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.