CHAPTER TWENTY SIX

Revalidation

Introduction

26.1 As I explained in Chapter 15, once a doctor qualifies to have his/her name entered on the medical register, s/he is entitled to practise medicine and to remain on the register unless and until such time as his/her name is suspended or erased from it. For many years, doctors have been under a professional duty to maintain their professional competence. However, there has been no means of ensuring that they do so and no sanction for failing to do so, unless and until the doctor's fitness to practise is called into question as a result of a complaint to the General Medical Council (GMC). In 1998, in the wake of at least two high profile cases in which doctors were seen to have been practising at unacceptably low standards over a period of time, there was a move within the GMC to introduce a requirement for some form of periodic assessment by which a doctor's fitness to remain on the medical register could be reviewed. This concept was developed and the GMC now proposes to introduce, in 2005, a requirement that all doctors wishing to retain a licence to practise must, every five years, undergo a process by which their entitlement to practise is 'revalidated'. It is said that the process of revalidation will require doctors to demonstrate on a regular basis that they are 'up to date and fit to practise'.

26.2 Revalidation is of considerable interest to the Inquiry. I have explained in this Report how the systems by which the NHS monitored the practice of general practitioners (GPs) during the period of more than 20 years in which Shipman worked as a GP failed to detect that he was obtaining large amounts of diamorphine illicitly and killing his patients. The GMC, as regulator of the medical profession, did not at that time undertake any routine monitoring of doctors; its role in the monitoring process was confined to reacting to complaints. It received no complaints that could have led it to suspect that Shipman might be killing his patients. Since 1998, there have been many changes within the NHS. I have described some of them in Chapter 5. In 1999, the NHS introduced clinical governance, which I described in Chapter 12. When these changes have had time to settle down and to develop to their full potential, they should result in much-improved monitoring of doctors' performance, with the twin benefits of detecting the development of substandard performance and the raising of standards generally. The GMC is now to introduce revalidation, which, as I have said, should involve a periodic demonstration of the individual's fitness to practise.

26.3 In this Chapter, I propose to examine the GMC's proposals for revalidation, the way in which revalidation will be linked to clinical governance and the potential that the two processes will have for the detection of poor or aberrant clinical performance. I am in no doubt that the problems caused by poorly performing doctors are significant. As Professor Dame Lesley Southgate, Professor of Primary Care and Medical Education, University College London, said at the Inquiry seminars: 'There are poorly performing doctors out there who are harming patients'. Professor Sir Graeme Catto, President of the GMC, speaking of the purposes for which revalidation was to be introduced, said that the performance of at least 90% of doctors gave rise to no concerns; that suggests that there

is or could be a problem of poor performance with as many as 10%. That estimate may be on the high side; others mentioned a figure of 5% or even 3% of doctors whose performance gives rise to problems. Whichever figure is the more accurate, the problem is not insignificant. As I explained in Chapter 12, the methods of identifying poor performance through local clinical governance procedures are limited. Revalidation could provide a significant additional means of achieving that end.

26.4 Plainly, any system of revalidation of registration must have wider aims than merely the detection of the activities of a mass murderer practising as a GP. However, as a broad brush test, it is pertinent to consider whether, if revalidation as currently proposed had been in force during the 1980s and 1990s, it would have brought Shipman's activities to light. My overall objective in the Inquiry is to make recommendations for change to bring about the provision of interlinking systems of monitoring and regulation which will detect not only doctors who deliberately harm their patients but also those who harm them for other reasons such as incompetence, ill health or an unwillingness to keep up to date. I have already made recommendations for the reform of death certification and coroners' investigations. I have also made recommendations for the strengthening of the rules relating to the use of controlled drugs. I believe that those recommendations, if implemented, could help in the detection of dysfunctionality. Now, I wish to examine the part that could be played by revalidation. If revalidation were to consist of a periodic assessment of a doctor's competence and fitness to practise, it could make a huge contribution to safeguarding the public against the incompetent and out of date doctor. Whether it would catch another Shipman may be a different matter. It might make a contribution, as one part of the interlinked systems. As well as considering its potential benefits, I wish to examine whether revalidation, as currently proposed, will in fact achieve the purpose for which it is intended.

Evidence

26.5 The GMC's principal witness on the issues relating to revalidation was Mr Stephen Brearley, a consultant general and vascular surgeon, a GMC member and the Chairman of the Registration Committee. Sir Graeme, and Mr Finlay Scott, Chief Executive of the GMC, also gave evidence about revalidation. Sir Donald Irvine, immediate past President, spoke on the subject during his evidence and made contributions at the Inquiry seminars. Dr Malcolm Lewis, a GP and Chair, Welsh Branch of the GMC, represented the GMC at the seminars. Other important contributions to the debate about revalidation came from Dame Lesley, Dr John Grenville (a GP, who represented the British Medical Association (BMA) at the seminars), Dr William Reith (a GP, on behalf of the Royal College of General Practitioners (RCGP)) and Dr John Chisholm (a GP and Chairman of the General Practitioners Committee (GPC) of the BMA).

The Development of the General Medical Council's Proposals for Revalidation up to the End of 2002

26.6 The possibility of requiring doctors to undergo some sort of periodic reassessment of their fitness to practise was first raised in the 1970s. In 1975, the Merrison Committee, whose

Report I mentioned in Chapter 15, referred to a growing interest in linking continued registration with periodic tests of competence. However, the Committee took the view that the issue lay outside its Terms of Reference. It passed on the evidence that it had received on the topic to another committee, which had been set up by the medical profession under the Chairmanship of Sir Anthony Ament, to review, *inter alia*, the existing methods of ensuring the maintenance of standards of continuing competence to practise. The Report of the Ament Committee, entitled 'Competence to Practise', published in 1976, stressed the importance of doctors keeping their practice up to date and accepted that there might be considerable value in some form of re-licensure. However, it concluded that there was no evidence to justify the introduction of re-licensure as a compulsory requirement. It was thought that **'a system of licensing for all could not be based upon measurements satisfactory enough to justify it'**. The Report recommended that, instead, doctors should be encouraged to keep up to date voluntarily. In short, the Ament Report concluded that there were insuperable practical difficulties in the way of any form of revalidation. Those members of the GMC who are currently charged with the responsibility of developing proposals for revalidation might be forgiven for thinking that perhaps the Ament Committee was right.

26.7 Proposals for re-licensure surfaced again in 1998 in the immediate aftermath of the GMC hearings of allegations of serious professional misconduct against three doctors, arising out of concerns about the paediatric cardiac service at the Bristol Royal Infirmary. Sir Donald, then President of the GMC, describes in his book, 'The Doctors' Tale'[1], how the idea developed. He said that, by June 1998, there was a growing awareness of **'the clear public expectation that medical regulation should include measures to assure patients that consultants, and general practitioners, continue to perform effectively throughout their working lives'**.

26.8 At that time, Sir Donald had in mind the introduction of some form of revalidation only for those doctors who practised unsupervised, i.e. consultants and GP principals. He envisaged that revalidation would operate in conjunction with the basic strategies for securing and maintaining good medical practice, which included the setting of clear general and specific standards, effective local clinical governance and effective local and central arrangements for dealing with poor practice. He suggested that the current specialist register (which contained the names of those doctors entitled to practise in unsupervised positions in the various secondary care specialisms) was not 'fit for purpose' if there was no check on the doctors' continuing fitness to practise over many years. He suggested that revalidation should take place at five-year intervals. At a meeting of the leaders of the profession, held in August 1998, there was general agreement that the idea was sound in principle; however, reservations were expressed about how revalidation was to be achieved in practice.

26.9 In the ensuing months, the debate about revalidation got underway within the profession at large. Support was not universal. There was perhaps a further stimulus towards action – at least within the GMC – when Rodney Ledward was struck off the medical register at the end of September 1998. He had been practising as a consultant gynaecologist in

[1] Irvine, Donald (2003) 'The Doctors' Tale'. Oxford: Radcliffe Medical Press.

Kent. His incompetence (manifested by an unusually high complication rate following operative procedures) had been evident to some for many years, but no action had been taken to prevent him from practising. As it happens, September 1998 was also the month in which Shipman was arrested on suspicion of the murder of Mrs Kathleen Grundy.

26.10 Revalidation was discussed at a meeting of the GMC in November 1998 but no firm decision was taken about what should be done. However, at a special conference held in February 1999, the GMC decided, by a very substantial majority, to introduce revalidation. It also decided that revalidation should apply to all doctors, not only to consultants and GP principals. It was further decided that revalidation should be linked directly with registration; in other words, no revalidation would mean no licence to practise. However, the GMC also decided that no doctor would be refused a licence to practise unless and until s/he had been through the GMC's performance procedures and had been found unfit to practise by a panel of the Committee on Professional Performance (CPP). I described the operation of the performance procedures in Chapter 24. In February 1999, these procedures were still relatively new, having been introduced in July 1997.

26.11 There was discussion at the special conference in February 1999 about how revalidation was to be carried out. It was expected that most would achieve revalidation without difficulty and that only a tiny proportion would fall to be dealt with under the performance procedures. According to Sir Donald, in 'The Doctors' Tale', the original proposal, set out in the paper prepared for discussion at the conference, **'introduced the idea of a staged model – local profiling, regular review, assessment and external quality assurance'**. Powerful voices spoke against any form of 'examination' as the basis of revalidation. There was general agreement that revalidation should dovetail with local clinical governance procedures. The Chief Medical Officer (CMO) for England, Professor (later Sir) Liam Donaldson, made an important contribution to the debate and was supportive of the principles behind revalidation. He was at that time closely involved with the development of clinical governance within the NHS. He said that he saw revalidation as **'an important piece of the overall framework of quality in the NHS which ... must be put in place'**. Sir Donald described how Professor Donaldson spoke of **'the strong interdependence between professional self-regulation – of which this** (*revalidation*) **was an important part – and clinical governance and the statutory duty of quality within the NHS'**. He also spoke of the potential of revalidation for improving quality of practice. It was envisaged that revalidation, properly implemented, would achieve two objectives: the weeding out of poorly performing doctors so as to protect patients, and the enhancement of performance in others.

26.12 There was another aspirational contribution to this debate that I particularly wish to mention. Professor David Hatch, Consultant Anaesthetist at the Great Ormond Street Hospital for Sick Children, said that, in his 30 years of practice:

> **'... nobody has given me an opportunity to demonstrate that I am fit to practise and up to date. I would welcome the opportunity to try to show that to the parents of the children I anaesthetise and the children themselves in some cases. I would hope that the Register, available 24 hours a day, seven days a week, would be the instrument for doing that.**

I hope that people will look up the Register, and the fact that I am on it will indicate that I am safe to anaesthetise their children.'

It appears that not all members of the GMC shared this positive approach to revalidation. But those who did not were in the minority and, as I have said, the proposals were carried and revalidation was on its way.

Developing the Practical Arrangements

26.13 A Revalidation Steering Group (RSG) was formed by the GMC to devise plans for the implementation of revalidation. Its aim was to produce fully developed proposals for discussion within two years. The target date for implementation was 2002. The RSG first reported to the GMC at a Council meeting in May 1999. The RSG recommended that revalidation should be based on the principles set out in the GMC publication 'Good Medical Practice'. As I understand the outline proposals at that time, it was intended that work would be done to compile a 'local profile' of a doctor's performance. Although the term 'profiling' was not explained, I take it to mean that the essential requirements for doctors of each particular type would be analysed, standards would be set and a means devised of assessing the individual doctor against the essential requirements. In that way, each doctor would be subjected to an individual judgement, based on material or evidence that s/he would produce. The precise way in which this was to be achieved was not at that time specified in any detail. More detailed development work was to take place. Meanwhile in May 1999, it was also envisaged that if, during the process of revalidation, any concerns arose about a doctor's performance, there should be an opportunity for local remedial action, followed, if necessary, by referral to the GMC's fitness to practise (FTP) procedures and action on registration (i.e. the imposition of conditions on or suspension of registration). The RSG stressed that the development of revalidation must be co-ordinated with that of clinical governance, which was then still in its infancy. At the same meeting, Council agreed that there should be full public consultation about the development of revalidation, based on the RSG proposals.

26.14 The RSG continued its work. It sought the advice of Dame Lesley, who had led the team responsible for developing the assessment instruments used by the GMC in its performance procedures. Dame Lesley provided advice and, together with Professor Mike Pringle (then Chairman, RCGP), set out their ideas in a paper published in the British Medical Journal (BMJ) in October 1999[2]. Dame Lesley and Professor Pringle envisaged that doctors would have to be revalidated in each aspect of the work they undertook. For each large specialty, there would be a number of local or regional revalidation groups. A small specialty might need only one revalidation group to serve the whole country. The membership of the groups would include representatives of the specialty concerned, the local professional organisation, the public and doctors in health service management. Members of the groups would be trained by national professional organisations, usually the medical Royal Colleges. These organisations would be recognised by the GMC for that purpose and also for the purpose of setting the standards that the doctors in each

[2] Southgate, Lesley, Pringle, Mike (1999) 'Revalidation in the United Kingdom: general principles based on experience in general practice', BMJ, Vol 319.

specialty would have to meet. A doctor would apply for revalidation to the revalidation group appropriate to his/her specialty. The group would examine the evidence submitted and would make a decision whether or not to recommend revalidation. The group would seek evidence of a safe standard of practice. The work of the revalidation groups would be monitored and quality assured by the relevant Royal College. Work would have to be done to ensure that consistent standards were applied nationally.

26.15 The BMJ paper also set out in some detail the kind of material that might have to be submitted with the application. This, it was said, would vary from specialty to specialty. The requirements must not place too great a burden on doctors. In all cases, there should be **'an extended curriculum vitae'**, in which the doctor would describe the nature of his/her education, experience and clinical practice. This document would set out details of the continuing medical education undertaken by the doctor. Dame Lesley and Professor Pringle also discussed the possibility of using material collected for clinical governance purposes but stressed that much development work would have to be done before this could be used. The BMJ paper also suggested that some doctors might wish to take a different route to revalidation, for example, by submitting themselves to the peer review accreditation schemes operated by some of the Royal Colleges. The RCGP's schemes for gaining Fellowship or Membership of the College by assessment of performance were mentioned as particular examples. These programmes set a higher standard than the basic standard of competence which it was envisaged would apply to the revalidation process. It was suggested that doctors who were able to demonstrate that they had achieved and were maintaining those higher standards should be entitled to rely upon them for revalidation.

26.16 In November 1999, the RSG reported again to Council. Broadly speaking, its recommendations reflected the ideas described by Dame Lesley and Professor Pringle in their BMJ paper. The RSG recommended that revalidation should be based initially on the 'profiling' of the doctor's practice, based on evidence collected in the locality where the doctor worked. That evidence would be scrutinised by the doctor's peers and by **'informed lay people'** who would then make a judgement whether to recommend revalidation or referral into the GMC's FTP procedures. The RSG recommended that the local processes upon which revalidation was to be founded should be supportive of continuous improvement and should not be restricted to identifying unacceptable practice.

The General Medical Council Consultation Paper of June 2000

26.17 In June 2000, the GMC published a Consultation Paper, 'Revalidating Doctors, ensuring standards, securing the future'. The Consultation Paper set out the philosophy behind revalidation and drew attention to the benefits it would bring. It would benefit patients by protecting them from poorly performing doctors, by promoting good medical practice and by making the register a valid indicator of current fitness to practise. It would also increase patients' confidence in doctors by giving them the assurance that doctors were regularly submitting evidence of competence. Revalidation would also benefit doctors; it would help good doctors to be even better; it would help doctors with weaknesses to correct them and it would enable doctors to defend themselves better against unfounded

criticisms about their fitness to practise. Finally, it would benefit the employers of doctors by providing an assurance that the doctors they employed were fit to practise and by providing an additional mechanism to identify and deal with poor performance. The Consultation Paper described the wider context of reform of which revalidation was a part. It mentioned a gradual change in culture that had taken place in the recent past, including the promotion of quality improvement and of openness and honesty about mistakes and poor performance. There was reference to the development of explicit standards of practice by the GMC and to the introduction of clinical governance arrangements. There was particular reference to appraisal as a means by which employers could monitor whether doctors were complying with their contractual obligations. It was said that revalidation of doctors' registration and appraisal were **'complementary professional and managerial functions'**, which required a common core of information about professional performance. The GMC's proposals on revalidation were, it was said, designed to make the best use of this common core of information.

26.18 Before describing the process by which revalidation was to be carried out, the Consultation Paper described the **'Principles of Revalidation'**. In summary, these were that it must be effective (i.e. it must sort out those who were fit to practise from those who were not); it must be locally based whilst reflecting the doctor's practice by reference to national standards; it must be transparent, comprehensive, thorough, proportionate to the risks posed by poorly performing doctors, fair, non-discriminatory, consistent and verifiable. By 'verifiable' was meant that the information used for making a judgement about a doctor's fitness to practise must be susceptible to audit. It was also said that revalidation must be as simple as was consistent with effectiveness and must build on, not duplicate, existing and planned arrangements; it must also be flexible, supportive and developmental, predictable (in the sense that it must not contain traps or ambushes) and properly resourced. The Consultation Paper also described the standards of good practice upon which revalidation would be based. The starting point for all doctors was to be 'Good Medical Practice', but more detailed standards were to be worked out for each of the specialties.

26.19 The Consultation Paper described the process of revalidation as it was then envisaged. The process would have three stages. The first stage consisted of the collection of the evidence on which the profiling of the doctor's performance was to be based. Every doctor was to maintain a revalidation folder, which should contain current information from several sources to show how well s/he was practising. The information was likely to include results of audit, a record of continuing professional development, the views of a sample of patients and the views of a sample of working colleagues, including those who referred patients to the doctor or received referrals from him/her. It was said that the revalidation folder would usually be reviewed annually; any deficiencies would be identified by the reviewer and advice given about how the doctor might remedy those deficiencies. It was envisaged that, in the NHS – at least within the hospital setting – the annual review would be conducted through employers' appraisal systems.

26.20 The second stage of the revalidation process would be an **'assessment'** which would take place every five years, when the doctor's revalidation folder would be assessed independently by a small revalidation group of doctors and lay people. The assessment

would be made against standards laid down by the GMC and the medical Royal College of the relevant specialty. The revalidation group would have to satisfy itself that the doctor was fit to practise and, if so satisfied, would recommend revalidation to the GMC. The third stage of the revalidation process was the action to be taken by the GMC. Usually, that action would consist of revalidating the doctor's register entry in accordance with the recommendation of the revalidation group. However, if the revalidation group considered that action on the doctor's registration was necessary, the GMC would have to decide whether to invoke one of its FTP procedures, which might result in the doctor's erasure or suspension or in conditions being imposed on his/her registration. It was made plain that if, at any stage in the five-year cycle, information came to light – as the result of clinical governance mechanisms or in any other way – which gave rise to serious concerns, these should be addressed immediately, usually by means of referring the doctor to local performance procedures but, in a bad case, by immediate referral to the GMC. The first and second stages of the revalidation process would be subject to external quality assurance. This was to ensure consistency, fairness and public safety.

26.21 In an important passage at paragraphs 20 and 21, the Consultation Paper explained that the quality assurance of medical care must involve several different bodies working together, of which the GMC was only one. The Consultation Paper stressed also that the intention was that clinical governance and revalidation would complement each other since **'neither on its own would be sufficient to protect patients'**. It said that there was broad agreement between the various bodies involved that revalidation should use existing and proposed local systems (for example, appraisal in the NHS), rather than devising new arrangements that would have the effect of taking doctors away from their patients.

26.22 In later sections, the Consultation Paper set out in greater detail how the revalidation process would work in practice. The type of evidence which it was expected would appear in the revalidation folders was described and comments were invited. It was expected that much of the information required should be **'generated as a by-product of quality assurance at their** (*i.e. doctors'*) **place of work'**. One suggestion was that information about patient complaints should be included. The Consultation Paper indicated that the GMC was working with other organisations to ensure that its requirements for the contents of the revalidation folder would be compatible with, *inter alia*, the emerging arrangements for the appraisal of doctors within the NHS. The medical Royal Colleges were to provide more detailed guidance as to what would be expected for each specialty.

26.23 The Consultation Paper contained a substantial section dealing with the link between appraisal and revalidation. Views were sought on this issue. At that time, appraisal for doctors within the NHS was in an early stage of development. The appraiser was to be another doctor. The Consultation Paper stated that appraisal was to be a formative process in that it was intended to support doctors in maintaining and improving their professional performance. Appraisal would include, but would not be limited to, a review of the contents of the doctor's revalidation folder. Any gaps in the revalidation folder should be identified and any deficiencies within the doctor's practice which were identified should be addressed by the appraiser arranging for any necessary

developmental or remedial action. That would give an opportunity for the deficiencies to be rectified before revalidation was due. One outcome of each annual appraisal should be a statement, which would go into the doctor's revalidation folder, confirming that a satisfactory appraisal had taken place and identifying any developmental needs. In this way, revalidation, when it came, ought to be straightforward.

26.24 The detail of the appraisal discussion was to be confidential as between the appraiser and the appraisee. This was considered necessary since it would be damaging to the appraisal process if appraisees felt unwilling to raise issues for fear that to do so might damage their prospects of revalidation. The revalidation folder used for appraisal would not be confidential. The revalidation group would examine the information contained in the revalidation folder, together with any other information about the doctor available to it from other sources, and would assess the accuracy, significance and sufficiency of that information before reaching a decision whether the doctor had demonstrated his/her fitness to practise. The Consultation Paper observed that the relationship between appraisal and the five-year revalidation assessment would need to be reviewed as the processes of appraisal and revalidation evolved.

26.25 The Government supported the GMC's proposals. Understandably, it was particularly anxious that those proposals should dovetail with NHS clinical governance arrangements and would not give rise to a lot of extra work for doctors. On 6th July 2000, Mr John Denham MP, Minister of State at the Department of Health (DoH), told a Parliamentary Standing Committee:

> **'We want to ensure that the system of revalidation on which the GMC has been working for some time fits well with the system of annual appraisal of doctors in the NHS and wider systems of clinical governance that we are putting in place. The systems must be seamless without duplication of time and effort in collecting information. I believe that the system that we are putting in place in the NHS will, if we get the details right, work effectively with the new measures from the GMC to introduce revalidation, which I welcome.'**

26.26 The GMC received many responses to its Consultation Paper. Most respondents were supportive of the principles of revalidation and approved the proposed methods of collecting of information, the proposed content of the revalidation folders and the method of scrutiny. Various concerns were expressed. In particular, it was felt that doctors would need a good deal of guidance. Almost all respondents approved the idea of a link between appraisal and revalidation. Many stressed the need to ensure that the formative nature of appraisal was not lost. Many respondents were concerned about what revalidation was going to cost the GMC. It was suggested that the GMC should undertake a cost benefit analysis. There was also a suggestion that, before the GMC adopted the proposals, they should be tried out in pilot studies.

26.27 In short, the public consultation revealed no concerted opposition to the proposals. There was, however, some opposition from within the medical profession. Sir Donald said, in

'The Doctors' Tale', that sections of the BMA were strongly opposed to the proposals. The opposition came particularly from the hospital consultants.

The First Pilot Study

26.28 The GMC decided to undertake a pilot study and this took place between February and April 2001 (the 2001 pilot study). It was conducted by a Revalidation Technical Group (RTG) which had been formed by the GMC. Its objective was to test the feasibility of using the revalidation folder as a means of evaluating a doctor's fitness to practise. Volunteer doctors were asked to assemble and submit revalidation folders. The folders were considered and assessed by mock revalidation groups, each of which was designated to deal with the revalidation folders submitted by doctors of a specified specialty. The groups had three options open to them. The first was to state that they were of the opinion that the doctor was up to date and fit to practise and to recommend that s/he should be revalidated. The second was to state that they could not certify that s/he was up to date and fit to practise and did not, therefore, recommend revalidation. The third was to request further information from the doctor before making any recommendation.

26.29 Five of the mock revalidation groups looked at all the 20 revalidation folders which had been submitted by GPs. It was found that there was great variability in the depth of information provided by different doctors and also in the time they had taken to prepare their material. It took group members an average of 21 minutes each to read the contents of a revalidation folder and an average of 13 minutes for a group to consider it together and reach a decision. There was a substantial degree of consistency between the decisions of the five groups; indeed, if the decisions of one of the five groups were excluded altogether, there was a remarkable degree of consistency between the results of the remaining four. The results for the GPs' groups showed that 86% of the recommendations were for revalidation; in only 11% of cases was further information requested and in only 3% was there a recommendation that the doctor should not be revalidated. I would have thought that those results were rather encouraging, especially as everyone involved was participating in a completely unfamiliar process. One might reasonably expect the process to improve and become quicker with repetition. The quality of material in the revalidation folders would improve as doctors gained a better idea of what was expected of them. More verifiable information would become available from clinical governance processes. Also, group members would gain in experience.

26.30 The RTG's report of the pilot study was generally optimistic for the future. It included the following observation:

> **'It is clear from the information generated by each panel** (*i.e. mock revalidation group*) **that there is a close correlation between positive recommendations for revalidation and those doctors who have been through appraisal. There are a number of reasons for this. Firstly, such doctors tended to have to hand the kind of information required by revalidation and were therefore able to supply the data needed to make a positive recommendation despite the short timescale of the piloting programme. Secondly, revalidation groups expressed greater**

confidence in making a positive recommendation where they knew that the doctor had already been subject to a review and documentation from that review had been made available. Thirdly, groups were in general reluctant to make positive revalidation recommendations where there was no third party verification of the data presented by the doctor. Third party verification is not limited to appraisal but clearly having an appraisal is helpful in this respect.'

26.31 In the light of subsequent events, that passage merits further attention. First, at the time of this pilot study, GPs were not subject to appraisal; appraisal for consultants was introduced very shortly afterwards. The observation that the revalidation groups had been more confident to recommend revalidation for doctors who had been appraised must, therefore, have related to hospital doctors below consultant grade – in other words, doctors in training grades, who could truly be said to be working in a 'managed environment'. All or most of the information used in their appraisals would have been provided by their employers and would be verifiable. Second, it appears that it was not only the fact that appraisal had taken place, but also the availability of the documentation from that appraisal, that gave confidence to the revalidation group. However, the statement that revalidation groups were reluctant to recommend revalidation unless the data presented by the doctor had been verified in some way is interesting and slightly puzzling. The revalidation groups had recommended revalidation in 86% of cases relating to GPs. It is difficult to see how much of the GPs' data could have been verified. They had not yet been appraised and there was – and still is – very little clinical governance data emanating from primary care organisations (PCOs) that relates to an individual doctor. However, apart from being slightly puzzled, I am not at all surprised that a revalidation group would find comfort in the knowledge that at least some of the data it was considering had been verified in some way. It seems likely that another factor would be that doctors who had undergone appraisal would have a better idea of how to assemble a revalidation folder that gave a good picture of their practice.

The Cost Benefit Analysis

26.32 Following the 2001 pilot study, the GMC undertook a cost benefit analysis or, at least, did its best to do so. It found, not surprisingly, that it was relatively easy to assess the costs of implementing its proposals for the revalidation process. However, it was almost impossible to assess the benefits of revalidation. The benefits were not assessable in the short term; they would accrue over a long period of time. In any event, revalidation was only one aspect of the drive for improved quality and it would be impossible to ascribe any particular improvement to revalidation, as opposed to any other measure. The exercise enabled the GMC to find out how much it would cost to implement the proposals but was otherwise inconclusive.

26.33 The cost analysis showed that, following the introduction of revalidation, the total annual financial deficit to the GMC which would result from the introduction of revalidation could be as much as £14 million. First, there would be the annual operational cost of £9 million. Then there would be a sum of nearly £5 million which would result from the loss to the GMC of the annual retention fees (ARFs) paid by a substantial number of retired or

non-practising doctors who, it was expected, would not choose to seek revalidation but would instead allow their registration to lapse. If some of those doctors transferred onto the supplementary list, for which a reduced ARF was payable, that £5 million loss would be reduced to some extent. So, the overall cost to the GMC would lie somewhere between £9 million and £14 million.

26.34 In addition, the human resource implications were assessed. Doctors would have to spend time preparing their revalidation folders; some would be taken away from clinical work to sit on revalidation groups; some would be involved with assessment of those found to be performing poorly. In all, it was thought that the revalidation proposals would require the annual full-time equivalent of 204 doctors.

Developments during 2001

26.35 During 2001, the GMC's thinking moved in the direction of making a closer linkage between revalidation and appraisal. This closer linkage developed from discussions and correspondence that took place between Sir Donald, then President of the GMC, and representatives of the BMA. The relevant correspondence did not become available to the Inquiry until May 2004, about five months after the GMC witnesses had given evidence. It is welcome as it allows me to fill in a gap in the history.

26.36 The disclosed correspondence shows that, from some time before May 2001, Sir Donald had been in correspondence with the BMA about the revalidation of hospital consultants. I mentioned earlier that Sir Donald had described in his book, 'The Doctors' Tale', how the hospital consultants were opposed to the idea of revalidation. The opposition was channelled through the Central Consultants' and Specialists' Committee (CCSC) of the BMA. At this time, the GPC of the BMA was strongly supportive of the proposals, as was the RCGP.

26.37 On 4th May 2001, Sir Donald wrote to the then Chairman of the BMA, Dr Ian Bogle. It is clear that the letter was written against the background of the recent successful conclusion of the negotiations between the CCSC and the Government about the introduction of a requirement that all consultants working in the NHS should undergo annual appraisal. The Government had been determined to introduce this requirement and the consultants had not been enthusiastic about the idea. However, a deal had been struck, the details of which are of no concern to the Inquiry. Appraisal was to be based upon the principles of 'Good Medical Practice'. At this time, there had not as yet been any agreement about the appraisal of GPs. Sir Donald's letter was about revalidation. He expressed his pleasure that the BMA was committed to the principle of revalidation. He went on to stress the importance of the Government's investment in clinical governance, in particular the collection of data, audit and appraisal. He stressed that the GMC wanted to ensure that revalidation was built on clinical governance. The GMC wanted revalidation to be as simple as possible, consistent with effectiveness. The more effective the NHS's clinical governance arrangements, he said, **'the lighter the GMC's touch can be'**. He then referred to the conclusion of the negotiations on appraisal for consultants and said:

> **'Provided that this agreement is robustly and effectively implemented, NHS appraisal documentation will be the vehicle for revalidation for the**

great majority of NHS consultants. We would take the same approach with other groups of doctors who have appraisal systems. In particular, we look forward to receiving details, when they are agreed, of the outcome of negotiations in relation to appraisal for GPs, academic clinicians, doctors in training and locum doctors working in an institutional setting.

Once these arrangements are in place, which should be soon, it will be possible to put revalidation for the vast majority of doctors in the country on a sound operational footing.'

26.38 That letter does not suggest that the idea of assessment by local revalidation groups was to be abandoned and replaced by NHS appraisal. What Sir Donald was suggesting was that the material to be assessed should be the documents resulting from the appraisal (i.e. the forms completed by the appraiser and the appraisee, which I shall refer to as the 'appraisal forms'), rather than the entire contents of the doctor's revalidation folder.

26.39 Later in that same letter, Sir Donald spoke of the GMC's intention to provide quality assurance of revalidation decisions by calling for a sample of doctors' revalidation folders and having their contents scrutinised by GMC assessors. The purpose of this scrutiny would be to check on a random basis that the outcomes of appraisal were consistent with, and fully supported by, the underlying evidence on which they were based. Sir Donald also outlined the programme for the implementation of the revalidation proposals. At the meeting to take place later that month (May 2001), Council members were to be invited to agree that the Government should be approached about the legislative amendment that would be necessary in order to implement the proposals. It was hoped that the necessary legislation would be in force by about May 2002 and that revalidation would actually begin in 2004.

26.40 At its May 2001 Council meeting, the GMC considered a detailed description of the revalidation process and duly resolved to request the Government to put the necessary legislative framework in place, on the understanding that much detailed work remained to be done.

26.41 On 27th June 2001, Sir Donald wrote to Dr Peter Hawker, Chairman of the CCSC, in reply to a letter from Dr Hawker, which I have not seen. In this letter, Sir Donald repeated the undertaking he had given to Dr Bogle about the use of appraisal documentation as a vehicle for revalidation of NHS consultants. He said that it had not been possible to pilot the use of appraisal documentation in the 2001 pilot study because there had been no such documentation available. This was a reference to the fact that, at the time of the 2001 pilot study, only hospital doctors below consultant grades had undergone appraisal and no standardised forms had been produced for completion by appraisers and appraisees in the course of the appraisal process. Consultant appraisal was launched in April 2001 and appraisal documentation was to be considered in a further pilot study.

26.42 In October 2001, Mr Scott, Chief Executive of the GMC, wrote to Dr Bogle. He repeated the GMC's assurance that, provided appraisal was **'robustly and effectively'** implemented, appraisal documentation would be the vehicle for revalidation of the great majority of NHS

consultants. Later in the same letter, Mr Scott clarified what written material would have to be produced by a doctor wishing to be revalidated. Each consultant would have to produce Forms 1 to 4 of the consultant appraisal documentation for each year of the revalidation period. I described these forms in Chapter 12 and specimen forms for use in GP appraisal are at Appendix D. Consultants would not be required routinely to produce the underlying documentation (i.e. the contents of their revalidation folders) but would have to do so on request. This might occur as part of the quality control sampling or if the revalidation group or the GMC needed **'for other reasons to look in more depth before a decision on revalidation can be made'**. I infer from this letter that it was the intention of the GMC to receive a full set (i.e. Forms 1 to 4) of the completed appraisal forms, which would then be scrutinised by the revalidation group. If the revalidation group was in doubt about whether to recommend revalidation, it would call for the underlying documentation, i.e. the contents of the doctor's revalidation folder.

26.43 The briefing papers circulated prior to the Council meeting in November 2001 contained a progress report, setting out the current position, as described above. The intention was to use for the purposes of the revalidation process the completed appraisal forms for all doctors who had undergone appraisal. Annex A to the briefing paper set out the state of development of the appraisal arrangements for various groups of doctors. In relation to NHS consultants, it was said that NHS appraisal would be the vehicle for revalidation provided that it was robustly and effectively implemented. The briefing paper described other ongoing work, including that with the medical Royal Colleges and their Faculties (i.e. sections dealing with small specialties), which were to develop the standards and criteria that would be imposed and the specific evidence that would be required to be produced by doctors within each specialty. A further pilot study was to be carried out. On a different topic, it was suggested that those doctors who were not in clinical practice (or not in full-time practice) should be eligible for revalidation if they were to submit the results of an assessment carried out at their own expense.

Taking Stock of the Position in 2001

26.44 It seems to me that the practical proposals for the revalidation process set out in the Consultation Paper had been well thought out. They were consistent with the underlying principles of revalidation. The 2001 pilot study had shown that revalidation by the review of folders was feasible, although the proposal for reviewing appraisal forms had not yet been tested. The methods envisaged for revalidation would be quite expensive to put into operation, in terms of both money and human resources. They would also impose a very substantial administrative burden on the GMC, a point to which I shall later return. The proposals complied with the requirements of the Government that there should be as little duplication of effort as possible between appraisal and revalidation. The doctor would prepare his/her folder of evidence for use in appraisal; that appraisal would be carried out either by an employer or under arrangements to be agreed for GPs, for which PCOs were to be responsible. The information within the doctor's folder would, where possible, be drawn from that gathered in the process of clinical governance. The folder or the appraisal forms would be used again in revalidation although, in the majority of cases, the folder would not have to be produced.

26.45 It is true that there were some obvious imperfections and uncertainties. In 2001, consultant appraisal was in its early days, so it was not known how much information would be contained in appraisal forms and how reliable it would be. Clinical governance processes throughout the NHS were in their infancy and the amount of information available from such sources was small; but it might reasonably have been expected to improve in the future. Those who were aware of the position in general practice would have known that there was, at that time, very little 'hard' information available about an individual GP's performance, unless s/he was a single-handed practitioner. Information was collected about GP practices, not about individual practitioners. Moreover, appraisal of GPs had not yet begun; it was scheduled to begin in 2002 but, in 2001, it was not known how it would work in practice. There was also a major concern as to whether appraisal would achieve its formative purpose if the same appraisal forms and folder of information were also to be used for revalidation purposes. Concerns of this nature were discussed within the profession and within the GMC.

26.46 One concern which does not appear to have been raised at this period was whether the standards of performance applied by the CPP in making findings on the issue of seriously deficient performance (SDP) were high enough to provide a satisfactory baseline for revalidation. It will be recalled that the GMC had decided at an early stage that any doctor who was not granted revalidation through the usual revalidation process would not be deprived of his/her licence to practise save as the result of a decision of one of its FTP committees. It must, I think, have been anticipated that the most likely form of FTP procedure that might result in the loss of a licence following an unsuccessful attempt to obtain revalidation would be the performance procedures. There was no discussion of whether the fact that a doctor's performance had been found by the CPP not to be seriously deficient could properly be equated with the assurance to be given to the public that revalidation would mean that their doctor was 'up to date and fit to practise'.

26.47 However, with the *caveats* mentioned above, it appears to me that the foundation for a system of revalidation that would command public confidence had been well laid.

Observations in the Report of the Bristol Inquiry

26.48 The Report of the Public Inquiry into children's heart surgery at the Bristol Royal Infirmary between 1984 and 1995, 'Learning from Bristol', was published in July 2001. The GMC had given evidence to that Inquiry and had explained its proposals for revalidation. These met with the warm approval of the Inquiry Panel, chaired by Professor (now Sir) Ian Kennedy. The Report noted that revalidation involved **'the submission of evidence to external assessors of continuing competence'**. If the doctor could not demonstrate continuing competence, his/her licence to practise would be called into question and ultimately withdrawn. It observed that the GMC's proposals were at an advanced stage of development. The potential value of revalidation was already coming to be widely recognised by the public, as well as within most (although not all) of the healthcare professions. The Report recommended that revalidation should become mandatory for all healthcare professionals and that the necessary processes should be developed as soon as possible. The Report stressed the importance of external assessment in the revalidation process. The fact that there was some resistance within the healthcare

professions must not, it was said, be allowed to stand in the way of progress. The Report observed that the public was entitled to the protection of an assurance that all healthcare professionals had reached agreed levels of competence.

26.49 The Report also discussed ways in which public confidence in the process of revalidation could be gained and retained. The Inquiry Panel plainly understood that the revalidation of doctors was to be carried out by revalidation groups or 'revalidation teams'. The Report recommended that the revalidation team should include **'an external presence'**, i.e. a person or member of an organisation external to the profession and to the employer. This was to be someone with an understanding of the public interest. The Report also suggested that there should be a mechanism for ensuring that the systems for revalidating healthcare professionals were integrated into other initiatives for protecting patients. It proposed that the task of co-ordinating these various systems should be a priority for the Council for the Regulation of Healthcare Professionals (now known as the Council for Healthcare Regulatory Excellence) which was to be established shortly.

The Second Pilot Study

26.50 The GMC's second revalidation pilot study took place in April 2002. Again it was conducted by the RTG. The report setting out the results of the study was issued in September 2002. The purpose of the second study was to examine the quality of the linkage between the **'outputs of appraisal systems'** and the information needed for the revalidation process. It was hoped that a better understanding would be gained of the documentation that would emerge from appraisal (i.e. the completed appraisal forms) and its capacity to demonstrate fitness to practise in accordance with 'Good Medical Practice'. The study also sought to compare the capacity of the completed appraisal forms to demonstrate fitness to practise with the capacity of the underpinning evidence contained in the doctors' folders to do so.

26.51 As I have said, consultant appraisal was introduced in April 2001 and, by April 2002, the process of appraising consultants was well underway. It is clear from the report of the second pilot study that the consultants' appraisal forms were similar to those which were just coming into use for GPs. GP appraisal officially began in April 2002. However, at the time of preparation for the second pilot study, GP appraisal had not yet begun and it appears that the detail of the appraisal forms to be used had not yet been finally agreed. The pilot study comprised consideration by mock revalidation groups of appraisal forms submitted by hospital doctors who had recently undergone appraisal. A few GPs were also included, using appraisal forms that had been developed in Wales as part of a GP appraisal pilot project.

26.52 Some of the mock revalidation groups examined the underpinning evidence contained in the doctors' folders, as well as the appraisal forms. Other groups just considered the appraisal forms. There were four forms. Form 1 provided factual background information about the doctor's career and professional status. Form 2 described the doctor's current professional activities. Form 3 comprised a list of the documents that were held in the doctor's folder and a statement about any continuing professional development that the doctor had undergone in the previous year. Form 4 contained an agreed summary of the discussion that had taken place during the appraisal interview.

26.53 The findings of the pilot study were that, when the evidence contained in doctors' folders was scrutinised by the revalidation group, it would have been sufficient to allow a positive revalidation decision in 69% of cases; in the remaining cases, more information would have been required. However, when only the appraisal forms were considered, the conclusions were that, although the forms were capable in some cases of providing sufficient insight into the doctor's practice to form a sound basis for revalidation, they did not do so in the majority of cases. Only in 32% of cases could a positive revalidation decision have been made; in the remainder, more information would have been required. In particular, there were four specific areas of 'Good Medical Practice' in which there was often a shortage of information. These were 'Working with colleagues', 'Relationships with patients', 'Health' and 'Probity'. Nevertheless, the overall conclusion of the report was that, if all four forms were completed and if Form 4 contained a summary of a **'robust appraisal discussion'**, it could be adequate for the purposes of revalidation. In other words, provided that those conditions were satisfied, there would be no need for a revalidation group to examine the underpinning evidence from the doctor's folder.

26.54 The report explained the RTG's plans for further work. It intended first to work on ways in which the provision of information could be improved, particularly in the four areas of 'Good Medical Practice' that had been identified as giving rise to difficulties. Its work would include the development of a patient questionnaire and of a questionnaire dealing with relationships with colleagues. Then, it was proposed to conduct further pilot studies, using those improved types of information. After that, the RTG intended to focus on the internal GMC procedures for handling the different aspects of the revalidation process. These plans for further work were never taken forward because a halt was called and the RTG was disbanded – I am not sure when.

The Amending Legislation

26.55 In December 2002, the Medical Act 1983 (the 1983 Act) was amended by the addition of new sections 29A to 29J. These were to come into force on a date which has still to be appointed. Section 29A imposed a duty on the GMC to make regulations with respect to **'licences to practise'**. The regulations were to cover the granting, refusal or withdrawal of a licence to practise and the **'revalidation of a medical practitioner of a prescribed description as a condition of his continuing to hold a licence to practise'**. Revalidation was defined in the Act as an **'evaluation of a medical practitioner's fitness to practise'**. The new provisions appear to me to impose on the GMC a duty to make regulations empowering it to revalidate doctors, in the sense of carrying out an evaluation of a doctor's fitness to practise. The legislation gave the GMC very wide powers to require the production of documents and the supply of information for the purpose of revalidation and, if a doctor failed to co-operate with the revalidation process, the GMC could withdraw his/her licence to practise. In the event that a doctor's fitness to practise was thought to be impaired, s/he could be referred into the FTP procedures. The legislation was therefore in place for revalidation to be implemented in accordance with the arrangements described in the Consultation Paper of 2000.

A Change of Direction

26.56 Until April 2003, an informed member of the general public who had been following the development of the GMC's proposals for revalidation would have thought that the GMC intended to be directly responsible for the revalidation of all doctors and that the process would involve an evaluation of the individual doctor's fitness to practise, undertaken by a revalidation group (usually a local revalidation group), of which at least one member would be a lay person. The perception would have been that the twin purposes of revalidation were to be to protect patients and the public from under-performing doctors and to improve the quality of health care generally. However, in April 2003, that informed member of the public would have discovered that the GMC's plans had changed, that it had abandoned the idea of evaluation of individual doctors by revalidation groups and that it now intended to revalidate, in most cases without further scrutiny, all doctors who had undergone five consecutive annual appraisals – or, in fact, fewer than five at the beginning of the revalidation cycle.

The Prospectus of April 2003

26.57 In April 2003, the GMC issued a document which it has since termed a 'Prospectus', but which was in fact a booklet issued to all doctors on the medical register. The Prospectus was entitled 'A Licence to Practise & Revalidation' and it was intended to inform doctors how revalidation was going to work in practice. The Prospectus was designed to enable doctors to start making preparations for revalidation. The purpose of revalidation was explained; it was to modernise the system of regulation and to increase public confidence. The aim was to ensure that doctors were up to date and fit to practise throughout their careers. Doctors were advised to **'start thinking now'** about how they would collect the information that would demonstrate to the GMC that they were fit to practise. The GMC said that, during 2004, it would ask all doctors on the register whether they wanted a licence to practise. If they did, a licence would be granted by the end of 2004, after which time it would be unlawful to practise without a licence. The licence granted would be a general one, not related to any particular specialty. The register, which is a public document, would state whether the doctor held a licence to practise.

26.58 The Prospectus said that revalidation of those doctors who had been granted licences to practise would begin in April 2005 and that, in order to retain his/her licence to practise, every doctor would have to be revalidated at some stage over the following five years. Revalidation would require the doctor personally to show the GMC that s/he had been practising medicine in accordance with the principles of 'Good Medical Practice', as applied to the doctor's specialty. The Prospectus stated that the GMC would not seek to prescribe exactly what information a doctor should collect for this purpose. Indeed, the GMC had formed the view (apparently on the basis of legal advice which it had received) that it did not have the legal powers to do so. I interpose to say that I find that surprising in view of the powers that it will have when sections 29A to 29J of the 1983 Act (as amended) come into force; but that is what was said. The information the doctor was to provide would have to cover all headings in 'Good Medical Practice'. It would be up to each individual doctor to decide how s/he would demonstrate to the GMC that s/he was fit to practise.

26.59 The Prospectus explained that there were to be two possible routes to revalidation: the **'appraisal route'** and the **'independent route'**. In order to take the **'appraisal route'**, the doctor would have to show the GMC that s/he worked in a **'managed environment'** and had **'participated in an annual appraisal system'**. For an appraisal to be acceptable to the GMC, it would have to be based on the principles of 'Good Medical Practice' and **'be operated within a quality assurance system'**. It was said that the GMC believed that **'full participation in annual appraisal'**, with **'completed supporting documentation'**, during the revalidation cycle was **'a powerful indicator of a doctor's current fitness to practise'**.

26.60 It seems that the GMC had arrived at this state of belief despite the fact that the second pilot study had shown that in only 32% of cases had the perusal of the completed appraisal forms been sufficient to allow a decision to be made that the doctor was fit to practise. Yet the Prospectus asserted that the GMC believed that merely taking part in annual appraisal (for the purpose of which appraisal forms were completed) would provide a powerful indicator that the doctor was fit to practise. It is not clear on what evidence this belief was based.

26.61 The Prospectus explained that doctors working in a variety of NHS settings, including GPs working under a General Medical Services (GMS) Contract, would be able to consider themselves as working within a **'managed environment'** for the purpose of revalidation. The justification for that was that GPs were participating in a scheme of annual appraisal with quality assurance. However, it does not seem to me that GP principals, who are independent contractors, can be said to work in a **'managed environment'** within the ordinary meaning of that term. The Prospectus said that, for those doctors who were already subject to appraisal, there was nothing additional that they needed to do to prepare for revalidation. They should not have to collect any data for revalidation over and above that which they would be required to record and keep for appraisal and other local systems. Provided doctors were confident that, by the time they came to be revalidated, they would have had at least one appraisal, they need do nothing more. The Prospectus made clear that the GMC would not usually ask to see the folder of evidence that a doctor had prepared for appraisal. However, the GMC might wish to examine a sample of such folders.

26.62 The Prospectus then outlined the independent route to revalidation. This might apply to doctors working outside mainstream health care, those with 'portfolio' practices or those taking a career break or working overseas. For such doctors, the onus would be on them to produce evidence to show that they were adopting the principles of 'Good Medical Practice' and were undertaking appropriate continuing professional development. Acceptable evidence would include **'appropriate quality indicators'**, where necessary supported by other data and information. The Prospectus explained that the GMC was developing a range of tools to help doctors who wanted to provide independent evidence for use in the revalidation process. These would include self-declaration forms to cover the 'Probity' and 'Health' headings of 'Good Medical Practice'. Also, there would be a patient satisfaction questionnaire to cover the heading 'Relationships with patients' and a professional colleague survey which could be used for the heading 'Working with colleagues'. The Prospectus said that the evidence would be reviewed in a way which

would be **'as efficient, effective and proportionate to the aims of the process as possible'**. The GMC did say that it would not normally ask the doctor to provide all the information used to support evidence of practice quality.

26.63 The Prospectus advised doctors that they would be given notice in due course of what was required of them and when. It also indicated that the GMC intended to carry out **'appropriate testing'** before revalidation began in 2005. It was not made clear to what this **'testing'** referred.

26.64 The Prospectus also provided an explanation of the processes which would follow if the doctor failed to provide sufficient or adequate information, and described the circumstances in which a doctor's licence to practise might be withdrawn. It explained that, if the information initially provided by the doctor was thought to be insufficient, the GMC would ask for further information. If, thereafter, it was considered that the information was **'inadequate'** the GMC would assess the doctor's case to see if there was:

> **'. . . positive evidence that you** (*the doctor*) **are not fit to practise.**
>
> **If there is not we will revalidate you and your licence to practise will remain valid. If there is we will refer you to the appropriate fitness to practise procedure. The process will be bound by statutory rules and you will have the right to appeal against our decision.'**

And later:

> **'We will only withdraw your licence if ... a fitness to practise panel directs that your registration should be suspended or erased.'**

26.65 The Prospectus did not explain how the stage between the initial consideration of information and the final stage of referral into the FTP procedures would be carried out. I feel bound to draw attention to the difference between the language used to address doctors and that later used to explain revalidation to the public. Doctors were told that they would be revalidated unless there was positive evidence that they were unfit to practise. The public was told that, to secure revalidation, a doctor would have to demonstrate that s/he was up to date and fit to practise.

26.66 This explanation was followed by a section headed **'Questions and Answers'**. One question asked how the proposed system of revalidation compared with assurance systems outside medicine. In the answer, the Prospectus stated that there was a **'good professional comparison'** with the periodic formal reassessment that airline pilots must undergo if they wish to retain their licence. It was said that this process was analogous in several ways to the new arrangements for doctors. First, it promoted the idea of regular confirmation of fitness to practise. Second, the purpose of reassessing pilots is, it was said, to ensure that they have remained good pilots, not to find out if they are bad pilots. There were more appropriate local and rapid ways of identifying bad pilots. Third, it was said that no airline would rely only on periodic reassessments; airlines have their own local management procedures to assess their pilots' suitability for specific work. In one respect, this comparison between doctors and pilots is particularly apposite; both doctors and airline pilots take our lives in their hands when working. I can see also that there may be

other similarities between the revalidation of doctors and the formal assessments undergone by pilots. However, the answer in the Prospectus did not mention an important distinction between the two processes, namely that pilots have to undergo a series of competence tests in the course of periodic assessment, whereas revalidation, as proposed in the prospectus, would not involve any such testing.

26.67 Another question and answer dealt with the role of lay persons. It will be recalled that, under the arrangements envisaged up to the end of the second pilot study, undertaken in April 2002, at least one member of the local revalidation group was to be a lay person. The Prospectus of April 2003 explained that lay people would be involved at two levels, **'in both the design of the systems and their operation'**. It appears that the reference to lay input to the design was a reference to the fact that lay people had been involved in the development of 'Good Medical Practice' and in **'shaping policy on revalidation'**. It was clear that lay involvement in the appraisal route to revalidation was to be limited to the fact that **'Appraisal systems based on *Good Medical Practice* require doctors to reflect on the quality of their relationship with patients.'** It was said that **'Doctors may use questionnaires completed by patients as a means of giving us information about the quality of their professional practice.'** Presumably, this related to doctors who were seeking revalidation via the independent route. Third, it was noted that **'The quality of doctors' relationships with patients will also be considered as part of clinical governance systems.'** Finally, it was said that lay people would monitor the GMC's processes; how they would do so was not explained. It was said that decision panels considering individual cases would have a lay member. I think that these would be the panels which were to hear appeals against licensing decisions. It was said that the GMC's Patients' Reference Group would **'regularly consider the revalidation process'**. What seems clear is that there was to be no routine lay involvement in the decision whether to revalidate an individual doctor. In short, there had been a retreat from the earlier commitment to active lay involvement in that process.

26.68 Thus it appeared that, by early 2003, not only had the GMC rejected the idea that revalidation should, for most doctors, be based on evaluation by local revalidation groups, it had also moved to a position where, as it was put in the medical press at the time, for doctors working in the NHS, **'five satisfactory appraisals equals revalidation'**. Indeed, in the early years, only one appraisal might equal revalidation. How and why the GMC had moved to this position was not made clear.

26.69 The implications of the change must be understood. The GMC had moved from evaluation by a revalidation group of an individual doctor's fitness to practise by means of examination of evidence (be it the contents of his/her folder or the completed set of appraisal forms) to a position where there was to be no individual evaluation at all but, instead, an assumption that, if the doctor had been through the appraisal process, s/he must be up to date and fit to practise.

Reactions to the New Proposals

26.70 Between April 2003 and the time when the GMC was due to give evidence to the Inquiry, there was considerable discussion in the medical press about the new proposals. By and

large, doctors seemed content with the proposals although some objections were raised from within the profession. For example, an article which appeared in the periodical 'Doctor', on 17th July 2003, reported that Professor Pringle, then Chairman of the RCGP and a member of the GMC, had warned that revalidation under the current proposals would not achieve what it purported to achieve. He said that it would not offer the public protection from poor or under-performing doctors. It would only **'create an illusion'** of protection.

26.71 During the second half of 2003, the Inquiry received a good deal of evidence about the appraisal of GPs, which had been introduced in the spring of 2002. By the time of the Inquiry hearings, one cycle of appraisal of GP principals should have been completed. The Inquiry heard evidence from a number of witnesses, in particular from Dr Chisholm, and also from Dr Reith, who gave evidence and attended the Inquiry seminars on behalf of the RCGP. I have referred to their evidence in Chapter 12. Both were enthusiasts for the concept of the appraisal of GPs – indeed of all doctors – but they expressed concern about the use of appraisal as the foundation for revalidation. The more I heard, the more concerned I became at the prospect that revalidation was to depend so heavily on appraisal.

26.72 The main concern that the witnesses expressed, the validity of which I came to accept, was that the appraisal of GPs had been designed for purely formative purposes; it was intended that it would provide for doctors an opportunity, in dedicated time, to think and talk about their practice and, by means of this process, to improve it. It had not been intended to provide any form of assessment or evaluation of the doctor. Appraisers were not intended to, and had not been trained to, form any judgement about an appraisee's fitness to practise. Appraisal was to be based upon (although not limited to) a confidential discussion based on a folder of documents produced by the doctor. The appraiser's role was to stimulate self-examination by the appraisee in circumstances of complete confidentiality and to help the appraisee to plan his/her future professional development. GPs being appraised were to feel free to raise concerns about themselves or their practices without any fear that they would be 'judged' upon them, let alone that they would be reported. Only if serious concerns arose would the appraiser stop the appraisal and report his/her concerns to the PCO. That was the only circumstance in which a GP could 'fail' an appraisal. If appraisal were now to be used for the purposes of assessment or evaluation, GPs might not be frank and open with their appraiser and the formative value of appraisal would be lost. GPs had initially been suspicious about the whole idea of appraisal and had accepted it only when satisfied of its formative nature.

26.73 The second concern was that the arrangements for the appraisal of GPs were consistent with its formative purpose and were not appropriate for an assessment or evaluation. The contents of the folder of information upon which the appraisal was based were selected entirely by the doctor being appraised. There was no list of documents that the doctor had to produce. Nor was there, in any of the areas examined by the Inquiry, any direct input by the PCO into the appraisal process of data collected from clinical governance activity. A doctor could submit such data if s/he had it and wanted to submit it but, if s/he preferred not to, there was no obligation to do so. In any event, as I explained in Chapter 12, PCOs have very little clinical governance data that relates to an individual doctor; in the main, it

relates to the GP practice as a whole. A further problem was that PCOs would not necessarily tell an appraiser if they had any particular concern about a doctor. As a result, a PCO might be aware of a serious complaint against the appraisee; the appraisee might or might not raise it for discussion with the appraiser but, if s/he did not, the appraiser would remain in ignorance of it.

26.74 During the hearings, I had the opportunity to examine some anonymised completed appraisal forms provided by the Tameside and Glossop Primary Care Trust (PCT). The amount and type of information contained on the forms produced was very variable but, in some cases, it was sparse and could never have provided a basis for an evaluation of fitness to practise, even if the appraiser had been qualified and trained to carry out that task. A further concern was that, apart from the section of Form 4 on which were set out the doctor's training needs for the coming year, some PCOs (including the Tameside PCT) did not receive any of the appraisal forms. It had apparently been intended that they should receive copies of Form 4 (which should contain a summary of the appraisal discussion) but it became clear in the course of the Inquiry's evidence that this was not happening in some areas. Moreover, it had never been envisaged that PCOs would see the contents of the doctor's folder and the evidence to the Inquiry was that they did not do so. Thus, although appraisal was said to be a part of clinical governance, many PCOs had no input and received very little output.

26.75 Yet another concern related to the variable arrangements made by different PCTs when introducing appraisal. In some places, many GPs had not yet been appraised; in others, they had been appraised, but the quality of appraisal as between PCTs appeared to be variable. Selection processes for appraisers were also variable; in some places, PCTs had insisted that only accredited GP trainers could act as appraisers; in others the PCT had simply called for volunteers. Appraisers underwent training but it was very brief and often provided little more than an introduction to the documentation. Some PCTs provided additional support and training; others did not. Certainly, there had been no attempt at teaching appraisers how to evaluate a doctor's fitness to practise. Indeed, this is hardly surprising as that was not the purpose of the exercise. Appraisers were advised that, in the unlikely event that a serious concern arose about a doctor's fitness to practise, the appraisal should be discontinued and the concerns reported to the PCT. How serious the concern would have to be before the appraiser took that action was not clear. Advice issued by the DoH suggests that it would be appropriate to discontinue appraisal if it appeared that the doctor's conduct, health or performance posed a threat to patients. The Inquiry has not heard of any case in which an appraisal has been stopped for that reason.

26.76 I agreed with those witnesses, including Dr Reith, Dr Chisholm and Professor Richard Baker, who told the Inquiry that this process of appraisal would not be an appropriate basis for revalidation. It could not be compared with the kind of appraisal that I know takes place in many employment situations, where an employee is appraised by a senior person who is in possession of a good deal of information about the employee's performance during the previous year. Nor did it appear to me that GP appraisal could be considered a suitable substitute for the scrutiny of a doctor's folder by a local revalidation group. It seemed to me that, under the arrangements described in the Prospectus of April 2003, the GMC had, in effect, delegated responsibility for revalidation of GPs to appraisers, who

were not expected and were not equipped to carry out an evaluation of the doctor's fitness to practise. The GMC was not intending to examine the doctors' folders and it was not clear from the Prospectus whether it would examine the appraisal forms. It subsequently became clear that there was no intention to examine the forms. In short, there was to be no **'evaluation'**, as required by the imminent amendments to the 1983 Act. It appeared to me that, instead, the GMC was going to renew, virtually automatically, the licence to practise of any doctor seeking revalidation provided that his/her appraisal had not been stopped on account of serious concerns having arisen about his/her fitness to practise. I became concerned that such a system would offer no greater protection to patients than that afforded by existing systems and that, therefore, the public could not reasonably have confidence in revalidation as then proposed.

When and Why Did the General Medical Council Change Direction?

26.77 The Inquiry invited the GMC to provide a witness statement dealing with its proposals for revalidation. The GMC submitted a written statement from Mr Brearley. Shortly before the Inquiry hearings reached the stage at which revalidation was to be discussed, the GMC announced an important modification to its previous proposals. This was the addition of a requirement that a doctor seeking revalidation should produce a 'clinical governance certificate', signed by a senior officer of the organisation employing the doctor or, in the case of a GP, by an officer (probably the clinical governance lead) of his/her PCO. The certificate would state that there were no (or no significant) unresolved concerns about the doctor, arising out of clinical governance procedures. There was still left in place the basic proposal that, for doctors working in a **'managed environment'**, revalidation would be based upon appraisal. I shall discuss this modification of the GMC's proposals later in this Chapter. For the moment, I shall attempt to focus upon the course of events in the months preceding April 2003 and the reasons for the change of direction.

26.78 Mr Brearley's witness statement did not explain the events that had led to the publication of the new proposals in April 2003. Accordingly, I examined the briefing papers and minutes of the Council meetings that took place during this period. I could find no paper dealing with proposals for the revalidation process or any reference to a proposal for change during the period between September 2002 and April 2003. The minutes of Council meetings during this period contain no reference to a decision to change the arrangements previously proposed. It seems that the decision may have been taken at a special internal conference in February 2003. I have seen no record of the discussion which took place there.

26.79 Dame Lesley Southgate told the Inquiry that the RTG, of which she was a member, had been disbanded. She did not say when this had happened. She seemed very reticent on this topic and I did not press her about it but she did say that she thought that the group had been disbanded because it had been 'parting company' with the GMC on the direction revalidation was to take. Mr Brearley said that the further work which it had been planned that the RTG should undertake after the second pilot study was not undertaken because of the GMC's increasing interest in using clinical governance processes for revalidation and a 'slight change of direction with regard to evaluation of evidence'.

26.80 Dr Chisholm told the Inquiry that the GPC of the BMA had been extremely supportive of the GMC's early proposals for revalidation based upon scrutiny of the doctor's folder. It had worked with the RCGP to produce the booklet 'Good Medical Practice for General Practitioners', which was to form the basis of the standards to be applied by those undertaking the revalidation evaluation. When asked about appraisal, he said that he and his Committee were strongly supportive of appraisal and were anxious to see it well resourced and implemented. However, he expressed reservations about the nature of the direct linkage between appraisal and revalidation that had been GMC policy since publication of the Prospectus in April 2003. He then volunteered that he thought that there were two reasons why the GMC had changed its policy. First, he thought that the GMC had found the concept of in-depth revalidation to be 'rather daunting in terms of the complexity of the task'. Second, he said that there was 'really quite strong enthusiasm from the BMA representatives of the hospital doctors to go down the route of five satisfactory appraisals being the way to revalidate'. He added that, at the last GMC meeting he had attended (which would have been the last meeting of the 'old' GMC of 104 members on 20th and 21st May 2003), Professor Pringle had 'made a very trenchant attack on the way in which appraisal and revalidation were now to be linked'. Dr Chisholm added that the debate was now over and that the April 2003 proposals were to be the 'way forward'. He accepted that this represented a considerable shift from the GMC's earlier proposals. Later in his evidence, he said that there had been voluble opposition to the original proposals and that the GMC had been concerned at their resource implications. When asked whether the opposition had been less voluble from GPs than from hospital consultants and junior hospital doctors, he said that he thought that it had, although he was more confident in saying that about the leaders of the GPs (who had been strongly supportive of the GMC's original proposals) than about the rank and file. He said that many GPs might not thank the RCGP and the GPC for campaigning for 'a more complex and thoroughgoing system'. When asked whether the leaders of the profession should give a lead to doctors and encourage them to accept the need for a real evaluation as part of the revalidation process, he said that several leaders of the profession had spoken out both in public and in private against the new proposals but that the 'floor' of the GMC had been against them, including the voices of some medical Royal Colleges (but not the RCGP) and of the BMA.

26.81 Mr Brearley gave oral evidence on behalf of the GMC in relation to the question of the change of direction. The thrust of his evidence was that the Prospectus of April 2003 did not represent a major change of direction at all. The underlying principles were exactly as they had been before. There had been a slight change of direction which had been made solely in order to achieve improvements to revalidation. The new arrangements were, he said, better than the old ones would have been.

26.82 In his written statement, dated 5th December 2003, Mr Brearley said that the pilot studies of 2001 and 2002 had revealed certain **'weaknesses'** in the arrangements that were then contemplated. These were that:

- despite regular local review, formal scrutiny of the folders would take place only once every five years
- the scrutiny would normally take place without the doctor being present

- there would be no obvious link to clinical governance
- it was doubtful that the system would be cost-effective.

26.83 With great respect to Mr Brearley, I find the first three of these supposed **'weaknesses'** wholly unconvincing as reasons for abandoning the earlier proposals. I can see that an assessment by a local revalidation group of the doctor's folder or appraisal forms that took place more frequently than once every five years might be better than what had originally been planned, but I cannot see that to remove all formal scrutiny would be an improvement. As to the second 'weakness', I can see that an assessment by a local revalidation group that was attended by the doctor might be better than one from which s/he was absent. But to abandon the assessment by a local revalidation group altogether would not remove that 'weakness'. Instead, it would throw away such benefits as would accrue from an assessment in the absence of the doctor. And it cannot sensibly be suggested that a wholly private and formative appraisal process can replace the objective scrutiny that would have taken place under the original proposals. Nor can I accept the third 'weakness', namely that the original proposals did not involve an **'obvious link to clinical governance'**. Indeed they did, to the extent that it was intended that the folder, on which both appraisal and revalidation were to be based, would contain information which came from clinical governance procedures. However, as I have pointed out, for individual GPs, this link was limited because there was and is not a great deal of 'hard' data from clinical governance. Under the original proposals, at least the contents of the doctor's folder would have been seen by people responsible for making an evaluation whereas, under the new proposals, there was and is to be no evaluation of that material at all.

26.84 As to the fourth 'weakness', I have already mentioned the cost benefit analysis of revalidation as a whole, which had been attempted in 2001 and had shown that it was not possible to evaluate the benefits. So far as I am aware, no analysis has ever been carried out of the 'value' of the use of local revalidation groups, as opposed to the 'value' of any other method of revalidation. I entirely accept that it would be a difficult exercise. The cost of using revalidation groups to examine the folders was known from the analysis carried out in 2001. It might well have been cheaper if appraisal forms only had been looked at. If what this 'weakness' amounted to was that the GMC came to the conclusion that the use of revalidation groups was too expensive, then I could understand that point of view. What I cannot understand or accept is that the abandonment of the local revalidation groups in favour of appraisal could be seen as an improvement in itself and could achieve a greater – or even a similar – degree of protection for patients.

26.85 In oral evidence, Leading Counsel to the Inquiry took Mr Brearley through the Consultation Paper of 2000 and the results of the two pilot studies. Mr Brearley said that the pilot studies had highlighted a number of problems. He mentioned some of those problems. He said that the pilot studies had been small, and that, because of the limited number and range of practice of the doctors involved, it had not been possible to assess the sensitivity of the method of evaluation being used. I see the logic of that and accept that the pilot studies left a degree of uncertainty. However, as I pointed out, further pilot studies could have been carried out. Mr Brearley mentioned that there was no 'gold standard' against which

to measure the effectiveness of the process of scrutiny. I agree, but I think that it would have been possible – although expensive – to devise an objective test, possibly by subjecting a group of doctors to the type of assessment used by the GMC in its performance procedures and comparing the results with an evaluation of their folders or appraisal forms. In short, although I could see that the pilot studies had not demonstrated conclusively that the proposed method would be effective, this was not a reason for abandoning the local revalidation groups at that stage.

26.86 Mr Brearley said that the second pilot study had demonstrated that examination of the appraisal forms alone would not be a sufficient basis for evaluation. Revalidation groups would also have needed to see the underlying documents contained in the doctors' folders. He accepted that the second pilot study had been of value in that it had shown what kind of information was useful for the purposes of making an evaluation of fitness to practise. He made the point, in relation to the current proposals (under which revalidation is based upon the completion of appraisal), that what had been learned from the pilot study could be used to improve appraisal, by ensuring that the right kind of information was included in the appraisal process. However, he accepted that the GMC had never sought to prescribe what information ought to go into appraisal; that, he said, was the role of the medical Royal Colleges. He hoped to see development along those lines and was sure that appraisal would improve over time.

26.87 As I have said, Mr Brearley said that there had been 'a slight change of direction with regard to evaluation of evidence'. He was asked whether there had been any resistance to the original proposals from the profession. He replied that doctors felt under tremendous pressure; medicine was a very stressful occupation and there were high alcoholism and suicide rates. Also there was a high drop-out rate. Any additional burden would make things worse. He added that appraisal had been made a contractual requirement and doctors had been promised dedicated time for it and for the necessary preparations. However, this had not been provided and all the work had to be done in the doctors' own time. Be that as it may, I cannot see that submitting the appraisal forms or the folder – already prepared – to a revalidation group imposes any significant burden additional to that imposed by the requirement to undergo appraisal.

26.88 Mr Brearley then said that the decision to change from revalidation groups to reliance upon appraisal and clinical governance had come about because of the rapid development of clinical governance. He said that clinical governance had been in its infancy when the process using revalidation groups had been designed. He accepted that, in the Consultation Paper of 2000, the GMC had talked about the advent of clinical governance and that it had concluded then that both clinical governance and revalidation as separate entities were necessary for patient protection. The Consultation Paper had said that neither would be sufficient without the other. Leading Counsel to the Inquiry suggested that it was somewhat disingenuous for the GMC to claim that it was the progress of clinical governance and appraisal that had removed the need for separate evaluation for the purposes of revalidation and had allowed the GMC to change its proposals and make revalidation dependent upon appraisal. Mr Brearley rejected that suggestion and asserted that, in 2000, the role of clinical governance had been unclear;

it was only recently that the GMC had seen what part clinical governance could play and would play in the future when it reached its full potential.

26.89 When Leading Counsel suggested that the GMC had made a substantial shift in direction, Mr Brearley suggested that she was making 'terribly heavy weather' of it. He asserted that the system that the GMC now proposed would be better than the one previously planned. When asked in what respects, he said that the new system brought in clinical governance information that would not otherwise have been available. Under the original revalidation plans, he said, some of the information held by the NHS trust or PCO would not have gone into the doctor's folder and would not have been considered by the revalidation group because what went into the folder was a matter for the doctor. However, he agreed that it had been the original intention that someone from the NHS trust or PCO, who would have knowledge of the doctor, should be on the revalidation group. But, he said, it would have been impracticable to arrange that in all cases. I can see that that might have been so. However, it does not seem to me that it would have been difficult to build into the original revalidation group system a requirement that the NHS trust or PCO should provide clinical governance data. In fact, it would also have been possible, had it been thought desirable, to ask the NHS trust or PCO to provide a clinical governance certificate as well.

26.90 When asked whether the GMC was now confident that appraisal and clinical governance were working well all over the country to the extent that it was safe to rely upon them for revalidation, Mr Brearley said that the GMC must assume that they were because the law of the land required it to be so. However, the evidence received by the Inquiry has shown that clinical governance and appraisal are not working well everywhere. I have already referred to the evidence received by the Inquiry in relation to appraisal. Evidence from the Commission for Health Improvement showed that clinical governance was operating patchily and the September 2003 Report of the National Audit Office showed a similar picture. At the Inquiry's seminars, Professor Aidan Halligan, Deputy CMO for England and Director of Clinical Governance for the NHS, said that clinical governance was not yet embedded in primary care. Mr Brearley himself had said in evidence that data collection in hospitals was 'a nightmare'. When reminded of that, he observed that data collection was only a part of clinical governance. That I accept, but it seems to me that no one who has considered the available evidence could conclude that clinical governance and appraisal were working well over the whole country. Indeed, Mr Brearley himself accepted that appraisal and clinical governance were not working perfectly but said that they were much improved and he was confident that they would continue to improve. He may be right, but it is difficult to understand how, at the time when the GMC decided to move away from its plans for evaluation of the doctor's fitness to practise, based on scrutiny of appraisal forms or folders, to a system that relied on taking part in appraisal and the provision of a clinical governance certificate, it could have had confidence in the operation of clinical governance or appraisal. As I shall shortly explain, the GMC was, in fact, well aware of the limitations of appraisal and clinical governance.

26.91 When Mr Brearley was asked to comment on the reasons given by Dr Chisholm for the GMC's change of stance, he repeated that none of those reasons was the principal reason. The principal reason was that the new model was better. Had the GMC found the

prospect of organising individual scrutiny of folders to be daunting? Mr Brearley's answer was 'yes', that it was a big task but that was not a problem. However, there was no point in the GMC doing something separate just so that it could claim ownership of the system. If clinical governance could provide a better system, there was no point in the GMC pursuing its own system. Had there been any opposition from the profession? Mr Brearley said that there had been opposition from some members of the profession because of the demands upon their time. Had cost been a factor? Mr Brearley said that it had to some extent because it is the doctors' money that the GMC spends and revalidation groups would be expensive. But he said that, if revalidation groups had been the only way of doing the job properly, the GMC would have funded them. However, if it was not necessary to spend that money, it was sensible not to do so.

26.92 Sir Graeme Catto and Mr Scott were also asked about the apparent change of stance. They too said that this was not a substantial change but a 'modification' or 'refinement' of the previous plans. There had, they said, been a recognition that reliance on clinical governance would be a better way of achieving the aims and objectives of revalidation. I must say that the move away from an arrangement whereby the evidence relating to the individual doctor seeking revalidation would be assessed by a revalidation group and the doctor's fitness to practise would be evaluated, to an arrangement where the doctor is assumed to be fit to practise if s/he has undergone appraisal and there are said to be no significant unresolved concerns about his/her practice, seems to me to be a major change. Moreover, it seems to me that, provided that the material on which the assessment was based was adequate, the former arrangement would have a much better prospect of ascertaining whether a doctor was or was not fit to practise and would, therefore, afford a greater degree of protection for patients.

Further Evidence after the Inquiry Hearings

26.93 However, further evidence was later discovered which threw light on the GMC's thinking on revalidation in the period between September 2002 and April 2003. In evidence, Mr Brearley mentioned that the GMC had commissioned management consultants (in fact, an organisation known as SHM Productions Ltd (SHM)) to undertake a study of how revalidation and recertification were carried out in other countries. A copy of SHM's study was submitted to the Inquiry in December 2003. On reading it, the Inquiry team found that it contained a reference to earlier reports on revalidation. Those were duly requested. The second (March 2003) report arrived shortly afterwards. A further request was made for the first report and this arrived in February 2004.

The First SHM Report

26.94 SHM's first report was dated December 2002. It was entitled 'GMC revalidation proposal – identifying key issues and alternatives'. The introductory section recorded that, because revalidation had **'far reaching implications both for the organisation and for the profession as a whole ... it is necessary to step back and consider what the potential pitfalls may be'**. This would require detailed evaluation and analysis (phase two) which would be carried out by SHM the following year (2003). For the present, there would be

an overview of the major issues and a discussion of the key areas of contention. The report would address five questions:

> **'• What is the current context for revalidation?**
>
> **• Which models have been used for professional revalidation and regulation elsewhere?**
>
> **• What precisely is the current proposal for revalidation?**
>
> **• What alternative models should be considered?**
>
> **• What are the next steps that constitute the body of the work required in phase two?'**

26.95 Four key **'areas'** of revalidation were identified, by reference to which the SHM analysis was to be carried out. These were:

> **'1. What evidence should doctors provide for review? *The inputs.***
>
> **2. How should the evaluation be carried out? *The review process.***
>
> **3. How can the 'hearts and minds' of doctors be captured? *Doctor buy-in.***
>
> **4. How can the public be reassured and made to feel ''safe''? *Public buy-in.*'**

26.96 The report described the activities undertaken by SHM during the first phase of the project. These included a review of GMC documentation, a review of externally published information about revalidation, telephone interviews with GMC members and staff, and a review of alternative models in operation abroad. These reviews had been followed by a discussion between the SHM team and the GMC revalidation team. I shall summarise the report's conclusions.

26.97 The report concluded that there was general acceptance on all sides that some form of revalidation was required, but there was considerable divergence of opinion among GMC members and staff about the form it should take. Areas of agreement listed were that:

- some form of revalidation was necessary and desirable
- the model adopted must be simple to implement
- the model adopted must be agreed by doctors and patient groups
- reviewing folders of evidence from 100% of doctors was not feasible owing to costs and resources
- the current thinking was that some sort of link with appraisal was inevitable, but there was concern that the **'platform'** offered by appraisal was **'patchy at best and very shaky at worst'**
- the key risks were of trying to do too much too soon or of panicking and doing too little. Either would damage the GMC's credibility

- no model could claim to prevent 'another Shipman'
- communication and understanding were key issues, for both doctors and the public.

26.98 It was reported that there was little agreement about what revalidation could achieve. There were strong views and diverging opinions on almost all aspects of the revalidation proposals from the objectives down to the criteria for success. These were analysed in some detail. For example, in relation to the question of what should be seen as the chief motivation towards revalidation, it was said that some saw revalidation as having emerged from the need to ensure that the public had confidence in doctors; others saw revalidation as having arisen as a result of Government pressure following high profile misconduct cases such as Shipman's; and yet others saw it as part of a worldwide trend towards modernisation of professional regulation. This was followed by a discussion about the advantages of presenting revalidation in a positive rather than a negative light. However, the point was made that to present revalidation as a means of ensuring high professional standards was somewhat undermined by the fact that revalidation would present only a **'very low bar'** for doctors to achieve. The report recorded the comment by one person interviewed that revalidation was **'merely an assessment of basic proficiency'**.

26.99 Another important topic discussed in some detail was the linkage between appraisal and revalidation. It was said that there was general agreement that **'some sort of link'** was necessary. There were two main arguments in support of a link. First, the use of the same material for both processes would minimise the workload for doctors. Second, the link would ensure that appraisal was given **'an edge'**; some of those interviewed expressed disapproval of the idea that appraisal should be purely developmental; one said, **'it is a form of assessment ... if it is purely chatting it is no use at all'**. There then followed a comprehensive list of concerns about using appraisal for the purpose of revalidation. These concerns must have been expressed during the interviews with GMC members and staff. They bear a strong resemblance to the kind of concerns that the Inquiry heard when receiving evidence about appraisal and its proposed link with revalidation. For example, concern was expressed about the **'immaturity'** of appraisal and about the patchy way in which it was operating. Doubts were also expressed about the ability of appraisal to pick up a bad doctor. Also mentioned was the dichotomy between the formative nature of appraisal and its use in the process of revalidation, which should be summative (i.e. pass/fail) in nature. It was said that appraisal had been presented as formative and supportive, while the Government saw it as a means of performance management. Doubts were expressed about the abilities of appraisers and the rigour with which appraisals would be carried out. One interviewee expressed a fear that under-performing doctors would be allowed to continue in practice on the basis of **'anything for a quiet life'**. There was no incentive for an appraiser to report poor performance; such a report would be bound to **'ruffle feathers'** and to damage professional relationships. It was said that, historically, there had been **'a cultural problem of doctors reporting their colleagues'**. One interviewee observed that employers might be unwilling to bring forward doctors who were not performing well, as they might think that it was **'better to ''contain'' a bad doctor than have no doctor at all'**. Also, the issue of consistency of quality of appraisal was raised, and of the materials on which appraisal was based. Some interviewees expressed concern about the lack of lay involvement in appraisal which might lead to a perception

by the public that revalidation would take place inside the **'club'**. Another point was that it might appear that the whole revalidation process was being passed over to employers and that the GMC was **'admitting defeat'**. If the GMC was to rely on employers, it would have to ensure that the employers' systems were **'strong'**. This section of the report concluded with the observation that these objections were a **'significant catalogue'** which could not and should not be **'dismissed lightly'**.

26.100 Another section of the report discussed the process by which the evidence provided by doctors should be reviewed for the purposes of revalidation and who should take part in that review. Some interviewees believed that it was critical that there must be active lay involvement. There was considerable divergence of view as to what the role of the GMC should be in the review; at the extremes, some thought that it should be wholly responsible for the revalidation process and others thought that it should limit itself to the quality assurance of a process to be carried out at local level. The role of employers was also discussed and an interesting range of views recorded. For example, it was suggested that employers could play a useful role in acting as the **'early warning system'** for identifying poorly performing doctors before they were identified through the revalidation process. Also, they could help by providing the GMC with the information which was required from doctors for the purposes of revalidation. However, concern was expressed that employers could not be relied upon to report **'at-risk'** doctors. That would require a **'considerable change of culture'**. Too often, it was said, NHS trusts allowed a poorly performing doctor to move on from post to post without reporting him/her to the GMC.

26.101 The next section of the report discussed various possible 'models' for revalidation. First, approaches in other countries and professions were considered. The mechanisms used were classified as **'soft'** (i.e. those with a developmental focus) and **'hard'** (i.e. those which depended upon assessment or testing). I note that the column relating to pilots in this country records that they are subject to the **'hardest'** mechanism, namely **'testing'**. I mention that because, in its Prospectus published a few months later, in April 2003, the GMC suggested, as I have previously mentioned, that there was **'a good professional comparison'** between its new proposals for the revalidation of doctors and the periodic reassessments undergone by airline pilots.

26.102 The report then listed seven possible models for the revalidation of doctors. These consisted of one model which was said to be **'currently under consideration'**, three possible models which had already been discarded and three more models which had emerged from discussions between SHM and the GMC and which were said to be worthy of further examination. In respect of each model, an attempt was made to describe how it would work in practice, and to assess its potential acceptability to doctors and patients, its feasibility and cost. Assumptions had had to be made but these had been based upon discussions with GMC staff.

26.103 The model **'currently under consideration'** was not one of the models that had been tested in the pilot studies; nor was it the model that was to emerge in April 2003. Under this model, doctors were to provide Form 4 (including their personal development plan) from their appraisal documentation (although not their folders and not Forms 1 to 3). They were also to provide one **'Ramsey-type questionnaire'** during each five-year cycle. The

GMC described a **'Ramsey-type questionnaire'** as a patient satisfaction or peer review questionnaire. The evidence (presumably Form 4 and the questionnaire) was to be **'reviewed'** by the GMC. How that was to be done was not stated. If the evidence was satisfactory, the doctor would be revalidated. If not, the doctor might be asked to provide further information or might be referred to a revalidation group. Revalidation groups (which would be made up of lay people and doctors) could request further information and could refer an **'at-risk'** doctor into the FTP procedures. This model was assessed as having **'medium'** acceptability to doctors, but to be likely to command **'low'** public confidence, since most members of the public would themselves have **'some experience of appraisals themselves which leads them to be cynical about their value as an input to revalidation'**. It was said that the feasibility of this model was **'low'** because of the resource implications for the GMC of a review of all doctors' evidence. Finally, the costs were assessed as **'high'**.

26.104 There then followed consideration of the original model, involving the examination by revalidation groups of the folders compiled by doctors. This had already been discarded. Its acceptability to doctors and the level of public confidence it was likely to command were assessed as **'medium'** but feasibility to the GMC was **'very low'** on account of the resource implications. The costs were assessed as **'high'**.

26.105 The next model (also already discarded) would have involved written and/or practical tests. These were to include a multiple choice test of knowledge. The tests might be supplemented by patient satisfaction and peer assessment questionnaires. Acceptability to doctors was assessed as **'v low'**, as doctors **'generally do not welcome the concept of their knowledge being put to the test'**. On the other hand, public confidence in the model was likely to be **'high'** because **'the public likes the rigour implied by a test (many currently assume that, like pilots, doctors have to take tests on a regular basis)'**. It was said that the GMC would regard feasibility as **'low'** because a very large range of tests would be required to cover a wide range of specialised areas of practice. Costs were assessed as **'medium'**. It appears to me likely that this model was discounted as being too 'hard'.

26.106 Also already discarded was a model that was based upon evidence of continuing professional development. This would have involved spot checks to ensure compliance with agreed plans. Although acceptability to doctors and to the GMC was assessed as **'high'**, it was considered that public confidence would be **'low'** since the public would think it was **'both cosy and ineffective'**. It appears to me that this model must have been discarded as too 'soft'.

26.107 Next came what was called the **'self-revalidation model'**. This was described thus:

> **'Local employers would use an ongoing range of measures including appraisal and peer/patient** (*word omitted but probably questionnaires*) **(working to GMC standards) in order to identify individuals** (*i.e. doctors*) **at risk. These cases would be referred to the GMC annually (and as required throughout the year) who would then employ FTP procedures if necessary. GMC would also exercise quality control on the appraisal process and carry out statistically valid spot checks on individual**

> **doctors. In addition, every five years doctors would be required to put together evidence of having met CPD** (*i.e. continuing professional development*) **requirements along with summaries of their appraisals which would be spot-checked by the GMC. The local systems are primarily focused on detection (via appraisal, observation, working relationships, patient questionnaires, etc.), while the GMC's focus is on action.'**

26.108 It was thought that acceptability to doctors would be **'medium'**, as would be the level of public confidence it was likely to command; the GMC would rate feasibility as **'high'** and the costs would be **'low'**. The main risks identified in this model were the doubts as to whether appraisal would be sufficiently rigorous, and whether local systems would be sufficiently robust and consistent. I note that acceptability to the public was assessed as **'medium'**. This model depended heavily on appraisal and the report had already observed that the public might well be cynical about the value of appraisal. Indeed the other model that depended on appraisal had been given a **'low'** public acceptability rating.

26.109 The sixth option was called the **'questionnaire model'**, under which doctors would have to submit peer and patient questionnaires annually. Doctors identified as being at **'some moderate risk'** would have to submit additional information, similar to the original folders of evidence, or undergo **'structured interviews ... by trained peers'**. Any doctors considered to be at risk would be referred into the FTP procedures. It was considered that this model would have **'medium'** acceptability to doctors but would command a **'high'** degree of public confidence (in particular on account of patient involvement in the questionnaires and the fact that doctors would be assessed by their peers). Feasibility for the GMC would be **'medium'** and costs would be **'low'**. It was noted that this model was used elsewhere but was untried in the UK. I observe that all the models save one were untested in the UK.

26.110 Finally, there was an **'assessment model'**. Doctors would undergo a formal assessment based on **'multiple inputs'** such as peer and patient questionnaires, interview, observation (presumably of clinical practice) and CPD. These would be carried out locally. If additional information were required, it would be submitted to a revalidation group. The GMC's role would be to provide quality assurance through an **'examine the examiner mechanism'**. It was thought that this would have **'low'** acceptability to doctors, who would resist any form of assessment. However, it was noted that there was evidence from other industries that, over time, professionals came to accept, and even welcome, the objectivity of such mechanisms. Public confidence in such a model was likely to be **'high'**. Feasibility for the GMC would be **'medium'**, as most of the responsibility would be carried at local level. Costs would be **'high'**. Risks would include lack of consistency and a doubt about the robustness of local processes. The human resource implications might deter employers and doctors.

26.111 I have set out these options in some detail to demonstrate, first, that this report sought to consider various options in an objective way. However, what is notable is that there was no attempt to assess the efficacy of the various methods in evaluating fitness to practise.

Nor did the report consider which model would afford the best patient protection. The report was about acceptability and public confidence, not efficacy.

26.112 Finally, the report considered what steps should be taken next. In essence, it advocated further and more detailed research and analysis and posed a number of highly pertinent questions for the GMC to consider. It did not point towards any of the possible models as the most appropriate. That was for the future.

26.113 The report shows that, in December 2002, the GMC was considering a wide range of options for revalidation. It does not appear that, at that time, it had a clear view of the way in which it intended to proceed. It is apparent that, by then, the idea of a link between revalidation and appraisal was already under consideration. However, there were those within the GMC who did not regard that link as appropriate or satisfactory – at least if appraisal was to remain a formative and supportive process. There were concerns as to whether appraisal, and local processes in general, were robust enough to form a basis for revalidation. At the heart of these concerns was plainly a doubt as to whether revalidation based on appraisal would provide an adequate indicator of a doctor's fitness to practise and a sufficient protection for patients. The GMC's 2000 Consultation Paper had listed first among the benefits of revalidation that it would protect patients **'from poorly performing doctors – who will be identified as early as possible'**. Clearly, there were doubts on the part of some within the GMC as to whether revalidation based on appraisal would be capable of fulfilling this purpose.

The Second SHM Report

26.114 SHM reported again three months later in March 2003. By that time, the GMC had made the decision that revalidation should, in most cases, be linked to appraisal and the Prospectus of April 2003 was in the course of production. There was no detailed discussion in the report of the model that the GMC had decided to adopt. Instead, the purposes of the report were to identify key issues within revalidation which remained to be resolved, to discuss the role of the GMC within the revalidation process and to advise the GMC on how to communicate its revalidation policy and effectively to get across its **'key messages'** to doctors, partner organisations, the press and the general public. Many of the GMC's subsequent statements on the issue of revalidation appear to have had their origins in the advice contained within this report.

26.115 The report referred to the divergence of opinions which had been expressed at the time of SHM's first report about what revalidation could and should do. It reported that there was now a **'high level of definitive agreement'** within the GMC about the purpose of revalidation, although there was **'considerable uncertainty from other quarters'**. The GMC had now defined revalidation as being designed to **'increase confidence in the Register'** by **'ensuring that doctors are up to date and fit to practise'**. In other words, it was intended to be **'a proportionate system which quality assures the register'**. It was not intended to quality assure individual doctors. The report stated that the production of this definition had led to **'confusion and dispute'** among a minority of stakeholder groups which had believed that revalidation should be designed to detect poorly performing doctors. The report indicated that it was **'one of the key tenets of**

revalidation' that it was not intended to identify poor performance and that it had never been suggested in the GMC's communication about revalidation that this was the case. In fact, as I have said, the detection of poorly performing doctors had been listed in the GMC's 2000 Consultation Paper as the first of a number of benefits that would accrue to patients as a result of revalidation. It was not surprising, therefore, that some people were confused and disappointed by the definition of revalidation which had been disseminated by the GMC in early 2003. The report did not refer to the definition of revalidation contained in the amendment to the 1983 Act which had recently been passed; this stated, as I have said, that revalidation was an **'evaluation of a medical practitioner's fitness to practise'**. This seems very different from the concept of 'quality assurance of the register' which was being propounded by the GMC in March 2003.

26.116 The report recorded greater support for linking appraisal to revalidation than had been the case at the time of SHM's first report, although some people gave their support **'grudgingly'**. There was a feeling that doctors would have to accept that there was an element of performance management in appraisal. Some took a **'more defeatist approach'**, acknowledging that there was **'no realistic alternative'** to appraisal. There was reference to concern about the training of appraisers and the content of the appraisal process, together with the fact that there was no guarantee of independence or lack of bias. The report drew attention to the fact that the precise role to be played by lay people in revalidation had still not been agreed. The GMC's move away from lay involvement in revalidation groups which would scrutinise the evidence of individual doctors had been **'met with some cynicism'**. However, SHM was optimistic that the proposals for lay involvement in the ways currently being considered by the GMC would gain support with time.

26.117 The report went on to discuss quality assurance of the revalidation system, noting that responsibility for the quality assurance of various aspects of the system rested with different organisations. I shall revert to that part of the report later in this Chapter. For the moment, I mention only that the report identified two **'important risks'** of the sharing of responsibility for quality assurance among different organisations. It suggested that it was **'almost inevitable'** that **'gaps'** would **'emerge between the boundaries of different responsibilities'**. It pointed out that the consequences of evidence or judgements falling through these gaps could be very grave indeed. It also referred to the absence of any **'clear overall responsible body or mechanism for providing overarching governance and co-ordination'**.

26.118 I wish to make two observations about the SHM reports and the GMC's decision to change direction. First, it seems clear to me that there was a recognition within the GMC that the new proposal was indeed a significant shift rather than a 'slight change of direction' or a 'refinement' of the earlier proposals. Second, the GMC changed direction notwithstanding the warnings that it had been given (in the first SHM report) about the shortcomings, perceived within the GMC itself, of appraisal as a basis for revalidation and (in the second SHM report) about the **'important risks'** inherent in a system which divided responsibility for quality assurance between so many organisations.

The Revalidation Proposals at the Time of the Inquiry Hearings

The Thinking behind the Proposals

26.119 I mentioned earlier that, shortly before the Inquiry hearings relating to the GMC began, the GMC had modified its plans for the revalidation of doctors working in a **'managed environment'**. In the Prospectus of April 2003, it was said that such doctors could choose the 'appraisal route'. They would have to show that they had successfully completed their annual appraisals. However, by late 2003 (probably as a result of evidence which had been given to the Inquiry), the GMC had recognised that evidence from the doctor alone that s/he had participated in appraisal would not be sufficient to generate the necessary confidence in revalidation. It therefore opened negotiations with the DoH for the provision of direct corroboration of that participation. At that stage, it was intended that the 'corroboration' should consist of a certificate to be signed by the clinical governance lead, chief executive or medical director of the **'managed organisation'** in which the doctor worked. The certification would be to the effect that the doctor had participated in appraisal and that **'no concerns about the doctor's fitness to practise have arisen locally through clinical governance systems'**. These terms were set out in the briefing papers for the Council meeting on 25th November 2003, at which the new arrangements were to be discussed. In the event, the draft of a proposed clinical governance certificate (described by Mr Brearley at the time as 'the bare bones of a deal') was delivered by the DoH to the GMC during the course of that meeting and the proposed terms (which were, as I shall explain, rather different from those referred to above) were agreed then. In future, the appraisal route was to be known as the 'appraisal and clinical governance route'.

26.120 Mr Brearley gave evidence to the Inquiry about the GMC's plans. From the outset, Mr Brearley stressed that it was not possible for the GMC, as keeper of the medical register, to monitor the day-to-day performance of all doctors. It had to work in conjunction with local processes. I think he had in mind local clinical governance processes including appraisal. He said that there had been a change of culture in the medical profession and that doctors were now more prepared to recognise that a colleague might not be performing adequately and to accept responsibility for that, by seeking to help that colleague but also, if necessary, by reporting him/her. As I understood him, Mr Brearley considered that, in this new atmosphere, clinical governance would be more effective at detecting poorly performing and dysfunctional doctors.

26.121 Mr Brearley described revalidation as the 'fulfilment of a professional duty'. He said that everyone readily agreed that there was a professional duty on every doctor 'to maintain one's standard of practice and to keep up to date'. This had led to the need for a formal statement to be made to patients that the doctor was up to date and fit to practise. This was, he said, a way of 'quality assuring the medical register' that would give patients a basis for making an informed choice of doctor. He accepted that, if the register was to contain only the names of people who were up to date and fit to practise, there had to be a means of detecting those doctors who were not fit to practise. That would be done, he said, when the doctor came to revalidation, if the dysfunctional practice had not already been detected and dealt with by the operation of clinical governance measures. It would be hoped and believed that most dysfunctional practice would be picked up well before it had persisted for as long as five years.

The Appraisal Element in Revalidation

26.122 Leading Counsel to the Inquiry wished to explore with Mr Brearley how the GMC thought that the new proposals would meet the objectives of revalidation. She reminded him of the objectives of revalidation as set out in the Consultation Paper of 2000. She was seeking to discover how appraisal could provide the necessary evaluation of fitness to practise that was required, when the appraisal of GPs was a purely formative process, with no specific requirements as to what material the doctor had to provide in his/her folder and no objective tests of any kind. The Inquiry had heard ideas from a number of other witnesses of how appraisal might be made more objective and more effective as a means of detecting dysfunctional practice. Counsel suggested that methods of assessment such as observation of doctors' consultations with patients, reviews of medical records, consideration of audit and of mortality statistics and discussion about complaints might be effective. Mr Brearley observed that many witnesses to the Inquiry had 'hobby horses' to ride and confessed that he had one or two of his own. But, he said, none of these methods of assessment had been validated by research. His personal preference was for patient and peer questionnaires. He described these, as operated by the American Board of Internal Medicine, and explained the results of some research carried out. His enthusiasm was manifest. When Mr Brearley was asked whether the GMC intended that questionnaires would be a part of the revalidation process when it came into force in 2005, he said that they would not be for doctors coming through the 'appraisal and clinical governance route', at least until the stage had been reached when a concern had been raised about the doctor being revalidated. If a concern was raised either as the result of appraisal or on account of the fact that the doctor was unable to obtain the necessary clinical governance certificate, such questionnaires (together with reviews of medical records and observations of consultations) might be used for the purpose of the more detailed examination required at that stage. He thought it highly desirable that questionnaires should be used by all doctors coming through the 'independent route'.

26.123 On the question of whether the GMC could specify what information should be included in the folder that would form the basis of appraisal, Mr Brearley explained that the GMC had taken legal advice in the early days of the discussions about revalidation and had, as I have said, been told that it could not prescribe exactly what type of information should be submitted for the purposes of revalidation. I can see that the GMC cannot prescribe what information must be provided for the purposes of appraisal; that must be a matter for the employer or 'main contractor', the NHS. However, the amendments to the 1983 Act give the GMC very wide powers to require the supply of information or the production of documents for the purposes of revalidation. I hope that the GMC will not hesitate to set out what it thinks is appropriate. It could ask the NHS to ensure that certain categories of information are provided for appraisal purposes. That material would then be available for the GMC if and when it wishes to scrutinise some doctors' folders.

26.124 Leading Counsel then turned to ask Mr Brearley whether, when first planning how the revalidation process should be undertaken, the GMC had thought that GPs might find any particular difficulty in collecting data to put in the folders. At that time, it was expected that the folder would be used for appraisal and revalidation purposes. He said that no such difficulty had been perceived. GP practices already had quite good data collection

systems; indeed, he thought the systems for data collection in general practice were rather better than those available in hospitals, which, as I have said, he described as 'a nightmare'. Now that it was proposed that revalidation should be based on appraisal, Counsel wanted to know whether the GMC was concerned about the robustness of GP appraisal. It was carried out by another GP, who did not require any particular accreditation, and it was based on material selected by the doctor him/herself. These factors did not appear to give rise to any concern in the mind of the GMC. Indeed, Mr Brearley's view was that GPs had gone about appraisal in a very thorough way and its introduction had been rather more successful for GPs than it had been in hospitals. For example, he said, many people carrying out appraisal in hospitals had had no training at all. Yet, despite that, it is apparently intended that doctors working in hospitals should be able to achieve revalidation by means of the appraisal and clinical governance route.

26.125 Mr Brearley said that the GMC was confident that appraisal for GPs could be made into a robust process. It was a rapidly developing and well resourced activity which was a statutory requirement for NHS trusts. He saw no reason why there should not be mandatory elements to appraisal; indeed, he said that the GMC would be in favour of that. Mr Brearley had in mind some of the elements described in the 'Revalidation Toolkit', published by the RCGP in Scotland.

26.126 Mr Brearley said that he believed – and the evidence I have heard leads me also to believe – that the great majority of GPs take appraisal very seriously and put a great deal of effort into it. For such doctors, it is very beneficial. The difficulty is how to deal with the small proportion of doctors who wish to conceal deficiencies in performance, ill health problems or other problems from the appraiser. Appraisers cannot probe into potential problem areas about which they have no information. Mr Brearley agreed that it would be helpful if some types of information had to be produced and if PCOs were entitled and expected to provide clinical governance information (including information about complaints and concerns) direct to the appraiser, as well as to the appraisee.

26.127 It appeared that Mr Brearley and the GMC agreed with the general proposition that the introduction of some mandatory elements and the provision of some mandatory types of information would give structure to appraisal and would make it more effective as a foundation for revalidation. There are several possible elements, including observed or videotaped consultations with patients, patient and peer questionnaires, reviews of medical records and, possibly, knowledge tests (which nowadays can be undertaken on-line). There are several types of information that PCOs could provide to appraisers, such as prescribing data and records of complaints or concerns about the doctor. However, any instructions to change the format of appraisal would have to go from the DoH to the NHS bodies affected.

The Role of the Clinical Governance Certificate

26.128 As I have said, in the briefing papers for the November 2003 Council meeting, GMC members were told that the clinical governance certificate was designed to provide corroboration that appraisal had taken place and that no concerns about the doctor had arisen locally through clinical governance systems. However, it became apparent that that

was not how Mr Brearley saw the certificate. He told the Inquiry that it might even be that PCOs would have sufficient information about the doctors on their lists to enable them to provide a clinical governance certificate that would be capable of standing alone as a basis for revalidation. Under the new GMS Contract, which came into force in April 2004, he said, a PCO is able to go into the practice premises and obtain all sorts of information useful for clinical governance purposes. Mr Brearley said that he would almost go so far as to say that the judgement that a PCO could make about a doctor might be sufficient for revalidation purposes, even without appraisal. If the PCO was not willing to provide the clinical governance certificate, the doctor would not be revalidated and would have to go through more detailed scrutiny by the GMC. In short, to his mind, it might be quite satisfactory for revalidation to be based upon local clinical governance activities. I had difficulty in reconciling that view with the emphasis that the GMC had laid on appraisal as the basis for revalidation since the publication of the April 2003 Prospectus. However, it was not Mr Brearley's view that appraisal should play no part at all in the process of revalidation. He said that it was to play a limited, but important, role in the summative process of revalidation, because appraisers would be required to stop the appraisal if 'important unresolved concerns' about the doctor's practice arose during the process. He also used the expression 'major concerns'. However, in Mr Brearley's view, the main summative tool was to be the clinical governance certificate.

26.129 This 'downgrading' of the importance of appraisal within the revalidation process represented a considerable change of emphasis from the 'appraisal route' which had been described in the April 2003 Prospectus. In that document, the GMC had declared that it believed that **'full participation in annual appraisal, with completed supporting documentation, during the revalidation cycle, is a powerful indicator of the doctor's current fitness to practise'**. As I have observed previously, the reasons for that belief were never explained. It appeared from Mr Brearley's evidence that the GMC no longer regarded appraisal as a powerful indicator of fitness to practise, but believed that the clinical governance certificate was; appraisal was by then regarded as just an additional safety net.

The Terms of the Clinical Governance Certificate

26.130 In the course of Mr Brearley's evidence, Leading Counsel to the Inquiry sought to investigate the adequacy of the terms of the proposed clinical governance certificate. This was not an easy issue for Mr Brearley to deal with, because the idea had arisen very recently and the terms of the certificate had not yet been finalised. Mr Brearley signed his written statement of evidence on 5th December 2003 and gave oral evidence on 17th December. In his written statement, Mr Brearley said that what the GMC wanted was **'confirmation that no concerns about the doctor's fitness to practise have arisen through clinical governance processes'**. At that time, the proposal (which had been received by the GMC at its meeting on 25th November) was that the chief executive, medical director or clinical governance lead of the relevant NHS body would certify that:

‘a Appraisal had been carried out and signed off by a trained appraiser

b The appraisal had produced an agreed personal development plan

c The process had included validated data

d The process was robust

e There were no concerns about the doctor’s probity or health

f There were no disciplinary processes under way

g There were no relevant disciplinary findings.’

26.131 As Leading Counsel took Mr Brearley through this list, it became apparent that some of the statements were problematical, at least in the context of GP appraisal. Under the existing arrangements, the certifier could not know whether any validated data had been included in the appraisal. The PCO is not entitled to see the folder of documents produced by the doctor for the purposes of appraisal. Nor could the certifier say whether the individual appraisal had been **‘robust’**. It would have taken place in private and the discussions which formed the basis of the appraisal would have been confidential to the appraiser and the appraisee. There was some discussion about whether item **‘d’** related to the robustness of the whole process of appraisal as operated by the particular NHS trust or PCO, or whether it was intended to refer to the robustness of the individual appraisal. If the former, the fact that (as was at that time the intention) the trust’s processes had been quality assured by the new Commission for Healthcare Audit and Inspection (now known as the Healthcare Commission) would have been sufficient to enable the certifier to state that the **‘process was robust’**. If the latter, the certifier would have no basis of knowledge on which to rely. The certifier would know whether the appraiser had been trained but little else. The certificate as to probity and health would, Mr Brearley explained, be in addition to the self-declarations that would be required of all doctors when applying for revalidation. Thus, the clinical governance certificate would provide some support for the self-declaration, although, as Mr Brearley observed, the signatory could sign only on the basis that there was no information to the contrary. As for **‘f’** and **‘g’**, Mr Brearley, who is not a GP, accepted that, if disciplinary processes were almost unknown in primary care (as has been the case since 1996, although there are now the new list management powers), then no information would be available in respect of these items. He stressed that what the GMC wanted to know was whether there were any concerns about the doctor’s fitness to practise.

26.132 As I have explained, the briefing papers for the Council meeting on 25th November 2003 had recommended that the GMC should seek a certificate **‘to the effect that the doctor has indeed participated in appraisal, and that no concerns about the doctor’s fitness to practise have arisen locally through clinical governance systems’**, although, elsewhere in the briefing paper, there was a reference to **‘significant unresolved concerns’**. When asked to look at the briefing papers, Mr Brearley immediately recognised that there was not a good match between what the GMC had wanted and what had actually been proposed by the DoH (see paragraphs 26.130–26.131). The minutes of the meeting recorded that the GMC should seek a certificate declaring that there were **‘no**

significant unresolved concerns' about the doctor. Mr Brearley was puzzled as he could not remember there being any discussion about the introduction of the phrase **'significant unresolved'**. He did not know how those words had come to be introduced. He said that he thought that the GMC ought to be told about *any* concerns about the doctor's fitness to practise and that the GMC would then want to know how, if at all, they had been resolved. He said that the Registration Committee, of which he is Chairman, would not feel inhibited from putting forward proposals to reflect the original intention that the GMC should be told about *any* concerns. The Inquiry heard nothing more about this until November 2004 although the draft Guidance which the GMC published in September 2004 (see paragraph 26.142) states, at different points, that the clinical governance certificate is to certify that there are **'no significant unresolved concerns'** and **'no unresolved local concerns'** about the doctor's fitness to practise. Neither wording contained in the Guidance accords with Mr Brearley's wishes.

26.133 Moreover, both wordings could give rise to difficult decisions for the certifier. What does **'significant'** mean in this context? It is not clear; this was one of Mr Brearley's objections. Second, what does **'unresolved'** mean? Does it mean completely unresolved or does it cover cases where a problem has arisen and steps have been taken to resolve it but it is not yet clear whether those steps have been completely successful? One can see immediately the possibility that different thresholds might be applied by different people. I think that Mr Brearley was sensible when he said that he and his Committee wanted the GMC to be told about *any* concerns.

26.134 Quite apart from those difficulties, it appeared to me that reliance on a certificate for which only one person was responsible would be problematical. First, there would be the problem of personal bias, in favour of or against the doctor seeking revalidation. It must be recognised that local medical communities are small; GPs know each other and often have personal and social relationships as well as their professional ties. A clinical governance lead is likely to be a GP who may well have practised in the locality; indeed, s/he may still be doing so on a part-time basis. It is asking a lot to expect such a person to refuse to sign a certificate for a colleague or a friend. Conversely, there would almost certainly be some GPs in the area about whom the clinical governance lead had formed a generally poor impression. Would such a person be treated fairly? It seemed to me that, if reliance were to be placed on a clinical governance certificate, responsibility should be shared by more than one person. If real importance were to be attached to the certificate – and it were not to be just corroboration that appraisal has taken place – the dangers of leaving the process in the hands of one person would be manifest.

26.135 Finally, the value of a clinical governance certificate must depend to a very large extent on the quality of the clinical governance arrangements in the area in which the individual doctor is practising. The evidence I have heard leads me to conclude that there is some way to go before clinical governance is fully implemented in primary care. Put another way, the quality of clinical governance cannot be relied on in all places.

The Effectiveness of the Post-November 2003 Proposals

26.136 The addition of a clinical governance certificate to the requirements for revalidation by the appraisal route was a step in the right direction, although only a modest one. The

post-November 2003 proposals were still dependent upon appraisal. Appraisal in its present form cannot provide an evaluation of fitness to practise. The clinical governance certificate would be of uncertain value because of its terminology, the circumstances in which it would be signed and above all because of the variability of the quality of the clinical governance activities underlying it. In an area with good clinical governance provision, with a clinical governance lead who was objective, conscientious and impartial and who applied a low threshold to the expression **'no significant unresolved concerns'**, the certificate would be of value. However, even then it could provide only a negative assurance. Revalidation is supposed to give positive reassurance based on evaluation of fitness to practise. In effect, under the November 2003 proposals, the overwhelming majority of doctors would be 'revalidated' without having gone through a process of revalidation, within the meaning of that term in the amended Medical Act. For the great majority of doctors, the process would depend upon the operation of local clinical governance procedures which would take place whether or not there was a process of revalidation. For the great majority of doctors and their patients, revalidation would provide very little value over and above the monitoring systems that had been put in place by the NHS. The GMC might provide some added value by quality assuring clinical governance procedures through its scrutiny of a proportion of folders kept by doctors for the purposes of appraisal, to which process I shall refer below. However, that would not give much comfort to the average patient who wants to know whether his/her doctor is up to date and fit to practise.

Further Work of Development

26.137 Since the Inquiry hearings, work on the development of the revalidation process has, of course, continued. The Inquiry has become aware of two different, but related, strands of work. In August 2004, the RCGP produced a consultation document entitled 'Portfolio of Evidence of Professional Standards for General Practitioners: a Tool for Continuing Professional Development, Appraisal and Revalidation'. It sets out proposals for the content of the folders that GPs should keep for these three joint purposes. It seeks to establish the standards for such folders and the evidence they should contain. It is based on the principles of 'Good Medical Practice'. It seems to me to be a very useful document. If adopted it would ensure that the material in the doctor's folder was capable of providing a basis for evaluation of fitness to practise. For example, in section 3, which is concerned with good clinical care, the doctor would be required to produce evidence of clinical audit and significant event audit. The evidence to be produced would be not just a statement that the audit had taken place; it would have to include some actual audit reports and some response to or commentary on what had been learned from the process. I would hope that that would include an explanation of the role that the individual doctor had played in the audit, as audits are often a joint effort. To be of value for revalidation, the content of the reports would have to be read; it would not be sufficient merely to check that an audit had been done.

26.138 The Inquiry has also received a document prepared by the NHS Clinical Governance Support Team Expert Group (NCGST), entitled 'Defining the evidence for Revalidation – supporting the Royal College of General Practitioners'. The purpose of this work was to

identify the minimum evidence that should be regarded as essential to allow a clinical governance lead to sign the clinical governance certificate for a GP. It appears that it was envisaged that the evidence would be assessed and 'signed off' quite independently from the appraisal process. The evidence would then be available for use during appraisal if the doctor wished. The work of the NCGST is also useful although its proposals are rather 'softer' than those of the RCGP. For example, under the section dealing with clinical audit, this document recommends that the doctor should provide a **'resume of his/her engagement with audit, giving examples'**. It is made clear that this would not require the doctor to generate his/her own audits but would require that s/he be able to describe how his/her practice has developed as a result of audit outcomes. In short, there is no need to produce an audit report. For significant event audit, the doctor is to produce **'evidence of meaningful participation'**. It is not clear to me whether that would require production of the reports. So, the requirements in respect of audit would be less demanding than under the RCGP proposals. Another example of the difference between the two sets of proposals is that, in the section dealing with relationships with patients, the RCGP proposes that the doctor should submit the practice's complaints procedures, copies of all complaints involving the doctor and evidence that any learning needs have been met. The corresponding section of the NCGST document suggests production of the complaints procedure and a list of complaints received and subsequent action taken. The RCGP proposal provides evidence that, if scrutinised, is much more revealing of the doctor's actual standard of performance. A third example of the difference relates to the way in which patient records should be reviewed. The RCGP calls for a standardised audit conducted by an independent colleague to demonstrate the appropriate quality of the doctor's clinical records. The NCGST suggests (at least initially) self-audit of records for legibility and accuracy to standards set by the RCGP. Here again, the evidence suggested by the RCGP would be more useful for the purpose of evaluation of fitness to practise than that suggested by the NCGST.

26.139 The work of these two groups represented a major advance on the stage that had been reached at the time of the Inquiry hearings. It appeared that the issue of a NHS clinical governance certificate might involve some positive evaluation of fitness to practise. I would welcome a positive process of evaluation of a doctor's folder. However, I was concerned about two aspects of the proposals as they seemed to be envisaged. First, the minimum content of the folder as suggested by the NCGST would not be very demanding or very revealing of the quality of the doctor's practice. It is, as I have said, far less revealing than the contents as proposed by the RCGP would be. Second, I did not think it either fair or appropriate to expect a clinical governance lead to carry out the scrutiny of folders alone. It would put an intolerable burden on that individual, both in terms of workload and responsibility and, ultimately, in terms of accountability, in the event that a decision to sign a certificate turned out to be wrong. He or she could not be expected to exercise the necessary degree of independence of judgement about doctors whom s/he might well know personally as friends or colleagues. There would be a real danger of bias and inconsistency. If such an assessment is to be carried out it should, in my view, be carried out by a small group, which should include (as well as the clinical governance lead) a lay person and a GP who is not from the same area and has no personal knowledge of the doctor to be assessed.

General Medical Council Internal Procedures

The First Stage of Revalidation

26.140 At the time of the Inquiry's hearings in December 2003, the proposed procedure to be followed by the GMC when handling applications for revalidation was this. The doctor would be expected to submit a completed application form, providing some basic information about him/herself. He or she would have to provide a description of his/her practice during the last five years, or since the last revalidation, if revalidation had been granted for a period shorter than five years. If seeking revalidation by the clinical governance and appraisal route, s/he would have to aver that s/he had undergone appraisal within a system based on the principles of 'Good Medical Practice' and would have had to enclose a completed Form 4 from appraisal. He or she would have to provide self-certification of his/her health and probity.

26.141 The GMC would examine all applications for the purpose of identifying the doctor as being one who had been called for revalidation. The contents of the application would be checked to ensure that each requirement had been fulfilled. That would not entail reading the content. Mr Scott said that it was anticipated that there would be some electronic scrutiny of the documents designed to pick up unexpected answers. So, for example, in the certificate of probity, if a 'yes' answer appeared where a 'no' answer was expected, the system would draw attention to that doctor and the matter would be looked into in more depth. It had not yet been finally decided whether electronic means would be used. In the second SHM report of March 2003, which contained advice to the GMC about scrutiny and quality assurance, it had been anticipated that this initial scrutiny (which would be done in all cases) would be carried out by junior office staff. When asked how the doctor's appraisal Form 4 was to be examined, Mr Scott told the Inquiry that the GMC had not yet made up its mind about these processes and that it intended to conduct further pilot studies because the original pilot studies had related to a different process entirely. The Inquiry has not been told of any further studies, although, of course, some may have taken place.

26.142 These proposed arrangements have now been modified, although only slightly. In a document entitled 'Licensing and Revalidation Formal Guidance for Doctors (draft)', dated September 2004 (the 2004 draft Revalidation Guidance), it is explained that doctors should normally make their applications via a secure internet connection direct to the GMC. Doctors working in a **'GMC approved environment'** must provide a description of their practice, demonstrate participation in appraisal **'mapped against the headings of *Good Medical Practice* and completion of an agreed Personal Development Plan'**, provide a statement declaring eligibility for local certification and provide evidence of health and probity. The statement of eligibility will require the doctor to identify the employer or PCO who will be responsible for the clinical governance certificate. The declaration as to health will be signed by the doctor him/herself and must be countersigned by another licensed doctor. It appears that the doctor will not be required to submit appraisal Form 4 although the Guidance is not wholly clear on this point. In evidence to the Inquiry, Sir Graeme Catto described Form 4 as the 'absolute minimum' that the GMC would expect to receive.

26.143 The 2004 draft Revalidation Guidance states that the information submitted must be **'capable of independent verification'**. The application will be examined to see that it is complete and that it demonstrates that the doctor is working in an approved environment. If the application is in order, the GMC will apply for a clinical governance certificate from the employer or PCO. If the certificate is satisfactory, most doctors will be revalidated at this stage. Doctors are warned that they may be required to submit a folder of information **'relating to the headings of *Good Medical Practice*'**. This could be either because the GMC wishes to scrutinise the doctor's folder for quality control purposes or because some doubts have arisen as to the doctor's fitness to practise, presumably as the result of the health or probity declarations or the request for a clinical governance certificate.

The Second Stage of Revalidation

26.144 The 2004 draft Revalidation Guidance contains some information about what will happen at the second stage of the revalidation process if the evidence that the doctor has submitted is **'insufficient or raises a question about fitness to practise'**. It is said that one or more actions might be taken. The doctor might be asked to provide further specific information or evidence. Further evidence might be sought through the use of secondary tools, such as peer and patient questionnaires or observation of practice. The doctor's evidence could be referred to a Registration Decisions Panel for advice. Finally, the doctor could be referred to the GMC's FTP procedures for investigation. It is also said that if a doctor is **'required or permitted'** to submit his/her folder, **'specially trained experts will review the folder, taking into account any relevant specialty-specific standards defined by the medical Royal Colleges or other authoritative bodies'**. The **'experts'** will prepare a summary report, which will be considered by a Registrations Decisions Panel, which will recommend to the Registrar what action should be taken.

26.145 I must express some concern about the imprecision of these arrangements. It is not clear whether action will be taken in every case. That is left open; action might or might not be taken. I can see that it would be difficult to be precise about exactly what further information might be required; that must depend upon the nature of the insufficiency identified or the question that has arisen about the doctor's fitness to practise. However, if further evidence is submitted, it is not clear who is to examine it and to judge its adequacy or what standards are to be applied. Not in every case will evidence be referred to a Registration Decisions Panel for advice. If a doctor's evidence is to be submitted to a Registration Decisions Panel, by what standards is the Panel to advise? As I understand the position, only doctors' folders (and not other evidence), are to be reviewed by the **'experts'**. It is not clear whether these will be experts who are medically qualified and practising in the specialty to which the doctor belongs or whether they are to be 'expert' in scrutinising folders. It is possible that these second stage procedures will be robust but it is not clear that they will be. The robustness of the second stage is crucial to the revalidation process. If a doctor who fails at the first stage is revalidated at the second stage without careful individual evaluation of his/her fitness to practise, the whole process will be without value.

The Third Stage of Revalidation

26.146 The third stage will apply only to those doctors who have been referred into the FTP procedures as the result of their failure to satisfy a Registration Decisions Panel. I anticipate that most of those cases will be doctors whose performance has given rise to concern. I can see that there might be a few cases who are referred for health reasons or because concerns have arisen about some aspect of the doctor's conduct. However, as I say, in the main, poor performance will more usually be the reason.

26.147 When a doctor is referred into the FTP procedures on account of concerns about performance, s/he will usually be required to undergo a full GMC performance assessment. I described that process in Chapter 24. Briefly, it comprises two phases. Phase I is a peer review. Phase II comprises three forms of objective assessment: a knowledge test, a simulated surgery and objective structured clinical examinations, placing the doctor in certain clinical situations to which s/he has to react. For GPs, the standard of the objective tests is calibrated at the level required for entry to general practice, known as summative assessment. Sir Donald Irvine told the Inquiry that he thinks that that standard is too low. He would like to see the performance assessment calibrated to the standard required by the RCGP for its Membership by assessment. Dame Lesley Southgate, who is a member of the Postgraduate Medical Education Training Board (PMETB), which is shortly to assume responsibility for overseeing the training of GPs, said that the intention was to devise a common standard for entry to general practice and for Membership of the RCGP. The standard for entry to general practice would be raised to some degree. Under the old FTP procedures, when a performance assessment revealed SDP but it was considered that the standard of the doctor's performance was likely to be improved by remedial action, the doctor would usually be invited to agree to a 'statement of requirements'. In the future, s/he will be invited to agree to voluntary undertakings. The statement of requirements usually comprised some requirements for re-education and they might also contain a requirement for supervision and impose some restrictions on the doctor's practice. My understanding is that, in the future, if the doctor who has failed the performance assessment accepts the proposed voluntary undertakings, s/he will be revalidated on those terms. The revalidation may be for a shorter period than the usual five years. Thus, the revalidated doctor will not be 'up to date and fit to practise' but will be practising under conditions. Mr Brearley said that this would be acceptable because the conditions will ensure that the doctor is not a risk to patients. I have no reason to say that he is not right about that. However, I must observe that a member of the public who understood that his/her doctor had been revalidated (and was therefore up to date and fit to practise) might be surprised to learn that the doctor was practising under restrictions and conditions that had been imposed in the interests of patient safety.

26.148 If a doctor who is offered voluntary undertakings declines to accept them or if the GMC member of staff (probably a case examiner) responsible takes the view that voluntary undertakings are not appropriate, the doctor will be referred to a FTP panel. There will then be a hearing at which it will be decided whether the doctor's fitness to practise is impaired and, if so, whether it is impaired to a degree justifying action on registration. The FTP panel may decide to erase or suspend the doctor from the register, in which case s/he will not

be revalidated, or may decide to impose conditions, in which case the doctor will be revalidated but must practise in accordance with the conditions.

26.149 As I understand the new procedures, a FTP panel in a performance case will operate to the same standards as the former CPP. In theory, that is the standard by which the performance assessment has been conducted, i.e. the standard required for admission to general practice. Sir Donald told the Inquiry that, when the performance procedures were first brought in, that was what happened. If the doctor had 'failed the assessment', the CPP would take action on registration. Quite apart from the fact that he felt that the official standard was too low, he expressed concern, echoed by Dame Lesley, that, over the last few years, there had been some slippage of standards. Doctors were able to attack the findings of the first phase of the assessment (or some of them) and the panels of the CPP had to form a view as to the validity of the criticism in the assessment report. The result, said Sir Donald, was that CPP panels applied their own views as to what was acceptable. This resulted in doctors whose performance was (in Sir Donald's view) quite unacceptable being allowed to continue in practice. Sir Graeme himself described the standards applied in the performance procedures as 'remarkably low'. That view confirmed the impression I myself had gathered from the files that I read. Sir Donald observed that, if such panels were to provide the 'baseline' for revalidation, it was vital to establish appropriate standards of practice and performance. Otherwise, revalidation would be meaningless as a means of protecting the public. I agree with him.

26.150 It seems to me that it is essential that agreed standards are laid down for the use of FTP panels in a form in which they can be readily applied. The GMC is able to establish standards for entry into the profession and the medical Royal Colleges, and the PMETB establishes standards for entry onto specialist registers. Nowadays, examination for these purposes is not limited to a written test. There are various forms of performance assessment, for example in the GPs' summative assessment. In my view, if revalidation is to command public confidence, it must have a 'baseline' which is capable of being objectively applied and within a reasonable period of time. In Chapter 24, I explained how there could sometimes be a delay of several years before performance procedures were completed. Meanwhile the doctor remained in practice unless s/he was obviously unfit. I think that there must be a clear threshold below which a doctor would be 'taken off the road' until s/he had improved and had been reassessed as performing at a satisfactory level.

The Relevance of a Doctor's Fitness to Practise History

26.151 It is not clear from the 2004 draft Revalidation Guidance at what point in the revalidation process it is intended that a doctor's FTP history with the GMC should be considered. Nor is it clear how, if at all, a FTP history will affect the outcome of the revalidation process. The Guidance refers to the introduction under the new FTP procedures of a system of warnings, which will be issued by the GMC where there has been a significant departure from 'Good Medical Practice' which is not so serious as to justify action on a doctor's registration. The Guidance states that the GMC **'will want to see evidence that the problems which gave rise to the warning have been addressed by the time of the doctor's next revalidation'**. The Guidance also indicates that, where necessary, the

doctor's revalidation date will be brought forward to ensure that problems have been addressed promptly. If they have not, it is said, the doctor's registration may be at risk. However, it is not clear at what stage evidence about the doctor's compliance with the terms of a warning will be sought, whether the evidence will be sought from the doctor him/herself or from some other person or body, what the nature of the evidence required is likely to be, by whom it will be scrutinised and against what standard. If a warning is to have any significance at all within the revalidation process, it will be necessary for independent, objective evidence of compliance with the terms of the warning to be sought and for that evidence to be scrutinised to an agreed standard by a competent (probably medically qualified) person or by a group of people, both medically qualified and lay.

26.152 The 2004 draft Revalidation Guidance states that the GMC may also wish to bring forward a doctor's revalidation date if s/he has been practising subject to conditions or undertakings under the FTP procedures or if s/he has resumed practice after a period of suspension or erasure. That said, it is not clear what, if any, effect the doctor's FTP history will have on the outcome of the revalidation process. Nor is it clear whether the doctor will be required to provide additional evidence over and above the basic documentation that must be provided by all doctors. It seems likely that, if additional evidence is to be required from a doctor who has been given a warning, it will also be required from doctors who are or have been subjected to other sanctions and to undertakings. In that event, the same questions arise about the nature and source of that evidence and how it is to be scrutinised. Another uncertainty is whether, when an application to revalidate is received by the GMC, any check will be made to ascertain whether there is any allegation against the doctor that is currently being investigated under the FTP procedures and, if so, what the procedure for dealing with the application to revalidate will be.

Quality Assurance

26.153 I mentioned earlier that the second SHM report contained some proposals in relation to quality assurance. Several areas were identified where quality assurance intervention was required. The first of these was **'setting the specialty-specific standards by which doctors' fitness to practise will be assessed'**. In fact, the model which the GMC had by that time decided upon involved no 'assessment'. However, it was (and still is) intended that the medical Royal Colleges should set standards, evidence and criteria against which the doctors' evidence should be measured. The second area was assuring the standards and planning local systems designed to identify and take action on performance and conduct issues. This was to be the responsibility of NHS trusts. Responsibility for ensuring the quality of appraisal systems and for clinical governance generally (the third area) was to lie with the Healthcare Commission and equivalent bodies in other parts of the UK. The GMC was to be responsible for scrutinising the revalidation evidence produced by doctors. It was envisaged that this would probably consist of a quick check in every case to ensure that doctors had complied with the obligation to submit evidence and that the documentation was complete. In most cases, that would be the only scrutiny. It seems that that advice has been largely accepted. I have already noted, at paragraph 26.117, that the second SHM report warned the GMC about the risks inherent in shared accountability for quality assurance.

26.154 The second SHM report also recommended a more detailed scrutiny of a sample of evidence. In evidence, Sir Graeme and Mr Scott said that the GMC intended to quality assure the first (external) stage of revalidation by taking a small sample of doctors who would otherwise be revalidated and subjecting their applications to detailed scrutiny. The report suggested a sample of 1.4% for doctors working in a 'managed environment'. Mr Scott told the Inquiry that the GMC was 'revisiting the sampling model'; he expected the percentage of cases sampled to be larger than originally suggested. The objective will be to see whether, within that sample, detailed scrutiny produces the same decision as the 'appraisal and clinical governance route'. More recently, the GMC has said that, in addition to taking a sample of cases with no specific risk factors, it intends to scrutinise a larger sample of doctors taken from groups which present known risk factors. The GMC has not said what these risk factors are to be.

26.155 When asked how this detailed scrutiny was to be conducted, Sir Graeme said that the GMC would want to see the original documents in the doctor's folder, which should contain some verifiable information derived from clinical governance activities and collected by the PCO. Other documents might originate from within the doctor's practice, rather than from the PCO. The GMC would want to see them all. At the time of the Inquiry hearings, the GMC had not decided who was to carry out the scrutiny. According to the 2004 draft Revalidation Guidance, the GMC has decided that this scrutiny is to be carried out by **'specially trained experts'**. No further detail has been given.

What Value Is Added by Revalidation?

26.156 In the course of evidence, I made the point to Mr Brearley that, if dysfunctional practice is to be detected by clinical governance procedures which are in continuous operation, and appraisal will provide a formative experience and 'safety net' once a year, there seemed little role left for revalidation as a separate process. What 'added value' did it provide? Mr Brearley's first point was that it would focus the mind of the officer of the NHS trust or PCO who had to decide whether s/he could properly sign a clinical governance certificate, saying that there were no (or no significant) unresolved concerns about the doctor. I could see the force of that, although the extent to which his/her mind would be focussed would depend upon the extent to which that officer were to be held accountable if s/he provided a 'sign-off' and it later transpired that his/her judgement about the nature or seriousness of a known concern was wrong. If the consequences for the officer were to be serious, I could see that having to sign the certificate would focus the mind. But if nothing much were to happen when a judgement to issue the certificate turned out to be wrong, then officers would soon discover that, and the 'mind-focussing' effect might be limited. Later in his evidence, Mr Brearley made a related point about the added value of revalidation, which I think is rather stronger. He said that, if the clinical governance lead of a PCT heard about a concern which did not seem particularly serious, s/he would be more inclined to take action upon it and try to resolve it, if s/he knew that in, say, two years' time, s/he would have to decide whether s/he could sign the clinical governance certificate for that doctor. That, I think, would add some value.

26.157 In relation to the issue of added value, Mr Brearley also suggested that, by undertaking the process of revalidation, the GMC was 'quality assuring' the medical register. This was

a reference to the definition of revalidation which, according to the second SHM report, had been promulgated by the GMC in early 2003. People will be able to look at the register, he said, and know that their doctor has been through a process and is fit to practise. It does not seem to me that, for the patients of NHS doctors, that provides much by way of added value. If revalidation is to be dependent on clinical governance, the real reassurance that patients will want is that clinical governance is working well and is detecting under-performing doctors. The fact of revalidation adds virtually nothing. However, for the patients of doctors who cannot take the 'appraisal and clinical governance route', revalidation could give real reassurance provided that the GMC puts in place an adequate method of scrutiny and evaluation. The same could be said for doctors who, although eligible to undergo revalidation through the 'appraisal and clinical governance route', fail to do so and have to undergo further scrutiny by the GMC. Again, the reassurance is of value only if the methods are good enough.

26.158 Mr Brearley also said that revalidation would have an independent value because, by undertaking quality assurance procedures – by means of the in-depth scrutiny of a sample of doctors who would otherwise be revalidated automatically on receipt of the clinical governance certificate – the GMC would find out whether clinical governance was really working and detecting dysfunctional practice. I could see the force of that point too. Of course, all depends on the thoroughness of the quality assurance mechanisms.

Developments since Early 2004

26.159 Since the conclusion of the hearings in December 2003 and the seminars in January 2004, the GMC has continued to provide the Inquiry with documents relating to a number of issues, including revalidation. As might be expected, there have been developments. I have already referred to work done by the RCGP and the NCGST.

26.160 In March 2004, there took place the first meeting of a joint working group set up between the GMC, the RCGP, the BMA and the NHS Modernisation Agency, the purpose of which was to consider ways of improving clinical governance in primary care. At this meeting, the joint working group agreed its Terms of Reference, which were to consider how clinical governance mechanisms within primary care can identify emerging poor practice and deal with it in a way that protects patients. Also, the joint working group was to consider how clinical governance mechanisms could support doctors working in primary care in the collection of objective, practice-based data, from which evidence to support revalidation could be drawn. One of the issues discussed at the first meeting was the need for clarification of the various standards and guidance documents currently in existence and for the development of a 'checklist tool' that made clear what practice parameters are not acceptable. It was said that the 'Revalidation Toolkit', developed by the RCGP in Scotland, might provide a useful template for use throughout the UK. There was reference to the need to link clinical governance data in primary care to an individual doctor. As I have indicated before, much data is practice-based and does not provide useful information about an individual. There was also a call for greater consistency of application of clinical governance systems throughout the country. It was thought that PCOs would benefit from the creation of local clinical governance support groups, which would have a role in reviewing information known locally about doctors and in reporting to

the clinical governance lead any concerns about a doctor. The view was expressed that the local clinical governance support groups would benefit from lay input, perhaps through the inclusion of the chairman of the relevant local patient group. It was thought that such groups might advise the clinical governance lead about the position of individual doctors seeking a certificate for the purposes of revalidation. Also, they might advise on remedial action.

26.161 I appreciate that this joint working group was concerned mainly to devise ways of improving clinical governance. However, it seemed to me that it could make a valuable contribution to the process of revalidation. If it could develop some standardised means of collecting and presenting 'hard' clinical governance data, there would be a greater prospect that under-performing and dysfunctional doctors would be detected. The clinical governance certificate could become more of a positive assurance of fitness to practise, rather than a negative statement that 'nothing adverse is known'. The certificate would have far greater value in revalidation, and revalidation could then provide a better reassurance for patients. The process of appraisal would also be enhanced. The joint working group also agreed that detailed criteria, standards and evidence for GPs (and doctors in other specialties) should be developed and could then be used to support the revalidation process. The medical Royal Colleges were to take a leading role in this work.

26.162 Pausing there, these developments seemed to me to be most encouraging. Many of the concerns that I had felt about the current proposals for the revalidation of GPs were to be constructively addressed. The joint working group was to have its second meeting in May or June 2004. The Inquiry has not received a copy of the minutes of a second meeting. However, in November 2004, the Inquiry did receive a note of the first meeting of a sub-group of the joint working group, which had taken place on 26th August 2004. I shall describe its contents shortly.

26.163 Meanwhile, at its Council meeting in May 2004, the GMC was asked to approve a draft for a document to be entitled 'The Policy Framework for Revalidation: a Position Paper' (the draft Position Paper). This was to be published in July 2004. I do not intend to summarise its contents other than to say that it described the GMC's current policy on revalidation broadly as I have described it in this Chapter. At the meeting, there was detailed discussion of the draft Position Paper. Some of the discussion related to concerns about matters that had been omitted from the draft Position Paper. In particular, Professor Pringle drew attention to the issues discussed at the first meeting of the joint working group and expressed regret that those ideas had not been reflected in the draft Position Paper. There was no reference in the draft Position Paper to the development of standardised means of collecting data or to improving the range of clinical governance data relating to individuals rather than GP practices. Nor was there any reference to the idea that a clinical governance support group, including a lay element, might assist and advise the clinical governance lead with decisions on certification and related issues. Professor Pringle proposed that these changes should be mentioned in the Position Paper, when published. The result was a modification of the draft Position Paper so as to presage some scrutiny of evidence at a local level. How or by whom this scrutiny was to be conducted was not made clear.

26.164 At the meeting in May, Professor Pringle pointed out that there was a need for the GMC to 'reactivate' the medical Royal Colleges and to encourage them to get on with the work of preparing detailed standards, criteria and evidence to be used in connection with revalidation. This is painstaking work and cannot be achieved in a short time. Concern was expressed that it would not be completed by the time revalidation was launched in 2005. I have already referred to the progress that has been made by the RCGP in this regard. This work is important as it will underlie not only the decisions taken at the second stage of the revalidation process but also the scrutiny of the small sample of cases that will be scrutinised for quality assurance purposes.

26.165 The Position Paper was published in July and was followed by the publication of draft Rules and Guidance in September. These were accompanied by a letter, inviting comments and suggestions. It appears to me that the draft Rules are uncontroversial. They provide a legal framework for what the GMC intends to do. However, the 2004 Revalidation draft Guidance contained a few new developments. In particular, the GMC has now created the concept of a **'GMC approved environment'**. This concept was mentioned in the April 2003 Prospectus although it was described differently. This is a working environment in which clinical governance procedures are applied and doctors have to undergo periodic appraisal. Doctors working in such an environment will be eligible to revalidate through the clinical governance and appraisal route. The concept of the **'GMC approved environment'** is also to be used in connection with doctors who have a restricted licence to practise (i.e. doctors who are licensed only to work in GMC approved environments). Already there is a long list of private healthcare providers who have been provisionally approved for these purposes and it is said that the list may be extended in future. How rigorous the approval procedures have been, I have no idea. The result of this change is that there will be very few doctors in clinical practice who will have to take the independent route to revalidation.

26.166 On 10th November 2004, very shortly before delivery of this Report was due, the Inquiry received from the GMC a note of a meeting of the sub-group of the joint working group of the GMC, the RCGP, the BMA and the NHS Modernisation Agency which had taken place on 26th August 2004 and to which I have already referred. I have previously reported on the first meeting of the joint working group, which took place in March 2004. The note revealed that the proposals for the provision of a clinical governance certificate had advanced some way. It appears that the discussions at the meeting related to those proposals and that it was not the function of the sub-group to make decisions. However, some points appear to have been agreed. The meaning of the note is not entirely clear to me. It will have been prepared for the benefit of those who attended the meeting and who would understand the context of the discussion. I may have misunderstood it to some extent. In some respects, the content of the note has been clarified by the receipt, on 11th November 2004, of a letter from Sir Liam Donaldson, the CMO.

26.167 The note of the meeting of 26th August 2004 made plain that it would be for the NHS to decide how to **'deliver local certification'**. Further work would be required, but the group (I assume that means the sub-group) and the bodies represented would work together to ensure readiness for the introduction of revalidation. Under the heading **'Local Support Groups'**, it was said that the NHS Modernisation Agency was continuing to work on

'defining the nature of local support groups'. It was also said that **'local certification groups'** would consist of three people drawn from the certifying organisation, such as a PCO. One of the members of the certificating group would be a lay person, presumably an employee or officer or board member of the PCO. The certifying organisation would decide who those individuals would be. I am not sure whether a **'local support group'** is the same as a **'local certification group'**. As I reported in paragraph 26.160, the joint working group, which met in March 2004, discussed the possibility of local clinical governance support groups reviewing information known locally about doctors and reporting any concerns about a doctor to clinical governance leads. This type of group would have some lay input. That seemed to be a different group from a 'local certification group', the name of which suggested that it would be responsible for signing the clinical governance certificate.

26.168 The sub-group welcomed the work being done on tools and guidance and said that it was for the NHS to produce this in conjunction with partners such as the medical Royal Colleges. The need for consistency throughout the UK was stressed. It was stated that the guidance should be generic and potentially applicable to all specialties and all four countries of the UK. It was also stated that the publication of documentation on local certification should be co-ordinated. This paragraph of the note does not appear to relate to the work done by the RCGP and NCGST to which I referred in paragraph 26.138. The RCGP's work was concerned with the evidence that should be produced by GPs for the purposes of CPD, appraisal and revalidation. The NCGST's work sought to identify the minimum items of evidence that a GP would have to produce to allow a clinical governance lead to sign a clinical governance certificate.

26.169 The note recorded that the GMC's formal guidance on licensing and revalidation would state what information about doctors would be required from local certification. The GMC envisaged that local certification would have two components. There would be certification of participation in appraisal and certification of the absence of **'unresolved significant concerns'**. Because those providing the certificates would need to understand the significance of the document they were signing, additional information would be provided. In respect of participation in appraisal, certification would confirm five points, namely, that appraisal had taken place; that the process had produced an agreed personal development plan; that the process had been carried out and signed off by a trained appraiser; that the process had been **'informed by validated data about the doctor's actual practice'**, and that local clinical governance processes including appraisal were quality assured. It is not clear to me what was meant by the process being **'informed by validated data'**; nor am I sure to what extent the clinical governance processes are to be quality assured.

26.170 In respect of the certificate relating to:

> **'unresolved significant concerns, certification would confirm that:**
>
> **i. There are no locally-known concerns about the doctor's health.**
>
> **ii. There are no locally-known concerns about the doctor's probity.**
>
> **iii. There are no local disciplinary procedures in progress.**

iv. There have been no relevant disciplinary findings locally over the specified period.'

These were quite specific requirements and it appeared that the certificate would not provide any general assertion about the doctor's fitness to practise or even the absence of concerns about other matters.

26.171 The note of the meeting recorded that it had been agreed that the information that would **'underpin local certification'** should be **'derived from clinical governance and verifiable data'**. I do not know what that means. If the clinical governance certificate were to deal with only the four specific items listed above, it would not be dependent on information **'derived from clinical governance'** or on **'verifiable data'**. The health and probity certificates could never be more than assertions that the NHS body knew of nothing that would call the doctor's health or probity into question. The third and fourth items were simply matters of record. I cannot see what role **'verifiable data'** could play. The note said that the information (that would underpin local certification) should enable certificating organisations to identify concerns about a doctor's practice. Where such concerns exist, appropriate action should be taken locally and information should be shared with other bodies, such as the GMC, where applicable. It was agreed that the NCGST would produce detailed working specifications on how local certification might work.

26.172 In the light of this document, some matters seemed tolerably clear. The clinical governance certificate would be negative in nature. In effect, it would say only that nothing adverse was known in four specific respects: health, probity, current local disciplinary procedures and local disciplinary findings within the revalidation period, usually five years. Mr Brearley's wish that *any* concern about the doctor should be brought to the GMC's attention had not been addressed. What was meant by **'disciplinary procedures'** in the context of general practice was not clear. As I have said, disciplinary proceedings hardly exist today in general practice; they have been replaced by list management powers. Does the term **'disciplinary procedures'** include the exercise of list management powers? It was however tolerably clear that a complaint from a patient that was under investigation and had, for example, been referred to the Healthcare Commission would not prevent the completion of a clinical governance certificate. Nor, presumably, would the knowledge that the doctor was being sued for damages in respect of the death of a patient, unless there were also local disciplinary procedures in train.

26.173 It seemed to me that, if revalidation were to be reliant on local clinical governance systems, the person or group providing the clinical governance certificate should be required to consider the totality of the clinical governance data available in respect of a doctor before signing the certificate which was to form the basis of revalidation. The certificate should not be based on only a few discrete aspects of that data. A member of the public who was told that a person or group had provided a certificate saying that there were **'no unresolved significant concerns'** about a doctor would not understand that what was being certified was only that there had been and were no disciplinary proceedings against the doctor and no concerns about his/her health or probity. He or she would understand the certificate to mean that there were no concerns about complaints

which had been made about the doctor and were as yet unresolved, no concerns about his/her general prescribing practice or prescribing of controlled drugs, no concerns about his/her lack of participation in audit – indeed that there were **'no unresolved significant concerns'** about the doctor at all. I believe a member of the public would expect – and would be entitled to expect – the person or group to review all the information available before reaching a conclusion as to whether or not to sign this important document. If the effect of the clinical governance certificate is limited to a statement that, so far as is known, the doctor has no health problems, is not dishonest and has had no involvement in disciplinary proceedings, the public should be made aware that this is the case.

26.174 What was not clear to me after reading the note of the sub-group was whether or not it was intended that there would be any local scrutiny of a doctor's evidence by a clinical governance lead (as was contemplated by the NCGST) or by a local clinical governance support group or local certification group. If that was not to take place, it would mean that there was to be no evaluation of the doctor's fitness to practise. That is, as I have observed, a fundamental statutory requirement for revalidation.

26.175 The CMO's letter, dated 10th November 2004, has shed further light on the proposals for revalidation, which now appear to be the joint proposals of the GMC and the DoH. In his letter, the CMO declared that, in his view, **'firstly, the culture and process of clinical governance are now strongly embedded in local NHS organisations and, secondly, appraisal of NHS doctors is now well established'**. I am not sure upon what evidence the CMO has reached these conclusions. They are very different from the views expressed by his deputy, Professor Halligan (and by others), at the Inquiry seminars in January 2004 to which I referred at paragraph 26.90 above. Certainly, the Inquiry has received no evidence from the DoH (or elsewhere) to support this change of view. Of course, it may be that the CMO is speaking about the position in the hospital service. The Inquiry is concerned only with general practice.

26.176 The CMO then explained that, because he had reached these conclusions, the DoH **'would endorse the General Medical Council's principle that local ''certification'' would provide an explicit assurance about the doctor's practice at the point of revalidation'**. He continued:

> **'There must be an explicit and positive confirmation that doctors' practice-based evidence really is being reviewed through annual appraisal, operating within an environment subject to clinical governance. There would be explicit, rather than implicit, local certification (delivered by the clinical governance lead or the medical director or chief executive, as appropriate, for the most senior doctors) covering two components – that the doctor had been appraised and that there were no unresolved local concerns that might call into question the doctor's fitness to practise.**
>
> **In the case of participation in appraisal, explicit certification would confirm that:**

a. **Appraisal had taken place;**

b. **The appraisal process had produced an agreed Personal Development Plan;**

c. **The appraisal process had been carried out, and signed off, by a trained appraiser;**

d. **The appraisal process had been informed by verifiable data about the doctor's actual practice;**

e. **Local clinical governance processes – including appraisal – were quality assured.**

In the case of the absence of significant unresolved concerns, explicit certification would confirm that:

a. **There are no locally-known concerns about the doctor's health;**

b. **There are no locally-known concerns about the doctor's probity;**

c. **There are no local disciplinary procedures in progress;**

d. **There have been no relevant disciplinary findings over the specified period.'**

26.177 It now appears that the position is that the first stage of revalidation, which all doctors will be required to undergo, will comprise the submission of personal information (including declarations as to health and probity) to the GMC and the provision of a clinical governance certificate comprising the listed assertions about the doctor's participation in appraisal as well as those about health, probity and disciplinary proceedings. It does now appear clear that it is the intention of both the GMC and the DoH that revalidation will not comprise an evaluation of the doctor's fitness to practise. As I have said, appraisal as currently carried out for GPs cannot provide such an evaluation.

26.178 It may be that it is intended that appraisal will be 'toughened up'. Indeed, I have read in the periodical 'Doctor' as recently as 5th November 2004 that **'GP appraisals are set to get tougher to ensure problem doctors are flagged up during revalidation'**. It was said that **'a source close to the Department of Health said discussions were going on about how appraisal could be monitored to ensure it was stringent enough to allow revalidation to pick up problem doctors'**. The same article reported differing views from sections of the profession. Some thought that 'toughening up' would be a good idea; others thought that appraisal should not be used as a tool for picking up poor performance. However, it appears from the CMO's letter to me that he is satisfied that appraisal is already an adequate foundation upon which to base revalidation. I regret to say that I cannot agree.

An Important Concern

26.179 Throughout my examination of the GMC's proposals for revalidation, I have felt some concern that the public was being led to expect more from revalidation than it could

reasonably be expected to provide, in terms of reassurance about the competence of an individual doctor. It is important that patients and all other interested parties understand exactly what revalidation means and what its limitations are. Mrs Joyce Robins, who represented Patient Concern at the Inquiry seminars, made a plea that patients should be put fully in the picture and should be told what revalidation involves in practical terms and why it is deserving of public trust. It is important that revalidation is not 'oversold'. There are three different, although related, foundations for my concern.

26.180 The first is that, if a member of the public is told that revalidation will ensure that his/her doctor is 'up to date and fit to practise', s/he will, I believe, have the impression that s/he can expect the doctor to be practising at a level of competence above the basic level of acceptability. The expression 'up to date and fit to practise' will, in the minds of most members of the public, convey the idea that the doctor is 'fully up to speed' – not that s/he has just 'passed muster'. Yet the position is that a doctor will be revalidated unless his/her conduct, performance or health is such that a FTP panel decides that it must take action upon the doctor's registration. Even then, the doctor might be revalidated subject to restrictions and conditions upon his/her practice. In order to be refused revalidation on the grounds of poor performance, the doctor's performance will have to be so seriously deficient that the FTP panel feels obliged to suspend or erase him/her.

26.181 I have already referred to the low standards that are applied in performance cases and have said that that low standard will form the baseline for revalidation. In the course of a discussion at a GMC Council meeting on 12th May 2004, Mr Brearley remarked that doctors know that 'if they participate in revalidation and they are really bad, their registration could be at stake'. The implication is that the doctor will fail to be revalidated only if s/he is 'really bad'. The reality of the 'remarkably low' standard above which doctors will be revalidated does not square with the claim that revalidation gives an assurance that the doctor is 'up to date and fit to practise'. In my view, there is a real danger that the public does not understand this.

26.182 In the course of his evidence, Mr Brearley explained that one of the purposes of revalidation was that patients should be able to make an informed choice about their doctor. They would be able to look at the register and see that their doctor had been revalidated. Yet Mr Brearley had also said that a doctor might be revalidated and yet be subject to restrictions on his practice, imposed by a FTP panel for the safety of patients. He considered that this provided an acceptable safeguard for the public because the conditions would ensure that the doctor could not practise in areas in which s/he might present a risk to patients. However, it seemed to me that, if patients were to be in a position to make an informed choice of doctor, they would need to know more than merely whether their doctor had been revalidated. Patients would need to know whether there were any restrictions upon the doctor's practice and, if there were, they might need to know what they were and why they had been imposed. Mr Brearley's reply to this was that it would not be right to reveal too much information about the doctor because this would lead to a disproportionate loss of confidence in him/her. He considered that, if the fact that a FTP panel had imposed a sanction were to go into the public domain and destroy confidence in the doctor so that s/he could not practise, FTP panels would be reluctant to impose those sanctions. From that evidence, it appeared that the public is to be told that the

doctor, if revalidated, is up to date and fit to practise and they can have confidence in him/her. That would be most unsatisfactory because the reality might be that s/he is on the borderline of being unfit to practise. I was concerned about this. However, I see, from the draft Guidance recently published, that it is the GMC's present intention that the medical register will include the information that the doctor has been revalidated subject to conditions. How much detail will be provided I do not know. The information is 'in the public domain' in that if an enquirer telephones the GMC and asks directly whether the doctor's registration is subject to conditions, s/he will be told. In my view, this information should be readily available to the public from the GMC's website.

26.183 My second concern about the position of the public is that they are told that, in order to secure revalidation, the doctor must demonstrate to the GMC that s/he has been practising in accordance with the principles of 'Good Medical Practice'. In fact, as I have explained, it is not at all clear that s/he will have to do any such thing. He or she will have to provide a description of his/her practice (in the sense of what s/he does, rather than how s/he does it), assert that s/he has undergone appraisal and make a declaration as to his/her health and probity. The GMC will then seek a clinical governance certificate, which may confirm that the doctor has taken part in appraisal and that there are no significant unresolved concerns relating to his/her fitness to practise. If given, the certificate asserts a negative; in effect nothing adverse is known. There has been no positive demonstration of the standard of the doctor's practice. It is important that, if the present arrangements are to continue, the true position is made clear. It may be that it is intended in future to introduce some local scrutiny of the evidence in the doctor's folder. I cannot tell.

26.184 My third concern is that the public is being given the impression that doctors undergoing revalidation have to pass some sort of objective test. This is not positively suggested in official GMC publications, although the GMC came very close to it in the Prospectus of April 2003 when it drew a comparison between revalidation and the periodic assessments that airline pilots have to undergo. However, my real concern on this issue is that the GMC has, on more than one occasion, to my knowledge, made statements that suggest that revalidation will involve either a test or some form of thorough check of fitness to practise. Under the present proposals, it will not. During the GMC's opening statement to the Inquiry, Leading Counsel for the GMC said that, in the process of revalidation, each and every doctor's competence and performance would be 'checked and rechecked' so that the public could have the assurance that doctors were not merely entitled to treat them by virtue of not having been found wanting. Instead, patients would be able to know and have confidence that a positive decision had been made that registered medical practitioners were fit to practise and that the information upon which a judgement had been made to that effect had been objectively verified and corroborated within a quality assured system.

26.185 On another occasion, revalidation was compared with the MOT test for vehicles. The MOT vehicle test is an objective test of the roadworthiness of an individual vehicle. Various features of the vehicle are examined against specified standards. If it fails any part of the test, it fails the whole test. There is no such thing as a pass with conditions. Revalidation for doctors is quite different. The overwhelming majority will be revalidated on the basis of appraisal, which is not a test of fitness to practise and does not incorporate any detailed

standards with thresholds by which it is possible to pass or fail. The only threshold by which the doctor can ultimately fail to be revalidated is, as I have said above, a very low one indeed. The point is that for most doctors the process is not a test at all and bears no resemblance to the MOT vehicle test.

26.186 Revalidation was described by Sir Graeme Catto as 'a sort of MOT test for doctors' in a BBC radio programme, 'Down With ...', broadcast on 12th May 2004. The programme comprised a debate about whether the GMC was doing all it should to safeguard and protect the interests of the public and patients. Sir Graeme said that the standards of practice and care that patients are entitled to get from their doctors are set out in 'Good Medical Practice' and that the GMC aimed to 'maintain and strengthen these high standards with a new system of revalidation – a kind of MOT for doctors'. Another contributor then spoke. This was Mr Alan Hartley, a member of the Patients Association and of the GMC's Patient Reference Group. He said:

> **'Approximately every five years, a doctor will be assessed as to his training and will have to show that he has kept up to date on training on new methods, so, from the public's point of view, what it means is they will know that when a doctor has been revalidated that he is fully up to speed with the latest innovations and the latest treatments. A huge step forward.'**

26.187 I interpose to draw attention to the way in which being 'up to date and fit to practise' was equated with being 'fully up to speed'. A while later, Sir Graeme again referred to revalidation as the 'MOT for doctors'. He expressed pride in the fact that no other country in the world had a system of time-limited licence dependent upon doctors demonstrating that they are up to date and fit to practise. To call revalidation a MOT for doctors is a catchword. It is easy for the listener to remember. I think that many people who heard that programme will have taken away the impression that revalidation is a test for doctors, just like the MOT. That is not a true impression.

Whither Revalidation?

26.188 It is not clear from the documents recently provided by the GMC whether its plans for revalidation are settled. It is fair to say that there has been a recognition that revalidation will evolve over time but it appears, from the 2004 draft Revalidation Guidance that the GMC does not expect to make any significant changes to its proposals in the near future. In my view, that is a pity, because the present proposals do not meet the requirements that were outlined so clearly in the Consultation Paper of 2000. Nor in my view will they satisfy the statutory definition of revalidation, which is an **'evaluation of a medical practitioner's fitness to practise'**.

26.189 It appears that the GMC has set its face against undertaking an individual evaluation of every doctor. However, that is what the statute requires. In the early days, the GMC took the view that it could not delegate that function; it rejected the suggestion that the medical Royal Colleges might offer an alternative route to revalidation. It has now accepted that it can delegate everything other than the final decision to revalidate. The statute does not

appear to forbid delegation. However, it does require an evaluation of an individual doctor's fitness to practise.

26.190 Quite apart from the statute, the GMC has always promised the public an individual evaluation of fitness to practise. In my view, its present proposals do not fulfil that promise. I propose to set out my ideas for how both the statute and the promise could be satisfied – only in the context of general practice, because that is the limit of my remit. My proposals would satisfy the GMC's wish to link revalidation closely with clinical governance. They would also, I believe, avoid doing serious damage to the formative nature of appraisal.

26.191 In my view, the main platform for revalidation should be the preparation by each doctor of a folder of evidence which demonstrates what the doctor has been doing in the last five years. Some of the contents of the folder would have to be specifically laid down and would be compulsory. They would include data derived from clinical governance. These would include, for example, prescribing data and records of complaints or concerns including any report from the Healthcare Commission or a GMC or NCAA assessment. I hope that, in the future, more information of that kind will be available to PCOs. Other compulsory items would originate within the doctor's own practice. These should, in my view, be much along the lines proposed by the RCGP in its consultation paper. For example, there should be a record of the CPD activities the doctor has undertaken. A copy of appraisal Form 4, a patient satisfaction questionnaire, the results of a clinical audit and some significant event audits should all be included. In addition, there could be a video recording of the doctor in consultation with patients. I would also suggest that the folder should include a certificate to show the successful completion of a knowledge test. I shall say a little more about that below. Of course, it would be open to each doctor to include additional material besides the compulsory items. The doctor's NHS contract of employment or contract for services would have to require the production of these compulsory items.

26.192 The preparation of the folder would take place over a five-year period. Its development could be discussed privately and in confidence during the annual appraisal, and advice could be given as to what more needed to be done. The appraiser would be entitled to see all the material, with the result that the appraisal would be of greater value; the doctor would not be able to conceal any problems. It would seem to me to be sensible if appraisers were to encourage doctors to produce one of the specific compulsory elements each year, for example a video recording or a patient satisfaction questionnaire, so that the appraisal could focus on a discussion of that topic.

26.193 At revalidation, the folder would be scrutinised – not by the GMC, but by a local group based within the PCO and probably chaired by the clinical governance lead. I do not claim this idea as mine; it is that suggested by the joint working group. I think it is a very good suggestion. The scrutinising group should, in my view, include a lay person from outside the PCO and a GP from another area, not personally known to the doctor under consideration. That GP should be accredited by the RCGP as an assessor to standards approved by the GMC. Scrutiny should not be undertaken by a single person; nor should a panel be drawn only from members or employees of the PCO. A positive addition could be that the doctor might be invited to attend the meeting. This would overcome one of the

'weaknesses' of the GMC's original plans identified by Mr Brearley. That group would make an individual evaluation of the doctor's fitness to practise, based upon standards to be set by the RCGP and approved by the GMC. If the local group were satisfied, it would recommend revalidation to the GMC; if it were not, the GMC would take over and proceed to the second stage.

26.194 I do not think that these arrangements would impose an undue burden on PCTs. On average, they have about 100 GPs each. That would mean evaluating about 20 GPs per year and some locums; I am not sure how many of those there would be. I would have thought that that would be manageable. However, there are several ways in which the numbers might be reduced by permitting alternative routes to revalidation. For example, the Membership by assessment of performance of the RCGP requires a high standard of performance. Any doctor who achieves that in the five-year period should, in my view, be automatically revalidated. If the RCGP were to devise a 'refresher assessment' (which could no doubt be approved by the GMC as a proxy for revalidation), I would expect that some doctors would take that route. I think, also, that GPs who are approved trainers could properly be automatically revalidated. Trainers have to be reassessed to a high standard of performance every three years. They could not possibly go through that process successfully if they were not fit for revalidation. Another possibility would be to exempt a GP from revalidation during the first five years after passing the summative assessment. That too would reduce the number of doctors that had to be scrutinised by the group. If it were thought that this proposal would still impose too much of a burden, I suggest that consideration should be given to stretching the revalidation period from five years to seven. Another alternative would be to keep the five-year period for GPs over the age of 50 and allow a longer period between revalidations for doctors under that age. In short, I think it is vital that there should be an individual evaluation of each doctor and I think that the burden that this would impose on individual PCOs could be made tolerable. I advance no proposals about the revalidation of doctors in the hospital service or the private sector.

26.195 So far as the second stage is concerned, the GMC must ensure that this is transparent and rigorous. It should ensure that there is adequate lay involvement. Above all, it must not permit a doctor who has failed to be revalidated at the first stage to be revalidated 'by default' at the second stage. At present, the uncertain nature of the steps to be taken makes that a real possibility. The GMC must ensure also that the standards by which second stage decisions are to be taken are clear and understood by all, including doctors and the public.

26.196 I have already expressed my concern about the low standards of the old performance procedures, which would, but for the advent of the new FTP procedures, have generally underpinned revalidation. The GMC has not said that the standards of deficient performance that will justify action on registration under the new procedures will be any higher than those in operation before. These standards are too low and do not provide adequate protection for patients. In my view, they must be raised if revalidation is ever to have credibility.

26.197 I said that I wished to mention the use of knowledge tests. The evidence received by the Inquiry is to the effect that no doctor can function well unless his/her knowledge base is

adequate and kept up to date, but the fact that the knowledge base is satisfactory is not, in itself, a guarantee that the doctor is practising well. This second factor is often used as a reason for not including any form of knowledge test in the revalidation process. In my view, that is not a satisfactory reason for excluding a knowledge test although it is a good reason for not basing revalidation solely upon such a test. I think that the real reason why so many people seem to veer away from the idea of knowledge tests is that they believe that doctors will not accept them. I cannot believe that there could be any rational opposition to what I am proposing. Nowadays, knowledge tests can be taken on-line and in private. The doctor can find out in the privacy of his/her own study whether his/her knowledge base is satisfactory. If it is, that will provide the doctor with a degree of comfort and might also draw attention to any areas in which a gap has been revealed. I am sure that most doctors who do not do well would wish to remedy the situation. Such a doctor can take another test – and yet another if necessary – until s/he reaches a satisfactory standard. If a doctor cannot bring his/her knowledge base up to standard within five years, surely s/he should not be practising. In my view, there should be a mandatory requirement to produce a certificate of satisfactory completion of a knowledge test taken at some time within the five-year period.

26.198 Clearly, the changes that I have proposed are not entirely a matter for the GMC. They call for the close involvement of the DoH. They would require consultation and I dare say that they would give rise to some consternation in the profession. I do not think that they need to. I believe that the profession has accepted that the public is entitled to the reassurance that doctors are up to date and fit to practise and I believe all those who are intellectually honest, which I believe to be the great majority, will recognise that, if that assurance is to be given, it must have a more solid base than that which is currently contemplated.

Could Revalidation Catch 'Another Shipman'?

26.199 Early in this Chapter, I said that it would be instructive to consider whether a system of revalidation would be capable of detecting the severely dysfunctional behaviour of another Shipman. I was not suggesting that 'catching another Shipman' was to be the litmus test of whether revalidation was worthwhile or whether any particular set of proposals was appropriate. Revalidation should detect a far wider range of deficiencies and much less serious deficiencies than those seen in Shipman. If revalidation can pick up a 'poorly performing doctor' it ought, one might think, to be capable of picking up a grossly dysfunctional one. That is not necessarily so, because many under-performing or dysfunctional doctors do not realise that their practice is deficient and do not make any attempt to conceal their shortcomings. Shipman, on the other hand, knew what he was doing. He was quite capable of giving a good standard of care and very adept indeed at concealing the fact that he was killing his patients.

26.200 First, it is clear beyond argument that Shipman would have done well in appraisal, as it currently operates. He would have produced evidence that many aspects of his clinical care were of a high standard. He could have produced the results of audits; the topics would have been chosen by himself and he would not have conducted an audit into the mortality rate among his patients. He might well have produced his prescribing data; the main interest in that would have been his insistence on prescribing proprietary drugs at a

time when doctors were being encouraged to use generic equivalents. Shipman's prescribing of diamorphine was on the high side but he was not an outlier and, if any questions had been asked, he would have produced the records of one or two patients who were being nursed at home during their terminal illness. He would have talked confidently about his reasons for insisting on the freedom to prescribe as he thought best for his patients. He would have explained why he often prescribed statins at a time when many doctors doubted their efficacy. He could have shown that he had been running chronic disease clinics as long, I think, as had almost any other practice in the area. His patient satisfaction questionnaires would have shown, I think, almost 100% satisfaction in all aspects of his practice. A peer questionnaire might have revealed that he was not liked but it would not have revealed concerns about his practice. There were very few complaints about him after 1994 and none of significance. That is remarkable as in the last four years of practice he killed over 100 patients. There is no possibility that he could have 'failed' at appraisal. In fact, it is quite likely that he would have volunteered (and been accepted) as an appraiser.

26.201 There can be no doubt that the clinical governance lead or medical director of Shipman's PCO would have signed his clinical governance certificate without a moment's hesitation. Shipman would have been revalidated without difficulty under the proposals that will come into force in April 2005.

26.202 Could Shipman have been detected by revalidation as the GMC originally proposed to carry it out? I do not think so, unless the RCGP had laid down, and the GMC had approved, specific items of information that had to be included in the doctor's folder and those items had included something that would have detected Shipman's vulnerability. Of course, he would have been detected if there had been a requirement for an analysis of mortality rates, backed by verifiable data, but I think that would have been a very unlikely requirement. A more likely one would have been a requirement that some of his patient records be submitted to independent review. They would have been found to be of a poor quality generally and not capable of conveying an appropriate amount of information to colleagues. However, only if there had been a review of the records of deceased patients could his criminal behaviour have been detected. A careful review of the records of the recently deceased patients should have revealed real cause for concern, as I explained in my Third Report. However, I must say that I think it very unlikely that anyone would have thought it appropriate to require such a review for the purposes of revalidation.

26.203 Would it be possible for 'another Shipman' to be detected by clinical governance activities, as they might be expected to operate in the foreseeable future? I think that is a real possibility. I have referred to that in Chapter 12.

Conclusions

26.204 When the GMC published its Consultation Paper in 2000, it had recognised the need to provide a mechanism to detect poorly performing and dysfunctional doctors without relying on a complaint from an aggrieved patient or a worried employer or PCO. It decided to require every doctor who wanted to practise to undergo a periodic evaluation of his/her fitness to practise. That would identify the doctors who were known to be, in Dame Lesley

Southgate's words, 'out there harming patients' but it was hoped also that the method by which this was to be achieved would raise the standards of medical practice generally. The GMC started out with sound principles, high aspirations and the best of intentions. Initial proposals were devised and tested but, by 2002, I think that the GMC had realised that the task was more difficult than had been expected. The initial proposals would have been expensive and would have imposed a considerable administrative burden on the GMC. Moreover, the proposals were very unpopular with large sections of the profession. The GMC changed direction. It abandoned the principle of evaluation of each individual doctor's fitness to practise. It decided to base revalidation for the great majority of doctors upon the mere fact that they had taken part in an appraisal process conducted either by their employers or, for GPs, by a GP appraiser instructed by the doctor's PCO. For GPs, at least, appraisal was and is a wholly formative process and, in my view, quite incapable of providing a basis for an evaluation of fitness to practise. The GMC made that change without conducting any study of the efficacy of appraisal as a means of identifying deficient performance. When the GMC made that change of direction, it knew, because it had been so advised by its management consultants, SHM, that there were many objections to the idea of linking revalidation to appraisal and that these amounted to a **'significant catalogue'** which should not be **'lightly dismissed'**. The change of direction was not slight; nor could it be described as a 'refinement' of the former proposals. In my view, that change of direction was substantial and it was made for reasons of expediency and not for reasons of principle.

26.205 About six months after this change of direction had been announced, the GMC felt constrained to attempt to improve its proposals. I am satisfied that it did so because of the evidence given to this Inquiry to the effect that appraisal could not provide a satisfactory basis for revalidation. It attempted to negotiate with the DoH an additional element, the clinical governance certificate, which was to provide an assurance to the GMC that there were, to the knowledge of the signatory, no significant unresolved concerns about the doctor's fitness to practise. This, as I have said, was a step in the right direction. However, the clinical governance certificate as it is now to be provided is of very limited value and the GMC's proposals still do not fulfil the essential requirement of revalidation, which is that it should be an evaluation of the doctor's fitness to practise. The public cannot properly have confidence that a doctor who has been revalidated is 'up to date and fit to practise'. That position may change in the future, if clinical governance improves, as everyone hopes that it will, and if the culture of one doctor's reluctance to report another's failings can be altered. Those changes may or may not come about. But if the GMC intends that revalidation should give the public a reassurance of real, as opposed to illusory, value it must accept that its present proposals are not adequate and must develop a system of revalidation which, at its first stage, entails a summative evaluation of each individual doctor's fitness to practise.