Chapter Ten: Conclusions and recommendations

1 Over the last five years, great progress has been made in the creation of a framework within the NHS to assure and improve the quality and safety of the care received by patients. Dame Janet Smith, Chair of The Shipman Inquiry, acknowledged this change in the 'quality landscape'. This framework includes: the establishment of a clear set of standards; a statutory duty of quality placed on providers of NHS services; the development of clinical governance systems within health organisations; a programme of inspection and performance review of local services; a system to collect, analyse and learn from adverse events and near-misses; mechanisms to ensure more patient-centred services; and national technical and support services to promote good governance and patient safety.

The need to develop the wider quality framework further

2 It is not within the core terms of reference of this report to comment in detail on the effectiveness of this quality framework. However, it does have direct relevance since the quality of an individual doctor's practice is influenced by the nature, culture, working practices and performance of the health organisation in which that doctor works.

3 In the course of compiling this report, and from my wider knowledge of the NHS today, I have concluded that the quality framework that has been developed is broadly the right one. However, much more work is necessary to make it fully effective.

4 The work of the Healthcare Commission in designing systems through which the Department of Health's core and developmental standards for the NHS can be assessed is notable. Discussion of standards and their achievement would not have been seen as mainstream just a few years ago. The patient safety movement has grown. Not only is there now an increased awareness of the scale and nature of the problem, but there is also a willingness to work towards tackling it. The early work of the National Patient Safety Agency set the agenda, but now, following the publication of a National Audit Office report, a review is under way to determine the direction of future development.

5 The quality and safety of the care received by patients is not yet central to the goals, culture and day-to-day activities of every organisation and every clinical team delivering care to NHS patients. Financial and activity targets often have a higher priority. It is misguided to think that these considerations are mutually exclusive. In the best healthcare organisations in the world, the 'business plan' and the 'quality plan' are one and the same.

Medical regulation in its widest sense

6 The term 'medical regulation' is used frequently and imprecisely. Some use the term to mean the work undertaken by the General Medical Council, others use it more generally to cover all activities directed at safeguarding standards of medical practice. It is perhaps of little importance that there is no agreed definition of the term. However, it is certainly of consequence that there is no universally accepted definition of what constitutes a 'good doctor'. This matters in that much of the effort of medical regulation, in its widest sense, should be directed at ensuring that patients, employers, other contracting organisations and the medical profession can expect that the doctors they consult, retain or count amongst colleagues are indeed good doctors. My remit in this report covers medical regulation in this holistic and pervasive sense.

The Shipman Inquiry and the other inquiries

7 The backdrop to my report features the findings and recommendations of four other reports that examined the cases of doctors whose conduct and practice harmed their patients. The most serious of these was the case of Harold Shipman, a serial killer, whose murderous activities went undetected for many years under the guise of routine clinical practice. *The Shipman Inquiry: fifth report* condemned the weaknesses and dysfunction in past systems, which had failed to protect patients from harm, and cast serious doubt on the effectiveness of proposals for the five-yearly revalidation of a doctor's licence to practise. Dame Janet Smith also criticised the structure, governance, culture and systems of the General Medical Council. The other three reports concerned doctors who were a danger to patients and whose unacceptable conduct and performance had also been allowed to go on for too long and had not been dealt with when it should have been.

The reputation of the General Medical Council

8 The subject of medical regulation has been a source of controversy, on and off, since before the passage of an Act of Parliament in 1858 establishing the General Medical Council. Some of the same issues that vexed the minds of 19th century commentators have required attention during the course of my review.

9 Ironically in this context, the General Medical Council is regarded as one of the better medical regulatory bodies internationally. Amongst the different bodies responsible for regulating health professionals in the United Kingdom the procedures developed by the General Medical Council are often seen as innovative and forward-looking.

10 Yet the General Medical Council seems to be neither highly valued nor fully trusted by either the general public or the medical profession. Too often, it is portrayed in the media (and perceived by those who suffer from the effects of poor practice) as 'protective' of doctors. On the other hand, it is increasingly being criticised by doctors who have been the subject of a minor or groundless complaint and believe themselves to have been subjected to heavy-handed, lengthy and stressful investigation with no true exoneration at the end of it.

11 It is not good for public confidence in medical regulation to see the main regulatory body so often mired in controversy. A great sense of confusion is created when the General Medical Council welcomes the move of the Council for Healthcare Regulatory Excellence to appeal decisions made by its own disciplinary panels. Even though there is nothing legally improper in this (given the respective statutory roles of the two organisations), it gives the appearance of a General Medical Council that is ambivalent about its core function.

12 The role of the General Medical Council is not an enviable one. It is clearly not the job of the organisation to be popular, but it is notable that at no point during its long history has it been able to command the respect of all its constituencies – public, doctors and politicians – simultaneously.

13 Criticisms of the General Medical Council should not be taken as criticisms of the individuals who run it: the job of medical regulation is a challenging one, and it becomes more difficult as the complexity of medicine increases and the expectations of society evolve.

Poor practice: a reality that is being addressed

14 The test often applied to the effectiveness of medical regulation is its ability to detect and deal with bad doctors. Indeed, bad doctors and how they remained undetected were the common focus of the four inquiries which preceded my report and which collectively cost over £28 million. The lessons of these inquiries must be learned.

15 Yet the subject of poor practice is not widely understood: it is not an infrequent finding, nor is its presence necessarily a marker of a generally bad healthcare system. Doctors whose conduct, competence or performance fall below an acceptable standard are found in every healthcare system in the world. The key is to recognise the problems early, before serious harm has come to patients, and deal with them effectively by rigorous, fair assessment followed, where possible, by rehabilitation and retraining.

16 Within the NHS, the National Clinical Assessment Service (formerly Authority) has been undertaking pioneering work in addressing the problem of poor medical practice. The Service dealt with 1,772 cases in the four years following its launch in April 2001, and has been contacted by over 90% of NHS organisations. It has enabled cases to be identified much earlier, reduced the number of long, costly suspensions, developed new systems of assessment and established a much clearer understanding of the frequency and nature of poor performance. The overlap between cases of poor performance or misconduct dealt with by the NHS in this way and those dealt with by the General Medical Council is 3%.

17 Misconstruing poor practice as a rarity (or worse still, denying its existence) and demonising doctors whose practice is poor are barriers to recognising the problem and developing practical and effective ways to address it.

18 One of the key functions of medical regulation is to make appropriate judgements about a doctor's fitness to practise when concerns are raised or complaints are made. Ten years ago, those judgements would have been made almost entirely by the General Medical Council, with a minority of cases taken before the daunting and legalistic NHS employers' disciplinary tribunals, which

governed such matters in the past. Today, as the data show, the NHS is addressing many more cases of poorly performing doctors. The expertise of medical and clinical directors locally has been developed, supported by the work of the British Association of Medical Managers. The National Clinical Assessment Service has provided local NHS employers with rigour, consistency of approach, specialist knowledge and expertise that was lacking in the past. Taken in the round, the NHS is now dealing with more so-called 'fitness to practise' cases than the General Medical Council.

19 The situation is less straightforward in primary care, where it is more difficult to identify poor practice. The employment position of general practitioners, who are typically independent contractors rather than employees, makes it difficult for primary care trusts to exercise control over practitioners whose performance raises cause for concern. Primary care trusts can demand access to only a very limited range of information. Practitioners can (if they so choose) obstruct the primary care trust when it seeks access to medical records. Moreover, in any investigation of a concern about a general practitioner's standard of care, those of whom questions are asked may be financially dependent upon the doctor, as their employer.

20 Those procedures that do exist, including the use of the recently introduced performers lists, can be daunting and bureaucratic. For all these reasons, the anecdotal evidence is that chief executive officers of primary care trusts have concerns that a small number of general practitioners within their jurisdictions may not be truly fit for purpose. Success stories with regard to the management of poor performance in primary care more often reflect the presence of strong leaders and good relationships within practices and primary care trusts, rather than the efficacy of procedures. More reliable and robust systems are urgently needed.

Medical regulation as a partnership

21 The NHS has no statutory role in medical regulation. When the main professional regulatory body – the General Medical Council – has stepped in, the NHS has been expected to stand back and patiently await the outcome of the Council's proceedings.

22 This is because medical regulation has traditionally been synonymous with 'self-regulation'. Until the late 1970s, medicine occupied a privileged and relatively protected position within British society. There was a belief that bad doctors were few and far between. A view prevailed that the quality of care was difficult to define and impossible to measure. There was also a pervasive philosophy that a doctor's performance was not the business of colleagues or management. Moreover, there was a culture in which information was neither forthcoming nor transparent to patients. In the 1980s and 1990s, high-profile cases of poor performance steadily eroded this consensus and the concept of pure self-regulation was increasingly perceived to be outmoded.

23 Simultaneously, society had moved on. Blind deference to the professions on the part of the public had largely disappeared. Instead, the public came to see itself as the consumer of services: as such, people were entitled to expect certain standards in return for the taxpayer's considerable investment.

24 If growing public awareness of high-profile medical scandals had eroded the implicit late-1970s consensus on the regulation of medical practice, then the inquiry into the failures of the Bristol children's heart surgery service exploded it. Richard Smith, the then editor of the *British Medical Journal*, quoted the Irish poet Yeats in his editorial following the General Medical Council's hearing into events at Bristol.[1]

> *"All changed, changed utterly."*
>
> W. B. Yeats (1865–1939)

25 The relationship between the doctors' regulator, the government and the profession has always been a complex one and there have been consistent charges from some quarters that neither the leadership of the profession, nor the regulator, is truly independent of government. The picture is now more complex still, with a multitude of employers and contracting bodies having a very legitimate interest in these matters. In many countries, medical regulation is now seen as a genuine partnership between the medical profession, the healthcare system and the public.

26 It is difficult to separate the financing of medical regulation from this debate. Traditionally, professionals have expected to pay for 'self-regulation'. With the increasing prominence of 'professionally led' or 'partnership' regulation as opposed to self-regulation, this acceptance has waned. Whether the government (on behalf of patients and the public), employers or individual practitioners should pay for medical regulation is a question that is to the forefront of the minds of many; in reality, of course, income tax arrangements mean that the Exchequer already makes a substantial indirect contribution to the funding of the health regulators, and the General Medical Council in particular.

Public expectation: safe care is the responsibility of the NHS organisation corporately

In June 2000, a fit 31-year-old father was admitted for knee surgery. Post-operatively, he became unwell with symptoms and signs suggestive of septicaemia. Two junior doctors failed to diagnose this condition, to institute appropriate management or to summon help. The patient died. In April 2003, the two doctors were found guilty of manslaughter through gross negligence and were each given a suspended prison sentence of 18 months. In November 2005, the General Medical Council completed its hearing into the case and suspended the two doctors from the Medical Register.

During the course of the investigation of this case, a number of areas of unsatisfactory management were noted within the NHS Trust, including a failure to take up professional references upon appointment, a lack of routine senior clinical input at weekends and the absence of a system through which nursing staff could easily raise their concerns. The organisation was prosecuted under the Health and Safety at Work Act. In April 2006, the Trust was found guilty of a failure of supervision, and a fine of £100,000 was imposed.

This is the first example of an NHS organisation being held to account in the courts in relation to a clinical incident of this nature. It highlights that responsibility for the safety of care is both individual and corporate.

The ethos of medical regulation

27 In this country, there has been long-standing discordance in the threshold for determining an unacceptable standard of practice between the General Medical Council and the NHS employer. The General Medical Council has to prove any case against a registrant to the criminal standard of legal proof before it removes the doctor's licence to practise. It is argued by some that the sanctions imposed by the General Medical Council are so devastating to an individual doctor's livelihood and reputation that the criminal standard of proof must apply (those who advocate this cite human rights legislation when it is suggested otherwise). This is a high hurdle, and can lead to a situation where a doctor survives a challenge to continued registration, but is not regarded as someone whom an NHS employer would trust to look after patients safely. Dame Janet Smith recommended that the General Medical Council should move to the civil standard of proof in fitness to practise cases.

28 The atmosphere for wider medical regulation in the United Kingdom is in large part set by the General Medical Council, which is adversarial in its outlook: indeed, the raised dais and dock were only removed from the General Medical Council's main chamber in order to accommodate the enlarged Council in the mid 1970s. Procedures have not been constructed with a view to the holistic assessment of a practitioner following referral, in order to put matters right; rather they were designed to establish the likelihood of meeting tightly defined legal criteria for action upon registration. When a doctor is subject to a General Medical Council investigation, they invariably seek legal representation.

29 An alternative model is one where the regulator strives to be approachable, and 'disciplinary' procedures are formulated to enhance the pick-up rate of poor performance and maximise rehabilitation, through expert assessment and supervision as necessary. Only where a demonstrable risk to patient safety remains, would the more formal adjudication procedures be adopted.

30 Importantly, a way needs to be found to integrate the handling of fitness to practise cases by the General Medical Council and by the NHS, or other organisations delivering healthcare. The General Medical Council, on account of both its rules and its culture, has been inflexible, legalistic and distant. Its decisions are binary: whether to consider a complaint or not, whether to investigate a complaint formally or not, whether to take action upon registration or not. Employers (and other contracting bodies) are pragmatic and require, as a minimum, doctors who are able to do the job well and within an acceptable level of risk. The best employers want doctors who are better than this – doctors who constantly strive to improve. There is a large regulatory gap between the General Medical Council and the least conscientious employer. This gap must close: more sophistication is required.

31 There are many other partners in the common endeavour of medical regulation: employers outside the NHS, colleagues who act as professional referees, patients and their representatives, and medical defence organisations who have unrivalled knowledge of poor performance and medical error more broadly.

Poor performance through ill health

32 A proportion of doctors will have impaired performance due to mental health problems or addiction. The size of this population cannot be accurately determined, but estimates suggest that as many as one in ten doctors could, at some point, have a problem with drugs or alcohol. The risk that they pose can only be managed effectively if the regulatory system is aware of them and engages constructively with them.

33 In my 1999 report, *Supporting doctors, protecting patients*, I proposed that the then NHS Executive should develop a policy to address the needs of sick doctors.[2] The majority of the other proposals in *Supporting doctors, protecting patients* have now been implemented, but action in this area has been very limited. Some hold the view that employer- or contractor-based occupational health and human resources staff can manage this problem adequately. However, there is no evidence that the magnitude of the issue of poor performance through ill health has been reduced over the intervening years. Indeed, a large body of anecdotal evidence leads me to believe that the reverse may be true. A successful system of medical regulation must encompass the needs of doctors with ill health and addiction problems. Otherwise, patients are being put at risk where action could be taken to protect them.

34 There is some emerging evidence that the specialised treatment of addicted health professionals may offer improved results. It is likely that such treatment would prove more acceptable to many addicted doctors, who would otherwise have hidden their problem because of a fear of reprisal by their employer, a sense of shame before their colleagues or a feeling of futility in relation to the prospects for treatment.

Diversity in practice

35 In many ways, the healthcare landscape has become more standardised since the inception of the NHS, and in particular the primary care environment has become more managed in recent years. The NHS offers an unrivalled opportunity to reduce inequalities in healthcare delivery. However, several evolving developments pose challenges for the regulation of individual healthcare professionals.

36 Despite the creation of primary care trusts to be the focus for management of NHS primary care services, they do not fully provide a framework for the monitoring or assurance of the quality of care provided by individual general practitioners. Primary care trusts are accountable for the quality of the services provided (and commissioned), and for the financial health of the organisation. In reality, however, primary care trusts are not empowered to assure the quality of many of the individual doctor-patient interactions that occur within practices. For many principals in general practice, the concept of line management within the primary care trust is an extremely abstract

one. This imbalance between the statutory responsibilities of primary care trusts and the level of influence and power that they are able to exercise in reality is notable.

37 Care is being delivered in an ever wider range of locations: surgeries, acute hospitals, community hospitals, walk-in centres, independent sector treatment centres, private practice, the patient's home and even across the world wide web. On occasion, care may be delivered by specialist doctors who are in the United Kingdom for only a short period of time. Increasingly, NHS patients are being treated in locations that, whilst conforming to NHS standards, are not owned and operated by the NHS in the conventional way.

38 Many doctors work in short-term, or locum, appointments, some through necessity, some through circumstance and others as a lifestyle choice. The majority of locum doctors provide excellent care to patients and many enrich the organisations in which they take up posts. However, doctors who do not have a long-term relationship with a specific healthcare organisation unequivocally represent a special challenge for regulation. Innovative methods will be required to meet this challenge.

39 The boundaries between professional groups have also become more fluid in recent times. The ability of the NHS workforce to deliver care more flexibly is welcome, but the disappearance of traditional barriers provides challenges to traditional models of regulation. As boundaries blur, there may be some scope to reconfigure health regulators to reduce costs and improve performance and consistency.

Medical regulation to promote good practice

40 Most of the impetus for change in medical regulation has been concerned with protecting the public from bad practice. The 'medical scandals' of the late 1980s and early 1990s, events in the Bristol children's heart surgery service and the murderous activities of Harold Shipman have created a climate where the test of the adequacy of any new procedures is whether they will identify bad or dangerous doctors early enough to protect patients from harm effectively.

41 To date, the General Medical Council has detected poor performance largely through complaints. Moreover, it tends to deal with only the more severe end of the spectrum of poor performance: those matters thought likely to result in action upon registration. Other complaints have traditionally been disposed of at a very early stage, although a dialogue does now take place with the doctor's employer or contracting organisation. Indeed, the General Medical Council now refers many complaints directly back to employers, although some recipients have been left feeling confused and uncertain as to what action is expected from them.

42 The work of the National Clinical Assessment Service demonstrates that when poor performance is identified, there has often been a long lead time during which concerns at some level have existed. An ethos of continuous improvement within the entire medical profession is likely to prevent the performance of some from ever reaching any threshold that defines poor practice.

43 Local NHS clinical governance systems, a willingness to address problems more quickly and the leadership and expertise of the National Clinical Assessment Service have meant that the NHS has become much better at identifying poor performance. The NHS is now providing earlier

protection to patients and creating opportunities for doctors in such situations to be retrained and rehabilitated, rather than thrown onto a disciplinary scrapheap.

44 It is important to ensure that the concept of medical regulation is not limited to the identification of poor practice. Arguably, debate and effort have concentrated on designing a system to deliver this objective, and thus the discussion on the future of medical regulation has been more negative and confrontational than it needed to be. Although one of the prime purposes of medical regulation must be to protect the safety of patients, it must also be the true guardian of professionalism. The regulatory system must be able to demonstrate that all practising doctors reach specified standards, which may themselves evolve over time to reflect changes in patterns of work, technology and the expectations of society.

45 In order to do this, the regulatory system, in its widest sense, must be accessible to, and engage with, every doctor. This is not the case at present. There is no systematic way in which doctors can assess the quality of their practice and identify opportunities to improve it. Partly, this is because the methods currently in use – annual appraisal, continuing professional development, clinical audit – do not adequately address the related but distinct tasks of assuring good practice, identifying poor practice and acting as a vehicle for quality improvement.

46 Indeed, for many doctors, medical regulation may come to be seen as a welcome chance to demonstrate ongoing competence to others (and indeed to themselves). It takes a substantial shift in mindset to view medical regulation as enhancing the quality of an individual's practice and the wider medical profession, rather than predominantly seeking out and punishing those who perform poorly. However, such a change in philosophy will be necessary if individual doctors are to view new regulatory processes as opportunities rather than burdens. In part, this will be a conscious choice for each and every doctor.

"I was appointed as a consultant anaesthetist in 1969. In that 30 years 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 and show that to the parents of the children I anaesthetise and the children themselves in some cases... I hope that people will look up the [Medical] Register, and the fact that I am on it will indicate that I am safe to anaesthetise their children. I can imagine that the parents of the Bristol children would say 'Amen' to that."

Professor David Hatch, speaking to an internal conference of the General Medical Council in 1999

Assessment

47 One of the key issues examined within my report is the role of assessment. In the evidence, opinions, deliberations and consultation which I have considered, a number of points stand out:

- Doctors are regularly assessed until they finish training but few are formally assessed in the rest of their career which may span 30 years.
- A majority of the public believe that doctors are already regularly assessed.
- A majority of doctors and of the public believe that regular assessment of doctors should take place.
- Assessment of competence, technical proficiency and performance are much better developed in some other high-risk industries.
- No single source of information is adequate to assess performance – multiple strands of information are necessary.
- There are no simple and universally agreed standards governing generic and specialist aspects of medical practice.
- Valid methods for assessment in the actual or simulated workplace are widely perceived to be non-existent, yet great improvements have been made in some quarters and there is potential for further major advance.
- Tests of knowledge, objective evaluation of clinical skills, and patient and peer ratings are now well-established methods in many settings.

48 The present position on methods of assessment is shaped by current attitudes and beliefs towards them. Many consider that full-blown assessment inside the NHS workplace would be potentially unworkable and unfair because it would be too managerially orientated and lacking in external peer input. Others believe that an assessment process outside the NHS workplace would lack credibility as a way of judging someone's actual practice.

49 Assessment must be underpinned by universally accepted standards or criteria on which to make objective judgements about the quality of an individual doctor's performance. Some professional bodies have developed such standards, particularly so in more specialist areas of practice. However, there is no universally agreed definition of a good doctor operationalised into a well-understood and easily assessed set of standards. This is badly needed.

50 A number of professional bodies have proposed domains that could be assessed. For example, the American Board of Medical Specialists has identified four: professional standing and behaviour; demonstration of life-long learning; continued cognitive expertise; and clinical performance evaluation.

51 The methods proposed by the Board to assess each domain include structured reference letters, peer and patient evaluation, and measurement of performance and outcome data.

52 This approach has arisen in a healthcare system that does not seek to establish a national comprehensive framework for such endeavours. One of the strengths of the NHS is its ability to introduce policies comprehensively, but this creates challenges of scale, logistics and consistency.

53 If regular assessment is to be introduced for doctors in this country, it is clear that patients and doctors have firm ideas of what qualities and attributes should be covered, and amongst these must be those traditionally seen as the 'softer' aspects of medical care (such as communication skills, according patients dignity and respect, and sharing in decision making).

The implications of light-touch regulation

54 An important part of the backdrop to the debate on medical regulation is the ethos of regulation in other sectors. Here, the movement to the modernisation of regulation has tended to emphasise reducing the regulatory burden. This has meant arguments for fewer regulators, less demand for information from those being regulated, and a more selective or risk-based approach to assessment by the regulator.

55 Whilst many such better regulation principles can and should apply to the future of medical regulation, others do not sit comfortably with it. For example, there is no easy way of defining all higher-risk groups in medicine. In the infamous case of Harold Shipman, few risk factors would have been identified in advance. Moreover, there is no evidence that the public accepts that those in high-risk industries – whether airline pilots or doctors – should be regulated less rigorously.

56 The bottom line is that lighter-touch regulation of medical practitioners – whether on grounds of cost, regulatory ideology, or professional unacceptability – would mean that some ongoing risks to patients would have to be tolerated by society.

Controversy about the role of appraisal

57 There has been extensive and ferocious debate within the medical profession about the nature of appraisal – should it only be formative (i.e. primarily developmental) or could it also be summative (i.e. primarily judgemental)? Even if formative, is the process of appraisal sufficiently rigorous? Is the cynical view of some, that appraisal is often nothing more than a 'cosy chat' with a sympathetic colleague, justified? Are the areas of practice that are appraised appropriate and consistent across the country? Are all appraisers sufficiently trained and skilled in carrying it out? What sources of information and data are drawn upon? These are questions that have been largely drowned out by the heat of the debate over appraisal versus assessment.

58 It is often pointed out that professional people in many walks of life undergo annual appraisal, and as such it should not be a threatening idea for doctors, even if it contains an element of assessment and judgement of a doctor's performance. Others argue that appraisal is relatively new within NHS medical practice and should be allowed to 'bed down', notwithstanding that it lacks rigour in many aspects of its implementation. The view is also expressed that, in some parts of the country, appraisal is rigorous and does contain an element of assessment in any case.

59 Six key functions might be expected in reviewing an individual and their practice:

- ensuring that practice is safe;
- ensuring that practice is of a good standard;
- taking opportunities to improve practice;
- reviewing performance in relation to service goals, objectives and targets;
- identifying and meeting professional development and training needs;
- checking that conduct is honest and ethical, and that the individual behaves with integrity.

60 No one could successfully argue that NHS appraisal is routinely addressing all these domains, and there would be major disagreement within the medical profession as to whether it is appropriate for an appraisal system even to attempt to address them. There would need to be a huge overhaul and redesign of the current process if its aim was to produce such a comprehensive judgement on an individual's practice.

61 In its present form, appraisal can potentially address the need to assess a doctor against their contractual requirements and work objectives. It creates an opportunity for service and quality improvement goals to be identified and their achievement planned. It is also the main vehicle for personal growth and professional development. Even these benefits cannot be realised unless appraisal is conducted rigorously, objectively and thoroughly by a skilled, trained appraiser. There is evidence that, at present, this does not happen consistently across the NHS.

62 Appraisal, as currently designed, does not set out to identify poor practice or judge how good a doctor the appraisee actually is, although the former sometimes occurs by virtue of local knowledge of a doctor's reputation or the complaints made against them.

Revalidation: no convincing model in place

63 In the 1970s, a young doctor could enter general practice immediately after completion of pre-registration posts. It was possible for an individual to begin independent (and often isolated) practice at the age of 24 years and not to have their competence assessed again before retirement, more than 40 years later. The last 20 years have seen changes to the structure of postgraduate training so that the young doctor is now assessed en route to independent practice. However, having stepped up to independent practice, there is no requirement for formal assessment until retirement. In contrast, an airline pilot is subject to in excess of 100 formal objective assessments over the same period.

64 It is clear from the MORI survey of public attitudes that the public believes systems are already in place to ensure that any doctor they might consult is up to date and competent in their field. Furthermore, the public and the medical profession wish for such an assessment to take place regularly (certainly every few years). Such systems are not in place. It is surely counter-intuitive that medical regulation can play its proper role in the wider quality assurance framework whilst this remains the case. A process of regular assessment must be introduced.

65 'Revalidation' is a term introduced into common parlance by the General Medical Council only in the last decade. It is not a widely used term internationally. Its meaning, as defined by an amendment to the Medical Act 1983, is 'the evaluation of a medical practitioner's fitness to practise'. Revalidation as proposed by the General Medical Council fails to provide an objective evaluation, because it is based largely on the current model of NHS appraisal. Furthermore, the term revalidation does not distinguish between doctors working independently in specialist areas of practice and others: rather it assumes that an appraisal process will be sufficiently sophisticated to take account of this fundamental difference.

66 In many ways, the terms re-licensure and re-certification are more meaningful. Re-licensure relates to the renewal of full registration (and therefore a generic licence to practise) and re-certification relates to renewal of a doctor's specialist certification (and their place on the specialist or GP register). Both aspects are required, and 'revalidation' must be an umbrella term for these two distinct processes.

67 For such a process of revalidation to be effective it must be built upon more than the current system of NHS annual appraisal. It needs to be based on a valid and reliable assessment of a doctor's everyday standard of practice so as to enable a judgement to be made about how good that doctor is, about the safety of their practice and about the extent to which quality is embedded in their everyday work.

68 It is also striking that in the form of assessment in use for airline pilots – one of the systems of regulation in other high-risk industries studied in my review – the onus is on the professional being regulated (i.e. the pilot) to prove their competence. In medicine, the onus is on the regulator to disprove the practitioner's competence. This was considered quite extraordinary by those in the airline industry to whom we spoke.

69 It has not been possible to identify a medical regulatory model in operation, within any sizeable jurisdiction in the world, where assessment against defined standards is explicitly, universally and unambiguously linked to the continuance of a licence to practise.

Complaints

70 Although the performance of the NHS complaints system was not within my terms of reference, it was a common theme in discussion within the advisory group and amongst respondents to the *Call for ideas* consultation.

71 In commerce, the most successful businesses tend to see complaints as vitally important feedback that provides the opportunity for the business to improve and thus achieve further competitive advantage through enhanced customer satisfaction. In healthcare, the individual's experience of the complaints system is often a marker of how much confidence they have in the services themselves.

72 The NHS needs to handle complaints in a more sophisticated manner. It is unacceptable for both the complainant, and the quality improvement agenda of the NHS as a whole, for complaints to be lightly dismissed or referred endlessly from pillar to post, without being meaningfully engaged. The

majority of complaints relate to several interlinked elements of care and a requirement to define a complaint and allocate it to a specific stream at an early stage is counterproductive.

73 An underlying reluctance on the part of the General Medical Council, and to a lesser extent the NHS, to engage openly with complainants allows feelings of injustice and poor treatment to fester. To engage in a dialogue with a complainant may have been felt to disadvantage the objectivity (and indeed the outcome) of any subsequent formal procedures. Such an aversion to active conflict resolution does not advantage any party.

74 Employing or contracting organisations need to become more holistic in their approach to complaint handling, and where multiple systems are involved the commissioners of services should take a lead in resolving issues and learning lessons. The approach to complaint handling within a given organisation should be as simple and transparent as possible. Furthermore, the role of independent, patient-centred advocacy and support in helping patients to navigate complaint systems is vital.

75 The current NHS complaints system is too often seen as complex, poorly publicised and difficult for patients to navigate. It is departmentalised, and as a result dealing with matters that cross organisational or clinical/non-clinical boundaries is challenging. Complaints about primary care are a particular issue, as complainants are required to raise their concerns within the practice itself, with no opportunity for distancing the resolution of a specific grievance from the more pressing need to maintain cordial long-term relationships.

76 A number of improvements to the complaints process have been proposed. Some, although on the surface attractive (such as a single complaints portal), would not be the solution. Perhaps as important as changes in process are changes in outlook: the NHS must come to value complaints as a vital learning resource.

Once a doctor, always a doctor

77 The medical student of today and the doctor of tomorrow are one and the same. Likewise, when a consultant reaches retirement age, knowledge, skills and experience are not lost overnight. Being part of a profession carries both privileges and duties. If regulation is to ensure ongoing fitness to practise, there will inevitably be a knock-on impact on both students and retired doctors.

78 Retired doctors, by definition, have ceased to have a substantive medical practice. The General Medical Council has long advised against doctors prescribing for themselves, family or friends, although this arouses strong feelings amongst the medical profession. A typical question from a doctor might be: 'Why on earth can't I prescribe an inhaler for a visiting grandchild with asthma, when their own has run out?' Following retirement, a doctor's ability to undertake other medical tasks will also decline with time. The prevailing view at present is that if a doctor has an insufficient practice to maintain their skills, they should no longer have a licence to practise, whether beyond the age of retirement or otherwise. However, it could be argued that permitting a small area of restricted practice, for example prescribing from a limited list of drugs, could be

justified, fair and safe. Good Samaritan acts, carried out in an emergency and in good faith, require neither a medical licence nor indemnity insurance.

79 Being a medical student is an enormous privilege but it is also a position of great responsibility which carries the potential to do harm to patients. Intuitively, it may be presumed that a student who exhibits certain behaviours or performs poorly is destined to have problems later: there is now some emerging evidence to support this. Medical students must be engaged by the profession's regulator.

Early markers of future poor performance in medical school

Is it possible to identify doctors destined to perform poorly at a much earlier stage? Although an attractive and intuitive suggestion, until recently there was little evidence to back it up.

A study reviewed 235 physicians who had been disciplined by the various American medical boards between 1990 and 2003. Each of these physicians had attended one of three medical schools, chosen by the researchers because the institutions had comprehensive records of student performance dating back to 1970.

The medical school records of the disciplined doctors together with those of matched controls were then examined for evidence of academic achievement, disciplinary issues or other concerns. The disciplined doctors were three times more likely to have a problematic medical school record than the controls. Particular predictors from the medical school records included:

- irresponsible behaviour;
- a diminished capacity for self-improvement;
- poor examination results (particularly during the course).

Over a quarter of the risk of disciplinary action during a doctor's career could be attributed to prior unprofessional behaviour in medical school.

Source: Papadakis M et al, *Disciplinary action by medical boards and prior behaviour in medical school.* N Engl J Med. 2005 353:2673–2682.

Medical students who struggle

Researchers at Nottingham University Medical School have identified a number of factors that may predict whether students will struggle during their courses at medical school. These factors include:

- negative comments in the academic reference;
- lower mean examination score at A level;
- late offer of a place;
- male gender;

Source: Yates J et al, *Predicting the 'strugglers': case-control study of students at Nottingham University Medical School.* BMJ 2006 332: 1009–1012.

80 Medical schools have a key role in ensuring the fitness to practise of tomorrow's doctors, through the selection of medical students and their supervision during training. Although medical schools do now have processes and structures analogous to the General Medical Council's fitness to practise procedures, it is not yet clear that these systems are consistent or proving effective.

81 Medical schools largely exist to produce doctors for the NHS of tomorrow: the quality of the education delivered and the fitness of graduates to practise is crucial. Indeed, for many years, some have argued passionately in favour of a single national examination to quality-assure the graduates of United Kingdom medical schools in a uniform manner. Others have resisted such a move, anxious to protect the independence and individuality of the medical schools.

Student fitness to practise

Following the publication of *Tomorrow's doctors* in 1993, the General Medical Council has expected each of the United Kingdom's 27 medical schools to operate fitness to practise procedures, analogous to those operating for registered doctors.

Experience so far has shown that:

- between 2000 and 2004, at least 92 cases were considered by formal fitness to practise committees within medical schools;
- of these 92 cases, 23 led to the termination of a student's course of study and 31 resulted in a student continuing their studies following a reprimand, or with conditions;
- the most common reasons identified for impaired fitness were mental illness (including personality disorder) and academic fraud;
- medical schools do not have confidence that current arrangements consistently ensure fitness to practise, and would welcome further national guidance.

Source: *Student fitness to practise.* GMC Today, Feb/Mar 2006.

In a separate survey of medical students, there was widespread support for the concept of assuring fitness to practise, but also concerns:

- A substantial minority of respondents felt that student fitness to practise procedures were difficult to understand.
- A substantial minority of respondents felt that student fitness to practise procedures were 'reactive'.
- Only around half of respondents were aware of the existence of student fitness to practise procedures within their medical school.

Source: *Medical students welfare survey report – student fitness to practise*. 2006 (www.bma.org.uk/students).

Transparency, openness and fairness

82 The processes operated by the General Medical Council should be clear, defined and transparent. Information regarding a doctor's fitness to practise should be made available to the public unless there is a pressing reason why this should not be the case. At present, there is too much disciplinary procrastination, too much 'grey information' and too many practitioners in a state of limbo, regarded as neither fit nor unfit to practise. Once concerns have been raised, the environment must be one in which decisions are made and communicated fairly and openly.

83 At present, there are too many potential sources of information. For example, a bona fide general practitioner's name must be on the formal Medical Register and the new general practice register (both maintained by the General Medical Council), and a primary care trust performers list (perhaps in a location distant from where they now work). The general practitioner may also be the subject of an alert letter. In addition, there may be significant information held secretively in 'dusty files' by employers and other contracting organisations, past and present. Such a situation is unsatisfactory. Those who need information about doctors (primarily employers, contracting organisations and patients) wish to obtain reliable information in a timely fashion.

84 Information comes in many shapes, from indisputable facts to mere gossip. The former might include information offered by practitioners themselves and certified by another body (such as degrees and diplomas held), or the results of a formal fitness to practise hearing held in public. However, a large pool of less formal information might exist, for example:

- complaints received from patients about a doctor but not acted upon, as in isolation they would not be likely to compromise employment or registration;
- comments about the inappropriate sexual remarks of a consultant made over the years by nurses and female junior doctors;
- knowledge within a community of surgeons that the complication rates of one colleague are unusually high;
- a widely held view amongst doctors that one would not choose to send a friend or relative to a particular physician.

85 A prospective employer, contracting body or patient would clearly wish to be aware of some of this so-called 'soft' information. However, at present it forms part of the tacit knowledge within a healthcare community, or is held in absolute secrecy, never to be passed beyond the walls of the organisation (and certainly not in writing) for fear of legal challenge. In a protective jurisdiction, such as medical regulation, these difficult issues must be addressed so that such information is better managed, in the wider interest of patient safety. Each of the four inquiries discussed in this report has highlighted the vital importance of information and the problems that arise where its handling is not robust.

86 The notion of free access to any, and all, information ever collected or held by the General Medical Council is superficially attractive. However, the prime purpose of medical regulation is to protect the safety of patients. Open access to all such information would be in the interests of neither patients nor the wider public, as it would without doubt reduce the quantity and quality of information entering the formal system. Information would continue to be held in secret within organisations. At best, such information can be used to protect patients inside that one organisation; but it cannot be used for the protection of the wider public unless it is offered into the formal, national system, and managed sensitively yet transparently when there. Systems can be designed to assure the public that information is being utilised in pursuit of patient safety. Limiting access to some forms of information is first and foremost about protecting patients. A free-for-all where every suspicion or passing observation ended up in the public eye via the regulatory system

would ultimately work against patient safety, as the knowledge that mattered would be withheld from the sea of information.

A need for legal clarity

87 Although free access to information is one important principle, a right to privacy and the opportunity to make a fresh start are also important considerations. It would clearly be inappropriate for the intimate details of a practitioner's medical history to be available to the world at large, even if fitness to practise was impaired: such information must be handled sensitively. Likewise, sanctions are usually intended to be time-limited and conditions on practice are generally used as temporary measures pending resolution of a performance issue: most should not be in place indefinitely and indeed their expiry or removal is one driver for rehabilitation and engagement. There is an inherent difficulty in using conditions and sanctions appropriately but at the same time keeping information permanently, such that it can be available in the future to those who need to know in a protective jurisdiction.

88 The handling of disciplinary and regulatory information is a complex area. In a protective jurisdiction, the secure retention of information at some level within the regulatory system is key. There are a number of types and tiers of information:

- hearsay or gossip;
- information that has been formally received but lies on file;
- information that has been put through a formal process which has culminated in 'acquittal';
- information that is admitted or has been legitimised by its acceptance through a formal process.

89 Information at each level of this hierarchy has potential implications for the safety of patients and could justifiably be stored on this basis. However, the Data Protection Act and the Human Rights Act are said by some to run contrary to this sentiment. Others feel that such concerns are not insurmountable, suggesting for example an automatic derogation from any relevant entitlements upon entry to the Medical Register.

90 Other issues that demand legal clarification are:

- the right of patients to give their evidence in camera in relation to regulatory cases;
- the point in time at which a patient becomes an ex-patient with regard to personal relationships with their doctor;
- the value of narrative accounts (perhaps from a complainant's confidant) where the complainant does not themself wish to pursue the issue;
- the scope of the term 'confidentiality' when considering disclosure of information given in confidence.

Indemnity and medico-legal work

91 The majority of doctors are privately insured to cover claims against them arising from their work, over and above the indemnity provided by the NHS. Companies that provide insurance cover already play a role in education and learning by publicising cases and outcomes to their customers. There may be some scope for these companies to re-examine the way in which premiums are set in order further to increase incentives for safe practice.

92 Lawyers working in the medico-legal sphere rely heavily upon expert witnesses. Some of these specialists have pointed out the ease with which a medical expert can be found to defend a given case: some doctors appear to be willing to 'defend the indefensible' and this is an area that warrants further examination by the courts, the Government, the profession and the General Medical Council.

A world without boundaries

93 Medical practitioners are very mobile and there has been a long tradition of doctors working outside their country of origin. This is a positive feature of the profession but it also poses a challenge for regulation. It is important that the General Medical Council tracks an individual practitioner throughout their career, such that all periods during which a practitioner works outside its jurisdiction are captured. The use of a unique identifier and a positive requirement for exchange of information between domestic employers, contracting organisations and the General Medical Council (in relation to commencement and termination of contracts of employment) may be useful in this regard: 'career gaps' would become apparent to the General Medical Council and explanations, most of which would be entirely reasonable, could be sought.

94 The General Medical Council has been a leader in promoting international cooperation and communication between regulators. This work is important and must continue.

The General Medical Council: moving forward

95 Much of the analysis in this report, in *The Shipman Inquiry: fifth report* and in the wider debate that has ensued on medical regulation has centred on the future of the General Medical Council. Some have called for its abolition.

96 As the complexity of both medicine and the system in which it is delivered increases, the General Medical Council cannot reasonably be expected to fulfil the roles of complaint recipient, processor, investigator, prosecutor, judge and jury. Involvement of a single organisation in all these processes brings with it difficulties that are philosophical, presentational and practical. The international trend is away from this 'under one roof' approach.

97 The other functions of the General Medical Council, aside from fitness to practise, are challenging and varied, the more so as medicine becomes increasingly specialised. Each one of these functions should be carried out by the organisation best equipped to undertake it.

98 The General Medical Council has undertaken important work in attempting to build consensus on a number of the important ethical issues that face modern society, including the withdrawal of treatment and consent. Often the General Medical Council has stepped into a 'policy vacuum' in these difficult areas. The General Medical Council is not a sufficiently representative body to attempt to resolve the ethical dilemmas that go beyond medical practice and face society at large. Nor has it been able to address all the ethical issues that have arisen.

99 The registration of doctors and the assurance of ongoing fitness to practise are in themselves sizeable tasks. Only by focusing upon these areas and engaging in an innovative and proactive way with the profession and the public will the General Medical Council be able to deliver that which is required. The governance and management structures of the General Medical Council will need to reflect any alteration in its role.

RECOMMENDATIONS

Recommendations to ensure effective and fair fitness to practise procedures

A series of recommendations is set out in this section aimed at creating a fairer, more reliable and better coordinated system for recognising and dealing effectively with concerns about a doctor's practice.

Key features of proposed changes

- an extension of regulatory powers into the local workplace (under licence from the General Medical Council);
- a diminution in the adversarial flavour of fitness to practise procedures; a greater emphasis on retraining and rehabilitation, whilst safeguarding patient safety;
- maintaining strong lay participation in fitness to practise procedures;
- separation of the investigation and adjudication functions in fitness to practise cases.

An important element of the proposed devolved regulatory powers is the introduction of a system of 'recorded concerns', where a practitioner falls short in their standard of care or conduct in a number of specified ways. If accepted, a recorded concern would lie on file against a practitioner's name at the General Medical Council, and would be apparent on the record if that practitioner came to the attention of the General Medical Council again. In some circumstances, a practitioner might be given the option of accepting the terms of a 'recorded concern' as an alternative to being subjected to a full national fitness to practise procedure.

Recommendation 1

In adjudicating upon concerns about a doctor's performance, health or conduct, the standard of proof should be the civil standard rather than the criminal standard.

This is in line with the recommendation of Dame Janet Smith in The Shipman Inquiry: fifth report. *Medical regulation is a protective jurisdiction and the civil standard should apply. This will reduce the number of cases where a doctor is not judged 'bad enough' to enter formal General Medical Council procedures but is still a cause of serious concern to professional colleagues, management or patients in a local service.*

Recommendation 2

The General Medical Council's role in investigating concerns or complaints about a doctor's standards of care or conduct should be extended to a local level by the creation of medically qualified licensed General Medical Council affiliates within each organisation (or group of organisations) providing healthcare.

This will ensure a common line of sight for the employer (or contracting organisation) and the statutory regulator. Through use of thorough programmes of training, agreed guidelines and protocols, there will be a consistent and coordinated approach to recognising and dealing effectively and appropriately with concerns or complaints about a doctor. General Medical Council affiliates will be clinicians of high standing, having credibility with, and the support of, doctors, managers and patients. It is important that this role is carried out by a local clinician in active practice. It should be seen as both a professional duty and a mark of distinction for doctors to undertake this role at some point in their career. Its prestige and importance should be reflected in reward schemes for doctors.

Recommendation 3

General Medical Council affiliates should be authorised to deal with some fitness to practise cases locally (according to detailed guidelines and definitions) and refer cases at the more severe end of the spectrum to the General Medical Council centrally. Affiliates should have the power to agree a 'recorded concern' (but not to impose sanctions affecting registration). The affiliate should inform a doctor's employer or contracting organisation and any complainant when a 'recorded concern' is accepted. 'Recorded concerns' should be reported to the General Medical Council centrally for collation.

This will enable the responsive and timely resolution of issues close to the workplace and align any regulatory action with that of an employer or contracting organisation, and should mean that many fewer cases are managed centrally by the General Medical Council. It will also provide further opportunities for workplace remediation where this is appropriate.

Recommendation 4

Where a doctor does not accept a recommendation from a General Medical Council affiliate that a 'recorded concern' be entered on the Medical Register, they will automatically be referred to the General Medical Council centrally.

If the General Medical Council determines that the doctor has a case to answer, it will investigate it afresh and will not be permitted to rely upon any concessions or admissions made to its affiliate.

Recommendation 5

Each General Medical Council affiliate should be paired with a member of the public, who should be trained in regulatory and disciplinary procedures. Together, they should operate as part of a wider team within each organisation. This team should include existing complaints management staff and should have administrative support.

This will ensure that General Medical Council affiliates do not work in isolation within their organisation, and that decisions relating to fitness to practise are made in partnership with public and patient representatives.

Recommendation 6

A national committee should routinely review all 'recorded concerns' entered on the Medical Register. This committee should be able to discuss individual cases with the relevant General Medical Council affiliate if necessary and, in exceptional circumstances, may choose to refer a practitioner for further assessment or investigation.

This committee will have a lay majority and will be convened solely for this purpose. It will enable the General Medical Council to monitor and quality-assure local processes carried out on its behalf. Moreover, it will demonstrate that the procedures operated by the General Medical Council in relation to 'recorded concerns' are transparent and publicly acceptable. Where it is in the public interest for information to be retained securely by the General Medical Council (and its network of affiliates), this national committee will provide rigorous, independent and lay scrutiny both of processes and of that secure information itself. In addition, General Medical Council affiliates should regularly submit returns to this central committee, outlining the nature of all disciplinary or performance issues encountered and the course of action taken (on an anonymous basis where formal action was not deemed appropriate).

Recommendation 7

Each healthcare organisation should identify, and bring to the attention of the relevant General Medical Council affiliate, those complaints that raise concerns about the performance or conduct of a specific doctor.

This will enable the General Medical Council affiliate to be aware of any complaints reaching a healthcare organisation that concern a specific individual, and strengthen the interface between two complaints systems that have traditionally been separate. Most complaints will not raise concerns about a doctor's fitness to practise. By virtue of their position, the General Medical Council affiliate will be able to identify situations that are a marker of potentially more serious concerns about a doctor's standard of practice, and arrange for their further investigation.

Recommendation 8

Patients and their representatives should be given the option of lodging complaints about services and individuals in primary care, either at the level of the practice, or at the level of the primary care trust. Such arrangements should be publicised widely in surgeries and within patient information resources.

This will afford patients a greater variety of routes through which they can report their concerns. It will prevent the situation whereby a patient must make a complaint directly to a doctor upon whom they may have to rely for future

medical care. At the same time, the option of addressing concerns face-to-face will remain for those who prefer such a course of action.

Recommendation 9

General Medical Council affiliates, together with the complaints management staff of the organisation, should offer to meet with individual complainants (where appropriate) to address their concerns about specific doctors, explaining any actions taken, or the reasons for apparent inaction. Individual doctors may be required to attend such conflict resolution meetings at the discretion of the General Medical Council affiliate.

This will reassure the public and complainants that their concerns have been heard by the medical regulator, will facilitate a dialogue with complainants and will enable the complainant to learn what action is being taken to prevent similar problems in the future. The meeting will also provide a forum for an apology to be made, where this is appropriate. These arrangements must be consistent with procedures under the new NHS redress scheme.

Recommendation 10

The General Medical Council should establish rigorous training, accreditation and audit for affiliates, along with comprehensive arrangements for their support in carrying out these functions.

This will ensure the rigour of the devolved activity and a robust and fair process. It will mirror good practice in some other high-risk industries where those in similar roles are formally approved (or licensed) and trained by the regulator.

Recommendation 11

In serious fitness to practise cases, which cannot be dealt with by local regulatory action, investigation and assessment should be carried out by the General Medical Council but formal adjudication should be undertaken by a separate and independent tribunal (with legal, medical and lay representation). Doctors and the General Medical Council should have the right of appeal against the decision of the independent tribunal to the High Court.

This will increase the transparency and public accountability of judgements about a doctor's registration. It is in line with the recommendation of Dame Janet Smith in The Shipman Inquiry: fifth report.

Recommendation 12

The Healthcare Commission and the Parliamentary and Health Service Ombudsman should be able to require the General Medical Council to assess or investigate an individual doctor's performance, health or conduct. These bodies should also be authorised to investigate and bring doctors before the independent tribunal in exceptional circumstances.

This will provide an additional mechanism through which the public can be reassured that poor practice is not being missed or ignored. It will bring another independent national body, responsible for standards of care, into the process of scrutiny. This recommendation flows from the Healthcare Commission's role in looking at NHS complaints that have not been resolved locally, in investigating major failures in standards of care in a service, and in monitoring

standards of care in the NHS and the private sector. The Ombudsman has an important statutory role and is experienced in the investigation of serious complaints relating to health services.

Recommendation 13

During its assessment of a practitioner whose fitness to practise has been called into question, the General Medical Council should make full use of the expertise of the National Clinical Assessment Service.

This will enable the General Medical Council, as well as employers and contracting organisations, to make maximum use of the skills offered by the National Clinical Assessment Service, rather than duplicating particular aspects. A process of independent audit of these assessment services, and of the outcomes of assessed cases, will be put in place. This will again strengthen the interface between the NHS and the medical regulator and improve consistency in judgement about poor performance, retraining, rehabilitation and treatment for ill health and addiction.

Recommendation 14

The National Clinical Assessment Service should further develop methodologies for the assessment of practitioners with mental health and addiction problems. The NHS should commission a specialised addiction treatment service.

This is one of the few proposals (addressed at the time to the then NHS Executive) in my report Supporting doctors, protecting patients *(published in 1999) which was not effectively implemented.[2] As a result, doctors whose performance is impaired by mental ill health or addiction continue to be a danger to patients.*

This recommendation will enable more effective handling of health and addiction problems. Previous attempts to address this have relied on local referral and treatment services, led by human resources and occupational health. This has not led to the resolution of the overall problem of unrecognised addiction and mental ill health amongst practising doctors, particularly in primary care, where such services are less readily available. Addiction problems that may currently be hidden will surface. Specialised treatment of addiction amongst health professionals should improve outcomes. Doctors using the service would do so under strict conditions, including follow-up drug and alcohol testing once they return to the workplace.

Recommendation 15

In managing cases where fitness to practise has been called into question but which cannot be dealt with locally through a 'recorded concern', the General Medical Council centrally should have the power to specify packages of rehabilitation and conditions on practice, following a comprehensive assessment. Cases should be brought before the independent tribunal only where a practitioner is uncooperative, where such measures have failed to remove serious risk to patients, or where specified serious misconduct has occurred. Arrangements for making interim orders concerning a registrant's practice where urgent action is required should remain in place. The Council for Healthcare Regulatory Excellence should review the handling of such cases, and refer for adjudication before the independent tribunal any for which it is considered that more serious sanctions were appropriate.

This will enable the General Medical Council to be pragmatic and flexible, which is essential if medical regulation is to manage poor practice in order to protect patients effectively. It will also foster more remediation and fewer adversarial stand-offs. Sanctions should include undertakings to comply with a wider range of practice conditions than at present, rehabilitation and training programmes, and interim suspension. Once this new system is established, it is anticipated that the number of cases reaching the medical tribunal for formal adjudication will fall. Certain misconduct offences would be exempt from being dealt with by the General Medical Council in this way and, after investigation, would proceed directly to the independent tribunal.

Recommendations to assure and improve the quality of medical practice

A series of recommendations are set out in this section aimed at the practice of the majority of doctors whose conduct, competence or performance is not giving rise to obvious concern. Giving the public, the doctor's patients and prospective patients, the doctor's employer or contracting organisation, and indeed the doctor themselves regular assurances that practice is safe, up-to-date and of good quality is the essential purpose of the proposals made here. So too is the aim of supporting the doctor to develop professionally and to take regular opportunities to improve their practice.

The key features of the proposed changes are:

- creating clear universal standards for generic and specialist medical practice so that everyone understands what a good doctor should be;
- adoption of the standards by the General Medical Council and their incorporation into every doctor's contract;
- regular assessment of standards through a system organised by the medical Royal Colleges and specialist associations in partnership with patient organisations;
- strengthening and standardising the system of annual appraisal of doctors;
- aligning more closely standards and regulatory processes within undergraduate and postgraduate education.

The overall philosophy of these recommendations is to assure and promote quality in the day-to-day practice of all doctors, and to systematise opportunities for practice improvement and professional development throughout a doctor's entire career.

Recommendation 16

A clear, unambiguous set of standards should be created for generic medical practice, set jointly by the General Medical Council and the (Postgraduate) Medical Education and Training Board, in partnership with patient representatives and the public. These standards should be adopted by the General Medical Council and made widely available. They should incorporate the concept of professionalism and should be placed in the contracts of all doctors.

This will, for the first time, give a universal, operational definition of a 'good doctor'. It will end the present perception that a doctor's employer or contractor is concerned only with contractual matters such as deployment of clinical sessions and productivity, whilst the General Medical Council is concerned with standards of care. It will

build upon the excellent work previously undertaken in the preparation of 'Good medical practice' by the General Medical Council. It will harmonise the approach to clinical governance, quality and safety of care, and give everyone – doctors, patients and employers – a clear understanding about what represents an acceptable standard of practice and conduct. Sharing this standard-setting role with the (Postgraduate) Medical Education and Training Board will reinforce the philosophy that high standards of practice are created by a strong system of education and training rather than being driven by the need to clarify what is necessary to avoid disciplinary sanction. It will also align strongly with the work of creating practice competencies to match specific medical roles.

Recommendation 17

A clear and unambiguous set of standards should be set for each area of specialist medical practice. This work should be undertaken by the medical Royal Colleges and specialist associations, with the input of patient representatives, led by the Academy of Medical Royal Colleges.

This will enable the specification of good practice to be extended from the generic into each specialist field of practice (including general practice) and provide the basis for a regular objective assessment of standards.

Recommendation 18

The process of NHS appraisal should be standardised and regularly audited, and should in the future make explicit judgements about performance against the generic standards, as contained within the doctor's contract.

This will lend the appraisal process an increased degree of objectivity, tie it in more closely to the quality of care and the local service of which the doctor is part, and help to align properly NHS appraisal with medical regulation. It will ensure that appraisal is carried out to a consistent and rigorous standard across the country. As methodologies and the quality of data improve, much more information should be used in the appraisal process.

Recommendation 19

The role of the General Medical Council to set the content of the medical undergraduate curriculum and to inspect and approve medical schools should be transferred to the Postgraduate Medical Education and Training Board (whose name should be changed accordingly).

This will enable the approach to curricula, standards and inspection in medical education from undergraduate through to postgraduate to be addressed more seamlessly than at present. It is accepted that this will be a major challenge for the relatively new Postgraduate Medical Education and Training Board. However, the case for change should not be constrained by current limitations in the capacity of this, or any other, organisation. The necessary changes should be made that will ensure that the Postgraduate Medical Education and Training Board is able to carry out this work to a high standard.

Recommendation 20

Any organisation contracting with doctors to provide services to NHS patients should ensure that all doctors have successfully completed an accredited assessment of English language proficiency in the context of clinical practice. The content of this examination should be approved by the (Postgraduate) Medical Education and Training Board.

This assessment will be introduced for doctors entering the Medical Register and seeking employment for the first time after a specified date. If an individual doctor wishes, successful completion of the language assessment may be recorded by the General Medical Council so that it will be readily available to any future employer. Prospective NHS employees may choose to undertake the assessment before or after provisional or full registration with the General Medical Council. This pre-employment assessment will guarantee that the language proficiency of all doctors delivering services to NHS patients is sufficient for medical practice. It will be good practice for providers of healthcare to patients outside the NHS to require that doctors contracted by them have also completed this assessment. Communication problems have repeatedly been shown to be a source of risk to patients and the recommendation aims to raise standards in this critical area.

Recommendation 21

A formal opinion should be sought in Europe as to the legality of the introduction of a standardised national examination as a requirement for initial registration with the General Medical Council (in addition to the clinical and other examinations necessary to obtain a university medical school degree within the European Economic Area). This examination would include assessment of both English language proficiency and clinical knowledge, and would be taken by all doctors seeking provisional or full registration, irrespective of their place of primary qualification.

If the introduction of a standardised national examination prior to registration (applicable to all medical graduates) was approved by the European Commission, this would provide additional and objective reassurance to the public that the quality of medical education received by their doctor was high and consistent, irrespective of their place of qualification.

Recommendation 22

Responsibility for the Professional Linguistics Assessment Board (PLAB) examination should pass to the (Postgraduate) Medical Education and Training Board. It is likely that the clinical components of the examination will be commissioned and delivered through United Kingdom medical schools.

For doctors qualifying outside the European Economic Area, a comprehensive examination (including a clinical component) remains necessary.

Recommendation 23

Medical students should be awarded 'student registration' with the General Medical Council, and medical schools should have a General Medical Council affiliate upon their staff who should operate fitness to practise systems in parallel with those in place for registered doctors.

This will enable medical students to become engaged with and understand the importance of medical regulation at an early stage, and will ensure that performance, health and conduct problems amongst medical students are identified and addressed at an early stage in their careers.

Recommendation 24

All doctors wishing to work in the United Kingdom should be registered with a healthcare organisation that has a General Medical Council affiliate. In addition, all agencies involved in the placement of locum doctors should be registered for this purpose with the Healthcare Commission and be subject to the standards operated by it.

This will enable the appropriate engagement of doctors who work in settings or roles other than mainstream NHS or private sector providers. The organisation NHS Professionals should also have a designated General Medical Council affiliate(s) and should engage with doctors involved solely in locum practice. The General Medical Council should determine, in conjunction with the Healthcare Commission, which organisations have the appropriate clinical governance framework in place to allow them to employ a General Medical Council affiliate. In addition, this recommendation will allow employers to have a number of set expectations of locum agencies.

Recommendation 25

At the conclusion of every locum appointment, the contracting organisation should be required to make a brief standardised return to the relevant General Medical Council affiliate, providing feedback on performance and any concerns.

This will help to ensure that the standard of practice of doctors who move frequently between employers and geographical areas is kept in view.

Recommendation 26

The process of revalidation will have two components: first, for all doctors, the renewal of a doctor's licence to practise and therefore their right to remain on the Medical Register ('re-licensure'); secondly, for those doctors on the specialist or GP registers, 're-certification' and the right to remain on these registers. The emphasis in both elements should be a positive affirmation of the doctor's entitlement to practise, not simply the apparent absence of concerns.

This will enable the General Medical Council to guarantee the ongoing fitness to practise of non-specialist doctors engaged in supervised posts, as well as those in independent practice. In addition, the General Medical Council will be able to assure the competencies of specialists.

Recommendation 27

As doctors approach retirement, they should be invited to a review with their General Medical Council affiliate, where registrant and affiliate should decide together whether a further five-year period of re-licensure is desirable and appropriate. The idea of maintaining a register of retired doctors (to extend beyond such a five-year period) should be considered in more depth: a working group should be established to examine this area and to establish which professional privileges should be permissible for those on such a register. In particular, the safety and desirability of the proposal to allow retired doctors to issue private prescriptions for a limited and defined range of medicines should be considered.

The registration status of retired doctors has been the focus of extensive debate since the late 1990s. Many doctors continue to make a valuable contribution to medicine beyond formal retirement, and further specific attention to this issue is warranted. Further to the recommendation above, Royal Colleges and other bodies involved in the re-certification component of revalidation should be sympathetic to doctors who wish to re-certify immediately prior to formal retirement (through full completion of the defined and standardised process for the relevant specialty), to enable a defined period of limited practice.

Recommendation 28

The re-licensing process should be based on the revised system of NHS appraisal and any concerns known to the General Medical Council affiliate. Necessary information should be collated by the local General Medical Council affiliate and presented jointly as a confirmatory statement to a statutory clinical governance and patient safety committee by the chief executive officer of the healthcare organisation and the General Medical Council affiliate. The chairman of this committee should then submit a formal list of recommendations to the General Medical Council centrally.

The General Medical Council affiliate will be able to submit such a statement, which will note any recorded concerns only if: the doctor is either satisfactorily engaged in annual appraisal or is participating in a recognised 'run-through' training programme; the doctor has participated in an independent 360-degree feedback exercise in the workplace; and any issues concerning the doctor have been resolved to the satisfaction of the General Medical Council affiliate. Such issues may arise from complaints received, continuing professional development activities undertaken, medical litigation claims in progress or any other relevant monitoring data.

Recommendation 29

When a practitioner changes employer or contracting organisation between re-licensure cycles, the previous General Medical Council affiliate should provide a standardised record outlining the practitioner's current position in relation to the elements contributing to re-licensure. In addition to any other professional references sought, prospective employers should ensure that such a record is obtained in a timely fashion.

This will ensure that engagement between a practitioner and the General Medical Council, through an affiliate, is continuous. It will ensure that the General Medical Council is automatically aware of any prolonged periods of time

during which a practitioner is not working within a regulated environment in the United Kingdom. A similar arrangement will be in place for medical students who transfer between medical schools during their training.

Recommendation 30

An independent organisation should be commissioned to design and administer the 360-degree feedback exercise required for appraisal and licence renewal.

The process of 360-degree appraisal is well established in some NHS appraisal programmes, involving feedback from medical and other professional colleagues, managers and patients. However, application is variable and inconsistent. This recommendation will enable the successful delivery of this major piece of work. Independence from employers and contracting bodies (in the delivery of the process) will allow for increased consistency, methodological rigour and reduced overall costs.

Recommendation 31

Specialist certification should be renewed at regular intervals of no longer than five years. This process should rely upon membership of, or association with, the relevant medical Royal College, and renewal should be based upon a comprehensive assessment against the standards set by that college. Renewal of certification should be contingent upon the submission of a positive statement of assurance by that college. Independent scrutiny will be applied to the processes of specialist re-certification operated, in order to ensure value for money.

This will enable the General Medical Council to maintain up-to-date specialist and GP registers, with the confidence that specialists remain fit to practise. The data on which specialist re-certification is based will vary between specialties, as will the frequency at which specialists must re-certify. This will allow a risk-based approach to re-certification and will permit, within limits, systems to be designed according to the skills and competencies required for a particular field of practice. Data may be drawn from clinical audit, simulator tests, knowledge tests, continuing professional development or observation of practice. The methods of assessment will need to be built up over time. In some specialties where technical procedures and tasks are more prominent, early progress with objective assessment should be made. External independent scrutiny will ensure that the activities undertaken for re-certification represent value for money: this oversight role will not in itself be burdensome, high-profile or costly, but the decisions made will be binding.

Recommendation 32

Where doctors fail to satisfy the requirements of either element of revalidation, they should spend a period in supervised practice or out of practice, prior to assessment, in order that a tailored plan of remediation and rehabilitation may be put in place.

This will allow the General Medical Council, supported by the National Clinical Assessment Service and other bodies, to ascertain why an individual practitioner has been unsuccessful in the licence renewal or re-certification component of revalidation. It is anticipated that in the majority of cases remediation will result in revalidation and successful return to practice.

Recommendation 33

A wide and inclusive clinical audit advisory group should be formed nationally to drive the further development of local and national clinical audit programmes, yielding publicly available information to accelerate improvement in practice and service delivery.

Valid, up-to-date information on the quality of clinical care is vital for patient choice, the assessment of clinical practice and identifying opportunities for service improvement. The work of the Society of Cardiothoracic Surgeons of Great Britain and Ireland has shown how valuable such data can be provided that the information system has the confidence of clinicians. It is important that programmes such as this are expanded and accelerated. Local clinical audit, within the framework of clinical governance, needs to be re-energised.

Recommendation 34

The NHS should support the routine monitoring of significant events in general practice through the contracts of general practitioners, further developing and piloting a national system for death monitoring as part of a wider clinical quality assurance framework in general practice. In addition, the Royal College of General Practitioners should be asked to work with the NHS Business Services Authority to assess the suitability of the information held on the prescribing habits of individual practitioners in primary care for use in assuring the performance of practitioners. Further work should also be undertaken with the College to examine the wider role of practice profiling and the use of other routinely available data in the assurance and improvement of the quality of services delivered in primary care.

This will enable reflective practice and learning within practices, drawing upon a wide range of clinically relevant data including information about deaths, prescribing habits and data from the quality and outcomes framework.

Recommendation 35

In their role as commissioners of services, the responsibility for assuring that lessons are learned from specific medical errors and complaints should be made statutory for primary care trusts.

This will promote learning within teams and organisations and ensure that the approach of all healthcare organisations to patient safety and quality is captured within the commissioning process.

Recommendation 36

Further attention should be paid to ensuring the formal and personal accountability of individual general practitioners to their primary care trust, through use of standard contracts and other mechanisms. In particular, primary care trusts should be guaranteed unfettered access to all patient records.

This will enable greater powers of investigation for primary care trusts in the assessment of potentially poor practice, an area where there are current constraints.

Recommendation 37

The opportunity to use financial incentives to promote safe practice should be examined by an expert group. In particular, the relationship between the quality of clinical governance processes within NHS organisations and the premiums paid by them to the NHS litigation authority, and the relationship between individual practitioners and the premiums paid by them to medical insurers, should be explored.

This will enable the development of insurance premiums as a more sensitive lever to promote patient safety.

Recommendations to address the need for better information for the public, employers and professional bodies

Several recommendations are set out in this section aimed at improving access to information relating to the quality and safety of a doctor's practice. Patients, the public, contracting organisations and employers have a right to expect that the doctor whom they consult or contract with is fit for practice and fit for purpose. Employers and the regulator must adopt a more joined-up and pragmatic approach if patient safety is to be protected. There are inevitably some tensions between the legal standing of information and the way in which it is managed. Professional bodies also have a need for access to information in order to make their contribution to the quality assurance of specialist doctors.

At present, there are numerous sources and types of data that may provide information about an individual's performance and fitness to practise. These multiple repositories of information each have their deficiencies. The integrity and primacy of the Medical Register as an information source must be central to effective regulation.

Recommendation 38

The Medical Register should be the key national list of doctors entitled to practise in the United Kingdom and should contain tiers of information (some publicly available, others available with restricted access) about each doctor and their standard of practice. The new Medical Register should be a continuously updated electronic document that would over time subsume a number of other lists and registers currently in place, including primary care performers lists, which should cease to be a statutory requirement.

This will enable the Medical Register to become an up-to-date and accurate source of information. For practitioners on primary care performers lists with current restrictions in place, special arrangements will need to be made. By the end of the current financial year, alert letters will be issued by strategic health authority directors of public health and managed through a web-based database operated by the National Clinical Assessment Service. In the future, the General Medical Council and its affiliates will be able to handle more effectively many of those cases currently subject to alert letters and the need for the alert system should therefore be revisited.

Recommendation 39

The Medical Register held by the General Medical Council should contain two tiers of information: that which is freely available to the public and that which is secure, with access limited to the individual registrant, General Medical Council affiliates and approved employers and contracting bodies. The following information should be freely available: registration status; date of expiry of licence to practise; specialist certification or inclusion on the GP register and date of expiry of the same; any interim restrictions on practice in force; and any substantive restrictions in force. The secure tier of information should include full demographic information (including electronic contact details), the fact that an investigation by the General Medical Council is in progress if that is the case, and any 'recorded concerns'.

These arrangements are designed to protect patients, by enabling the public and prospective employers to have access to meaningful information whilst also ensuring that a doctor's right to confidentiality is upheld. In a protective jurisdiction, it is vital that all information is retained and used purposefully.

Recommendation 40

Each doctor on the Medical Register should be given a unique and permanent identifier. Those doctors who wish to gain full registration without having previously held student and provisional registration should be required to submit written references from all their previous medical regulators. They may also be required to attend for interview.

This will enable closer scrutiny to be paid to those doctors who have not previously been engaged by the General Medical Council. It will also help to identify any specialists working in the United Kingdom intermittently and not participating in re-licensure and re-certification (by repeatedly applying and re-applying for brief periods of full and specialist registration).

Recommendation 41

Systems should be developed such that when a patient switches registered doctor without changing their address, that patient is offered a confidential interview with a member of staff from the primary care trust, at a place of their choosing.

This will enable a potentially vital source of information on patient experience to be captured.

Recommendations to address the structure and governance of the General Medical Council

Several recommendations are set out in this section in relation to the structure and governance of the General Medical Council. The future role of the organisation, as proposed in this report, differs in a number of ways from that carried out currently. The overall effect on the General Medical Council of the other proposed changes is an enhanced focus on the core and linked activities of fitness to practise, registration and maintenance of the Register. These proposals require the General Medical Council to engage effectively with multiple organisations, proactively

to seek out practice that endangers patient safety, to resolve matters consensually where possible and to oversee a comprehensive system of revalidation.

Recommendation 42

The primary role of the members of the General Medical Council should be the appropriate corporate governance of the organisation. This role is one of accountability for the quality of services delivered by the organisation in respect of: registration functions; the maintenance of accurate, up-to-date information; the investigation and prosecution of fitness to practise cases; the operation of the devolved system of licensed affiliates; the oversight of revalidation, and the effectiveness of working arrangements with partner organisations.

This will ensure that the General Medical Council, as the governing body of the organisation, holds the executive to account. The role of members is a strategic one aimed at assuring excellence in delivery in the long term, and not an operational one.

Recommendation 43

The composition of the General Medical Council should be changed to reflect its new responsibilities. It should become more 'board-like'. Its members should be independently appointed by the Public Appointments Commission, and its President elected from amongst those members.

This will enable the General Medical Council to function effectively in holding the executive to account. It will remove the concept of members having constituencies to represent. It will also reduce any perception of professional protectionism.

Recommendation 44

The General Medical Council should be accountable to Parliament, to which it should be required to present a detailed annual report.

The General Medical Council, as proposed, will have a large amount of flexibility and discretion in the way in which it manages aspects of medical regulation and fitness to practise, particularly in relation to cases that do not proceed to tribunal. This recommendation will enable the General Medical Council to be open with both registrants and the public as to its performance, its activity and the challenges that it faces in its work. The General Medical Council will be independent of the government of the day but accountable to the public through Parliament.

References

1 Yeats W. *Easter 1916*. 25 September 1916, quoted in Smith R. *All changed, changed utterly.* BMJ 1998 316: 1917–1918.

2 Department of Health. *Supporting doctors, protecting patients*. Crown, London, 1999 (www.dh.gov.uk).