a will, a way will be found. Once that has been done, I recommend that a pilot scheme for national monitoring be undertaken, along the lines discussed at the seminar. Any national monitoring system must be supported by a proper system of investigating those cases where a doctor's patient mortality rates signal as being above the norm. Those investigations must be well organised, consistent and objective. They cannot be left to individual PCTs, although much of the local knowledge which will inform such investigations will be available from the PCTs.

27.107 At the time of the seminar, it was envisaged that a central analytical unit for carrying out monitoring would be operated by the Healthcare Commission and that investigations would be carried out by local Healthcare Commission offices, in conjunction with the relevant PCT. Since then, it seems that the Healthcare Commission's intentions – both as to the housing of a central analytical unit and as to the establishment of local offices – may have changed. If so, national monitoring and analysis will have to be carried out by another body (probably under the auspices of the DoH), with investigation being done by the skilled inter-PCT investigative teams to which I have previously referred in connection with the investigation of complaints and concerns.

Practice Death Registers

27.108 As I have said, I am of the view that data relating to patient deaths would be of value for clinical governance purposes. The Inquiry was told that some GP practices keep a deaths record or register in which a full copy of each Medical Certificate of Cause of Death (MCCD) issued is maintained. That seems to me to be good practice and would, among

other things, provide the material needed for an audit of deaths. Discussion of such material might be a useful topic at appraisal. In my Third Report, I recommended the reform of death certification. If my proposals are accepted, the form that would be completed by a GP following a death would contain a great deal more information than is currently contained in a MCCD. Such forms would provide an even more useful basis for an audit of deaths and would be an extremely valuable resource in the event that an investigation into a GP's patient mortality rate had to be undertaken as a result of routine monitoring of mortality rates. For patient deaths that occur in hospital or elsewhere, for which the GP does not complete a MCCD, equivalent information should be entered in the register.

Review of the Medical Records of Deceased Patients

27.109 The Inquiry was told on a number of occasions that the examination or review of a GP's medical records is a valuable tool in the assessment of the quality of clinical care and the detection of substandard clinical performance. The process plays an important part in the assessment procedures for the purposes of authorisation as a GP trainer and for Membership by assessment of the RCGP. It could play a part in appraisal. However, I do not think that it will generally be feasible for PCTs to undertake such record reviews themselves; for one thing, there would be problems of patient confidentiality. Nonetheless, it seems to me that use could be made of the records of deceased patients for such purposes. The records of deceased patients are sent to the PCT. It would not be at all difficult for PCTs to review such records. It would be easy for the patient's identity to be removed by one member of staff and for the review to be carried out by a different person, who would of course have to be suitably qualified. It would be necessary to ensure that a full set of records was sent to the PCT, including any records kept only on a computer. The use that would be made of this tool would depend upon the resources that the PCT could apply to the task. Ideally, each doctor should be subject to a periodic review of one or two sets of records, relating to patients who were cared for in the community up to the time of their deaths. My experience on this Inquiry suggests that the care provided to patients in the last few months of life would be a particularly good indicator of the general standard of care offered by the doctor. If resources did not stretch to a periodic review of a few records of all doctors, the process could be limited to those doctors whose performance gave rise to concern in some other respect.

Appraisal in the Context of Clinical Governance

27.110 I described the present system of appraisal of GPs in Chapter 12 and in Chapter 26 I explained the way in which the GMC's proposals for revalidation came, at least for a period, to rest entirely on the 'successful' completion of appraisal. In my view, that situation was unacceptable. It has now changed in that, in addition to the 'successful' completion of appraisal, a GP seeking revalidation will also be required to produce a clinical governance certificate. I have made recommendations about the way in which I think revalidation should develop. I now wish to discuss the future of appraisal, primarily in the context of clinical governance, but remembering all the while the role that it is expected to play in revalidation.

27.111 First, it seems to me that it is essential that the purpose of appraisal should be clear. Is it intended to be a purely formative process or is it intended to be multi-purpose – part formative, part summative, part performance management? In industry and in many employment situations, there is no difficulty about appraisal having several purposes. As I understand it, appraisal of doctors in the hospital service, at least for those in training grades, is intended to be a performance management tool. It is based upon information collected by the employer, and the employer can in large measure dictate the areas covered by that information and the topics to be discussed at appraisal. I believe that it was the DoH's original intention that the appraisal of GPs should be similar and should have both a formative and a summative function. As Dr John Chisholm, Chairman, General Practitioners Committee, BMA, told the Inquiry, even those negotiating on behalf of the doctors expected that appraisal would be based upon hard information provided by the PCT from clinical governance sources. In the event, as it has come to be operated, it is a purely formative process. It is based on material chosen by the appraisee. Much, even all, of that material may not be capable of being verified. It seems to me that, as a formative tool, it is as good as the individual doctor wants it to be. If s/he wants it to be searching, it can be; but if s/he wants it to be little more than a cosy chat about areas of practice that s/he is quite confident about, that can be engineered. I do not suggest that many doctors do that. Indeed, I have the impression that most of them want to make positive use of the opportunity that appraisal offers. But, if appraisal is to be used to any extent as a summative tool, it must be capable of detecting that small group of doctors who have something to hide. It must be a much less 'soft' process than it is at present.

27.112 So, somebody must decide whether appraisal is to be a clinical governance tool (in which case it must be 'toughened up') or whether it is to be a purely private opportunity for personal professional development. I have no strong personal view. I can see the benefit of a purely formative session with a colleague, provided that the colleague is someone with high standards, worth learning from. On the other hand, appraisal is a costly business and I wonder whether the money is being well spent, at least unless there can be some guarantee of the quality of the appraiser's contribution. The expenditure of the time and money might be more readily justified if the appraisal were to be based on specific information capable of being verified. It might be more readily justified if more information came out of appraisal for the benefit of the PCT's clinical governance function. These are issues for others, not for me. If I were to recommend that appraisal should contain a summative element, I cannot say whether that would be practicable. I do not know whether the profession would accept such a change. I do not know whether doctors would be prepared to act as appraisers if that were their function. I do not know whether the Government would wish to insist on such a change.

27.113 All I can say is that, if appraisal is to remain as it is – an essentially private matter between appraiser and appraisee, based upon material selected by the appraisee – then it must not be regarded as a clinical governance tool. It will be capable of helping a PCT to decide what types of continuing professional development it should provide. That is all. It must not be regarded as being capable of making any useful contribution to the process of revalidation. Revalidation must depend upon something else.

27.114 If the Government and the profession were to decide that appraisal should be 'toughened up' so that it is capable of being used as a clinical governance tool, then I would have a

number of suggestions to make as to how that might be done. These ideas come from witnesses to the Inquiry, participants in the seminars and sometimes from published documents such as the Revalidation Toolkit published by the RCGP for Scotland and the recent Consultation Document, 'Portfolio of Evidence of Professional Standards for General Practitioners: a Tool for Continuing Professional Development, Appraisal and Revalidation', also published by the RCGP.

27.115 On that basis, I would recommend first that appraisers must be more thoroughly trained and should be accredited following some form of test or assessment. They would have to be trained to evaluate the appraisee's fitness to practise. GPs should be appraised by an appraiser from another PCT. Second, the standards by which a doctor either 'successfully completes' or fails the appraisal must be specified. At the moment, appraisal is 'successfully completed' unless serious concerns arise and the appraiser stops the process. It is not clear how serious the concern has to be before that happens. Third, all appraisals should be based upon a core of verifiable information supplied to both parties by the PCT. That would not mean that the doctor could not introduce other material in addition; but there would have to be a compulsory core. The list of essentials would have to be agreed nationally. Important categories would be prescribing information, information about complaints, continuing professional development activity, mortality statistics (if a monitoring system is introduced) and audit results. I also consider that it would be appropriate for one particular type of activity to be undertaken and discussed in each year. Given that revalidation will generally take place every five years, there could be a cycle of five different activities. One should be a video film of patient consultations. Another should be a patient satisfaction survey. I am unsure of the value of peer review questionnaires in the context of general practice. If research shows that they are of value, they could be included. Another activity should be a review and discussion of a selection of patient records. Another could be the discussion of a report about a critical or untoward incident and another a discussion about a clinical audit report. In my view, it is important that the whole of Form 4 (the summary of the discussion and the personal development plan) should be made available to those at the PCT responsible for clinical governance. I understand that the DoH intends to ensure that this is done.

27.116 If those changes were made to appraisal, there may be some justification for regarding the process as an evaluation of fitness to practise, such as would provide an adequate basis for revalidation. Whether that is a good idea or whether it is preferable to keep appraisal and revalidation apart, I cannot say.

Miscellaneous Proposals

The Use by Primary Care Trusts of Their List Management Powers

27.117 The list management powers of PCTs are new and the evidence received by the Inquiry suggests that some PCTs are uncertain about when and whether they should be used. At paragraph 5.72, I suggested that it would be useful if the Family Health Services Appeal Authority (Special Health Authority), whose powers are soon to be transferred to the NHS Litigation Authority, were to collect and analyse the information relating to the use of these powers by PCTs. I thought that it would also be useful if PCTs were required to indicate

why they had used their powers in each case. Such analysis would assist the DoH in providing guidance to PCTs about the types of circumstance in which they might properly use their powers. Also, it would draw attention to those PCTs that were using their powers either much more or much less than the average.

Practice Accreditation Schemes

27.118 At paragraphs 5.111–5.119, I described various practice accreditation schemes in operation in England and in Scotland. I expressed the view that it would be valuable if all GP practices could be encouraged to achieve accreditation, as it is intended they should do in Scotland. As remuneration under the new GMS Contract is based upon a series of financial incentives, it seems to me that it would be sensible to provide a financial incentive for the achievement of practice accreditation by means of an accreditation scheme similar to that operated by the RCGP in Scotland. I recommend that the Government consider the feasibility of such an incentive scheme.

Support for Single-Handed and Small Practices

27.119 At paragraphs 9.134–9.135, I wrote about the particular problems of practice staff working in small or single-handed practices. They face problems of isolation; they may not recognise aberrant behaviour or practice in a healthcare professional because they are used to it and do not realise that it is unusual. I have suggested ways in which PCTs could help to reduce the effects of isolation.

27.120 In Chapter 13, I discussed the problems which can be faced by small and single-handed practices. I described a number of initiatives that are already being taken in some parts of the country to resolve or mitigate those problems. I do not propose to repeat that discussion here. At paragraphs 13.69–13.70, I recommended that a more positive approach should be taken to the problems of small practices. The doctors running such practices should be given more support and encouragement and, in return, more should be expected of them in terms of group activity and mutual supervision. I suggested that there should be a pooling of ideas, a willingness to examine the way in which things are done in other countries, such as the Netherlands, and a determination to solve the problems. I recommend that the DoH take responsibility for this initiative.

The Recruitment and Appointment of General Practitioners

27.121 Under current procedures, the extent of the involvement of a PCT in filling a GP practice vacancy varies according to the type of post. The PCT is responsible for recruiting to single-handed practices and salaried posts but, if the vacancy is within an existing partnership, the practice itself selects a candidate, subject to inclusion on the PCT's list. The question was posed in the Inquiry's Consultation Paper as to whether a PCT should have input into the selection process for a vacancy in a group practice and, if so, how and to what extent. As I reported at paragraphs 5.50–5.53, PCTs are entitled to refuse to admit a doctor to their medical lists on specified grounds.

27.122 Those respondents to the Consultation Paper and participants at the relevant seminar who supported the idea of PCT involvement in the recruitment and appointment of GPs did so

for two main reasons: first, because PCTs are responsible for clinical governance and will, therefore, be to some extent accountable for the actions of the doctor appointed and, second, because they felt that GP practices did not have the necessary human resources expertise to recruit and appoint satisfactorily. It was suggested that the necessary expertise might be provided by the PCT, or even the SHA.

27.123 Professor Martin Roland, Director, National Primary Care Research and Development Centre, and Professor of General Practice, University of Manchester, emphasised that there were two separate issues relevant to the PCT's involvement in GP appointments. The first was the responsibility which PCTs have for ensuring that only competent doctors are appointed to their lists. The second issue was the role that should be played by the PCT in the appointment of a doctor to a GP practice. Dr Grenville, representing the BMA, also made this distinction and expressed the view that external standards should be set (for example, governing the requirements for acquiring a licence to practise and for joining a PCT's list), but that, provided a candidate met those requirements, the decision to appoint should be made by the GP practice concerned.

27.124 There was a consensus at the seminar that the role of PCTs in the appointment and recruitment process should be limited to providing advice. Respondents to the Consultation Paper (including the RCGP) emphasised that professional partnership involves close personal and financial relationships and that, ultimately, the decision as to who should be admitted to a GP practice must be taken by the existing members.

27.125 There was, however, widespread support for the proposal that PCTs should provide human resources expertise and advice. The Inquiry heard about some initiatives at PCT level; for example, at the seminar, Ms Fiona Freedland, Legal Director, Action against Medical Accidents (AvMA), described the arrangement in City and Hackney PCT, where a GP vacancy officer had been appointed to help practices which were having difficulty in filling their vacancies. Mrs Webdale, representing AMSPAR, said that, in her experience, many GPs did not have the necessary skills to recruit effectively; however, some did not recognise this and were unwilling to seek help. Dr Reith, representing the RCGP, agreed that GPs were not experienced in recruitment and needed human resources advice. Although he did not believe that a PCT should be able to compel a practice to accept such advice against its will, he recognised that PCTs had a responsibility to ensure that proper recruitment processes were implemented; he accepted that there would be a place for 'robust discussion' between a PCT and a GP practice which was reluctant to accept such advice.

27.126 Professor Baker thought that it would be helpful for practices to have input from the PCT in the drawing up of a job description and specification. He suggested that the PCT could also help in sifting applications and in preparing a shortlist. This seems to me a good idea if, given the current shortage of GPs, it is possible to compile a shortlist. Professor Baker also suggested that, at that point, the PCT could check whether any of the candidates were unsuitable before interviews took place. I can see the value of undertaking some of the suitability checks before the interview stage. At present, PCTs might object that it would be too time-consuming to make all the necessary checks for several applicants for a vacancy. However, if the GMC were to put more information about doctors on its website

(as I shall recommend that it should) and if a central database of information about doctors were to be created (as I shall also recommend), it would be quick, easy and worthwhile to make these checks before the interview stage.

27.127 The view of Patient Concern was that, in order to ensure an appropriate balance of skills and mix of expertise in a particular PCT area, a PCT representative should be included on the panel which interviewed applicants for a GP post. Dr Reith said that he would not object to PCT involvement in an advisory capacity at the shortlisting or interview stages. In its written response to the Consultation Paper, South West Kent PCT expressed the view that a PCT member should be present during the interview process, but that his/her role should be limited to observing the proceedings. Another respondent to the Consultation Paper suggested that there should be professional input from the PCT at the point of shortlisting and lay input at the interviewing stage.

27.128 In my view, PCTs should be willing and able to provide advice on good recruitment practice and should also be willing to offer support in drafting a job specification and advertisements. If the response to an advertised vacancy is such as to give rise to the need for a shortlist, no doubt many practices would welcome help in sifting applications. As I have said, I think it would be useful if preliminary checks on suitability could be made before the interview stage. I would not think it desirable to take up references before a selection had been made. Nor do I think it appropriate that the PCT should play any part in the interview process unless requested by the practice to do so. Selection of the right person from among the suitably qualified candidates must be a matter for the practice concerned.

27.129 I also think that it would be sensible if a standard reference form were developed for use in connection with appointments to GP practices. It is not sufficient for a reference to comprise a general statement that the doctor has been satisfactory. Also, in my view, PCTs should insist that a reference be obtained from the previous employer or PCT. In the case of a previous PCT, the reference should be signed by the Medical Director or Clinical Governance Lead, i.e. the person who has access to the clinical governance information held about that doctor.

Involvement of Lay People in the Recruitment of General Practitioners

27.130 The Inquiry's Consultation Paper also raised the issue of whether patients should be involved in the process of selection of GPs and, if so, to what extent. It was suggested that there might be patient representation on interview panels. Views were also sought on the type of patient representation; for example, one or more patients at the relevant practice could be involved, or members of the local Patients Forum or some other representative group.

27.131 The Inquiry became aware of examples of patient involvement in the recruitment of GPs. The Clinical Governance Review of Harlow PCT, undertaken by the Commission for Healthcare Improvement (CHI) in 2003, reported patient and public involvement in many trust activities, including participation in the recruitment of GPs.

27.132 Respondents to the Consultation Paper were divided on the issue of patient involvement. Some respondents were wholly opposed to the idea. Others welcomed the idea in theory

but saw practical difficulties. Many respondents felt that patient involvement was important. A number saw a role for the new Patients Forums, which could be involved directly in the recruitment process, or could at least be consulted on priorities before the practice embarked on the selection process. Others thought that a lay member of the PCT should provide lay input. AMSPAR suggested the setting up of new patient groups covering several PCTs.

27.133 Some respondents thought that it would be helpful to have lay input at the stage of shortlisting candidates, while others felt that the most appropriate stage was at interview and that the interviewing panel should include a lay representative. One suggestion was for all shortlisted candidates to meet informally with a group of patients who would give feedback to the interviewing panel. However, there was opposition to this idea on the grounds that it did not give much insight into the quality of a candidate's clinical practice. The need for members of the practice to make the ultimate decision about who was to be admitted was again emphasised.

27.134 There was a general view that lay participants would require training in selection and would need to be knowledgeable about issues in general practice. Professor Baker suggested in his written response that low level indirect involvement might be appropriate. Patients at a practice could be consulted about preferences: for example, whether patients would like a woman doctor to be recruited in what had hitherto been an all-male practice. Dr Grenville, representing the BMA, raised a number of potential problems with lay participation. He said that it might be difficult to find a patient or patients who were truly representative of the practice patient list. He gave as an example of the problem the patient representative who had a specific issue on which s/he felt strongly: for example, s/he might want a doctor who would always prescribe antibiotics for a cold, whereas other patients might want a doctor who would not expose patients unnecessarily to the dangers of antibiotics. Like Professor Baker, Dr Grenville was in favour of indirect patient input. He thought that patient participation groups could helpfully inform a practice of broad areas of concern to patients; that information could then be taken into account in recruitment.

27.135 Ms Freedland, representing AvMA, stressed that the overriding imperative from the patient perspective is that the doctor be safe, and that other considerations are necessarily secondary to patient safety. She suggested that patient involvement would be of most use in assessing the doctor's communication and interpersonal skills. She thought that it would be helpful to have a patient at the interview so as, for example, to test the candidate's ability to explain to a patient in simple language a complicated diagnosis or prognosis and treatment plan. Professor Dame Lesley Southgate, Professor of Primary Care and Medical Education, University College London, was supportive of exploring innovative interviewing techniques such as that proposed by Ms Freedland. She observed that lay assessors for the GMC's performance procedures currently test communication skills in a similar way with considerable success. She said that, in certain geographical areas (such as the inner cities where many people do not speak English), the attitude of the doctor is paramount in providing good care to patients. She added that it is important to observe candidates in practical situations, interacting with patients. Professor Aidan Halligan, Deputy Chief Medical Officer for England and Director of Clinical Governance for the NHS, also supported the proposal and said that the principle

of patient participation was a very legitimate one and should be welcomed. Dr Reith pointed out that doctors entering general practice would already have undergone summative testing of their communication skills. Dr Grenville thought that communication skills were central to the work of GPs and that their communication skills should be tested on a regular basis. He envisaged that, in the future, GPs would have a portfolio of videotaped consultations which could be used in applying for a new post. Sir Donald Irvine thought that communication skills would be better tested as part of revalidation, for example, by using videotaped consultations.

27.136 Dr Reith and Dr Sarah Wilson, Director of Public Health and Medical Director, Trent SHA, thought that it would be helpful for research to be carried out to see if patient involvement improved the recruitment process. They thought it should not be built into the process 'for the sake of it'. I think that such research would be a good idea, although it would depend upon the availability of funding for such a project.

27.137 My conclusion about this debate is that there should not be any attempt to be prescriptive about whether or how lay people should participate in the process of selection. I agree with Professor Baker and Dr Grenville that practices really ought to canvass and take account of the views of their patients about the kind of doctor the practice needs. However, I would be opposed to the imposition of any particular format or process by which lay people should be involved in selection. There are obviously a lot of different ideas in circulation. If any GP practice wishes to adopt any of these ideas it should be free to do so, but I do not think it should be under pressure to do so. I must say that I am attracted by the idea that material used in the revalidation process (such as a videotape of consultations) should also be used in the recruitment process. Indeed, it may be that, in the future, doctors will be expected to produce a good deal of clinical governance material for the benefit of a prospective employer or partner.

General Practitioners' Personal Files

27.138 Evidence received by the Inquiry suggests that, at least in the past, it has been the practice for a primary care organisation (PCO) to keep information about individual GPs in different files, dealing with specific topics (such as complaints, remuneration or practice profile), rather than keeping a single file containing everything relating to an individual GP. It may be that the recognition of the importance of clinical governance has led to the adoption of a different practice. For the avoidance of doubt, it seems to me essential that every PCT should keep a separate file (whether on paper or in electronic form) which holds everything in relation to that doctor, or at least everything that could have any possible relevance to clinical governance. A reliable and comprehensive source of information might in certain circumstances be useful to the PCT officer or group responsible for signing the clinical governance certificate for the purposes of revalidation. If a doctor moves from one PCT to another, that file (or a copy of it) should be sent to the new PCT. It should not be possible for doctors with a poor clinical governance record to move on and leave it behind. PCTs should also keep files on doctors who have been admitted to their lists and who work as locums in the area. It might be helpful if the DoH were to establish national criteria for the content of such files.

The Raising of Concerns

Facilitating the Raising of Concerns by Staff in General Practice

27.139 At paragraphs 9.128–9.139, I discussed the need for arrangements to support members of GP practice staff who wish to raise a concern about any matter arising within the practice, in particular about the clinical practice or conduct of a healthcare professional within the practice. I do not propose to repeat the detail of that discussion here. Suffice it to say that I recommend that every practice should have a written policy, setting out the procedure to be followed by a member of the practice staff who wishes to raise concerns, in particular concerns about the clinical practice or conduct of a healthcare professional within the practice. I also recommend that staff should be encouraged to bring forward any concerns they may have openly, routinely and without fear of criticism. However, I recognise that circumstances may arise in which a member of the practice staff feels unable to raise his/her concern within the practice. In readiness for such occasions, I suggested that PCTs should designate a member of staff to act as a point of contact for all practice staff. The contact details for that person should appear in practice 'whistleblowing' policies. He or she should make him/herself known to all the practice staff working within the PCT area. If the 'single portal' is created, in whatever form, the policy should set out contact details of that also. PCTs should also ensure, through training, that practice staff understand the importance of reporting concerns and know how to do so.

Facilitating the Raising of Concerns by Staff in the Private Sector

27.140 I recommend that the Healthcare Commission should require all private healthcare organisations to have a clear written policy for the raising of concerns. I also recommend that the Healthcare Commission and the GMC should be 'prescribed persons' for the purpose of receiving expressions of concern under the Public Interest Disclosure Act 1998 (PIDA), about any healthcare matters, whether arising in the public or the private sector.

Support at a National Level for Those Who Wish to Raise Concerns about Health Care

27.141 In Chapter 11, I discussed the provision of support and advice for those who wish to raise concerns about any aspect of health care. I made a number of recommendations about possible amendments to the PIDA, in particular at paragraphs 11.91–11.115 and 11.124. I shall not repeat the discussion relating to those recommendations here. I also recommended, at paragraph 11.117, that policies for raising concerns in the healthcare sector should be capable of being used in relation to persons who do not share common employment. For example, a doctor or nurse working in a hospital should have a route by which to raise a concern about a GP and *vice versa*. A doctor or nurse working in the private sector should have a route by which to raise a concern about the practice of a healthcare professional working in the NHS and *vice versa*. I also recommended that there should be some provision (probably a telephone helpline) to enable any person, whether working within health care or not, to obtain advice about the best way to raise a concern about a healthcare matter and about the legal implications of so doing. In my view, this should be provided on a national basis. I have not made any recommendation as to the

means by which this should be provided. However, it seems to me that it might be possible to link this helpline with the 'single portal' which is under consideration and which I mentioned at paragraphs 27.85–27.88 above.

The Availability of Information about Doctors

Information Available to Employers and Primary Care Organisations

27.142 One of the issues discussed at some length during the Inquiry was the difficulty experienced by PCTs in verifying information about doctors who apply to join their lists. I listed the checks to be made at paragraph 5.43. One of the witnesses described the process of obtaining this information as a 'real chase-round'. Even the process of checking registration at the GMC, the Criminal Records Bureau (CRB) and the NHS Counter Fraud and Security Management Service can take a good deal of time. Several PCT staff suggested that a more co-ordinated method of making these checks would be very welcome.

27.143 Quite apart from the information that can be gleaned from those three sources, there exists an enormous amount of other information about doctors which would be of value to PCTs and to potential employers. At the moment, there is no way in which such persons or bodies can find out all they would like to know about an applicant for a post or for admission to a list. For example, they will receive a reference from one, or maybe two, previous employers or PCTs but they will have no idea whether there are other employers by whom the doctor may have been dismissed or disciplined. They cannot find out whether a complaint has been made or even a series of complaints. In the Report of the independent investigation into how the NHS handled allegations about the conduct of Clifford Ayling (the Ayling Report), the problem of drawing together and tracking records of separate complaints about the same doctor was highlighted. A similar concern was expressed in the Report of the investigation conducted by CHI into the various complaints made about the GP, Peter Green.

27.144 During the Inquiry, the idea emerged that there should be a central database of information about every doctor working in the UK. This would not be open to the public, but would be accessible to the officers of NHS bodies and to accredited employers in the private sector, as well as to other bodies with a legitimate interest, such as the Healthcare Commission, the GMC, the NCAA and the DoH. Several different classes of information would be fed in.These would include the current records held by the GMC (including any FTP history), although it might be more convenient to create a link to the GMC website, the contents of which I will discuss below.The database would have to contain information provided by the CRB or be linked electronically to that organisation. CRB information would include details of convictions (including those resulting in an absolute or conditional discharge) and cautions; the existence of other, more sensitive, information could be 'flagged' so that further enquiries could be made. In addition, the database would contain information from the NHS Counter Fraud and Security Management Service, a record of any disciplinary action by employers, the details of any list management action by PCTs, any adverse reports prepared following the investigation of a complaint, any adverse findings by a Healthcare Commission panel or by the Health Service Ombudsman and

any findings of negligence in clinical negligence actions and settlements of clinical negligence claims above a pre-determined level of damages. The level of damages should be set at a low threshold, say £5000, so as to catch cases involving the deaths of children, where the damages are unlikely to exceed about £11,000 on full liability and may well be settled for less than full value. In addition, an entry would be made in respect of every post taken up by a doctor in employment, thereby creating a running *curriculum vitae*. For self-employed doctors, an entry would have to be made for each GP practice or deputising service for which the doctor worked. The identity of the doctor's medical defence organisation (if any) could be included. Also, if the doctor had any financial interests which should be declared, they too could be incorporated. Doctors would be able to access their own entries to check the accuracy of the information held.

27.145 I would suggest that private sector employers should be required to provide relevant information. The Healthcare Commission could require this as a condition of registration. Also, deputising services should be required to provide information to the PCT with which they are contracted and would then be entitled to access to the information on the database, again through the relevant PCT.

27.146 The NHS has already made a start on the collection of information about individual doctors working in the hospital service through the use of NHS Occupational Health Smart Cards. I would have thought that this provision could usefully be extended to doctors working in primary care and that the categories of information that the cards contain might be extended to include those that I have mentioned above.

27.147 At the seminars, there was also discussion about whether unsubstantiated allegations should be included on the central database. Not surprisingly, opinions differed. The view was expressed that it would be grossly unfair to include such material. Others thought that, in the light of cases like that of Peter Green, where a number of unsubstantiated complaints had been received but not co-ordinated, it would be in the interests of patient safety if such information were to be included on the database. During the Inquiry hearings, there was discussion about evidence being given to the Independent Inquiry arising from the Soham Murders, chaired by Sir Michael Bichard. The gist of this discussion was that, if Humberside Police had retained information about unsubstantiated complaints against Ian Huntley and had passed them to Cambridgeshire Police when they made their pre-employment enquiries, Huntley would probably not have been employed at Soham Community College and Holly Wells and Jessica Chapman might not have died. Those contributors to the debate who had previously objected to the gathering of information about unsubstantiated complaints or concerns immediately realised that such material might be of great importance to patient protection. The view was that such material should not be entered into the central database, but that the entry should be flagged to indicate that confidential material was held by a named body. Disclosure of that information would have to depend upon who was asking about it and for what purpose, and questions of access would have to be determined at a high level.

27.148 Not only would such a central database make it far simpler for an employer or PCT to conduct pre-employment or pre-admission checks, the reliability of those checks would be greatly enhanced. The great majority of doctors would have nothing to fear; their entries

would contain no more than their qualifications and their *curriculum vitae*. However, those doctors who cause problems, and who move on from place to place causing more problems, would very soon be identified.

27.149 The question arose as to who should keep this database. To be useful it should cover the whole of the UK and should include doctors who work in the NHS, in the private sector and in both. That being so, it seems to me that it would have to be funded by Government and a suitable host would have to be found. The Healthcare Commission would seem to be a suitable candidate. It might even fit in with the Commission's own plans for information systems.

Further Information to Be Provided to Primary Care Organisations

27.150 In Chapter 5, I described the information that GPs now have to provide when seeking admission to a PCT list. This includes information about convictions, cautions, various types of disciplinary or FTP findings and ongoing proceedings. Doctors already on a PCT list are under an obligation to inform the PCT about any new relevant information. At the Inquiry, there was some discussion about whether other categories of information should be included, in particular information about clinical negligence claims.

27.151 The debate generated some heat. On the one hand, it was said that a clinical negligence claim was just another way of making a complaint or raising a concern and was of real importance for clinical governance purposes. On the other hand, it was said that many clinical negligence claims are brought which have no merit at all and that, therefore, they should not be reported to the PCT or recorded in any way. It was said that, in many cases, a letter before action was written and then the matter did not proceed further. It was also argued that some clinical negligence claims were settled for quite large sums even though there was no merit in them; this was done for commercial reasons, to avoid costs. My long experience of personal injury litigation teaches me that that is not so. Offers of settlement are often made, it is true, to buy off the risk that the action will succeed but not where it is judged that there is no risk.

27.152 In my view, civil actions are analogous to complaints and concerns. It would be illogical to retain records of complaints and concerns because their clinical governance importance is recognised, and to ignore clinical negligence claims. The fact that the allegations made in some such claims may have little merit seems to me to be unimportant. Some complaints have little merit but that is not a reason for disregarding them; the value of investigating them is recognised. If a record were to be kept of those clinical negligence claims which resulted in a finding of negligence (of which there are very few) and those which were settled for £5000 or above, I do not think any injustice would be done and the PCT would have useful and relevant information on its file. That information should also appear on the central database, if created.

27.153 I consider also that it would be appropriate for PCTs to be given notice when an action is brought. In my view, the trigger for notifying the PCT about a civil action should be the receipt (either by the doctor or by his/her medical defence organisation, or that organisation's legal representatives) of a letter of claim which complies with the requirements of the pre-action protocol in the Civil Procedure Rules. Such letters are sent

only where there is a serious intention to proceed. In my view, doctors should be under a duty to notify any PCT to whose list they have been admitted of the fact that such a letter of claim has been received and the gist of the allegation made. They should also be required to report the outcome.

27.154 As I have said, there is an ongoing requirement under the provisions of the National Health Service (Performers List) Regulations 2004 on doctors to make relevant declarations to their PCTs. In my view, failure to do so, and to do so accurately, should amount to misconduct of sufficient gravity to warrant referral to the GMC.

Information Available to the Public and Patients

27.155 During the Inquiry, there was discussion about how much information about doctors should be made available to the public and to the doctors' patients. This was appropriate in the context of an Inquiry into the activities of a doctor who, 24 years before it was discovered that he was a murderer, had been convicted of a series of offences of dishonesty in connection with his dependence upon a controlled drug. It is entirely natural that the relatives of Shipman's victims should say, 'If only we had known.'

27.156 The information available to patients and prospective patients about an individual GP is very limited under the present system. The public may become aware of a doctor's criminal convictions or about disciplinary matters through press coverage. However, there is no means by which comprehensive information can be obtained. At the time of the Inquiry hearings, the GMC would, in answer to a specific enquiry, provide information to members of the public about current conditions on a doctor's registration and on any previous disciplinary findings. However, that information was not – and still is not – available on the GMC website and will be provided only in response to specific enquiries by telephone. At the seminars, Dr Lewis, representing the GMC, said that the GMC did not at that time have an established strategy on disclosure but was in the process of developing such a strategy through public and professional consultation. That has now taken place and I shall describe the new GMC policy on disclosure later in this Chapter.

The Principle of Disclosure

27.157 Respondents to the Inquiry's Consultation Paper were asked whether patients and prospective patients should be provided with more information about their GPs to enable them to make an informed choice in deciding whether to consult a doctor and whether to submit to treatment by him/her. Respondents were asked what information should be available including, as examples, previous criminal convictions, disciplinary findings and current or past restrictions on a doctor's licence to practise. Respondents were also asked to comment on how the information should be provided to patients.

27.158 Respondents to the Consultation Paper and participants at the seminars were divided on the principle of whether more information should be provided to patients. One of the strongest advocates for complete openness was Sir Donald Irvine. He said that the issue was one of patient autonomy; patients are entitled to have access to information which is already in the public domain. Sir Donald said that he was aware of two cases in which

patients had become aware of a doctor's history after a problem had arisen; they had been angry that information had previously been withheld from them and that they had been denied the opportunity to make a decision in the knowledge of all the facts. The patients had been left with a feeling that there had been a 'cover up'. A number of other seminar participants agreed with that view, including Professor Halligan, Deputy Chief Medical Officer for England and Director for Clinical Governance for the NHS. He said that the need to inform patients and to allow them to make up their own minds about how and from whom they receive treatment arose out of the privileged position of doctors and the trust that patients necessarily place in a doctor.

27.159 A large number of respondents to the Consultation Paper expressed the opposing view. Their argument was that it was for the GMC, a PCT or a doctor's employer to decide whether a doctor was fit for practice and that patients should be able to rely on those bodies to fulfil their respective roles. There was (or should be) no need for patients to receive further information about their doctors. The BMA said in its written response to the Consultation Paper that patients should be reassured that minimum standards apply, which reduce as far as possible the chances of patients coming into contact with a GP who might cause them harm. In that context, it was said that the GMC and PCTs should be more robust in their approach to their respective roles of licensing and appointing doctors. Mr Michael Summers, Chairman of the Patients Association, agreed that the responsibility to ensure fitness to practise lay with the GMC and the PCTs. He thought that providing further information might cause patients to worry, which would be particularly damaging to those patients who live in parts of the country where it is not possible to change doctors. With due respect to Mr Summers, it seems to me that the issue is not only one of choosing a doctor. If the only GP to whom a female patient has access is a male one who has been convicted of indecent assault, she might wish to be accompanied when consulting him.

27.160 A number of respondents pointed to practical problems associated with the provision of information. Dr Grenville, who represented the BMA, said that the mere knowledge of an event would be insufficient to give the patient informed choice and that the patient would need to be able to ask and get satisfactory answers to questions about a doctor's history. He said that, in practical terms, this would be very difficult to achieve. I see the force of that argument. Some respondents thought that providing some types of information would make it impossible for a GP to continue practising, because patients would be unwilling to be treated by that doctor. My reaction is that, if the doctor's past record is so bad, perhaps the patients might be right and s/he ought not to be practising at all.

27.161 Professor Roland said that he had been involved in research into the impact of providing information to the public. The research was aimed specifically at providing information on quality of care. It had shown that publishing the information had made more of an impact on doctors and healthcare managers than on patients. Although he acknowledged that releasing details of, for example, a doctor's criminal convictions might cause patients to refuse to be treated by that doctor, the research suggested that this would not be the case. Ms Freedland agreed, saying that she did not think that the provision of information to patients about a GP would necessarily lead to an exodus of patients. In its written response to the Consultation Paper, CHI said that it thought there was a need for further research on the impact of sharing such information with patients.

27.162 During the course of receiving evidence, the Inquiry was told about the case of a doctor who had been convicted of the manslaughter of a patient and, as a condition of his registration, was required to undergo a period of supervised practice. A suitable supervisor was found but he and other members of the practice decided that they could not keep their patients in ignorance of the situation. A letter was sent to patients setting out the doctor's history, describing the remediation programme he was undergoing and explaining the precautions that were being taken to protect patients. The patients' reaction was good; it appears that they were willing to consult the doctor.

Categories of Information to which Patients Should Have Access

27.163 There are several categories of information to which patients might wish to have access, including criminal convictions and ongoing criminal matters, a doctor's GMC FTP history and ongoing FTP matters, action taken on the doctor's inclusion on the PCT list and findings of clinical negligence. There was broad agreement that information about existing restrictions on a doctor's licence to practise should be available.

27.164 A number of respondents to the Consultation Paper and participants at the seminars thought that the guiding principle should be that any information that has at any time been in the public domain should be available to patients. However, that principle is less easy to apply than it is to enunciate. Criminal convictions are in the public domain at the time they occur but the public soon forgets about them. After some years, they are deemed to be 'spent' under the provisions of the Rehabilitation of Offenders Act 1974 (the 1974 Act). The 1974 Act is designed to allow persons convicted of offences to put the past behind them. Such persons are not in general required to disclose spent offences when applying for jobs. There are, however, certain exceptions to this general rule, one of which extends to work concerned with the provision of health services. Doctors are required to declare any convictions they may have in response to questions from a prospective employer or PCO.

27.165 Of those respondents who thought that the public should have access to information about criminal convictions, some believed that access to such information should be available throughout a doctor's career. Others felt that the information should be available only until the conviction was spent, as defined by the 1974 Act. One respondent thought that there was a need for flexibility about past events and that information about past events should be made available only if it was 'too material/significant not to be shared with patients'. I can see the force of that but think that such a scheme would lead to uncertainty and endless argument. There was broad support among seminar participants for the proposition that matters that were under investigation should not form part of the information available to patients until findings of fact had been made.

27.166 There was some support among respondents to the Consultation Paper for the proposition that information about the outcome of successful clinical negligence claims against a doctor should be accessible to patients. Some findings of clinical negligence against doctors enter the public domain because civil courts generally sit in public and the findings of a judge in a clinical negligence action are publicly available. However, there was some opposition to this idea. It was said that the cases of clinical negligence that go

into the public domain are a minority, and that disclosure of them would therefore be unrepresentative and misleading. It is quite usual for the worst cases of negligence to be settled privately with no public hearing. Also, a claim for damages might fail, not because the doctor was not negligent but because the negligence did not have the consequences alleged. Finally, it was said that negligence on the part of a doctor is often part of a more wide-ranging failure and the contribution of the doctor is difficult to determine.

27.167 Dr Reith suggested that it would be sensible to canvass the views of patients on the sort of information they thought they ought to have.

Methods of Making Information Available

27.168 A variety of different methods of providing information to patients was suggested in the written responses to the Consultation Paper and at the seminars. One respondent argued that the information should be provided proactively so that all patients received it, not only the few who had sufficient determination to seek it out. Another respondent took the opposite view and thought that the information should be provided only to patients who made a specific application for the information. Moreover, that respondent thought that the request for information would have to be justified; in other words, reasons should be given for making the request.

27.169 At the seminars, Dr Wilson said that it would be better if the information were provided to patients on a one-to-one basis by someone at the PCT or from the GP practice, rather than by way of a letter. It seems to me that that ideal would be difficult to meet. Dame Lesley Southgate said that doctors themselves should have the responsibility for providing information about restrictions on their practice. She suggested that one method would be for a joint letter to be agreed between the Chief Executive of the PCT and the doctor, setting out the information that should be disclosed as well as the steps that were being taken to ensure that patients were not put at risk, together with any other matters that might be appropriate in an individual case. Dame Lesley agreed that such a system would be more effective in the case of a GP working at one practice than, for example, in the case of a locum doctor or a doctor working for a deputising service.

27.170 Another possibility is for the relevant information to appear on a website, to which patients and members of the public generally would have access, as is provided in a number of overseas jurisdictions.

International Perspective

27.171 As part of his presentation to the Inquiry, Dr Rocco Gerace, Registrar, College of Physicians and Surgeons of Ontario, Toronto, spoke about the website which is operated by the College. Patients can obtain from the website details of a doctor's referral to the College Disciplinary Committee together with any findings made by the Committee. The College is currently seeking legislative change in order to permit publication of undertakings provided by doctors in cases which do not come before the Disciplinary Committee.

27.172 Dr Gerace said that various categories of information are kept in the public domain for different periods. Findings of the Disciplinary Committee relating to sexual abuse on the

part of a doctor, for example, would remain on the record throughout the doctor's career. For lesser findings, there are fixed periods during which the information will be available, and, for certain categories of activity, the Registrar has a discretion as to how long the information should remain on the website. If a doctor were to go into the equivalent of the old GMC health procedures, then the fact that s/he was in the health procedures would not go on the website, but any restrictions on his/her practice would be published and would remain on the website while the restrictions were in force. I think the practice in Ontario might be worth copying.

27.173 Dr Perry Pugno, Director, Division of Medical Education, American Academy of Family Physicians, said that, in the USA, a number of resources providing information on a doctor's fitness to practise were available to members of the public. The State Medical Boards run websites which provide details of disciplinary action against doctors, criminal convictions and other information, such as the status of a doctor's licence to practise. In addition, a number of websites exist which are operated on a commercial basis and contain similar material. One example mentioned by Dr Pugno was 'Choice Trust', which covers the whole of the USA. The website is partially funded by advertising, and the basic service of establishing a doctor's administrative details is free, but a charge is made for information about a doctor's disciplinary history. Dr Pugno said that the information on the commercially run websites is not wholly accurate and, for example, in his own case, some of the practice addresses listed on 'Choice Trust' were incorrect and more than five years out of date.

Information Currently Made Available by the General Medical Council

27.174 At the present time, the only official provider of information about a doctor is the GMC. At the time of writing, only information which is on the medical register is available to the public, although, for reasons which I will shortly explain, that may well change in the near future. Of course, anyone who is prepared to use a search facility on the internet will be able to discover a great deal more.

27.175 There are two means of access to information held on the medical register. Some information appears on the GMC website. Alternatively, an enquirer can either telephone or email the GMC. I suppose it must also be possible to write. The website contains very limited information. If the doctor is currently registered and if there are no conditions attached to registration, his/her entry will appear on the website. The entry provides basic factual information, states whether the registration is full, limited or provisional and specifies any specialist register to which the doctor has been admitted. If there are any conditions attached to the doctor's registration, the website will indicate that it is not possible to display an entry that matches the request but that this does not mean that the doctor is not registered. A telephone number is provided as well as an email address so that further enquiries may be made.

27.176 If the enquirer telephones the number provided and asks about the doctor's registration, s/he will be told whether or not the doctor is registered and whether the registration is full, limited or provisional. Even if the doctor has conditions attached to his/her registration, the caller might well be told that the doctor is 'fully registered'. That means only that the

registration is not provisional or limited. If a lay caller had heard that his/her doctor was or might be subject to conditions and was telephoning to check whether that was so, the statement that the doctor was 'fully registered' might give a misleading impression, even though it would in fact be true. Only if the enquirer asks a specific question, such as whether the doctor has been suspended or whether s/he is subject to conditions, will the enquirer be told of any such matters. The GMC does not volunteer a full account of the doctor's registration status; it waits for the enquirer to ask. Indeed, the person who answers the telephone is able to provide only the level of information that appears on the website. If the enquirer wishes to ask any further questions, s/he is passed to someone else, apparently in another department. The experience of a member of the Inquiry staff who made a registration enquiry (on my instructions) about a doctor whose registration was subject to conditions was that she was kept waiting and that it was necessary for her to be quite persistent in order to obtain the information requested. Indeed, it appeared doubtful that she would ever have been given the information at all if she had not been able to quote the doctor's GMC number. Initially, when she gave the doctor's (correct) name, she was told that no doctor of that name was registered. When she volunteered the doctor's registration number, she was advised that the doctor was registered but his name was hyphenated on the GMC database.

27.177 It seems to me that this process is unhelpful to the public. All information about a doctor's registration is in the public domain and it should be made readily available. For those who wish to access the website, the full information including any history of erasure, suspension, conditions and warnings should be shown. For those who prefer to telephone, the full information should be volunteered, without the enquirer having to ask specific questions. I had hoped that, by now, the GMC would have recognised that this should be done. When Professor Sir Graeme Catto, President of the GMC, gave evidence to the Inquiry in December 2003, he said that, in his view, for the GMC to decline to make available anything that is already in the public domain was a 'weakish stance from which to start'. He accepted that it was not satisfactory that an enquirer had to ask the right questions before s/he would receive full information. However, at the end of October 2004, there had been no change in the amount of information available on the website and no change to the practice of requiring enquirers to ask specific questions before they would be told the full details in respect of the doctor's registration. I hope that that change will be made very soon.

27.178 As I have said, conditions imposed upon a doctor's registration are matters in the public domain. In the past, if conditions were imposed by the Health Committee, only the restrictions upon the doctor's practice were recorded on the register and any conditions of a medical nature were not. That seems appropriate, as any conditions relating to the doctor's health (such as a condition that s/he submit to medical supervision) should, I think, be treated as confidential, at least so far as the public is concerned. For the future, under the new FTP procedures, I envisage that any conditions on registration (other than those relating to medical matters) imposed by a FTP panel will appear in the doctor's entry in the register. However, it seems to me that conditions and restrictions entered into voluntarily ought also to appear in the register. A statement of requirements or a set of voluntary undertakings agreed following a performance assessment is, in reality, every bit

as much a 'condition on registration' as a set of conditions imposed by a FTP committee or panel. If the doctor will not agree to the undertakings, s/he will be referred to a FTP panel. The undertakings would be proposed in the first place only if the view had been taken that the doctor could not safely practise without restriction. Similarly, if the doctor voluntarily accepts a series of undertakings on account of his/her ill health, they are, in effect, conditions on registration. It is verging on sophistry to suggest that restrictions accepted voluntarily are not conditions on registration. I note that the report of the Performance Procedures Review Group suggested that restrictions agreed following a performance assessment should be treated as conditions on registration. In my view, it should be a condition of acceptance of voluntary undertakings that they are to be treated as the equivalent of conditions imposed.

Imminent Changes to General Medical Council Practice

27.179 When Sir Graeme Catto gave evidence to the Inquiry in December 2003, he said that the GMC intended to consult publicly in 2004 on questions of public disclosure. That consultation has now taken place and the results were considered at a meeting of the GMC in July 2004. Several new principles of disclosure were established. I do not think that these changes have yet been put into operation but I think that they must be imminent.

27.180 First, it was decided that, as a general principle, all information that has been in the public domain should be disclosed to any enquirer. That would include any aspect of the FTP procedures that has been in the public domain, even including the fact that a doctor has been charged with SPM but has been acquitted. Second, as a general principle, historical information that has not been placed in the public domain should be disclosed only in limited, defined circumstances, to the police, a coroner or **'an official inquiry'**. Third, it was agreed that information that has been in the public domain but is no longer of relevance to the doctor's registration should be disclosed for as long as the doctor remains on the register. The transcript of the meeting shows that it was agreed that this type of information should be disclosed to enquirers but that the answer should be accompanied by an explanation that the information is no longer of relevance to the doctor's registration.

27.181 The fourth resolution was that any finding of SPM, whether or not that had been followed by the imposition of a sanction, should be disclosed to enquirers. This should continue for as long as the doctor remains on the register. The fifth decision concerned information relating to the findings of fact that had been made against the doctor but had not resulted in a finding of SPM. After some discussion, it was agreed that such information would be provided to enquirers but that it must be set in context so that it would not reflect unfairly on the doctor. It was pointed out that this would be easy in respect of recent and future findings because reasons are now given, whereas, in the past, they were not and it would be difficult to put the information into context. Sixth, it was agreed that, where there had been findings of 'not guilty' and no findings 'in relation to the allegation', the information would be disclosed to enquirers but, again, it would be put in context.

27.182 Seventh, it was agreed that, if a warning were to be issued in the future under the new FTP procedures, it should be disclosed to a prospective employer at any time during the

following five years. The Council decided to postpone its decision about whether warnings should remain on the doctor's record indefinitely for some purposes, including enquiries from potential employers. Finally, the Council decided that, during the first five-year period after the issue of a warning, it should be disclosed to any enquirer, not only to prospective employers.

27.183 It appears therefore that, in future, the GMC will give full replies to questions about a doctor's past FTP history. However, it appears that the Council did not question the present practice of giving only the amount of information expressly requested. Mr Finlay Scott, Chief Executive and Registrar of the GMC, told the meeting that the GMC received about 1000 registration enquiries each day but that 999 of them went no further than finding out whether the doctor was currently registered. It does not appear to have occurred to the Council that this suggests that many prospective employers (or PCOs) are not finding out whether the doctor whose application they are considering has a FTP history, or even whether s/he is subject to current conditions. I find this very worrying. Evidence received by the Inquiry suggests that pre-employment checks are made by clerical staff. It would be quite possible to give such staff a list of questions that must be asked, but it appears from Mr Scott's advice to the Council that this is not being done. It seems to me that there ought to be much more information on the website and that, in the interests of clinical governance, much more information should be volunteered to telephone enquirers whether or not they ask the right questions.

Recommended Framework for General Medical Council Disclosure

27.184 I recommend that the GMC should adopt a policy of tiered disclosure. It may already have such a policy; if so, my recommendation is that it should be modified in the following way.

The First Tier

27.185 The first tier of disclosure should relate to information which is relevant to the doctor's current registration status together with certain limited information about his/her past FTP history. First-tier information should be posted on the GMC website and should also be volunteered to anyone who requests registration information, regardless of the questions asked.

27.186 The information to be disclosed in respect of the doctor's current registration status should include not only those conditions imposed by a FTP panel but also those voluntarily accepted by the doctor, save those that relate to the doctor's medical condition or supervision. It should also include the existence of any interim orders in effect. When the provisions for revalidation come into force in 2005, information about a doctor's registration status should include the year in which the doctor is due to be revalidated and, when s/he has been revalidated, the term for which the revalidation will be effective. Thus, it should be possible to see from the register whether the doctor has been revalidated in the year in which revalidation was due.

27.187 The preparation of a list of additional items of information that should be disclosed at the first tier will require public consultation. I shall not attempt to provide a definitive list. However, in my view there are some essentials, which I shall enumerate.

27.188 If a doctor has been erased from the medical register and restored, those facts and the circumstances behind them must be included. If the erasure was voluntary, that can be stated. If it was ordered by a FTP panel, that must appear, together with the underlying reason, in summary form. For example, the doctor was erased following his/her conviction for an offence of manslaughter at the XXX Crown Court. The date of erasure should be given. The date of the restoration should be given. In a case of erasure following a finding of SPM, the nature of the misconduct should be explained, for example, 'irresponsible prescribing of controlled drugs' or 'indecency with patients'. In my view, such information should be available for as long as the doctor remains on the register.

27.189 The fact that a doctor has been erased from the register and the reasons for it should be accessible to the public at the first-tier level for a limited period after erasure even if the doctor has not applied and may never apply for restoration. Now that the minimum period that must elapse before an application for restoration can be made is five years, I would suggest that such information should be available for seven years after erasure.

27.190 The fact that a doctor has been suspended from the register should be disclosed at the first tier, not only during the period of suspension, but for a period afterwards. I would suggest that a period of, say, seven years might be appropriate. The fact that conditions have been imposed should also be disclosed. The period of time for which these should remain on the register ought, in my view, to depend upon whether the condition related to some requirement for retraining (in which case a fairly short period would suffice) or whether it entailed some restriction on the circumstances in which the doctor was permitted to practise, in which case a longer period would be appropriate.

27.191 The fact that a warning has been given should be disclosed at the first tier. I would suggest that an appropriate period for disclosure would be five years. A brief explanation for the reason should be given: for example, a warning was given after an assessment of performance, or a warning was given following the receipt of a report of a conviction for stealing goods to the value of £20 from a shop.

27.192 Past convictions should, in my view, be disclosed at the first-tier regardless of the sanction, if any, imposed by the GMC. The period for which this information should stay at first-tier level should, I suggest, follow the periods laid down in the Rehabilitation of Offenders Act 1974.

27.193 In respect of any past FTP history or convictions, when the period of first tier disclosure has expired, a note should appear on the doctor's website entry to the effect that there is further information about the doctor which can be obtained (in effect at the second tier) by telephoning the GMC number. Any person seeking first-tier disclosure by telephone should be told if there is any further information which may be disclosed at the second tier.

The Second Tier

27.194 Disclosure at the second tier should be to people who make a specific request for information about a doctor's past FTP history. They should not be asked to identify themselves; nor should they be required to justify their request. The information should be

imparted without more ado to anyone seeking either further or full information about the doctor's FTP history. I do hope that the GMC will instruct its staff to be forthcoming with information rather than waiting for specific questions to be asked. This must not be a game of 'Twenty Questions'.

27.195 At its meeting in July 2004, the GMC accepted as a general principle that it must provide all information about a doctor that has at any time been in the public domain. It has not yet decided what to do about warnings after the expiry of five years. I think that the GMC's decisions were sensible. I quite understand the concerns of Council members that some items of past information should, for reasons of fairness, be put into context. This applies particularly to cases in which the doctor has been found not guilty of an allegation of misconduct but the fact that s/he was charged is in the public domain. It seems to me obvious that information that has been in the public domain should be provided by the GMC for as long as the doctor remains on the register.

27.196 The effect of the second tier would be that any person who was contemplating joining the list of a particular GP or who knew that s/he was about to be referred to a particular consultant would be able to find out what s/he needed to know to make an informed choice, at least so far as any history with the GMC was concerned. For example, if this system had been in operation when Shipman was in practice, anybody thinking of joining his list who had looked him up on the website would have seen that his current registration status was full and unrestricted and that he had no recent disciplinary history. However, they would have been alerted to the fact that there was something more to be known about him and would, by telephoning the GMC, have been able to find out about his convictions in 1976. I think that this arrangement provides a reasonable balance between the interests of the doctor in being able to put the past behind him/her (which would be difficult if full information remained on the website indefinitely) and the right of the public and patients to find out, if they are prepared to make a telephone call, everything that has at one time been in the public domain.

The Third Tier

27.197 The GMC has identified a number of types of information that should be disclosed only to a limited class of persons who have a need to know about it in the public interest. These classes of information must, I think, be matters that have never been in the public domain. I think that this approach is entirely reasonable. I would call disclosure of this confidential information to a limited class of persons third-tier disclosure. If my recommendations for a central database were accepted, it would be appropriate for the GMC to 'flag' the names of doctors about whom confidential information was held.

Information That Ought to Be Given to Patients of a Practice

27.198 So far, I have discussed only information that should be made available to any member of the public who wishes to obtain it. However, there are some situations in which, in my view, a positive duty to impart information arises. I mentioned above the action taken by a GP practice which had taken on, for supervision and remediation, a doctor previously convicted of manslaughter. The action taken was, in my view, exemplary. The

circumstances were rather unusual and it might be said that it would obviously have been wrong to allow the doctor into the practice without informing the patients. However, in my view, the good practice adopted in that case should apply to all cases in which a doctor is subject to conditions on his/her practice. It should also, I think, apply when a doctor has resumed practice following a period of suspension or erasure. In my view, the practice should send a letter of explanation to all patients. The draft should be approved by the PCT. Patients should have the opportunity to refuse to be treated by a doctor who is subject to conditions or has previously been suspended or erased. However, the experience of the practice to which I have referred suggests that they will not necessarily do so.

27.199 It is not part of my remit to make recommendations in respect of doctors working in hospitals. However, having read of the circumstances that arose in the case of Sadler v General Medical Council[1], to which I referred in Chapter 24, I will permit myself to observe that any patient who is to be operated on by a doctor who is subject to conditions should, in my view, be told about them and should be told what arrangements are proposed for the supervision of the operation. This information should not be imparted at a late stage when the patient is asked to sign the consent form. It should be given at a time when the patient can, without throwing all his/her personal arrangements into chaos, exercise a choice not to consent to that doctor carrying out the operation.

Proposals for Change Affecting the General Medical Council

The Fitness to Practise Procedures

27.200 In Chapter 25, I explained why it had been necessary for the Inquiry to examine the GMC's proposals for its new FTP procedures in some detail. I said that my examination of the old FTP procedures had identified a number of shortcomings and that it was important to find out whether those shortcomings would be remedied under the new procedures. In the course of Chapter 25, I reported my view that some of the defects of the old procedures had been remedied but that, in other important respects, the old shortcomings were to be perpetuated. I also found that some changes had been retrograde. I have already made a number of suggestions as to how the new FTP procedures might be improved. I have made these detailed recommendations because the Inquiry's Terms of Reference require me to make such recommendations as I consider necessary for the protection of patients in future and because I do not intend to recommend that the GMC should be deprived of its FTP function. In this section of this Chapter, I shall draw together those recommendations. In some cases, I shall only refer back to the passage at which the original recommendation was made.

The General Medical Council's Role in the Wider Regulatory Framework

27.201 In Chapter 18, I referred to the ambiguity in the GMC's perception of its role in the wider regulatory framework. In the past, it encouraged the public to see it as a repository for all complaints about doctors but did not have the resources to investigate all the complaints

[1] [2003] 1 WLR 2259.

it received. The result was that it sought to divest itself of many complaints that had not already been investigated by other bodies, often without even considering whether they raised a question of SPM. In effect, it was behaving as if it were a secondary referral body rather than an initial recipient of complaints. It does appear that this problem may have been resolved. First, the GMC has taken on a substantial number of investigators and should be in a position to deal with all allegations that it receives which fall within its jurisdiction. Second, as I have said at paragraphs 25.118–25.119, it appears that the GMC will no longer close cases, and advise complainants that they should pursue their complaints through local complaints procedures, before it has decided whether or not the allegation falls within its jurisdiction. It will give advice to that effect only after it has decided that the case does not fall within its jurisdiction. If that is indeed the case, it will be satisfactory.

27.202 It is inevitable that there will be complaints that are directed to the wrong destination. No doubt the GMC will continue to receive some that do not fall within its jurisdiction and other organisations will receive complaints and concerns which ought to be directed to the GMC. As I have said, the GMC has suggested that there should be a 'single portal' to assist persons who wish to make a complaint or raise a concern in directing that complaint or concern to the correct complaints handling body. This seems to be a good idea and, as I have already said, the Healthcare Commission is considering various options for the provision of such a service. However, the number of misdirected complaints would, I think, be reduced if the GMC were to ensure that its publications contained accurate and readily understandable guidance as to the types of case that do and do not fall within its remit.

27.203 The GMC has said that, where a case is referred to it by a person acting on behalf of a public body (usually an employer or a PCO), it may suggest that that body investigates the allegation before the GMC takes over the case. This may be done even though the allegation does, or might, fall within the GMC's jurisdiction. However, I presume that this procedure would not be followed if the case required urgent interim action by the GMC. This procedure is acceptable provided that the other body, the employer or PCO, is content to investigate it and has the expertise and resources to do so and provided also that the GMC does not lose sight of the case. The GMC has said that it recognises the importance of bringing such cases back for further consideration after they have been investigated. In fact, the GMC should be able to use its influence with the PCT or NHS body to ensure that the investigation progresses satisfactorily. As these procedures will be new to GMC staff, I recommend that their operation should be audited, especially in the early days. As I understand it, it is not the GMC's intention that this procedure should be applied to allegations made by private individuals. That would not be acceptable in my view.

Separation of Functions

27.204 In Chapter 25, I reported that, despite the GMC having recognised the need for separation of the investigation and adjudication functions, both the investigation and the adjudication stages of the new FTP procedures are still to be under the control of the GMC.

27.205 At the investigation stage, there is a casework function, which will be undertaken mainly by members of the GMC staff and case examiners. The Investigation Committee (IC) will

also undertake some casework in cases where the case examiners disagree and in cases where there is an oral hearing to decide whether to issue a warning. The IC's casework will be carried out by panels. At the moment, the Rules allow GMC members (as well as associates) to sit on IC panels. However, the GMC has told the Inquiry that the 'operational intention' is that they should not. If it is indeed intended that membership of IC panels should be limited to non-members of the GMC, the Rules should be amended to reflect that. There are also governance functions within the investigation stage. These include the setting of standards, criteria and thresholds, general supervision of the investigation stage and audit of the casework done by members of staff and case examiners and of decisions taken by IC panels. It was originally intended that the IC would undertake all these governance functions, in addition to its casework function. Recently, however, it has been recognised by some within the GMC that this would not be appropriate. In the immediate future, the governance functions relating to the investigation stage will be undertaken by the Fitness to Practise Committee. As I explained in Chapter 25, there is uncertainty about the future role of the IC. Whatever the eventual outcome, in my view, there must be complete separation of the casework function and governance function. It is inappropriate for one committee to have complete control of all aspects of the investigation stage.

27.206 The adjudication stage presents much greater problems of separation of function. The GMC initially considered hiving off the adjudication stage altogether but decided against it, preferring to keep both adjudication and investigation within the GMC and intending to introduce a measure of separation by using only non-members of the GMC for its adjudication stage casework. However, it appears to me that there is no real separation at all. As I have observed, under the present proposals, the GMC will select the FTP panellists (both for inclusion on the list of panellists and for inclusion on a panel in an individual case), train them, provide them with guidance, audit their decisions, appraise their work, and call them in for discussions about decisions with which it disagrees; it will also have the power to dismiss them if dissatisfied. The GMC is also proposing that, in future, it will or might indicate to a doctor, in advance of a hearing, the outcome that the GMC will seek in his/her case. If done, that might well have the effect of restricting FTP panels to the sanction sought by the GMC. Even without such a restricting indication, panellists will have very little independence. The GMC will also select the legal assessors and any specialist advisers or assessors who may be required. In 2000, the GMC rightly recognised that, under the Human Rights Act 1998, doctors were entitled to a fair and public hearing by an independent and impartial tribunal. I think that, in the future, it might well be alleged against the GMC that its FTP panels are not independent of the 'prosecuting' authority. Whether that allegation were to come from a dissatisfied doctor or a dissatisfied complainant does not really matter. The process would be much more satisfactory from the points of view of both patient protection and fairness to doctors if separation were to be achieved.

27.207 I realise that a great deal of effort has gone into the selection and training of the FTP panellists but I regret to say that I do not think the present arrangements are satisfactory. I must recommend that some mechanism be found for the appointment, training and management of both lay and medically qualified FTP panellists by a body that is independent of the GMC. That body would also have to provide administrative support for

hearings. I recommend that consideration should be given to the idea of appointing panellists who could sit full-time or nearly full-time on disciplinary or FTP panels for all healthcare regulators. They would acquire far greater experience than GMC panellists currently can. If this idea were adopted, it would be possible to have full-time legally qualified chairmen. The GMC should also divest itself of the right to appoint legal assessors; in any event, if legally qualified chairmen were to be used, legal assessors would not be required. Legally qualified chairmen could also undertake case management work. In any event, it would not be appropriate for the GMC to appoint case managers.

27.208 Precisely how this separation should be achieved, I cannot say. I have heard no evidence about the way in which other regulatory bodies arrange matters. It occurs to me that the other healthcare regulators may also have a need for independent panellists. It may be possible to set up a joint facility. I had thought that the Council for the Regulation of Healthcare Professionals, now known as the Council for Healthcare Regulatory Excellence (CRHP/CHRE), might be able to undertake this function but, on reflection, I do not think that it could. I think that there would be a conflict between its role of appealing unduly lenient decisions and a responsibility for appointment of the panels whose decisions it might wish to appeal. Having ruled the CRHP/CHRE out, I am unsure which other existing body could undertake the task. However, I consider that some way must be found because this is the only means by which the GMC can avoid the charge of being prosecutor and judge in the same case.

27.209 Hiving off the adjudication function would not deprive the GMC of all interest in the adjudication process. The GMC would still be involved in the development of standards, criteria and thresholds for all stages of the process, including the adjudication stage. It would also be able to monitor the outcomes of cases and thereby to inform itself of the need for any adjustment in the standards, criteria and thresholds. At paragraphs 27.213–27.230 below, I shall discuss the possible methods for the development of standards, criteria and thresholds.

27.210 If adjudication were to be hived off, as I have recommended, some of the recommendations that follow will be irrelevant. I shall make them nonetheless, in the event that this is not done.

The Statutory Tests

27.211 At paragraphs 25.41–25.69, I explained why I consider that the statutory test for the adjudication stage and the GMC's formulation of the investigation stage test will both give rise to difficulties of operation. I do not propose to repeat those reasons here or to restate what I think should be done to alleviate those difficulties. I recommend that the tests I have suggested be adopted.

A New Route to Impairment of Fitness to Practise

27.212 At paragraphs 25.70–25.71, I have explained why I consider that it would be desirable for section 35C of the Medical Act 1983 (the 1983 Act) to be amended to add a further route

by which there might be a finding of impairment of fitness to practise. This would be 'deficient clinical practice' and would be designed to cover those cases which involve, say, one or two incidents of negligence or poor clinical practice which do not amount to misconduct and which also do not show the pattern of poor clinical performance which is necessary in order to trigger a performance assessment. I recommend that that change should be made on the next occasion when the 1983 Act is amended.

Standards, Criteria and Thresholds

The Need

27.213 The need for the setting of standards, criteria and thresholds to be applied by those taking decisions at each stage of the GMC's FTP procedures runs as a thread through almost all of the last ten Chapters of this Report. Indeed, as I have said earlier in this Chapter, the need for agreed thresholds for the standards of professional conduct and medical care goes beyond the GMC. Patients should know what they are entitled to expect from the healthcare system. Those are the standards by which patient complaints should be judged. People working in healthcare management – and I include those working in PCOs – need standards by which they can decide whether they should take disciplinary action against a doctor or invoke their list management powers. At the moment, such managers have to make up their own minds about whether the conduct or practice under consideration is acceptable or not. They have to make up their own minds whether unacceptable conduct or practice is serious enough to justify a report to the GMC.

27.214 Elsewhere in this Report, I have referred to the occasions on which the GMC has been urged to formulate standards, criteria and thresholds for use by its decision-makers. In 1996, 2000 and 2003, Professor Isobel Allen, Emeritus Professor of Health and Social Policy, University of Westminster Policy Studies Institute, urged the GMC to produce agreed standards, criteria and thresholds by which decision-makers could determine whether a set of facts amounted to SPM. Until recently, the response of the GMC has been that, at least until 2000, all decisions about SPM or SDP were being taken by highly qualified and experienced members of the GMC. There was no need for them to have standards, criteria or thresholds because they could recognise SPM and SDP when they saw them. They were also able to apply the appropriate tests at the preliminary stages of the FTP procedures. I cannot accept that that was so. In Chapter 17, I described the difficulties that had arisen in defining SPM. I reported that Sir Donald Irvine, who had very long experience as a member of the GMC, culminating in six years as its President, had said that disputes about whether a particular set of facts amounted to SPM gave rise to much 'heat' and 'emotion'. In addition, the need for standards, criteria and thresholds has been underlined by the many occasions on which, in this Report, I have drawn attention to inconsistency in decision-making at every stage of the old FTP procedures.

27.215 SPM and SDP as concepts have now disappeared, but I am convinced that the concept of 'impairment of fitness to practise' will be even more difficult to define and recognise. I accept that most doctors may believe themselves to be able to recognise impairment but, in doing so, they are applying their own personal standards. They are not applying agreed standards and, unless standards, criteria and thresholds can be agreed,

decisions on 'impairment of fitness to practise' will be inconsistent, as decisions on SPM were in the past. There will be no diminution in the 'heat' and 'emotion' of the debate or in inconsistency of outcome unless and until there are some agreed standards.

27.216 The GMC also argues that it provides standards and criteria in its publication 'Good Medical Practice'. Its stance is that departures from those standards might result in referral into the FTP procedures, with the possibility of action on registration. Yet it is clear that not every departure from the standards in 'Good Medical Practice' will result in referral into those procedures. The problem is that no one knows how serious a departure from 'Good Medical Practice' has to be before disciplinary action will be taken or action on registration will follow.

27.217 Another objection raised by the GMC to the suggestion that it should prepare agreed standards, criteria and thresholds for approaching decisions about SPM was that the process of doing so was difficult to the point of impossibility. SPM, the GMC argued (and I paraphrase) was capable of covering a very wide range of conduct and practice. It was not possible to devise a threshold for every single circumstance in which SPM might be found. I agree that the task in respect of SPM in the past would not have been an easy one. The task for the future, in respect of 'an impairment of fitness to practise' and 'an impairment of fitness to practise to a degree justifying action on registration' will be even more difficult. But just because it is difficult does not mean that it must not be tackled. The new FTP procedures have now come into operation and decision-makers will have very little help in deciding on which side of the various 'lines' a case will fall. The GMC has produced some draft guidance for case examiners and panellists at the investigation stage and for panellists at the adjudication stage. This guidance is in many respects sensible and helpful; it identifies relevant factors for decision-makers to take into account. But it does not go far enough; it does not help them to decide where to draw the line. They are still left to apply their own personal standards.

27.218 At the Inquiry hearings in December 2003, Sir Graeme Catto and Mr Scott said that it was the GMC's intention to provide a series of 'case reports' which would contain examples of circumstances in which SPM had or had not been found in the past. It was hoped that these would prove useful for decision-makers in the future. As I reported in Chapter 21, nine months later, five very brief case studies were published. These are so brief as to be 'unfit for purpose'. In addition, two of the five appear to be mutually inconsistent.

27.219 In Chapter 25, I have suggested tests for the investigation and adjudication stages which would, if adopted, make the task of decision-makers easier. These tests would help decision-makers to analyse the allegation or the established facts to see whether what is alleged would, if proved or admitted, amount to impairment of fitness to practise. However, I do not suggest that the new tests will remove the need for standards, criteria and thresholds. If the existing guidance, the case studies and my proposed tests are all that is to be provided (and these last may be rejected by the GMC), I foresee real problems of inconsistency at each stage of the process because individuals will be applying their own personal standards.

27.220 In the area of guidance on the imposition of sanctions, the GMC has made some progress, in that it has published Indicative Sanctions Guidance (ISG). This is helpful; it provides a

general idea of what kind of sanction is appropriate where certain features are present in a case. The guidance is particularly helpful where it descends into the detail of how to approach a particular class of case. However, although the ISG is helpful, in my view, panellists need more help. I recognise that there is now a means by which any decision on sanction can be appealed, either because it is too severe or because it is unduly lenient. However, I think the GMC would agree that it would not wish to rely upon the appeal process in order to establish a proper framework for the imposition of sanctions. I am sure that it would agree that it would be preferable if the decisions were right in the first place.

What Should Be Done?

27.221 I have said enough about the need for the development of agreed standards, criteria and thresholds. I accept that the task of development is not easy. I have observed earlier in this Report that it is easier to criticise the work of others than to propose a better way. I do wish to be constructive. It appears to me that there are two possible ways of approaching the problem of standard and threshold setting.

27.222 One method would involve analysing a number of sets of circumstances (topics) that might be expected to arise in FTP procedures and envisaging gradations of increasingly serious examples of conduct or practice within that topic and deciding where the thresholds should lie. I did not know whether this idea would be feasible. Accordingly, the Inquiry invited Professor Baker to produce a paper setting out his ideas about how the task of analysing topics and setting standards, criteria and thresholds might be tackled. His work has now been published on the Inquiry website. I shall summarise his suggestions as briefly as I can.

Professor Baker's Paper

27.223 Professor Baker envisages that research would have to be done into the likelihood that certain features in a particular case are valid indicators of a doctor's fitness to practise. Conduct of the research would require the collection of evidence from a wide variety of sources. The starting point would have to be actual cases in which decisions had been made, either by the GMC or by NHS trusts, about allegations of misconduct, etc. There would have to be systematic follow-up of such cases to find evidence of the likelihood of further complaints or problems associated with particular categories of complaints. There would also have to be comparisons between doctors with selected characteristics who have or have not had complaints made about them. In addition to evidence derived from actual cases, Professor Baker suggests that further information would also be required about public expectations and about the ethical codes of healthcare professionals, including international codes. When all this information and evidence has been assembled, some means would have to be found of combining it so as to produce a set of standards and criteria suitable for use in medical regulation. That process would involve the making of value judgements. Accordingly, in Professor Baker's view, the public and healthcare managers should be involved, as well as members of the medical profession.

27.224 Professor Baker then considers a number of options by which this process might be undertaken. He discusses the advantages and disadvantages of the various methods,

including their validity, feasibility and cost. He considers options for the scope of the standards and criteria, for example, whether the scope should be limited to the issues covered by 'Good Medical Practice' or whether it should cover issues raised in wider consultation within and outside the GMC. Another set of options relates to the classes of people who might be involved in the standard-setting process. He assumes that the GMC will be at the heart of the process but considers the advantages and disadvantages of involving other groups. He examines various options for discussion and decision-making in the standard-setting groups. He considers different options for the testing and updating of the standards and criteria that would result from the initial standard-setting process. Professor Baker does not say which of these various options should be adopted, although he expresses a preference for processes which involve a wide range of consultation, as he considers that the results would be more likely to attract and retain public confidence.

27.225 Finally, Professor Baker gives some hypothetical examples of the way in which standards might be set on various specific topics, all taken from the principles set out in 'Good Medical Practice'. These include establishing a clinical history, taking suitable and prompt action, keeping clear records, taking part in audit, dealing with patients who decline to take part in teaching or research, raising concerns about fellow healthcare professionals and the duty of honesty in record keeping, document preparation and certification. The resulting hypothetical standards do not demonstrate actual thresholds but they do produce categories of conduct which are to be regarded as 'acceptable', 'unacceptable' and 'seriously unacceptable'. It seems to me that, if standards of this kind could be produced for a large number of topics, the task of decision-makers both within and without the GMC would be made very much easier.

An Alternative Approach: the Use of Case Summaries

27.226 Another possible approach would be to use a collection of case summaries, in which decisions that are agreed to be 'correct' could be collated into topic groups and published. Such collections of cases would not seek to define thresholds but would, rather, seek to illustrate where the threshold had been (correctly) set on other occasions. It would be necessary to have examples that fall on either side of any dividing line so that the decision-maker is able to 'get his/her eye in' as to which side of the line the particular case under consideration should fall. This is a process which is used extensively in legal work. For example, there exist two encyclopaedias on employment law, containing a large number of case summaries from which practitioners and decision-makers can develop a 'feel' for whether a dismissal has been fair or unfair. There is a book containing cases about road traffic accidents; the decision-maker can 'get his/her eye in' about whether, in a particular set of circumstances, a driver, cyclist or pedestrian has been negligent. There are encyclopaedias on sentencing in criminal cases and on awards of damages in personal injury cases. None of these case collections seeks to provide the 'right answer' in any particular case because the facts of all cases are different and because there must be an element of discretion for the decision-maker. But they do enable practitioners and decision-makers to 'get their eye in'.

27.227 Because it is important that the GMC decision-makers should have guidance on thresholds for use at both the investigation and the adjudication stages, the preparation

of the case summaries would entail the examination of quite a large number of cases which had come into the FTP procedures. For a start, all the cases entering the procedures during a three-month period might be examined. All would be anonymised and the available information summarised using a standard template so that different cases could be readily compared one with another. After the investigation stage decision had been taken, all cases would be considered by a group of assessors who would decide whether, in their view, the decision taken was 'correct'. Cases with 'incorrect' decisions would be discarded; cases with 'correct' decisions would be used as guidance on the investigation stage test. Cases which had gone before FTP panels would also be considered by the group of assessors. If a decision on 'impairment of fitness to practise' and/or 'impairment of fitness to practise to a degree justifying action on registration' was considered 'incorrect', the case would be discarded. Those cases with 'correct' decisions would be used as guidance. The assessment group would also consider any sanctions imposed or decisions not to impose a sanction. Once again, 'incorrect' or inappropriate decisions would be discarded and 'correct ones' would be kept as guidance. As more cases were collected, it would be possible to divide them into groups and subgroups relating to different types of commonly occurring case. For example, it would not be long before there were groups of cases involving the abuse of drugs, dishonesty, indecency and improper relationships with patients. In due course, there would be groups of cases of many different types, including health and performance cases.

27.228 If this approach were to be adopted, the assessment group should, in my view, comprise some doctors, other healthcare professionals, healthcare managers and some lay people from a variety of backgrounds. In Chapter 21, I mentioned the Sentencing Advisory Panel, which advises the Court of Appeal (Criminal Division) on sentencing policy. Some of its members are judges, barristers and solicitors but there is also a strong non-legal membership. I have in mind a comparable mixture of medical and lay members. I would expect the GMC to have a major voice within the group but the objective would be to reach a consensus acceptable to both the medical profession and the public.

The Way Forward

27.229 It is not my intention to recommend either the use of Professor Baker's suggested method or the alternative method of collecting case summaries. It seems to me that the advantage of Professor Baker's method is that the results would be soundly based in scientific evidence. The major disadvantage is that I think it would take a long time to produce results that could be used by decision-makers. The advantage of the case summary method is that it would be easier to set up and results could be expected in a shorter time. The results would be based on actual cases and would therefore soon provide guidance on the kinds of case that crop up regularly. The GMC Presenting Officers and the doctors' representatives would soon become familiar with the published case studies and would be able to draw a FTP panel's attention to any that were comparable to the case under consideration. Panellists would not be expected to become familiar with all the case summaries. Such case summaries would also be useful for the courts when dealing with appeals. The GMC might have other ideas about how this work should be done. Yet more ideas might come from other quarters. I hope that there will be a debate about the best

way forward. However, it is vital that this problem must not be shelved. Some way must be found – soon – to provide guidance on standards, criteria and thresholds so that decision-makers will be able to reach reasonably consistent decisions at both the investigation and the adjudication stages.

27.230 It appears to me that, whatever method of standard setting is to be adopted, a panel or group of people will be required. This is essential if the public is to have confidence in the results. It seems to me that the CRHP/CHRE could play an important role here. Indeed, it may be that it would welcome the opportunity to facilitate the setting of standards across the whole field of healthcare regulation. Many of the issues that arise in GMC cases, such as dishonesty, indecency, breach of confidentiality and failure to obtain proper informed consent, must arise in other contexts. I recommend that the CRHP/CHRE be invited to set up a panel of professional and lay people, similar in nature to the Sentencing Advisory Panel, which would be the vehicle for whatever method of standard setting is eventually adopted. It could remain in existence and review standards periodically.

Standards in Relation to Performance Procedures

27.231 In the passage above, I have discussed the need for the setting of standards in respect of many aspects of misconduct and clinical practice. In the past, the problem has been lack of agreement as to what amounted to SPM. However, a different problem arose in respect of the GMC's performance procedures. There, a standard had been set. The GMC performance assessment tools (for GPs) are calibrated against the standard of summative assessment, the process used to assess whether a doctor's competence and performance are adequate for him/her to be admitted to general practice. The problem is that, in the past, panels of the Committee on Professional Performance (CPP) appear on occasion to have applied their own personal standards (rather than the standard at which the performance assessment tools are set) when considering whether a doctor's performance was seriously deficient. I have mentioned more than once in this Report the fact that the standards applied within the GMC's performance procedures have been very low. I shall not quote the evidence relating to this again. There is no indication of an intention to raise them under the new FTP procedures. This low standard will, to a very large extent, underpin revalidation. In my view, for reasons of patient protection, there is an urgent need for this standard to be raised. There can be no justification for judging the performance of an experienced GP by a standard lower than the equivalent of the standard set for admission to general practice. I do not know how this problem should be solved but I recommend that the GMC should give urgent attention to it. Unless this is done, patients will be left at risk and revalidation will be without value.

The Investigation Stage

The Preliminary Sift: the Test for Jurisdiction

27.232 At paragraph 25.115, I have expressed the view that the rule which sets out the test to be applied by the Registrar (or by a member of the GMC staff, exercising his legal powers) on receipt of an allegation should be amended to give greater clarity. I have suggested an appropriate wording. It may be that there is no confusion within the GMC about the

meaning of the rule. However, the meaning of the words should be clear to all. There is a need for decisions taken at this stage to be audited to ensure that the test is being correctly applied. I also recommend that criminal cases in which a doctor has been conditionally discharged should be treated as convictions.

Advising the Makers of an Allegation to Use Local Complaints Procedures

27.233 At paragraphs 25.116–25.120, I discussed the practice (which, so far as I know, was followed until the termination of the old FTP procedures) of closing cases in which local complaints procedures had not been exhausted, without considering whether they raised a question of SPM. I have said that, in my view, this practice was not only unlawful but also not in the interests of patient protection. I had hoped to see a clear and unequivocal statement that the practice had been abandoned under the new procedures. No clear statement has been made. As I have said, I have examined the Rules, the draft Guidance, the November 2004 draft Investigation Manual and the initial processing and assessment form. The only reference to the giving of advice about the use of local complaints procedures appears in a context which suggests that such advice will be given only in cases in which the GMC has already decided that the case does not fall within its remit. I would feel completely reassured by that state of affairs, were it not for the fact that there was no reference to this practice under the old Rules. The practice went on 'outside the Rules' and was followed in hundreds of cases every year. I want to give the GMC the benefit of the doubt. I want to conclude that the GMC has indeed abandoned this bad practice under the new FTP procedures. I do not feel that, at present, I can do so with confidence. It would have been quite possible for the GMC to put an immediate stop to the practice at any stage; no legislation would have been required. I hope that this practice has stopped with effect from 1st November 2004. However, there is a danger that the practice will linger on because staff are so used to it. I recommend that there should be an audit of the reasons why cases are closed and of cases where consideration by the GMC is deferred. That audit should take place quite frequently.

Preliminary Discussions and Disclosure to Employers and Primary Care Organisations

27.234 At paragraphs 25.122–25.126, I discussed the practice, introduced in May 2004, whereby the GMC communicates informally with employers and PCOs before deciding what action, if any, should be taken in response to an allegation. Such communications should be an important source of information to the GMC. The idea of adopting this procedure was discussed in evidence at the Inquiry hearing when Mr Scott said that the GMC would consider it. He has since reported to Council that the practice is yielding useful information. I have noted that it has been reported that some of the medical defence organisations have objected to this new procedure but, as the November 2004 draft Investigation Manual provides for staff to communicate in this way, I assume that the GMC has decided that it should continue. I recommend that the Rules be amended to make formal provision for this practice, and to give the GMC power to require from the doctor the necessary details to enable it to make such a communication.

The Power to Direct Investigations

27.235 I recommend that case examiners should have the power to direct that particular investigations should be undertaken. They would have had that power under the 2003 draft Rules. Under the November 2004 Rules, the power to direct investigations lies solely with the Registrar, which, in practice, means that it lies with the GMC staff. I also recommend that IC panels hearing cases where the case examiners have disagreed should have the power to direct investigations.

Case Examiners

27.236 I recommend that case examiners, who are not lawyers, should be given advice about two matters. They should not take into account mitigation advanced by or on behalf of the doctor. It is not relevant to their decision at the investigation stage: see paragraph 25.163. Also, they should be advised to consult a lawyer if they are in any doubt as to whether there is a realistic prospect of proving the allegation: see paragraph 25.169.

Performance and Health Assessments

27.237 The November 2004 Rules provide that the Registrar may direct a performance and/or health assessment during the investigation stage. I recommend that case examiners and the IC should also have that power. I do not know what the policy will be for directing such assessments. I know that a full performance assessment is expensive and time-consuming. The Inquiry heard evidence that the GMC was considering the possibility of devising an abridged assessment and there were also suggestions that the work of assessment might be undertaken on a modular basis or that it might be 'outsourced'. I do not know what developments there have been in these respects. In my view, it would be highly desirable for there to be an abridged form of assessment which could be used as a screening tool to detect whether there is a problem with the doctor's performance, rather than seeking to measure the extent of it, as the full assessment does. I would have thought that an adaptation of the Professional and Linguistic Assessment Board test, or possibly a modified version of Phase II of the current performance assessment, might suffice. In my view, such an abridged assessment should be ordered in any case in which an allegation is made which potentially calls into question the doctor's clinical practice, either because there are one or more allegations of bad clinical practice (such as perhaps a prescribing error) or because there are allegations that raise more general issues of poor performance. If the work has not already been undertaken, I recommend that the GMC should develop an abridged performance assessment and should use it as a screening tool. The GMC will, of course, also need a full performance assessment tool, on which to rely as evidence to place before a FTP panel. In order to avoid multiple assessments, I also recommend that the GMC should investigate the development of a modular assessment: see paragraphs 24.200–24.205.

27.238 As I explained at paragraphs 25.240–25.241, the draft Rules published in May 2004 would have provided that, on receipt of the report of an assessment of a doctor's performance, the Registrar should send a copy to the doctor's employer or PCO. The effect of this would have been to ensure that those with responsibility for clinical governance were fully aware

of any problems of performance which might affect the doctor's fitness to practise and which thus might have an impact on the safety of patients. However, the provision does not appear in the November 2004 Rules and it appears that it has been dropped.

27.239 I do not see how local NHS bodies can properly discharge their clinical governance obligations if they do not have access to this kind of information about the doctors for whom they are responsible. I therefore recommend that the provision should be reinstated as soon as possible.

Criteria for Letters of Advice

27.240 At paragraphs 25.174–25.180, I observed that the circumstances in which letters of advice were to be sent to doctors under the new procedures had remained as obscure as they were under the old procedures. The GMC recognised the need for greater transparency in this respect but has not made any changes to improve the position. I recommend that criteria for the sending of letters of advice should now be prepared and the power to send letters of advice should be incorporated into the Rules. The need for transparency is related to patient safety. If there are no clear criteria for the sending of letters of advice, there is a danger that this procedure will be adopted in cases which should be dealt with more severely; in other words, it may be used as a 'soft option'. The use of letters of advice should be audited to ensure that this does not happen.

The Issuing of Warnings at the Investigation Stage

27.241 At paragraphs 25.181–25.196 and 25.204–25.218, I have discussed the difficulties which I think will arise in connection with the GMC's proposals to issue warnings at the investigation stage. I fear that the proposed procedures for a 'summary' oral hearing will be almost unworkable. I recommend that the GMC should reconsider these proposals in the light of my observations. I think that, in most cases in which a warning might be given at the investigation stage, it would be more appropriate for there to be a full hearing before a FTP panel which should decide whether the doctor's fitness to practise is impaired. In the event that the GMC decides to proceed with its proposals as planned, I consider it important that the issuing of warnings by case examiners and the IC should regularly be audited. In particular, the question of whether it would have been more appropriate for the case to proceed to a FTP panel should be considered. There should also be audit of those cases in which an invitation is issued to a doctor to make written representations about the giving of a warning but where, on receipt of the representations, no further action is taken after receipt of the doctor's representations.

The Procedure for Cancellation

27.242 At paragraphs 25.243–25.250, I reported on the GMC's proposals for the cancellation of cases which have already been referred to a FTP panel. These provisions lack transparency and are open to abuse. I recommend that they be changed in the way that I have suggested, so that decisions on cancellation should be taken by panels of the IC and the reasons for the cancellation formally recorded. Both applications to cancel and cancellation decisions must be monitored and audited, and the reasons for the

applications and decisions should be scrutinised with a view to steps being taken to minimise the number of cases in which referrals are subsequently cancelled. The number of cancellations and the reasons should be published in the GMC's annual report.

Consensual Procedures

27.243 At paragraphs 25.251–25.253, I have sounded a note of caution about the GMC's intention to introduce consensual procedures for cases other than those raising problems of adverse health or deficient performance. There is a danger that such procedures might lead to the 'fudging' of factual issues. Such procedures could be open to abuse, as I explained in Chapter 25. I recommend that, if the GMC pursues its present intention to extend consensual procedures to all categories of cases, the disposal of such cases should take place in public at the adjudication stage and not in private as part of the investigation stage.

Revival of Allegations

27.244 At paragraphs 25.254–25.256 I mentioned that the practice of 'reviving' closed cases was to be discontinued under the new procedures. I recommend that there should now be proper provision, enshrined in the Rules, whereby closed allegations can be revived. I have suggested that the usual 'cut-off' period should be five years but that it should be possible, in exceptional circumstances and in the interests of patient protection, to reopen a case at any time.

Review of Investigation Stage Decisions

27.245 At paragraphs 25.257–25.264, I have welcomed the GMC's proposal to introduce a review of investigation stage decisions, albeit only in limited circumstances. However, I recommend that the review should be carried out not by the President of the GMC, as is currently proposed, but by an independent external commissioner, appointed for the purpose. The commissioner could be appointed by the SoS. I also recommend that the right to a review should be extended to decisions of members of staff to reject an allegation rather than refer it to a case examiner.

Voluntary Undertakings in Cases with a Health Element

27.246 In Chapter 25, I have expressed a number of concerns about the way in which the giving of voluntary undertakings in cases with a health element will operate in future. First, at paragraphs 25.223 and 25.232, I lament the decision to remove responsibility for the operation of many aspects of the voluntary procedures from case examiners to GMC staff, who are not medically qualified. Under the 2003 draft Rules, it appeared that the voluntary procedures would be operated very much as they had been under the old health procedures, with an appropriately medically qualified case examiner taking over all the responsibilities formerly held by the health screeners. Those old arrangements were working well and it seems to me wrong to change them without good reason. I recommend that the GMC reverts to its original intention in this respect and employs one or two case examiners suitably qualified to carry out the former role of the health screeners.

I recommend that the November 2004 Rules should be amended so as to provide that the arrangements for the obtaining and consideration of health assessments and for the management and supervision of doctors who are the subject of voluntary undertakings relating to health should be directed by a medically qualified case examiner. If a case is to be closed on the basis of a health assessment, the decision should be taken by two case examiners, one medically qualified and one lay and, if they disagree, by an IC panel.

27.247 If that recommendation were to be accepted, my only other recommendations in respect of cases involving a health element concern various issues arising out of supervision and the cessation of supervision. As these issues arise both in cases which will be dealt with by way of voluntary undertakings and in cases where conditions are imposed by a FTP panel, I shall deal with them later in this Chapter.

Voluntary Undertakings in Cases with a Performance Element

27.248 At paragraphs 25.238–25.239, I expressed my regret that most of the functions that used to be performed by medically qualified performance case co-ordinators will now be carried out by GMC staff, who are not medically qualified, rather than by medically qualified case examiners. Under the 2003 draft Rules, the functions of case co-ordinators were to be transferred to case examiners but, in 2004, most of them were transferred to members of staff. In Chapter 25, I have explained why I regard that change as retrograde. I recommend that the November 2004 Rules should be amended so as to provide that the arrangements for the obtaining and consideration of performance assessments and for the management and supervision of doctors who are the subject of voluntary undertakings relating to performance should be directed by a medically qualified case examiner, who should fulfil the functions previously carried out by a performance case co-ordinator. If a case is to be closed on the basis of a performance assessment, the decision should be taken by two case examiners, one medically qualified and one lay and, if they disagree, by an IC panel.

27.249 In evidence, the Inquiry was told that, in the future, the GMC intended to concentrate on regulation and not to become involved in the long-term remediation of doctors whose performance was deficient. I am not sure whether that remains the GMC's intention. It appeared to me to be an appropriate change of approach.

The Adjudication Stage

Fitness to Practise Panels and Procedures at Panel Hearings

27.250 I recommend that there should be an explicit power in the Rules to allow the GMC to undertake any further investigations it thinks necessary after a case has been referred to a FTP panel and before the hearing. Such a power may be implicit but the position should be clear.

27.251 I have already recommended that the GMC should think again about its decision to retain control of the adjudication stage and should divest itself of the right to appoint, train and manage panellists. However, in the event that the GMC resolves to continue on its present course, I have some recommendations to make in respect of the adjudication stage.

27.252 I have welcomed the introduction of case management provisions, although I must point out that it is inappropriate that the GMC should have responsibility for 'management' of case managers. I recommend that the committee charged with governance of the adjudication stage should audit the work of case managers to ensure that the orders made are adequately tailored to the needs of individual cases and to achieve the desired effect. I recommend also that case management should apply to cases with a performance element.

27.253 For reasons I explained in paragraph 25.285, I recommend that panellists should be advised to exercise caution about drawing adverse inferences from the failure to comply with case management orders.

27.254 In the event that the GMC decides to continue to be responsible for adjudication, notwithstanding my recommendation that it should be hived off, I recommend that the GMC should appoint a number of legally qualified chairmen who should, as an experiment or pilot scheme, preside over the more complex FTP hearings. The results of the pilot scheme should be scrutinised to see whether there are benefits in terms of the improved conduct of hearings, more consistent outcomes, improved reasons and fewer appeals.

27.255 I recommend that, as part of their training, FTP panellists should be advised about their discretion to admit hearsay evidence and other forms of evidence not admissible in a criminal trial. Panels have had such a discretionary power for many years but the evidence received by the Inquiry suggests that it was not used as flexibly or frequently as it should have been. Panellists should also be advised, during training, that it is entirely appropriate for them to intervene and ask questions if they feel that any issue is not being adequately explored. The proceedings should not be strictly adversarial; the FTP panel has an inquisitorial function.

27.256 I recommend that the GMC should reopen its debate about the standard of proof to be applied by FTP panels. The GMC has recognised that, in the future, FTP panels will sometimes have to consider allegations of misconduct and deficient performance at the same hearing. The application of different standards of proof may cause difficulty. Also, there should be full recognition that the GMC's primary function is to exercise a protective jurisdiction and not a punitive one. That means that the civil standard of proof will usually be appropriate. I recommend that the GMC should introduce the civil standard of proof for all FTP decisions. However, I do accept that it is arguable that, for allegations which also amount to a criminal offence, the criminal standard of proof may be appropriate.

27.257 For reasons that I explained at paragraphs 25.274–25.279, I recommend that the GMC should abandon its intention to inform the doctor of the desired outcome of a case in advance of the hearing. It is not inappropriate for a GMC representative to make a submission as to outcome after the evidence has been heard, but it must be plain that this is only a submission and cannot in any way bind the panel.

27.258 For the reasons given in paragraph 25.309 I recommend that FTP panels should be required to give brief reasons for their main findings of fact.

27.259 At paragraph 25.310, I noted that, before deciding whether a doctor's fitness to practise is impaired, a FTP panel will have the power to order a health or performance assessment.

That power arises under rule 17(4). I welcomed that development. However, I expressed concern that, under rule 17(5)(b), on receipt of the assessment report, the FTP panel is empowered (without deciding whether the doctor's fitness to practise is impaired or even without making findings of fact) to send the case back to the investigation stage so that case examiners can consider whether it would be appropriate for the doctor to be dealt with by way of voluntary undertakings. I said that such a course would not be satisfactory and explained why. Rule 17(5)(b) deprives the proceedings of transparency. I recommend that rule 17(5)(b) be revoked.

27.260 At paragraphs 25.313–25.315 and 25.317, I drew attention to the fact that there is no specific provision in the November 2004 Rules which requires or enables a FTP panel to take into account a doctor's FTP history when considering the issues of impairment of fitness to practise and of sanction. The 2003 draft Rules had included such a provision. The omission in the November 2004 Rules is puzzling since it surely cannot be intended that FTP panels should not consider this information. It is all the more surprising since the rules governing the procedure of IC panels specifically empower them to take into account a doctor's FTP history with the GMC or any other regulatory body when deciding whether to issue a warning. I recommend that rule 17(2)(j) should be amended to make clear what types of further evidence should be received before the panel decides whether the doctor's fitness to practise is impaired. In my view, that should include evidence of the doctor's FTP history. I had also envisaged that it would include any evidence the doctor wished to advance in mitigation, including purely personal mitigation. Also, rule 17(2)(l) should be amended to make clear what categories of evidence might be received after a finding of impairment of fitness to practise but before determination of sanction. I do not know what further evidence the GMC contemplates might be admitted at this stage.

27.261 At paragraph 25.316, I referred to the inconsistency between, on the one hand, the provisions of section 35D of the 1983 Act and rule 17(2)(k) of the November 2004 Rules and, on the other hand, the contents of the September 2004 draft Guidance for Panellists. The draft Guidance must be corrected as it will confuse panellists. I have also referred to what I consider to be the illogicality of the various outcomes open to a FTP panel. As I have explained, the November 2004 Rules require a FTP panel to decide whether the doctor's fitness to practise is impaired. If the FTP panel decides that his/her fitness to practise is *not* impaired, the FTP panel has the power, under the 1983 Act, to give the doctor a warning as to his/her future conduct or performance. Although at first sight this appears odd, I can understand that a warning might be appropriate in a case where a doctor has done something wrong in the past but where the panel considers that there is no current impairment of fitness to practise. However, if the FTP panel finds that the doctor's fitness to practise is impaired, it has no power to issue a warning. The options open to it in that event are to take no action at all, or to take action on the doctor's registration – by imposing conditions on or suspending registration, or by erasing the doctor's name from the register. I recommend that the legislation be amended to permit a panel to issue a warning where it has found an impairment but one that is not of a degree justifying action on registration.

27.262 At paragraphs 25.324–25.326, I referred to the new provision (rule 17(2)(m)) which would permit a FTP panel to 'take into account' any written undertakings (including undertakings

relating to limitations on his/her practice) entered into by the doctor which the FTP panel considered to be sufficient to protect patients and the public interest. I said that it was not clear to me at what point in the proceedings it was intended that such undertakings should be taken into account. If the FTP panel were to take undertakings into account at the stage of deciding what sanction to impose (e.g. by accepting the undertakings rather than imposing formal conditions), that might be acceptable provided that there was provision within the Rules for supervision of the doctor to ensure compliance with the undertakings and for dealing with a breach. There would also have to be provision for review hearings in cases where undertakings had been given. At present, there is no such provision and I recommend that, if rule 17(2)(m) is to be retained, the Rules should be amended as a matter of urgency to include such provision. If there is no means of ascertaining whether a doctor is complying with undertakings which s/he has given and no means of dealing with him/her if s/he is not, patients cannot be adequately protected. That said, I do not see the necessity for undertakings to be given at the sanction stage. By that time, the FTP panel will have made its findings in relation to impairment of fitness to practise and action on registration and will have heard evidence and/or submissions. It will be in a position to impose conditions of its own choosing. If it does so, provision for review hearings and for action in the event of breach are contained within the existing Rules. I cannot see anything to be gained by the new provision and I recommend that the best course of action is for rule 17(2)(m) to be revoked.

27.263 My concern is that it may be intended that undertakings should be 'taken into account' by a FTP panel before it has made findings of fact and/or a decision on impairment of fitness to practise. The provision is wide enough to permit this. That could lead to the 'fudging' of these important issues and would be most unsatisfactory. I recommend that, if it is to be retained, the rule should be redrafted to make clear that undertakings can be taken into account only at the stage of deciding on sanction after findings of fact and of impairment of fitness to practise have been made.

The Need for Supervision

27.264 I recommend that, throughout the period that a doctor's registration is subject to conditions, someone within the GMC (I would suggest a case examiner) should take responsibility for monitoring the doctor's progress and for ensuring, so far as is possible, that s/he is complying with the conditions imposed. That is vital for the protection of patients. I further recommend that, in every case where a doctor is continuing to practise subject to conditions, a professional supervisor should be appointed to oversee the doctor's progress. I recommend that such professional supervisors should be in direct contact with the case examiner appointed by the GMC and should be required (like medical supervisors under the old voluntary health procedures) to provide regular written reports on the doctor's progress and on his/her compliance with conditions and restrictions on practice. I consider that the direct contribution of the professional supervisor would enhance the quality of the overall supervision and thus reduce the risk to patients of allowing such doctors to continue in work. In a case where the doctor's health is an issue, a medical supervisor should be appointed as under the old voluntary health procedures.

27.265 Any breach of a condition imposed by a FTP panel (save for the most minor breach) should result in the doctor being brought back before the panel so that consideration can be given to imposing a sanction which affords a greater degree of protection to the public.

27.266 So far, I have referred to the need for supervision of doctors who are subject to conditions imposed by a FTP panel. However, the same considerations apply to doctors who have given voluntary undertakings or had undertakings 'taken into account' by a FTP panel. Where the case raises issues of health, the doctor should be subject to medical supervision as under the old voluntary health procedures. In all cases where voluntary undertakings are in place and the doctor is continuing to practise, a professional supervisor should be appointed. I recommend that such professional supervisors should be in direct contact with the case examiner appointed by the GMC, even in health cases where, in the past, the arrangement has been for a professional supervisor to be in indirect contact only, through the medical supervisor.

Review Hearings

27.267 The most recent guidance from the GMC suggests that, where a period of suspension of or conditions on registration has been imposed, there will **'generally'** be one or more review hearings at which the FTP panel may, *inter alia*, extend the period of suspension or conditional registration or revoke or vary the conditions or permit the doctor to resume unrestricted practice at the expiry of the period of suspension or conditional registration. Review hearings are extremely important. They are the 'teeth' behind the sanctions other than erasure and should focus the doctor's mind on the need to undertake any necessary remediation. I recommend that the Rules should be amended to ensure that there is at least one review hearing in all such cases, unless there are exceptional reasons why no hearing should take place. The period within which the first review hearing is to be held should be set at the original hearing and should be within a reasonably short period (no more than a year in a case where conditions have been imposed); this will enable the FTP panel to ensure that the doctor is complying with his/her conditions and making progress. A second review hearing can then be fixed for a time near to the expiry of the period of conditional registration at which the fitness of the doctor to return to unrestricted practice can be considered. There should be an expectation that the doctor will give evidence and answer questions from the FTP panel.

27.268 The November 2004 Rules provide that the Registrar (in practice, the staff exercising his legal powers) may carry out any necessary investigation and obtain any expert or other evidence that he considers necessary in preparation for a review hearing. He may also invite the doctor to undergo an assessment of his/her performance or health. Under the 2003 draft Rules, these functions would have been carried out by a designated case examiner. I recommend that the arrangements set out in the 2003 draft Rules should be reinstated. The kind of investigations to be undertaken (in particular, the commissioning and consideration of expert reports and assessments) should be undertaken by medically qualified case examiners. Of course, they will require the support of staff in administering the arrangements but a case examiner should take the decision about the type and extent of evidence that will be required by the FTP panel at the review hearing. If, as I have suggested, the case examiners are to have responsibility for monitoring the progress of

doctors who are subject to conditions, it will be even more appropriate for them to direct the preparations for review hearings.

27.269 In the past, doctors have been permitted to return to practice after the expiry of a period of suspension or conditional registration without any further hearing of their cases by a panel of the Professional Conduct Committee (PCC). Sometimes, the doctor has been released from conditions on registration on the basis of a report from the person overseeing his/her remediation. It has not been unusual for the PCC and the CPP to allow a doctor to return to unrestricted practice without any objective assessment being made to ensure that the deficiencies which led to the original sanction being imposed have been cured and that the doctor is indeed fit to practise. Under the November 2004 Rules, as I have said, the Registrar has the power to invite the doctor to undergo a performance or health assessment but there is no requirement that the Registrar should do so. In my view, this is unsatisfactory and does not afford adequate protection for patients.

27.270 I recommend that, in all but exceptional cases, a doctor whose registration has been suspended should be required to undertake an objective assessment of his/her fitness to practise before being permitted to return to practice. The kind of exceptional circumstances I envisage are where the doctor has been subject to a short period of suspension which was intended to be a 'sharp rap on the knuckles' for an incident of misconduct which did not affect his/her clinical competence or performance. In all other cases, it is likely that the doctor will have been found to have a serious impairment of fitness to practise and that the period out of practice will have rendered him/her even less fit to practise than hitherto. An assessment is, therefore, imperative. That assessment should be considered by a FTP panel and a decision taken as to the doctor's fitness to practise. Even when a doctor who has been the subject of a suspension is deemed fit to return to practice, it will in most cases be appropriate for him/her to be subject to conditions (in particular a condition of professional supervision) for a period after s/he resumes practice and for a further hearing to be fixed at which his/her progress in practice can be considered and a decision taken as to whether s/he is fit to practise unrestricted.

27.271 Where a doctor has been subject to conditions on his/her registration, s/he should be required to undertake an objective assessment of his/her fitness to practise before being permitted to return to unrestricted practice. That assessment should be considered by a FTP panel at a review hearing in the way that I have described above.

27.272 The nature of the assessment will vary according to the aspects of the doctor's performance, health or conduct that gave rise to the suspension or conditions. It will not necessarily be the full performance assessment although, in cases where there has been a multiplicity of deficiencies, this may be necessary. In a case where the doctor's competence has been deficient, it may be appropriate for him/her to undertake an assessment comprising all or part of Phase II of the performance assessment. Where a doctor has been required to undergo a specific type of retraining, an assessment based on his/her competence and performance in that particular area of practice might be suitable. What is essential is that the doctor should not be allowed to return to unrestricted practice unless and until the deficiencies which led to action being taken on his/her registration have been successfully addressed and s/he meets an acceptable standard

of practice. At present, the appropriate standard for GPs is that set for summative assessment; it is to that standard that the performance assessment instruments are calibrated.

27.273 If a doctor undergoes an assessment to ascertain whether s/he is fit to resume practice or unrestricted practice and the assessment reveals that s/he does not meet the required standard, it is undesirable that s/he should 'limp on' with repeated periods of conditional registration. The time will come when it becomes apparent that the doctor is unlikely ever to meet the standard for unrestricted practice. At the time of the Inquiry hearings, the GMC appeared to have recognised that, if a doctor has been given a chance to improve and is unable or unwilling to do so, the GMC's primary duty to protect patients requires that it should remove him/her from practice. I am uncertain whether or not this remains GMC policy. I thought that that was the right policy and recommend that it should be adopted. In cases of this type, it might be necessary to commission a new full assessment with a view to the doctor's erasure. I do not suggest that this policy should be adopted in respect of impairment caused by adverse health. In such cases, erasure is rightly not available and indefinite suspension may be appropriate.

27.274 It is, in my view, important that the same standards of supervision, review and reassessment should apply in cases in which voluntary undertakings have been accepted or 'taken into account' by a FTP panel as apply where conditions have been imposed. Any breach of such undertakings should be referred to a FTP panel; that should happen now, although the Inquiry heard evidence that it does not always happen when it should. There should be a reassessment before voluntary undertakings are allowed to lapse. Moreover, voluntary undertakings should not be allowed to continue in force and be renewed indefinitely. The time should come when enough opportunity for improvement has been given. In my view, if undertakings have been given at the investigation stage, it should be for the case examiner to decide when the time has come for the doctor to be referred to a FTP panel with a view to further action being taken.

Applications for Restoration to the Register

27.275 The 2003 draft Rules provided for a case examiner to be appointed to consider and prepare the evidence to be placed before a FTP panel at the hearing of a doctor's application for restoration to the register. The case examiner was to have the same powers to procure expert and other evidence as in relation to a review hearing. Subsequently, these proposed arrangements underwent change and, under the November 2004 Rules, the functions which were previously to have been undertaken by case examiners will be given to members of the GMC staff. I recommend that the arrangements contemplated under the 2003 draft Rules should be reinstated. I do so for the same reasons as I have previously outlined in relation to review hearings. Preparation will include the commissioning of an appropriate assessment dealing with the doctor's fitness to resume practice and may also involve obtaining other expert evidence. It might also involve the consideration of complex evidence relating to the events giving rise to the original erasure. All these functions, it seems to me, require the input of a case examiner, preferably one who is medically qualified. Support from the administrative (and probably legal) staff of the

GMC staff will obviously be needed, but the preparations for the hearing should in my view be directed by a case examiner.

27.276 My understanding is that, since 2000, every doctor whose application for restoration to the register has reached the second stage of the procedure has been required to submit to an assessment for the purpose of satisfying the PCC panel as to his/her good character, professional competence and health. I entirely agree that it is essential that there should be an independent objective assessment of the doctor's fitness to practise. This should be directed in part at the deficiencies which led to his/her original erasure but must also take into account that, even if the problem was not one of poor performance, following a period of more than five years out of clinical practice, his/her competence and clinical skills must also be in doubt. The assessment must, therefore, be directed at every aspect of fitness to practise and the doctor should not be restored unless s/he has met the required standard. Panels considering restoration need guidance as to the standards and criteria to be applied. I recommend this be provided through a collection of case summaries.

27.277 I understand the reasons why the GMC has decided against the automatic imposition of conditions on the registration of a doctor who has been restored to the register and I do not propose to recommend that course. Instead, I recommend that, as an additional safeguard for patients, doctors who are restored to the register should be required to have a mentor whose task it will be to monitor their progress in practice and to report to the GMC on their progress. I suggest that those reports should be considered by the case examiner appointed to deal with the restoration application. If it appears from the mentor's reports that further problems are arising, s/he will be able to take appropriate action within the FTP procedures.

Cases Involving Drug Abuse

27.278 In Chapter 23, I have discussed the need for a more searching examination of the circumstances underlying allegations of drug abuse by doctors, and convictions for offences related to drug abuse. I have said that any factual disputes must be resolved and that there must be a more thorough investigation of how the doctor's drug abuse began. I also recommend that the GMC should commission research into the outcomes of the cases of those doctors who have gone through the GMC health procedures. In past cases, the GMC has access to a pool of valuable information. The research might well inform the development of new or improved methods of supervision; the GMC would be able to find out what had worked best in the past. Also, by finding out which drug abusing doctors had relapsed or had otherwise not 'done well', the GMC would gain valuable insight into the characteristics of drug abusing doctors.

Transparency

27.279 I have said that it is important that the GMC's processes should be transparent. Doctors, those representing them and the public should be able to understand exactly what the GMC does and why. There are several respects in which the present arrangements should be improved. First, there are some matters that should be covered in the Rules but are not.

Examples include the tests that are to be applied at each stage of the process and the provisions for the issue of letters of advice. I recommend that every aspect of the procedures in which either doctors or makers of allegations have a direct interest should appear in the Rules. So far as purely internal procedures are concerned, I can see that it would be impractical and restrictive if every aspect of the procedures had to be enshrined in the Rules. However, that is not to say that the internal procedures should be shrouded from the eyes of the public. They must not be. I recommend that the GMC should publish a FTP manual containing all its relevant Rules and guidance for panellists, case examiners and staff and any relevant Standing Orders. This would include such documents as the ISG and the standard forms used by staff and case examiners when recording their decisions. It may be sensible for this to be produced in loose leaf form so that it can be amended periodically. It could also go on the GMC's website so that it could readily be accessed by anyone who needs to use it.

27.280 At various points in this Report, I have mentioned the need for clear statistical information to be provided by the GMC. For example, at paragraph 25.148, I said that the way in which reports of convictions are dealt with should be made clear to the public. Other categories of information that should be made public in a clear and comprehensible form are the numbers of cancellations of referrals to a FTP panel and reviews of decisions made at the end of the investigation stage. I recommend that the GMC should publish an annual report which should amount to a transparent statement of the year's activities in relation to the FTP procedures and revalidation.

Revalidation

27.281 In Chapter 26, I expressed my concern and dissatisfaction about the GMC's current proposals for revalidation. The GMC has told the public that revalidation will require every doctor to demonstrate that s/he is up to date and fit to practise. Section 29A of the 1983 Act imposes a duty on the GMC to make regulations providing for the revalidation of doctors. At section 29A, revalidation is defined as an **'evaluation'** of a doctor's fitness to practise. I have explained that the process that the GMC intends to use for revalidation does not entail an evaluation of fitness to practise. In my view, this process is not fit for the purpose for which it is intended.

27.282 At paragraphs 26.191–26.197, I have set out some suggestions for the way in which the revalidation of GPs could be carried out. In brief, I suggest that the folders of evidence that all doctors working in the NHS have to compile for the purposes of appraisal should be examined by a panel of at least three assessors. One would be the clinical governance lead of the doctor's PCT. Another would be a GP from another area, accredited by the RCGP as an assessor to standards approved by the GMC. The third would be a lay person. The folder would have to include certain specific items of evidence, to be determined by the GMC in consultation with the RCGP. I have also proposed that there should be various 'proxy' methods of achieving revalidation.

Recommendation Relating to the Council for Healthcare Regulatory Excellence

27.283 At paragraph 21.187, I observed that the provisions of section 29 of the National Health Service Reform and Health Care Professions Act 2002 had given rise to considerable

difficulty of construction in the case of Ruscillo. I recommend that, on the first occasion that the Act is to be amended, the opportunity should be taken to clarify that the Act provides for the CRHP/CHRE to appeal against 'acquittals' or findings of 'no impairment of fitness to practise' as well as in respect of sanctions which it believes were unduly lenient. There should in the future be a review of the powers of the CRHP/CHRE with a view to ascertaining whether any extension of its powers and functions is necessary in order to enable it to act effectively to ensure that patients are sufficiently protected by the GMC.

The Culture within the General Medical Council

27.284 In considering what recommendations I should make for the protection of patients in the future, I have had to consider whether, in my view, the GMC should retain responsibility for the conduct of the FTP procedures which, as I explained in Chapter 2, form an integral part of the present systems of monitoring and supervision of doctors, including GPs. These are the procedures by which the GMC should protect patients from dysfunctional doctors, i.e. doctors who, by reason of their misconduct, adverse health or deficient performance, put patients at risk of harm. The Inquiry has received evidence and submissions from some quarters suggesting that the GMC should no longer carry out that function. It has been suggested that the GMC does not have the protection of patients as its first priority; it is said that, rather, its priority is to safeguard the interests of the medical profession. I have already indicated that it is not my intention to recommend that the GMC should be deprived of its FTP function. It is important that I explain my reasons for reaching that conclusion.

27.285 The words that have appeared in the top right-hand corner of virtually every communication disseminated by the GMC in the recent past are 'Protecting Patients – Guiding Doctors'. In modern parlance, this has been the GMC's 'strapline'. The words are intended to encapsulate the aims and philosophy of the GMC. I understand they may shortly be changed, although I do not know what form of words is proposed. Those aims and philosophy should have applied to all the GMC's activities but they were perhaps of greatest relevance to the operation of the FTP procedures. In this Report, I have described the FTP procedures as they have been operated over the last 30 years. I have sought to examine the extent to which their operation has protected patients in accordance with the GMC's primary purpose. For those who have had the patience and endurance to read Chapters 15 to 24, it will come as no surprise that I have reached the conclusion that the GMC has not, in the past, succeeded in that primary purpose. Instead, it has, to a significant degree, acted in the interests of doctors. Of course, I accept that the GMC also has a duty towards doctors; it must be fair in all its dealings with them. But, in the past, the balance has been wrong and, as I have illustrated, the imbalance was due to a culture within the GMC, a set of attitudes and an approach that put what was seen as being 'fair to doctors' ahead of what was necessary to protect patients. Chapters 15 to 24 contain many examples of the way in which this culture operated. I do not propose to repeat them here.

27.286 It is important for the Inquiry to consider whether the culture within the GMC has changed. The GMC's corporate attitudes and culture are fundamental to its capacity to function in the best interests of patients and of the public, as it is under a duty to do. It is also important

that the GMC should recognise the shortcomings of its old FTP procedures and its inability to detect doctors whose practice was either aberrant or substandard. If, at the GMC, there had not been some change of culture and a recognition of the need for change, I would have had little hesitation in advising the SoS that he must make provision for some other way of dealing with doctors whose fitness to practise had been called into question. However, the need for changes to the FTP procedures was recognised, as was the need for an improved method of detecting aberrant behaviour and poor performance. Also, for reasons that I shall explain, I think that there has been some change of attitude and culture, although that change is by no means complete.

27.287 It is clear that the GMC did not recognise the need for change without some prompting from outside. The emergence of a number of medical scandals during the late 1990s must have played a significant part in the development of a resolve to reform. I have no doubt that there were, in the GMC, some who had for many years wished to see a change of both culture and practice. However, scandals such as those involving Shipman, Ledward, Green and others appear to have had the effect of bringing the majority within the GMC to the view that reform was necessary. Since that time, the GMC has been in a state of transition.

27.288 The transition has comprised three major reforms. First, the GMC's constitution was changed with effect from July 2003. The Council was reduced in size from 104 to 35 members and the proportion of lay members was increased from 25% to 40%. However, elected medical members still wield an overall majority. I shall return to constitutional issues later. The second main reform was the development and introduction of the new FTP procedures, which came into effect on 1st November 2004. The third was the development of the process of revalidation, which is due to come into effect in April 2005. The practical effects of the new FTP procedures and revalidation cannot yet be known. In addition to making preparations for those major reforms, during the last five years, the GMC has introduced some more modest changes to its FTP procedures. These were not dependent upon the introduction of the new procedures. I shall list a few because the circumstances in which these changes were introduced is of some significance in considering the extent of the culture change during the last five years.

27.289 In late 1999, the GMC discontinued the practice whereby medical screeners could also sit on the Preliminary Proceedings Committee (PPC); thereafter, screeners could not fulfil both functions. It appears that this change was made in anticipation of the coming into force of the Human Rights Act 1998, which was to take place in October 2000. In 2000, the GMC took greatly increased powers to make interim orders suspending or imposing conditions on a doctor's registration in a case in which it is necessary for the protection of members of the public, or in the public interest or in the interests of the doctor concerned. This change was made because the GMC had been unable to take action to suspend Shipman from the register in August 1998, when he was under investigation for murdering his patients. At about the same time, in 2000, legislation was also introduced to require the GMC to disclose certain adverse information about doctors to employers and PCOs. Hitherto, the GMC had been reluctant to disclose such information as it had been thought that this might be unfair to doctors. The Government had insisted upon this change; as the

major employer of doctors, the NHS wanted the information. No doubt that change too was precipitated, in part at least, by Shipman's case.

27.290 In November 2002, the rule requiring a complaint from a private individual to be supported by a statutory declaration was abolished. That change had been recommended by Professor Allen and her colleagues in 1996. Mr Alan Howes, who was employed by the GMC between 1977 and 2002 and was Head of the Conduct Section from 1987 to 1994, told the Inquiry that there had been tension on this issue between some members of the Council who wanted the rule to be abolished and other members who wanted to keep the rule for the protection of doctors against false or frivolous complaints. It had taken a long time for the majority to accept the need for abolition. In the same month, November 2002, the Registrar was given power to send reports of serious convictions straight to a PCC panel, unless there were public interest reasons for not doing so. Previously, such cases had had to be considered by a screener and the PPC. This change had been recommended by Professor Allen in 2000.

27.291 In May 2004, the GMC introduced the practice of having an informal dialogue with the employer or relevant PCO in respect of doctors about whom complaints had been received. This had never previously been done and was perceived by some to be unfair to doctors since it involved disclosing to the employer or PCO the fact that a complaint had been received. Mr Neil Marshall, who has been employed by the GMC since 1996, told the Inquiry that, between December 1998 and April 2000, there had been a debate within the GMC about the seeking of background information about a doctor. He said that it had become apparent that, by not carrying out such searches, the GMC might be failing in its duty to protect the public. Eventually, it was decided that discussions should take place, but only in 'more performance-like cases'. It was clear from the evidence, however, that it was common for no such discussion to take place. It appears that the change was made as the result of evidence given to this Inquiry. Another change was made as the result of observations made at Inquiry hearings. Until recently, doctors charged with or convicted of a criminal offence had not been required to report the fact to the GMC. The GMC now requires doctors to report these matters and a doctor would be guilty of professional misconduct if s/he failed to do so. A further example of a change brought about as the result of evidence given to the Inquiry relates to the identification of doctors against whom complaints have been made. In 2003, Professor Allen and her colleagues reported that 25% of doctors about whom complaints had been made in 2001 had never been identified. That meant that the GMC was unable to ascertain whether the doctor had a previous FTP history and that, if another similar complaint about the same doctor were to be received, the two could not be linked. The GMC could not even confirm that the 'doctor' complained of was in fact on the medical register. At the Inquiry's hearings, Mr Marshall acknowledged that the GMC should consider making more effort to ascertain the identity of doctors against whom complaints were made. It was clear from the evidence that, in some cases, all that was required was a telephone call. The Inquiry has been told that, since the hearings in December 2003, the GMC has taken steps to improve its systems for identifying doctors reported to it.

27.292 All those changes were for the better. They improved the position of complainants and the ability of the FTP procedures to protect patients. To some extent, the GMC is to be

congratulated on making those changes. However, the disappointing feature is that all the changes appear to have been made as a reaction to some form of external pressure or advice. None of them appears to have been made because the GMC realised for itself that it was not acting in the best interests of patients and the public. Those changes do not demonstrate that there has been much of a change of culture within the GMC.

27.293 During the same period, the GMC failed to make a number of changes which, in my view, it would have made if it had had patient protection at the forefront of its collective mind. I shall mention four. Until very recently, the GMC has not employed staff for the purpose of investigating complaints or allegations against doctors. In general, in a conduct case, it has accepted the complaint, obtained the doctor's response, obtained the complainant's response to the doctor's response and then decided whether to send the case through to the PCC for hearing. Thereafter, if the case was to go forward to the PCC, it would be investigated. As Mr Scott observed at the Inquiry, that was to 'put the cart before the horse'. The GMC knew that this was the practice and should have realised that it was not satisfactory in the interests of patient protection. As a consequence of the practice, it was inevitable that some complaints against doctors would fail at the early stages for lack of investigation. Professor Allen had made this point in 1996. It is true that the GMC did not have statutory powers to compel the production of evidence before the stage when a case was referred to the PCC; but that was no bar to investigation. Only now, under the new FTP procedures, is it intended that the GMC should investigate cases at an early stage.

27.294 My second example relates to the GMC's practice of closing complaints from private individuals and advising the complainant to use local complaints procedures; this was done without considering whether the complaint raised an issue of SPM and in the knowledge that NHS complaints procedures were profoundly unsatisfactory. It was a practice that plainly disadvantaged complainants and reduced the ability of the GMC to protect patients by dealing promptly with all potential allegations of SPM. Mrs Jean Robinson, formerly a lay member of the GMC, had, in 1988, drawn attention to the practice and its effects. Professor Allen had drawn attention to it again in 1996 and pointed out that some of the complaints being redirected were of a serious nature. It was not stopped, although it could have been stopped at any time as it was not sanctioned by the Rules; indeed, it was a breach of the Rules. Far from being stopped, in November 2002, the practice was extended to complaints about treatment in the private sector. The practice was the subject of discussion and some criticism at the Inquiry in December 2003. The briefing papers for the Council meeting in July 2004 suggest that the practice was still in operation at that date. So far as I am aware, it remained in operation until the demise of the old FTP procedures at the end of October 2004.

27.295 My third example relates to the GMC's unwillingness to establish agreed standards, criteria and thresholds by which the FTP procedures, and particularly the old conduct procedures, could operate. Professor Allen and her colleagues drew attention to the need for them in their Reports of 1996 and 2000 and in their Paper of 2003. They made it plain that the absence of standards was resulting in inconsistency of decision-making and lack of transparency. The implications for patient safety were obvious. No real progress has been made.

27.296 Finally, I refer to the disclosure of information relating to a doctor's registration status to persons making enquiry of the GMC. I described at paragraphs 27.174–27.178 how this information is imparted. I explained that, at the Council meeting of July 2004, Mr Scott explained that information was imparted only in response to specific questions, and that 999 out of 1000 callers asked only whether the doctor was registered. No further questions were usually asked. No member of Council made any observation about this. Nobody remarked that it appeared therefore that many prospective employers were receiving incomplete information about the registration status of the doctors they were about to employ. They were putting down the telephone having assured themselves that the doctor was registered, but they had not discovered whether the doctor was subject to conditions or even whether s/he had a recent FTP history. Similarly, it did not appear to be appreciated that members of the public might not be getting the information they were seeking. In short, nobody seems to have noticed that the way the GMC handles these enquiries is not in the best interests of patient protection.

27.297 My examination of the events of the last five years leads me to conclude that, although the GMC has made a number of beneficial changes, its culture has not altered radically. However, the GMC would have me believe that, insofar as there ever was any need for a change in culture, it has already occurred. In his opening submission to the Inquiry, made in November 2003, Leading Counsel for the GMC, Mr Roger Henderson QC, accepted on the GMC's behalf that, in many ways, its FTP procedures had not been as they should have been. There had been problems of inflexibility, inadequacies of training and guidance and resulting inconsistency of decision-making. It was, I think, accepted that these shortcomings must at times have resulted in the GMC failing to act in the best interests of patients and for their protection. Mr Henderson acknowledged that some cases had been closed that should not have been closed. However, he did not volunteer any acceptance that there had been anything fundamentally wrong with the GMC's attitudes or culture. The thrust of the evidence presented to the Inquiry by the GMC was that its priorities were clear; its primary duty was to protect patients and that is what it was doing.

27.298 The most important transitions effected in the last few years have been the preparations for the introduction of the new FTP procedures and of revalidation. I turn to consider whether the GMC's approach to those important innovations demonstrates a change of culture and attitude.

27.299 In Chapter 25, I examined the development of the proposals for the new FTP procedures in detail – some might say in too much detail. I wished to understand the thinking behind that development. The GMC's vision for the future procedures was clearly set out in its Consultation Paper published in 2001. That paper demonstrated a firm commitment to FTP procedures that would operate for the protection of patients, without compromising the need to be fair to doctors. On the basis of that document, I would have said that there had indeed been a change in the culture of the GMC. However, the translation of the vision into reality has been, in some respects, disappointing. As I explained in my conclusions to Chapter 25, I found that there had been no consistent transition from the initial vision to the implementation of the new procedures. The major change is that the old 'silos' of the conduct, health and performance procedures have gone and are to be replaced by a single basis for the GMC's powers to erase, suspend or impose conditions on a doctor's

registration, namely 'impairment of fitness to practise'. There have been many other changes, some for the better, some for the worse. There has been a good deal of 'chopping and changing' in the detail of the proposals and it is often hard to see any coherent principle behind the changes. The GMC has adopted a number of suggestions that have been made in evidence to the Inquiry. It has reacted positively to some of the criticisms and concerns about which the GMC witnesses were asked. But I do not feel confident that the GMC has maintained the clarity of purpose that it exhibited at the time it published its Consultation Paper in 2001. I do not feel confident that there is currently a determination that the new procedures will be operated with the primary objective of protecting patients.

27.300 Examination of the development of the GMC's proposals for revalidation leads me to a similar conclusion. In Chapter 26, I described how, in the late 1990s, the GMC recognised that, in order to protect patients adequately, it must take proactive steps to identify under-performing doctors, instead of waiting for someone to make a complaint or allegation. It set out its principles with clarity in the Consultation Paper of 2000. This was another seminal document, setting out proposals that were manifestly designed to protect patients. Again, on the basis of that document, I would have said that the GMC had changed its culture. But again, implementation has been a disappointment; there has been a retreat from the early ideals. Revalidation was to involve the evaluation of the fitness to practise of every individual doctor who wished to hold a licence to practise. A method was devised and pilot studies were carried out. Then it became apparent that the task of evaluating every doctor every five years was more daunting than had been thought. The process would be expensive and the doctors would have to pay for it. Moreover, the proposals were unpopular with a powerful section of the profession. So the GMC retreated from its earlier vision and devised a system that it calls 'revalidation' but which does not involve any evaluation of the individual doctor's fitness to practise, certainly so far as GPs are concerned. I know that that retreat caused dissent within the GMC but it was accepted by the majority. I am driven to the conclusion that, for the majority of GMC members, the old culture of protecting the interests of doctors still lingers on.

27.301 It is not possible for me to understand the internal dynamics of the GMC. I can see from the transcripts of the public discussions in Council that there is sometimes a lively debate. That is, of course, as it should be. I do not know and cannot tell when or why the GMC takes some of its decisions. For example, in 2003, the GMC decided that, under the new FTP procedures, when a performance assessment report was obtained, it would be sent to the doctor's employer or PCO. At some time, that decision has been reversed; it will not now happen. That is a retrograde decision but I do not know when or why it was taken. Similarly with the decision to allow FTP cases to be cancelled on the say-so of a single member of the IC, to which I referred at paragraphs 25.243–25.250. I do not know when or why that decision was taken. In short, I do not know what goes on but I do gain the impression that the old culture has not entirely disappeared.

27.302 Why then have I not recommended to the SoS that the GMC should no longer be responsible for the FTP procedures? In fact, I have recommended that responsibility for the adjudication stage should be hived off to an independent organisation. However, I have recommended that because it is inappropriate for the GMC to control both the

investigation and the adjudication stages of the process. I would have made that recommendation even if there had been no suggestion that the GMC's culture could be criticised. There are four reasons why I have not recommended that the GMC should cease to be responsible for the FTP function.

27.303 First, fitness to practise and revalidation are closely linked. Revalidation and registration are closely linked. It is preferable therefore that fitness to practise and registration should be under the control of the same body. I do not consider that my Terms of Reference permit me to consider whether the GMC might lose its responsibility for registration (or indeed for setting the standards for admission to the register and all the educational responsibilities that accompany that function). That would, in effect, be to recommend the abolition of the GMC. I could not do that. This is a Public Inquiry, not a Royal Commission on the regulation of the medical profession. If I were to recommend the detachment of the FTP function, it would create practical difficulties for the future, although I do not think they would be insurmountable.

27.304 Second, the task of creating a body to take over the FTP function would not be an easy one. If improvements to the GMC could be effected, so that it acted more consistently in the interests of patients and the public, that would seem to me to be a preferable course to take.

27.305 So far, I have given two reasons; both are negative. There are some positive reasons for my conclusion. The GMC has just introduced a new set of FTP procedures. I do not know how well they will operate in the interests of patient protection. Broadly speaking, the new procedures are an improvement on the old. Change has been in the right direction. No doubt the new procedures will be changed in some respects during the next few years in the light of experience. It seems to me to be sensible that the new procedures should be allowed to develop and to settle down before their adequacy and fitness for purpose is judged. It will be important to see whether any future changes move in the right direction.

27.306 There is a major reason to hope and expect that change for the better might continue. The CRHP/CHRE may be expected to play an important role in the further development of the new FTP procedures. The CRHP/CHRE is a new body; it came into existence in 2003 as the result of a recommendation of Professor (now Sir) Ian Kennedy in his Bristol Inquiry Report. The CRHP/CHRE has already made its mark by exercising its power to refer to the High Court any decision of the GMC which it considers to be unduly lenient and which should be reviewed in the public interest. It also has the power to refer to the High Court cases in which a doctor has been 'acquitted' of SPM and it will in the future have the power, in some circumstances, to refer cases in which a FTP panel's failure to find that a doctor's fitness to practise was impaired, or its failure to find impairment of a degree justifying action on registration, was 'unduly lenient'. However, the CRHP/CHRE's powers are not limited to referring individual decisions to the Court. It has wide powers of oversight of the GMC's FTP function. It can audit outcomes of cases; it can examine processes and it can require rule changes. That is not to say that the CRHP/CHRE could or should attempt to 'manage' the GMC. That would be impractical and inappropriate. But the fact that it exists and that it has shown that it intends to use its powers will, I believe, have an important effect on the GMC. The GMC must know that, if it fails to act in the best interests of patients and

the public, the CRHP/CHRE will intervene. Moreover, this Inquiry has shed a great deal of light on GMC practices, particularly on those that are not usually open to public scrutiny. I hope that what the Inquiry has revealed will help the CRHP/CHRE in that it will know where to look to see how well the GMC is doing its job.

27.307 The Inquiry has revealed many shortcomings in the GMC's operation of its old FTP procedures. How the new procedures will operate in practice it is not possible to say. In my view it is important, in the public interest, that, in about three or four years' time, there should be a thorough review of the operation of the new procedures, to be carried out by an independent organisation. It seems to me that that task should be undertaken by or on the instructions of the CRHP/CHRE. The cost should, in my view, be borne by public funds. That review should not be limited to consideration of administrative systems, but should be empowered to examine casework decisions at all levels as well.

27.308 I would like to believe that the GMC's culture would continue to change in the right direction by virtue of its own momentum. However, I do not feel confident that it will do so. I am sure that there are many people within the GMC, both members and staff, who want to see the regulation of the medical profession based on the principles of 'patient-centred' medicine and public protection. Indeed, I think it is likely that all members are theoretically in favour of those principles. The problem seems to be that, when specific issues arise, opposing views are taken and, as in the past, the balance sometimes tips in favour of the interests of doctors.

27.309 In Chapter 15, I observed that, for an organisation like the GMC, issues are bound to arise in which there is a conflict between the interests of doctors and those of patients and of the public. Members have to deal with that conflict. To do their work properly as members of a regulatory body, they have to put the public interest first. That is very difficult for a member who depends for his/her position on an electorate of doctors. I am sure that some manage to do it. I think that others find it more difficult. At present, the GMC is effectively controlled by elected members. It seems to me that one of the fundamental problems for the GMC is the perception, shared by many doctors, that it is supposed to be 'representing' them. It is not; it is regulating them. It may be that this perception goes back to the 1970s, when the profession objected to being asked to pay an annual retention fee and raised the cry of 'no taxation without representation'. If the profession perceives that the GMC is supposed to represent it, that would explain why some GMC members tend to adopt a representative role. In fact, the medical profession has a very effective representative body in the BMA; it does not need – and should not have – two.

27.310 I have come to the conclusion that one of the reasons why the GMC has not been able to rid itself of the old culture lies within its constitution and the overall majority of elected 'representative' members. I think that the GMC should look again at its constitution. I know that the constitution was changed as recently as July 2003. I realise that further upheaval would be unwelcome. However, my considered view is that it is not appropriate that the GMC should be dominated by elected members. It should certainly be dominated by medical members; I am not suggesting that there should be any increase in the proportion of lay members. But I do suggest that there should be more appointed medical members – people who are not beholden to an electorate and do not see themselves in the position

of representatives of the profession. Rather, they should see themselves as servants of the public interest.

27.311 Accordingly, I recommend that the constitution be reconsidered. It occurs to me that the sharp reduction in size that occurred in 2003 might have gone a little too far. The GMC may wish to consider whether it needs a few more medical members than it has. It needs medical members for many tasks that cannot be carried out by lay people, such as the development of policies and medical guidance. That is not a recommendation, merely a suggestion. As Sir Donald Irvine observed, it may be preferable for the GMC to 'hire' the medical expertise it needs from the experts in particular fields. What I do recommend, however, is that the balance of the Council should be changed so that the elected members do not have an overall majority.

27.312 I also recommend that medical and lay members who are to be appointed (by the Privy Council) should be selected for nomination to the Privy Council by the Public Appointments Commission following open competition. It would seem sensible for the universities and medical Royal Colleges to have the right to nominate medically qualified candidates for consideration. However, the competition should also be open to medically qualified persons who wish to put themselves forward. I have seen, from the DoH prospectus inviting applications for the position of lay membership in 2003, the emphasis that was laid – quite rightly – on the lay members' duty to safeguard the public interest. I would like to see the same emphasis on the public interest applied to the appointment of medical members.

27.313 During the course of the evidence, concern was expressed about the number of lay members who have a background in health service management. In Chapter 15, I expressed the view that it would be desirable that lay members should come from a wide range of backgrounds.

Public Accountability

27.314 In the past, the GMC has been accountable to the public only in very general terms. It has had a duty to regulate the medical profession in the best interests of patients and the public. However, there has been no person or body to whom the GMC has been directly accountable. Since 2003, the CRHP/CHRE has had the power to oversee and correct some aspects of the GMC's work. The GMC itself recognised and drew the Inquiry's attention to the fact that, although the GMC derives its powers from Parliament, it is not directly accountable to Parliament for the way in which it exercises its powers. The GMC suggested that it might be appropriate if it were to be directly accountable. I think that that is a good idea. I have in mind that the GMC would be required to publish an annual report of its activities, which could be scrutinised by a Select Committee. For this to be a worthwhile exercise, the report would have to contain specified categories of information, including statistical information, in a form that was readily understandable and, in effect, transparent.

Conclusions

27.315 In the course of this long Report, I have on many occasions been critical of the GMC, its procedures and its attitudes. I realise that the fact that this Inquiry has been conducted in

public and that my Report will be in the public domain must make those criticisms even more unwelcome than they would have been if made in private. Indeed, I recognise that their effect is likely to be bruising. It has not been my intention to be hurtful or indeed to be critical of any individual at the GMC. My criticisms have been of the corporate body and its collective actions. I have made a large number of recommendations affecting the GMC and I realise that some of them will be unwelcome. However, I hope that it will be accepted that they have been made in a constructive spirit and with the intention of helping the GMC to achieve its primary purpose of 'Protecting Patients – Guiding Doctors'.

27.316 In this Stage of the Inquiry, I have examined the parts that are or could be played by Government, the GMC, the Healthcare Commission, the CRHP/CHRE, NHS organisations, practice staff, patients and members of the public in protecting patients who might be at risk from an aberrant or poorly performing GP. In this Report, I have made a large number of recommendations which, together with the recommendations in my Third and Fourth Reports, are designed to extend and improve the existing framework of protective systems. In this Report, I have suggested improvements to clinical governance systems; in particular I have stressed the need for the proper investigation of complaints and the need for a system of monitoring mortality statistics. I have recommended ways in which the protective role of PCTs can be enhanced, for example by providing them with improved information about the doctors on or seeking admission to their lists. I have made recommendations that will provide patients with more information about their doctors and will enable them to exercise some, albeit limited, degree of choice. I have made recommendations designed to ensure that the GMC's FTP procedures work effectively for the protection of patients and are also fair to doctors. Finally, I have suggested a way in which revalidation could be made to comply with the requirements of the 1983 Act and to fulfil the high aspirations of those who have sought to promote it.

27.317 To some extent, these recommendations are bound to give rise to tension and conflict between the interests of those affected by them. However, I am confident that there is a large body of opinion both within and outside the medical profession that will recognise the need for all those involved to work together and to pull in the same direction. In making these recommendations, I have striven to achieve three things: first, that, if ever there were to be another potential Shipman, he would be detected very quickly; second, that the prospects of detecting all forms of aberrant behaviour or substandard performance in doctors should be enhanced; and, third, that the good quality of care provided by the large majority of doctors should have scope and opportunity for continued improvement.