



respect
competence
simulation
assessment
GOOD PRACTICE
dignity
JUDGEMENT
professionalism
patients
accountability

Good doctors, safer patients

*Proposals to strengthen the system to assure
and improve the performance of doctors and
to protect the safety of patients*

A report by the Chief Medical Officer

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Application across the four countries of the United Kingdom

The main statutory body responsible for medical regulation, the General Medical Council, has authority across the whole of the United Kingdom.

Whilst *Good doctors, safer patients* discusses the background and proposals for change in the context of the NHS in England, it is recognised that policies, functions and services vary in the other United Kingdom countries.

These differences have not been described in detail because it would have further increased the complexity of this document. However, further discussion of the implications for each of the four countries will take place in the weeks after publication.

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Talking points

“ [Revalidation, as proposed, was an] expensive rubber stamping exercise that would have misled the public. ”

Dame Janet Smith, Chair of The Shipman Inquiry, 2006¹

“ Professionals only have duties – they do not have privileges. They have duties over and above the duties of being a citizen. ”

Professor Sir Ian Kennedy, Chairman, Healthcare Commission, 2005²

“ The General Medical Council is the crucible of our professionalism and, without it, doctors in this country would become mere technicians. Any alternative to professionally led regulation is unthinkable. ”

Dr Brian Keighley, elected member of the General Medical Council, and others, 2001³

“ Harold Shipman would, of course, have passed any appraisal of fitness to practise with flying colours. ”

Jonathan and Bridget Osborne, doctors, 2005⁴

“ The efforts to prevent the abuse of trust are gigantic, relentless and expensive; their results are always less than perfect. ”

Baroness Onora O'Neill, ethicist, 2002⁵

1 Dame Janet Smith speaking to a conference at the Royal Society of Medicine, London, 2 May 2006.

2 Professor Sir Ian Kennedy giving evidence to a working party of the Royal College of Physicians of London, 20 May 2005.

3 Keighley B et al. *Letter*. BMJ 2001 322:1599.

4 Osborne J and Osborne B. *Regulating doctors: should we swallow Dame Janet's medicine?* BMJ 2005 330:546.

5 O'Neill O. *A question of trust*. Cambridge University Press, Cambridge, 2002.

“However bad a doctor is, another doctor, acting as an expert in disciplinary proceedings, will usually be willing to say that the doctor’s actions were within the limits of acceptable practice.”

Janice Barber, Managing Partner, Hempsons Solicitors, 2005⁶

“The GMC’s proposals, prior to Dame Janet, much as we might wish them to have been adequate, were more appropriate to a golf club’s membership committee.”

Dr Roger Neighbour, President, Royal College of General Practitioners, 2005⁷

“Looking back, it’s a sorry tale. The stark reality is that from the beginning of 1858 right up to the early 1990s, statutory self-regulation as operated by the GMC failed the public and conscientious doctors.”

Sir Donald Irvine, former President, General Medical Council, 2006⁸

6 Janice Barber speaking to the Chief Medical Officer’s advisory group on medical regulation, London, 2005.

7 Neighbour R. *Rotten apples*. *Brit J Gen Pract* 2005 55:241.

8 Irvine D. *A short history of the General Medical Council*. *Medical Education* 2006 40:202–211.

Summary

- 1** There are around 130,000 registered doctors in active practice in the United Kingdom. The vast majority practise medicine of very high quality. A small proportion practise at a standard that is not acceptable, whether through inadequate training, insufficient support, ill health, lack of motivation, or, on rare occasions, malice. Most doctors know of another doctor whom, on balance, they would prefer not to treat their own family. Unsatisfactory practice compromises patient safety. The medical profession has a duty to identify such practice and to remedy it. The profession owes this not only to patients, but to itself.
- 2** The 130,000 doctors practise in one or more of the 57 medical and surgical specialties, in general practice, in public health or in one of a diverse range of roles such as in the pharmaceutical industry or in research units.
- 3** The settings in which doctors practise are also very diverse: most will see patients within NHS premises, others will be based entirely in consulting rooms or private hospitals, and many will function both in the NHS and in the private sector. New settings for clinical practice are emerging as the pattern of healthcare provision changes (for example independent sector treatment centres and premises operated by primary care out-of-hours cooperatives).
- 4** The current system of regulation of doctors aims to provide an assurance that each of these doctors, whatever their clinical role and practice setting, is safe and performing to an acceptable standard. The scale of the task is huge and the complexity daunting. The main body responsible for it is the General Medical Council, but the medical Royal Colleges and other professional bodies also play important roles, particularly in relation to standard setting, education and training.
- 5** The system of medical regulation and the structures and processes for assuring and improving the quality of care and patient safety in local health services have not related well to each other in the past. This needs to change: they need to work together effectively and efficiently to promote good practice and to ensure that poor practice is not overlooked or ignored and does not fall into ‘grey areas’ of inaction.
- 6** The end result of the changes proposed in this report must be that patients, the public, the medical profession, employers and other contracting organisations become able to trust that every doctor will deliver good clinical care throughout their careers.

The track record of medical regulation

- 7** The system of medical regulation was last reviewed in the early 1970s by the Merrison Committee, following a crisis of confidence in the General Medical Council on the part of the medical

profession. After almost three years of deliberation, the Committee laid the foundations for the role of the General Medical Council in the modern era, firmly based on the principle of self-regulation.

- 8 Through the 1970s, 1980s and early 1990s, the system of medical regulation again faced mounting criticism, increasingly from the public and independent commentators, much of it focusing on the failure to identify early, and deal effectively with, doctors who were a danger to their patients.
- 9 In the early 1990s, a series of highly publicised medical scandals, some to do with poor practice by individual doctors, others to do with local service failures in which patients were harmed, gave rise to mounting public concern. The Bristol Inquiry into the poor standard of care offered in the paediatric cardiac surgery service in that city, and the needless deaths that resulted, was a major turning point.

Reforms to the General Medical Council

- 10 The General Medical Council has led a series of reforms to its structure and procedures through the late 1990s to the present day. Lay participation in the work of the Council, its committees and its fitness to practise panels has increased. The size of the Council has been reduced and its composition altered. Fitness to practise procedures have been streamlined and public access to information has been enhanced. Another major reform was also proposed: revalidation, a new system which would enable each doctor to have their fitness to practise reviewed every five years and their licence to practise renewed only if they satisfied the requirements of that review.

The NHS quality landscape

- 11 Over the last seven years, the NHS has placed greater emphasis on the quality and safety of care. Key changes have included the creation of a legal duty of quality for all NHS organisations, clear national standards, the introduction of comprehensive local clinical governance arrangements, a system of independent inspection against standards in hospitals and primary care services, the establishment of a national patient safety programme (including adverse event and near miss reporting) and a range of measures to empower patients and their representatives. A specific service to support the NHS in assessing and dealing with concerns about the performance of doctors, the National Clinical Assessment Service, has also been established.

The judgement of The Shipman Inquiry

- 12 My review was commissioned by the Secretary of State for Health following publication of *The Shipman Inquiry: fifth report*. Harold Shipman was a general practitioner who killed about 250 of his patients between 1972 and 1998, usually with narcotic drugs that he had stockpiled illicitly. I was also asked to take account of the reports of three other inquiries into doctors' conduct and standards of practice.
- 13 Dame Janet Smith, who chaired The Shipman Inquiry, condemned weaknesses and dysfunctions in past systems to protect patients from harm and cast serious doubt on the effectiveness of the

proposals for the five-yearly revalidation of a doctor's licence to practise. In particular, she criticised the proposed reliance on the annual appraisal of NHS doctors, judging it not to constitute a true evaluation of the full range of a doctor's performance and delivery of care and, thus, an ineffective method of detecting doctors who are incompetent, dysfunctional or delivering care to a poor standard. She was also highly critical of the General Medical Council in that its culture, membership, methods of working and governance structures were too likely to support the interests of doctors rather than protect patients. The other three reports dealt with doctors who were also a danger to patients but whose unacceptable conduct and unsafe care had been allowed to go on for too long without effective action being taken.

The process for this review

- 14** In order to compile my report, I commissioned three research studies to examine medical regulation in other jurisdictions, regulatory frameworks in other high-risk industries and public and professional attitudes to medical regulation. I published a *Call for ideas* paper, inviting thoughts and comments on the way forward from professionals, organisations and the public. I gathered data relating to poor performance from the General Medical Council, the National Clinical Assessment Service and others. I established a high-level advisory group to assist me in my assessment of the many complex issues involved. We met on 11 occasions, receiving valuable presentations and evidence from a number of experts and organisations. I kept abreast also of the ongoing debate in the academic and professional press on the subject of medical regulation. The comprehensive and considered reports of inquiry into the cases of Ayling, Neale, Haslam, Kerr and Shipman provided a vital mine of information, and the often chilling narrative contained within those various reports provided a constant stimulus to my work.
- 15** However, this is not a committee report. The thoughts and opinions expressed within it represent my synthesis of the challenges faced in medical regulation, in its broadest sense, and my considered view as to the way forward.

The review in context

- 16** The key context for my work emerged at an early stage:
- Medical regulation has been a source of controversy since the establishment of the General Medical Council in 1858, with some of the issues that were prominent in the 19th century still featuring in today's debate.
 - Reform to the system of medical regulation over the last 150 years has generally been piecemeal. Whilst the last major review was 30 years ago, there has never been a comprehensive consideration of the core purpose of regulation and how the different elements (including the healthcare system) should work towards achieving it.
 - Commentary has heavily focused on describing and diagnosing the problems and dysfunctions in the present system. I discovered few ideas for solutions that went beyond statements of principle or aspiration, and even fewer that drew on hard research evidence or documented experience of what would work.

- Doctors whose conduct, competence or performance falls below an acceptable standard are an inevitable feature of any medical workforce, in any part of the world. So too will there always be a very small number of individuals with the potential to fall into patterns of extreme misconduct.
- Most attention has been given to the important task of detecting bad doctors, whilst much less emphasis has been put on supporting, quality assuring and improving the practice of the vast majority of doctors who already perform to an acceptable standard.
- Appraisal has been heavily criticised by some, but the benefits that it does bring should not be overlooked. Appraisal is a sound process, but, as presently designed, it cannot serve the multiple purposes of detecting unsafe practice, quality assuring good practice, ensuring compliance with contractual duties, improving practice and facilitating continuing professional development.
- The current system of medical regulation is not visible to the general public and most people think that doctors' performance, knowledge and skills are regularly assessed, even though they are not.
- Unsafe care can arise in two main ways: from human error in a weak system (addressed in my earlier report, *An organisation with a memory*) and from poorly performing doctors; both are important, but the risks posed by the former are many times greater than those posed by the latter.
- Regulation of doctors is much less thorough than that of professionals in other high-risk industries, such as civil aviation.
- A great deal of comment on the way forward has focused on polarised opinion within the medical profession, where views are expressed most dramatically; whereas there is much common ground within the profession, and between it and the public, which is less often emphasised.

The size and nature of the problem of poor performance

- 17** The scale of the problem of poor performance is better understood now than previously. It may occur for a variety of reasons, which may be particular to doctors themselves or a result of the interplay between them and their wider working environments. The reasons include inadequate training and support, poor motivation, behavioural misconduct, a stressful workplace, poor relationships within a clinical team and physical or mental ill health. Health problems, particularly those that relate to mental ill health and addiction, are the most difficult to quantify.
- 18** Existing data show that:
- the annual rate of referral to the National Clinical Assessment Service is approximately 0.5% for all doctors, increasing to 1% for those in the most senior posts;
 - the performance of over 1,700 NHS doctors was brought to the attention of the National Clinical Assessment Service between 2001 and 2005;
 - the number of doctors who perform poorly in the private sector is not known;

- isolated behavioural concerns are more common amongst younger doctors, whereas concerns relating to clinical capability increase markedly with age;
- over 500 alert letters, warning the NHS of doctors who may represent a source of risk to patient safety or to the effective functioning of clinical teams, have been issued since 1997;
- sub-standard and dangerous performance, alleged sexual indecency and addiction problems together make up the majority of concerns which lead to the issuing of alert letters;
- the General Medical Council receives over 4,000 complaints each year relating to the fitness to practise of doctors;
- approximately 300 doctors appear for the first time before fitness to practise committees of the General Medical Council each year;
- upwards of 10% of doctors may be drug-dependent or addicted to alcohol;
- risk factors for the poor performance of a doctor later in their career may emerge at medical school. Research has shown these factors to include irresponsible behaviour, a diminished capacity for self-improvement and poor examination results.

Modern approaches to regulation

19 Approaches to regulation in the world outside medicine have undergone a paradigm shift in recent years. Regulatory activity is often seen as unnecessary, costly and stifling of innovation. More attention is paid to the potential impact of new regulatory activity, and in many areas it is assumed that the free market and competition will ultimately assure quality in goods and services. In areas where the requirement for quality impacts upon safety, rather than being an issue primarily of profit or convenience, other shifts have occurred. Rather than reducing regulatory activity per se, regulation has, in many spheres, been devolved towards the regulated unit and away from central, statutory or governmental regulators.

Regulation in other high-risk industries

20 Medicine is not the only safety-critical industry in recent times to reflect upon its regulatory framework following a series of significant events. The nuclear industry responded to events at Chernobyl by revisiting the arrangements in place for regulation, as did the offshore oil industry after the explosion on board the Piper Alpha platform. The civil aviation industry also developed a new system for the quality assurance of pilots at a time when its safety reputation was flagging.

21 Nuclear power plant desk operators, oil installation managers and pilots are all regulated, and the systems in operation are very different to those in healthcare: in all three industries, practitioners are regularly assessed against demanding and objective standards. Failure is greeted by remedial action, not ridicule or shame. Multiple sources of data are utilised in order to triangulate information and confirm impressions. Responsibility for regulation is often devolved to the workplace. Practitioners take pride in their licence to practise and employers value the role that practitioner regulation can play in the wider quality improvement agenda. Regulation in these industries may be expensive but the fruits, in terms of quality and safety, far outweigh this cost.

Medical regulation in other countries

22 Neither the requirement for, nor the aims of, a system of medical regulation are unique to the United Kingdom. Other countries too have had medical scandals that have led to the questioning of the status quo. No one jurisdiction has all the answers. There is no blueprint for us to copy. However, regulatory systems in other nations, both through their contemporary approaches and also in their historical experience, offer much to the debate. To the extent that a worldwide trend can be identified, medical regulation is moving from the premise of pure self-regulation to one of regulation in partnership between the profession and the public. Regulatory bodies are becoming more accountable, lay involvement is much increased and adjudication is often an independent function. Whilst there are moves towards ongoing assessment of competence, there is no model whereby such assessments are explicitly and universally linked with a practitioner's ability to practise. Medical regulators have come to be positioned within the wider quality assurance framework: they no longer stand detached.

Public and professional attitudes

23 Few members of the public claim to know a great deal about the ways in which the ongoing competence of doctors is assured; many believe that a satisfactory process must already be in place and almost all feel that regular assessment is appropriate. The majority of doctors whose views were sampled also agreed that regular assessment should take place. Both the public and doctors have firm views as to which aspects of practice can and should be assessed: these views are not very different. Furthermore, the public wants the assessment of doctors to go beyond technical skills to address the doctor's communication skills, whether or not the doctor is up to date, whether the doctor involves patients in treatment decisions and whether the doctor affords their patients dignity and respect.

Key findings

- 24** There is no universally accepted and operationalised standard to define a good doctor.
- 25** Once a doctor achieves independent practice (for example, as a consultant or principal in general practice) they have no formal assessment of their knowledge, competence, clinical skills or performance until they retire: an airline pilot would be assessed about 100 times over the same period.
- 26** The distinction between complaints about services and complaints about doctors is not readily understood by patients and the public. This leads to ongoing concern that current complaints systems are fragmented, overly complex and lack transparency for the user.
- 27** Despite improvements in recent years, poor medical performance continues to be dealt with separately by the NHS and by medical regulation, and to differing implied standards. Some doctors fall between these two stools, being judged as not 'bad enough' for action by the regulator, yet not 'good enough' for patients and professional colleagues in a local service to have confidence in them. There is thus a significant regulatory gap and it is this gap that endangers patient safety.

- 28** A culture of blame and retribution has dominated the approach to this whole field so that it has been difficult to draw a distinction between genuine misconduct, individual failure, human error provoked by weak systems, and untoward outcomes which were not the result of any specific failure. An ‘off with their heads’ approach to every problem will ultimately make healthcare and medical practice more dangerous, since no one will admit their own mistakes, nor will they want to condemn a colleague’s career to ruin.
- 29** There is a clear, comprehensive and appropriate framework within the NHS to enable quality assurance, quality improvement and patient safety to be embedded in all day-to-day activities. However, a more rigorous approach is needed to implementation, because the framework still falls short of its full potential. For example, clinical governance is a strong feature of some services but largely lacking in others; the size of the problem of unsafe care is well documented but there are few instances yet where risk has been systematically reduced; and few chief executive officers of health organisations match the depth of their fear of missing budgetary and productivity targets with the strength of their passion to improve quality and safety of services for their consumers. In the best healthcare organisations in the world, the ‘business plan’ and the ‘quality plan’ are one and the same.
- 30** Methods of assessment are better developed than is generally realised. Valid, reproducible and objective measures of knowledge, skill and clinical performance are now used within some undergraduate and postgraduate training programmes. However, there are only a few examples of their use at a more senior level and a view persists that reliable assessment is a dream rather than a reality.
- 31** There is a wide range of data from which valuable information about an individual practitioner’s performance can be gleaned. Such data may be specifically gathered for this purpose or collected as a by-product of some other, routine process. However, there has been no organised attempt to assemble data to allow the valid and reliable assessment of clinical practice as a routine.
- 32** Access to data about individual doctors is a contentious issue. The medical profession is protective of its members’ rights to privacy and confidentiality. Sections of the public are adamant that all information held should be publicly available. In reality, patient safety and the public interest are best served by taking the middle ground. All information must be handled in a way that is open and transparent to the public, but access to information itself may in some circumstances be limited so as to ensure that information continues to be made available to those responsible for regulation, rather than not being generated at all.
- 33** Care is being delivered in an ever wider variety of settings in the private and public sectors. Even within NHS care, many settings are not owned and operated by the NHS in the conventional way. Many doctors work in short-term or locum appointments, whether through necessity or circumstance or as a lifestyle choice. The majority of these doctors provide excellent care to patients and enrich the organisations in which they work. However, such doctors unequivocally represent a special challenge for regulation.

- 34** An important part of the backdrop to the debate on medical regulation is the modern approach to regulation in general which has emphasised reducing the regulatory burden. Whilst some elements of this approach can and should apply to the future of medical regulation, others do not sit comfortably with it. The bottom line is that lighter-touch regulation of doctors – whether on grounds of cost, regulatory ideology or professional acceptability – would mean that some ongoing risks to patients would have to be tolerated by society.
- 35** 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 of these processes brings with it difficulties that are philosophical, presentational and practical. The international trend is away from this ‘under one roof’ approach.

The need for change

- 36** Against this background, the report aims to create a new approach to promoting and assuring good medical practice and protecting patients from bad practice. It addresses the need to:
- design a strong, effective interface between local healthcare systems for assuring good clinical governance and patient safety, and the system of regulating the practice of individual doctors;
 - establish clearer and more rigorous public accountability for the performance of the systems intended to promote and assure good practice and protect patients from bad practice;
 - introduce a system of regular assessment of doctors’ practice which overcomes the weaknesses of the current revalidation proposals, is valued by the medical profession, is trusted by the public, is effective and is sustainable in the long term;
 - create for generic and specialist domains of medical practice clear standards that are valid, reliable, capable of assessment and transparent to the public, professionals and employers;
 - develop good methods of assessment that: measure a doctor’s performance against a predetermined standard; assess knowledge, skills and task performance; are relevant to the day-to-day work that a doctor undertakes; represent value for money, and create the opportunity for a doctor to develop and improve;
 - reduce the climate of blame, retribution and disciplinary action that usually attends poor medical performance, and introduce stronger elements of prevention and earlier recognition of problems, retraining and rehabilitation;
 - eliminate situations where poor practice is not recognised and acted upon because of adverse organisational culture, weak local clinical governance, poor employment practice, variable standards for judging performance, doctors being between jobs, or locations or situations where it is unclear whose responsibility it is to take action;
 - reshape the role, structure and functions of the General Medical Council to focus it on the core activities of investigating serious complaints (rather than adjudicating on them), maintaining the medical and specialist registers, and overseeing the system of quality assurance of standards of practice whilst devolving more assessment and decision making to a local level;

- ensure a stronger interface between complaints about clinical services and complaints about doctors;
- give educational and standard-setting bodies a more formal role in medical regulation.

Recommended action

37 There are 44 recommendations in the report, each presented with a detailed rationale. They propose changes in a number of key areas. If acted upon, they will introduce a major programme of reform. They include:

- major changes to the structure, functions and governance of the General Medical Council;
- extension of the processes of medical regulation to the local level to create a stronger interface with the healthcare system;
- the creation of a clear, unambiguous and operationalised standard to define a good doctor, and its adoption into the contracts of all doctors;
- measures to reduce the risk of poorly performing doctors falling through the net, especially since the expansion in the diversity of roles, working patterns and practice settings;
- steps to further the consistency with which medical education is managed across undergraduate and postgraduate curricula;
- processes to bring medical students within the scope of medical regulation and to further assure the quality of all doctors upon initial employment, irrespective of their place of qualification;
- improve access for the public to timely and meaningful information about doctors, coupled with measures to ensure that such information is handled intelligently.

Chapter One: Introduction

Key points in this chapter

- The report reviews current arrangements for assuring the quality and safety of a doctor's practice, including the system for medical regulation.
- The report addresses the implications of the findings and recommendations of The Shipman Inquiry and three other recent inquiries into doctors' conduct and standards of practice.
- The quality landscape of the NHS has changed greatly in the last eight years with a new comprehensive framework for quality and safety of care.
- More needs to be done to develop the quality framework and make its key elements a day-to-day reality for patients and staff.
- The structure, functioning and governance of the General Medical Council is a key area of the review.
- The Shipman Inquiry and others' criticism of the proposed approach to revalidation of all doctors' fitness to practise is also central to the review.
- Inputs to the review have included: the work of an advisory group; commissioned research (on medical regulation in other countries, on licensing and competence assurance for safety-critical roles in other high-risk industries and on public and medical attitudes); and responses to a public *Call for ideas* document.

1 This report was commissioned by the Secretary of State for Health following publication of *The Shipman Inquiry: fifth report*.¹

The Shipman Inquiry

2 Harold Shipman was a general practitioner who worked mainly in the north west of England. The Shipman Inquiry concluded that the doctor killed about 250 of his patients between 1972 and 1998 (218 were positively identified).² Harold Shipman usually used overdoses of narcotic drugs that he had stockpiled illicitly to kill these patients.

- 3 Dame Janet Smith, the High Court judge who chaired The Shipman Inquiry, sought to establish, inter alia, whether local NHS organisations and the General Medical Council should bear any responsibility for Shipman's murderous activities going undetected for over 20 years.
- 4 Dame Janet concluded that local NHS organisations did not at that time have systems in place that would have allowed such conduct to be detected. She was highly critical of the General Medical Council, concluding that its culture, membership, methods of working and governance structures were too likely to support the interests of doctors rather than to protect patients.

Doctors with problems

- 5 Harold Shipman's was a case of unparalleled gravity, shocking in the scale of harm caused to patients and their families by the conduct of just one doctor, let alone the distressing circumstances of the victims' deaths. Nevertheless, the extensive material in The Shipman Inquiry's reports has echoes of other past incidents of poor or dangerous clinical practice.
- 6 The reports of three other inquiries into the actions of Clifford Ayling, Richard Neale, William Kerr and Michael Haslam – all doctors who harmed their patients over an extended period of time – are embraced within the scope of my review.^{3,4,5} An earlier inquiry carried out by Jean Ritchie QC into the conduct of gynaecologist Rodney Ledward revealed weak NHS systems, an inappropriate tolerance of aberrant conduct and deviant practice as well as a culture of deference towards senior doctors and their reputations.⁶
- 7 The Bristol Inquiry chaired by Sir Ian Kennedy (now Chairman of the Healthcare Commission) examined failings in the children's heart surgery service at the Bristol Royal Infirmary.⁷ He found serious shortcomings in the attitudes, decisions and judgements of doctors and managers in that service which caused unnecessary harm to babies and children who were treated by it. Tellingly, he spoke of a 'club culture' that operated at the time and which was highly detrimental to the interests of children and their families.

Past culture of inaction

- 8 In my earlier report, published in 1999, *Supporting doctors, protecting patients*, I reviewed and analysed the so-called 'medical scandals' of the 1980s and drew attention to some of the common factors underlying them.⁸ These still stand out and are reinforced by the inquiries into past events described above. Some are highlighted in the reports of The Shipman Inquiry and they include:
 - problems with a doctor's performance extending over many years without definitive action being taken to protect patients;
 - weak, inadequate and daunting NHS procedures for detecting and dealing with poor clinical performance;
 - a 'conspiracy of silence' whereby concerns about a doctor were well known but denied or avoided because it was too uncomfortable or seen as inappropriate to confront them;

- an absence of rules on information sharing between and amongst professional, educational and regulatory bodies and NHS employers so that concerns about a doctor were seldom brought together or viewed in the round at an early enough stage;
 - a culture that lacked true patient-centredness so that the interests of the patient were too often subordinated to other considerations.
- 9 On the other hand, it was clear that there was something of a climate of fear and retribution, so that any lapse in performance or simple human error was seen as punishable by suspension, disciplinary action and referral to the General Medical Council. This remains the case today.
- 10 Further adding to these problems, the media tended to focus on any deaths as ‘scandals’, with much energy devoted to identifying those perceived as responsible and pinning blame firmly upon them. This ‘off with their heads’ approach created a climate in which it was more difficult to draw a distinction between individual failures, system failures and genuine untoward outcomes which were not the result of any specific failure.

The changing quality landscape

- 11 In her covering letter submitting *The Shipman Inquiry: fifth report* to the Government, Dame Janet Smith pointed out that ‘the landscape [with respect to quality of care within the NHS] has changed a great deal since 1998’.
- 12 So, whilst the report of The Shipman Inquiry has been described as ‘a wake-up call’, it is clear that the NHS and the medical profession had to some extent already woken up to the need for quality and safety to be at the heart of good clinical care.
- 13 Some of the key initiatives that have transformed the ‘landscape’ include: the introduction of annual appraisal for all career grade NHS doctors and the establishment of a specialised service to support the NHS in assessing and finding solutions to problems of poor individual practice (both proposals came from *Supporting doctors, protecting patients*);⁸ the creation of the concept of clinical governance;⁹ the establishment of national standards backed up with a system of inspection (initiated by the policies in *A first class service*);¹⁰ and the promotion of a culture of patient safety backed up with an incident reporting system (proposals set out in *An organisation with a memory*).¹¹

Quality and safety: a journey incomplete

- 14 These and other measures represent a clear and comprehensive framework for quality assurance, quality improvement and patient safety in healthcare. The approach has been admired internationally as forward looking and innovative. However, there is little doubt that, to achieve its full impact, a sustained commitment to rigorous implementation is required. The current ‘landscape’ reflects that. For example: clinical governance is deeply embedded in some services but is largely lacking in others; annual appraisal of doctors is positive and effective in many parts of the country but superficial and meaningless in others; the size and scale of the problem of unsafe care is well recognised, and willingness to report is growing, but there are few instances where risk has been systematically reduced; and, whilst most chief executive officers are committed in their

mission statements to the quality of the patient's experience, in reality most do not lose sleep over this compared to ensuring that they are fulfilling financial balance and productivity targets.

Appraisal and assessment

- 15** Dame Janet Smith, in *The Shipman Inquiry: fifth report*, concludes that annual appraisal does not provide the information to fulfil the clinical governance function of a local primary care service because it is not a true evaluation or assessment of the full range of a doctor's performance and delivery of care. As such, she considers it to be an ineffective method for detecting doctors who are incompetent, dysfunctional or delivering care to a poor standard.
- 16** It could be argued that it is not the purpose of appraisal to detect poor performance. Indeed, this has been a particularly contentious driver of debate within the medical profession. One school of thought holds that appraisal can only ever be 'formative' (i.e. developmental) and should never be 'summative' (i.e. assessment). Others believe that extensive judgement is inevitable within a good appraisal system and therefore that the element of assessment within it should be formalised.

The General Medical Council

- 17** A major part of *The Shipman Inquiry: fifth report* concerns the General Medical Council. The Council was established by an Act of Parliament in 1858 as the registration and regulatory body for doctors who practised in the United Kingdom.¹² The General Medical Council has a wide range of functions but it is the 'fitness to practise' procedures that are most visible to the public. The Council's most serious sanction is to strike a doctor's name from the Medical Register. During the 1990s, the General Medical Council introduced reforms to its fitness to practise procedures.^{13,14} Dame Janet Smith acknowledges the potential benefits of these reforms but is not convinced that they will give adequate protection to patients. She points to the culture of the General Medical Council as the root cause of the problem and makes a number of recommendations to rectify this.
- 18** Addressing the functions of medical regulation and the future role of the General Medical Council is a key element of my report.

Revalidation

- 19** From the year 2000 onwards, the General Medical Council presented and developed plans for so-called 'revalidation': a new system whereby each doctor would have their fitness to practise reviewed every five years and their licence to practise renewed only if they satisfied the requirements of the review.¹⁵
- 20** An amendment of the Medical Act 1983 was passed late in 2002 to permit revalidation as one of the functions of the General Medical Council.¹⁶

- 21** The General Medical Council was undertaking the necessary groundwork to implement revalidation at the time that The Shipman Inquiry was hearing evidence. The eventual conclusion of the inquiry on revalidation was extremely critical. Dame Janet Smith considered that the method to be used for revalidation – largely based on a record of satisfactory NHS appraisals – was lacking in rigour, departed from the original concept of revalidation and was not fit for purpose. This led to the Government announcing that it would ask the General Medical Council to postpone the introduction of revalidation until my review had looked at the subject afresh.
- 22** Considering the future arrangements for revalidation is another key area of my report.

Terms of reference

- 23** On 27 January 2005, the following terms of reference were announced for my review by Dr John Reid MP, then Secretary of State for Health:¹⁷

I have asked the Chief Medical Officer for England, Sir Liam Donaldson, to undertake a review and report his advice to me on what further measures are necessary to:

- *strengthen procedures for assuring the safety of patients in situations where a doctor's performance or conduct pose a risk to patient safety or the effective functioning of services;*
- *ensure the operation of an effective system of revalidation;*
- *modify the role, structure and functions of the General Medical Council.'*

Method of working

- 24** To assist me in the review and to provide information, ideas and analysis for my report, I:
- established an advisory group (membership at Annex A) which met 11 times between 15 March 2005 and 20 December 2005;
 - commissioned three pieces of research: a review of medical regulation in other countries (carried out by Professor Judith Allsop, Visiting Research Professor at the University of Lincoln);¹⁸ a review of licensing and competence assurance for safety-critical roles in high-risk industries (undertaken by Professor Rhona Flin, Industrial Psychology Research Centre, University of Aberdeen);¹⁹ and research into attitudes to medical regulation and revalidation conducted by MORI;²⁰
 - put out a public *Call for ideas* which generated 167 responses.²¹
- 25** Although I have drawn heavily on all these inputs, the report represents my own synthesis and analysis of the underlying issues and my own proposals for change.

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Annex A

Members of the advisory group

Dr Sheila Adam, Director of Public Health, North East London Strategic Health Authority

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Professor Sir Graeme Catto, President, General Medical Council

Harry Cayton, Director for the Patients and Public, Department of Health

Professor Angela Coulter, Chief Executive, Picker Institute

Malcolm Dean, Journalist, *The Guardian*

Niall Dickson, Chief Executive, King's Fund

James Johnson, Chairman, British Medical Association

Professor Sir Ian Kennedy, Chairman, Healthcare Commission

Professor Sir Bruce Keogh, President-elect (now President), Society of Cardiothoracic Surgeons of Great Britain and Ireland

Dr Mayur Lakhani, Chairman of Council, Royal College of General Practitioners

Dr Jock Lowe, former Chief Pilot, British Airways

Clara Mackay, Director of Policy and Research, Breast Cancer Care

Ed Mayo, Chief Executive, National Consumer Council

Michael Morgan, Director, Change Partnership (formerly HR Director, Northern Foods)

Professor Jenny Simpson, Chief Executive, British Association of Medical Managers

Karen Straughair, Chief Executive, Sunderland Teaching PCT

Jane Wesson, Chairman, Council for Healthcare Regulatory Excellence

Chapter Two:

Quality and safety in healthcare

Key points in this chapter

- The NHS operates within a duty of quality and a framework of clear national standards, local clinical governance and robust inspection.
- There is still marked variation in adherence to best practice standards in different parts of the country and in different clinical services.
- The implementation of clinical governance at local NHS level has made clinical quality issues more mainstream and has increased accountability for clinical performance.
- More progress is needed to instil a culture of clinical governance in every local NHS service and clinical team. Doctors are contractually obliged to participate in activities related to clinical governance.
- Patient care occurs in multiple settings. Increasingly, care funded by the NHS is delivered through the independent sector, which is also subject to inspection and quality assurance.
- The commissioning of care is potentially a powerful lever through which to assure and improve quality.
- National clinical databases (such as the one for cardiac surgery) have the potential to provide a wider range of information on clinical performance. It is important that the programme of national clinical audits now builds upon its achievements.
- It is difficult to establish the extent of local clinical audit activity or its impact upon patient care.
- Data from national or local clinical audits rarely feature in current appraisal systems for doctors.
- Patients and the public are now more meaningfully involved in making decisions that impact upon their care and the management of local health services.
- Developments in information technology within the NHS allow for innovative new approaches to knowledge management within healthcare, facilitating the delivery of safe and effective care.

Good doctors, safer patients

- Much more of the harm caused to patients stems from error in unsafe systems than from incompetent or negligent doctors, though the latter can cause substantial harm to a minority of patients.
- The local NHS, supported by the National Clinical Assessment Service, is now much better at identifying and dealing with poorly performing doctors earlier, thus protecting patients.
- A systems-based programme to improve patient safety by learning from mistakes and adverse events is underway, but faster progress needs to be made.
- The current arrangements for quality in the NHS should provide the right environment for safe, quality-assured and well-regulated medical practice, but they need to be developed further to be fully effective.

1 The provision of good healthcare to everyone who needs it has been an expectation placed on the NHS ever since it was founded in 1948. Fulfilling that expectation depends in large part on the skill, dedication and commitment of its workforce. It depends also on the level of resources allocated to the health service, how they are used and the way that the health system is designed, organised, managed and led.

2 In addition, it is important that any health service that is dedicated to providing high-quality care has in place clear policies, effective processes and appropriate incentives to deliver on quality.

3 Over the last six or seven years, the Government, working with the NHS and the major professional bodies, has put in place a comprehensive framework to assure and improve the quality of care and to secure safer services for patients. This framework has the following key elements:

- clear national standards;
- strong local clinical governance mechanisms;
- robust systems of inspection;
- support programmes to promote and implement higher standards of care and patient safety.

4 This chapter discusses this wider 'landscape' of quality and safety in a modern healthcare environment. This is vital context when considering the way in which medical regulation fulfils its purpose.

Clear standards

5 Looking back 30 years, most health systems in the developed world operated without clear and explicit statements of the standards of care that their citizens could expect. Ironically, in contrast, standard setting by professional bodies has a long and strong tradition and has made a very important contribution to improving the quality of professional practice and training.

- 6 The focus on standards and their importance to the mainstream activities of the health service, and not just the domain of professional practice, was probably created by four main factors:
- the evidence-based medicine movement which started in the early 1990s and consistently showed that the findings of research and best practice experience translated very slowly into routine care;
 - evaluative studies of health services showing variation in standards of care across a wide range of illnesses;
 - ‘postcode prescribing’: concerns about the variable availability and use of essential medicines in different parts of the country, partly reflecting local resource allocation priorities;
 - public expectations that standards of care should be more transparent and explicit.
- 7 Action has been taken to ensure that clear, evidence-based standards are established at national level and followed through by local NHS services. The key elements of this standards-based approach to national health policy are:
- *Standards for better health* – a set of core and developmental standards that NHS services must address and which are subject to inspection by the Healthcare Commission;¹
 - a National Institute for Health and Clinical Excellence (NICE) which produces clear guidance on the clinical- and cost-effectiveness of a wide range of treatments;
 - national service frameworks which set clear improvement and best practice goals for the treatment of particular illnesses or groups of patients (e.g. heart disease, mental health, diabetes mellitus);
 - clear standards for professional practice covering the general context of medical practice (the General Medical Council’s *Good medical practice*) and specialist areas of practice (a wide range of policy documents published by medical Royal Colleges and specialist associations).²
- 8 There is clear evidence already of how this standards-based approach to policy and service delivery in the NHS has brought benefits to patients and improvement of services. This is particularly so for the standards contained in the national service frameworks. For example, premature deaths from coronary heart disease have continued to fall, life-saving drugs (thrombolysis) are delivered to those having heart attacks more promptly than before and preventive measures are employed more reliably and uniformly than they were in the past.³ Patients suspected of having cancer are now seen in hospital within two weeks of referral by their general practitioner and investigations and treatment are initiated quickly. Cancer care is now managed by teams, rather than individuals in isolation, and standard practice now reflects what was best practice until just a few years ago.
- 9 The work of the National Institute for Health and Clinical Excellence has also ensured that new technologies are robustly assessed and, if approved, made available across the whole NHS. Clinical guidelines have been produced to define best practice in the treatment of specific diseases: this unambiguous guidance not only educates clinicians but helps to drive service improvement. Such authoritative guidance is envied in many other parts of the world. The National Institute for Health and Clinical Excellence is now working to improve the dissemination and implementation of its work.

- 10** It is too early to judge the impact of the new core and developmental standards for the NHS set out in the policy document *Standards for better health*. Moreover, there is still evidence of unacceptable variation in standards of care between local NHS services, and a ‘postcode lottery’ continues in some fields. This may be felt most acutely in those areas that have not been the focus of headline targets and where patient groups are least vocal: the patchy provision of continence care for older people would be one such example.⁴ There is still much work to be done: Julian Tudor Hart stated in 1971 that ‘the availability of good medical care tends to vary inversely with the need for it in the population served’ (his ‘inverse care law’).⁵ Millennial census data tell us that there continue to be areas of clear mismatch between the number of resident medical professionals and the health needs of the local population.⁶

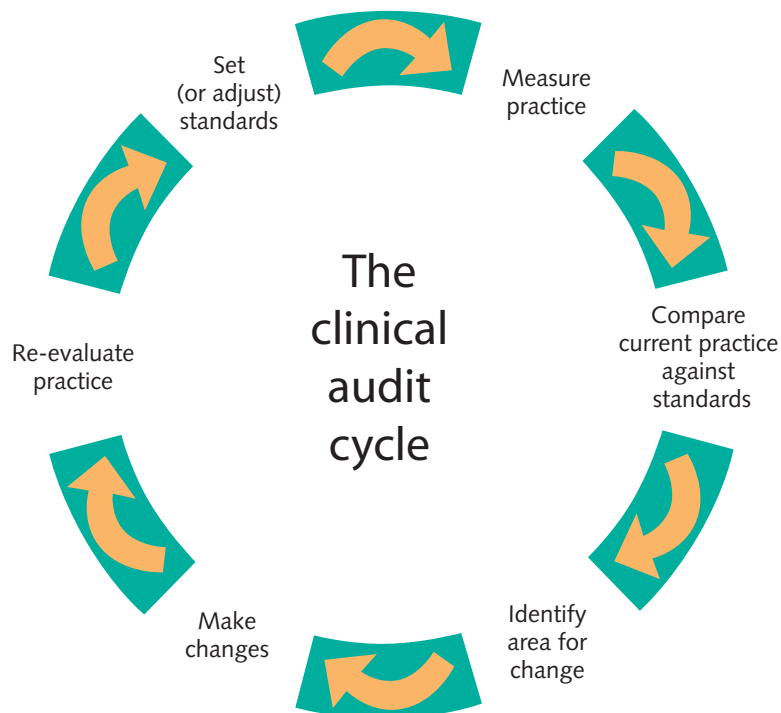
Local clinical governance

- 11** In 1999, the Government passed legislation that, for the first time, placed a ‘duty of quality’ on all providers of NHS services.⁷ This duty of quality is discharged at local level largely through implementing clinical governance programmes.
- 12** Clinical governance is the framework through which providers of NHS services are accountable for continuously improving the quality of their services and safeguarding high standards of care by creating an environment in which excellence in clinical care will flourish.⁸
- 13** The underpinning philosophy of clinical governance advocates:
- patient-centredness;
 - shared, well-evidenced standards;
 - individual and organisational accountability;
 - systematic learning from untoward incidents;
 - mechanisms for continuous quality improvement;
 - strong local leadership;
 - organisational, professional and occupational cultures that value excellence.
- 14** Established in 1999 under the Director of Clinical Governance for the NHS, the Leicester-based National Clinical Governance Support Team is charged with developing the concept of clinical governance and supporting its implementation throughout the service. Historically, the team has shared its information, expertise and advice through a number of structured training and development programmes, principally targeting multidisciplinary clinical teams, NHS Trust boards and some specific professional groups. An example of the latter is an e-learning programme for primary care managers. The National Clinical Governance Support Team’s development programmes were run up until April 2005, and engaged hundreds of NHS Trusts nationally. Over 1,800 multidisciplinary teams, or 11,800 individual healthcare staff, have been involved in individual learning or support projects. Participants have produced often small-scale, but tangible, well-documented, sustained and highly patient-centred improvements in the quality of care.

- 15 In addition, the National Clinical Governance Support Team has established a reputation for effective and supportive interventions in NHS organisations or departments that have experienced high-profile clinical or organisational failures. Some 55 such interventions have been made.
- 16 The National Clinical Governance Support Team helps to drive forward the governance agenda more generally through a series of communications products and events, including conferences, speaking engagements and academic and professional publications, as well as a public access website.
- 17 In 2003, the National Audit Office examined the progress made by NHS organisations in adopting and embedding the structures required for good clinical governance.⁹ The review, at the halfway point in the Government's 10-year NHS plan, focused on secondary and tertiary care. It concluded that clinical governance was delivering some clear and demonstrable benefits:
 - Clinical quality issues have become more mainstream.
 - There is greater and more explicit accountability for clinical performance.
 - There has been a change in professional culture, towards more open and collaborative working.
- 18 Furthermore, the National Audit Office found that virtually all NHS Trusts had laid the necessary foundations for clinical governance, though not all components had been fully embedded within all clinical directorates. Indeed, it described overall implementation as 'patchy' and concluded that the structural response to the governance agenda had not been fully matched by a behavioural and cultural shift in approach to the issues of safety and quality.
- 19 The National Clinical Governance Support Team concluded that the concept of clinical governance had been initially understood as both a structural and cultural initiative. However, in some places there was a misconception that implementing particular committee structures, roles, responsibilities and lines of reporting was sufficient to ensure safely governed, high-quality care. In fact, significant clinical failures could continue to occur even in the presence of these prescribed governance structures, principally because individual and collective behaviour was poorly aligned to their purpose.
- 20 The current phase of the National Clinical Governance Support Team's work within the NHS has been less about specific organisational, managerial or change management models, and more about creating professional and organisational cultures that accept and promote accountability and the pursuit of excellence as widespread behavioural norms. Specifically, the current engagement with local NHS organisations emphasises:
 - the identification of local, natural leaders in the organisation, irrespective of their current managerial or leadership role, or lack of it;
 - the incorporation of authentic patient feedback into planning and prioritising service developments;
 - the innovative and widespread communication of that feedback to all levels of the organisation;

- the creation of a unified and rationalised governance function which collapses individual governance functions (for example clinical effectiveness, risk and audit) into a single forum, which is chaired by the chief executive of the organisation.

- 21 For each of these broad functions, the National Clinical Governance Support Team offers appropriate access to its knowledge, expertise, and project and coaching support, and to a set of tools and techniques that support the organisation in realising each of these elements.
- 22 Clinical audit is one component of clinical governance. It involves measuring aspects of clinical process and comparing results to predefined standards.



- 23 Clinical audit has long been part of the routine clinical practice of doctors. Following the audit cycle (see diagram), or a similar approach, a doctor can assess their individual practice and that of the clinical team in which they are working against evidence-based best practice.
- 24 At various points in the last 20 years, clinical audit has played a prominent part in discussions about quality and standards of medical practice. For example, in the early 1990s, the Government's policy was that all doctors should take part in 'medical', later (to emphasise the multi-professional nature of practice) called 'clinical', audit. A considerable sum of money was invested to facilitate its introduction within the NHS. In the late 1980s, around £10 million was allocated to medical audit each year, largely through ring-fenced funds awarded to hospitals. Medical audit advisory groups were also set up to finance the introduction of medical audit across cooperatives of primary care practices. In the early 1990s, funding increased still further, particularly in primary care. At that time, major teaching hospitals attracted in excess of £130,000 of ring-fenced funds. By the mid 1990s, ring-fenced funding had ceased and the amount of money spent on clinical audit activity is now difficult to ascertain.

- 25 Some Royal Colleges and other professional bodies have required their members to participate in clinical audit as a condition of continuing membership. Career grade doctors working in the NHS in 2006 are contractually required to participate in clinical audit and related activities.

“The contractor shall have an effective system of clinical governance.”

Standard general medical services (GMS) contract for general practitioners (April 2005)¹⁰

“You must also comply with our clinical governance procedures.”

Standard consultant contract (June 2005)¹¹

- 26 The approach to clinical audit at local or individual practice level has often been criticised. Concerns commonly raised are:
- there is no clear statement of return on investment;
 - there are no aggregated data to show how the hundreds or thousands of local clinical audits are improving services;
 - there is no mechanism for important experience or findings of local clinical audits to be systematised into service improvements nationally;
 - there is a perception that clinical audit is too often carried out by health professionals in secret.
- 27 Today, clinical audit is seen as a key element of local clinical governance programmes. It is one of a number of important quality improvement methods necessary to ensure good clinical governance. It remains a valuable tool for clinical engagement in quality assurance and quality improvement. Partly because it has a chequered reputation amongst health service managers and commentators and partly because of the lack of visibility of its benefits, clinical audit falls short of its potential.
- 28 In addition to clinical audit being carried out locally by individual practitioners and teams, various so-called ‘national clinical audits’ have been established over the years. They are disparate in their origins and traditions. Some have been established by professional bodies and societies through research funds, others with NHS or government funding support. Some have been set up by research groups or by enthusiastic, committed individuals.
- 29 In many cases, the term ‘national clinical audit’ is a misnomer since few follow the formal audit cycle of identifying standards, comparing current practice against those standards, examining the reasons for shortfalls and planning and agreeing action to bring about improvements. Nevertheless, national data sets, which gather data, analyse clinical performance and draw conclusions, are very valuable and have the potential to bring even greater benefits.

30 Existing national clinical audits fall into two broad groups:

- schemes which gather data on key aspects of care in clinical specialties (e.g. cardiac surgery) or for care groups (e.g. stroke patients) and present them according to processes and outcomes of care given;
- confidential inquiries that examine factors which contribute to particular outcomes of care with a view to identifying possible causes.

Examples of national clinical databases

Adult cardiac surgery¹²

Cardiac surgeons in the United Kingdom submit mortality and other data relating to coronary bypass and valve replacement procedures to a central database operated by the Society of Cardiothoracic Surgeons of Great Britain and Ireland, first piloted in 1994. These data have allowed for the production of raw and risk-adjusted figures for mortality by centre, and by individual surgeon. Since April 2006, cardiac surgery mortality figures by hospital (drawn from the same data set) have been available on a public website, co-sponsored by the Healthcare Commission. It is anticipated that data for all units will be available there in the near future.

Stroke¹³

The national stroke audit has been conducted on a biennial basis through the Royal College of Physicians of London since 1998 and seeks to establish the facilities that are available for stroke patients within individual NHS organisations and also to examine the care actually received by a sample of consecutive patients. All eligible hospitals participated in the audit in 2004.

Paediatric intensive care¹⁴

The Paediatric Intensive Care Audit Network (PICANET) was established in 2002 and collects data relating to all children admitted to paediatric intensive care units in England and Wales (over 10,000 children per year). It is coordinated by the Universities of Leeds, Leicester and Sheffield. The core data set allows an individual unit to compare its activity, processes and outcomes to a national benchmark.

The national confidential enquiries

Confidential Enquiry into Maternal and Child Health (CEMACH)¹⁵

The first Confidential Enquiry into Maternal Deaths was published in 1952 and aimed to investigate the causes of the significant number of maternal deaths then observed, in order to share lessons across the NHS. The Confidential Enquiry into Stillbirths and Deaths in Infancy (CESDI) began in 1992 and aimed to improve the understanding of how the risks of death in late foetal life and infancy might be reduced. In 2003, these enquiries were reconfigured as the Confidential Enquiry into Maternal and Child Health.

National Confidential Enquiry into Patient Outcome and Death (NCEPOD)¹⁶

In 1988, the National Confidential Enquiry into Patient Outcome and Death commenced. This enquiry examines different aspects of medical and surgical care with a number of studies running simultaneously at any one time. Recent projects include studies of acute medicine provision and services for abdominal aortic aneurysm.

National Confidential Inquiry into Suicide and Homicide by People with Mental Illness (NCISH)¹⁷

Since its inception in 1996, the National Confidential Inquiry into Suicide and Homicide by People with Mental Illness has collected data on suicide and homicide, undertaken case-control studies of in-patients and recently discharged patients, and examined the relationship between suicide and homicide rates and service configuration.

- 31** Prominent amongst the former group of activities (see paragraph 30 above) is the database operated for cardiac surgery. This was first developed in 1994 by the Society of Cardiothoracic Surgeons of Great Britain and Ireland. The majority of cardiac surgeons now submit mortality and other data in relation to coronary artery bypass and valve replacement surgery. This has allowed the production of raw and risk-adjusted figures for mortality by hospital and by individual surgeon. Not only has the database increased the information available to prospective patients but it has also played a significant role in assuring and improving the quality of adult cardiac surgery. Much of the attention given to this work and to the potential for the development of other such databases has focused on the use of the analyses produced for public reporting of outcomes of care.
- 32** The development of these national clinical databases (i.e. ‘audits’) has been problematic because:
- there has been no clear national policy on how many should be developed and what fields of care they should cover;
 - there have been uncertainties about funding and sustainability;

- there are no common standards for the scope and quality of the data to be collected;
- there have been clinical concerns that judgements made on the basis of incomplete data would mislead the public and frighten off doctors from participating;
- valid risk adjustment for patients with more complex problems is vital to success but is methodologically complex;
- although most medical care (and hence patient outcome) is delivered by teams, there is a greater public and political appetite for surgeon- or physician-specific data;
- Freedom of Information Act conditions mean that raw data, prior to proper interpretation, may reach the public domain and conclusions may be drawn prematurely.

33 The current responsibility for developing national clinical databases rests with the Healthcare Commission. Over the last five years, funding for this programme has passed from the Department of Health to the National Institute for Health and Clinical Excellence, then to the Commission for Health Improvement and now to the Healthcare Commission. There are currently around 20 ongoing projects at varying stages of maturity, from those in development to those that have collected data nationally and made reports based upon their analyses. Projects examine areas as diverse as the management of venous leg ulcers, violence in mental health settings and the treatment and diagnosis of bowel cancer. Data from some of the projects in the portfolio feed in to the Healthcare Commission's annual assessment of NHS organisations. Such data are rarely applied to the appraisal of individual doctors.

34 The position with national confidential enquiries is now more straightforward. They are run independently of both government and the professional associations, and funding for all three flows from the National Patient Safety Agency.

Inspection and regulation of NHS services

35 The Healthcare Commission was formed in 2004, incorporating the functions of the former Commission for Health Improvement (itself an early component of the NHS clinical governance framework), and inspects healthcare organisations in order to form a judgement, in the form of an annual rating, as to their performance. The Healthcare Commission has recently developed new systems of assessment, aligned to the core and developmental standards in *Standards for better health*,¹ to replace the 'star' ratings that it inherited. Not only do these systems attempt to objectively measure the current performance of NHS Trusts but they also aim to promote improvement. The new systems of assessment will devolve more responsibility to the organisations themselves: hands-on inspection will become less frequent but more targeted and focused. Patients and local communities will be asked to play a more significant role.

36 The Healthcare Commission is responsible for a number of other areas including:

- producing an annual report on the state of healthcare;
- commissioning national patient and staff surveys;
- hosting a programme of national clinical audit;
- handling complaints that cannot be resolved locally;

- licensing private healthcare providers;
- investigating services where there are concerns about the quality of care.

- 37** From 2008, the Healthcare Commission and the Commission for Social Care Inspection will merge in recognition of a need to integrate and work across health and social care and to reduce the burden of regulation.
- 38** Monitor is a new health regulator, established to assess the suitability of NHS Trusts for foundation status and to ensure that they maintain financial viability. Following authorisation of foundation status (by the Secretary of State for Health), organisations cease to be ‘line managed’ through the NHS management structure. The Healthcare Commission continues to inspect services provided by foundation trusts in the usual way.

The new NHS – commissioning and choice

- 39** There has been a significant change in the way in which the NHS is managed over recent years. The emphasis has shifted from secondary care to primary care, from cure to prevention, and from illness to health. One of the ways in which this change is being achieved is through the new arrangements for the financing of services. Activity is to be ‘purchased’ by commissioners close to the patient in primary care (practice-based commissioning), and providers will soon be paid according to a standard national tariff (payment by results). For some aspects of medical care, patients are offered a range of choices as to which organisation they would prefer to provide that care.
- 40** One of the intended consequences of these new arrangements is competition. The independent sector has been invited to compete to provide care for NHS patients, funded by the NHS and in accordance with NHS standards. An independent sector treatment centre (ISTC) is one location in which such care may be delivered.
- 41** The independent sector provides a regulatory challenge, in that it is not necessarily subject to all of the aspects of the quality framework that applies to the NHS. However, the independent sector is regulated: the Healthcare Commission inspects and licenses independent providers of healthcare. Indeed, at the present time, the inspection regime to which the independent sector is subjected could be regarded as more traditional and less ‘light touch’ than that used in the NHS. The standards against which the NHS and independent sector are measured currently differ, but efforts are being made to better align them. Some commentators have highlighted the particular challenges of regulating doctors, often surgeons, who work predominantly in the independent sector. This challenge grows in circumstances where specialist doctors come to the United Kingdom on short fixed-term contracts to deliver elective surgery in high volume.

Medical management

- 42** For the first 40 years of the NHS, hospital consultants traditionally viewed themselves as clinically autonomous, with a clear hierarchy of other doctors beneath them. General practitioners saw themselves in a similar light, as fully independent practitioners. Until 20 years ago, senior doctors

often expected to make the major strategic and operational decisions about healthcare delivery locally, with administrators acting on their wishes.

“In short, if Florence Nightingale were carrying her lamp through the corridors of the NHS today, she would almost certainly be searching for the people in charge.”

Griffiths NHS management inquiry report, 1983

- 43 In 1983 the Griffiths report was published and the concept of general management was introduced into the NHS.¹⁸ Since then, management structures have developed and the pace of change has often been rapid. Today, senior clinicians retain considerable clinical autonomy, but systems have grown up around them to support the increasingly complex business functions necessary in a large organisation. In addition, healthcare organisations have a responsibility to ensure both the clinical quality of the care delivered and the financial performance of the organisation. Where it works best, the management of healthcare organisations is now a joint enterprise between managers and clinicians.
- 44 Management systems in the hospital sector are now mature, with a degree of consistency between NHS organisations. Doctors in secondary care are employees. Directorates, divisions and committees feed up to the NHS Trust board and lines of accountability are clear. The line management of individual consultants is, at least on paper, established through a network of clinical and medical directors.
- 45 Arrangements in primary care are more complex. General practitioners are often contractors (rather than employees of a primary care trust) and those doctors who are salaried may be employed by other contractors, rather than directly by the primary care trust. Formal management systems are a more recent development in primary care and consistency in structure and function is therefore less. Primary care trusts may be responsible for care over a wide geographical area, often in premises owned by doctors themselves. The relationships between an individual general practitioner and their senior partner, the primary care trust's medical director (where this post exists) and indeed the NHS Trust itself are difficult to define. Line management in primary care is often not a tangible concept and, in reality, organisations have little power to exercise over individual contractors, despite being accountable for the quality of clinical care. This has knock-on implications for the detection and management of poor performance.
- 46 The British Association of Medical Managers has undertaken some excellent work in improving the skills of doctors in management and, in many areas, the quality of clinical input into the management of organisations has improved significantly. However, those most in need of training and support may be least likely to seek it and there remain organisations in which medical management is tokenistic.

Addressing poor practitioner performance

- 47 A number of high-profile cases of poor clinical performance in the 1980s and early 1990s revealed serious deficiencies and dysfunction in the NHS response to doctors whose performance or conduct posed a risk to patients.
- 48 The scale of such problems in a medical workforce has been reported in research studies, and the five-year prevalence is estimated at around 5%.¹⁹
- 49 The NHS was not good at detecting such problems at an early stage, action to protect patients was too slow to be taken and local services seemed to have enormous difficulty in resolving problems effectively. The reasons for this are set out in detail in my 1999 report *Supporting doctors, protecting patients*.²⁰ This report made proposals for reform (see also Chapter One of *Good doctors, safer patients*), most importantly the creation of a National Clinical Assessment Authority (now Service) to act as a source of expertise and support for doctors and the NHS.
- 50 Over the last five years, the National Clinical Assessment Service has brought about a transformation in the previous position. In particular:
- The number of long-term exclusions (suspensions) has been halved.
 - Two-thirds of cases in 2004/05 were problems of less than one year duration compared with two-thirds being more than one year old in 2002/03.
 - Alternatives to suspension, whilst still providing protection for patients, were offered in 85% of new cases.
- 51 The National Clinical Assessment Service is being used as a source of expertise, advice and support by the NHS. Help has been given to over 90% of NHS bodies and, at any one point in time, around half of all NHS organisations are actively working with the Service on a case.
- 52 The new lessons from the experience of improving the system for dealing with poor practitioner performance in the NHS over the last five years are:
- There must be a clear recognition that the medical workforce will always contain a proportion of doctors whose performance or conduct has the potential to harm patients or disrupt the effective delivery of patient care.
 - Cases of poor clinical performance are highly complex to investigate and resolve: 600 local NHS organisations cannot therefore be expected to handle effectively the more serious cases without expert advice and support of the kind that has been provided by the National Clinical Assessment Service.
 - Doctors can be successfully retrained and rehabilitated if detected early, but this is a complex and intensive process which needs expert oversight and control.

Procedures in NHS primary care organisations to deal with poor practice

- 53** The power of a primary care trust to investigate and deal with concerns about a general practitioner's performance or conduct are different to those found in hospitals. Many of these differences flow from the independent contractor status of the majority of general practitioners and the distance this creates in the relationship with the contracting organisation, compared with that of a salaried contracted employee (such as a hospital consultant).
- 54** These powers are governed by a framework of general legislation relating to the operation of the NHS (e.g. the 'duty of quality') and highly specific regulations relating to medical practitioners in primary care. Notable in the latter respect are the NHS (Performers Lists) Regulations 2004.²¹
- 55** Essentially, a primary care trust can address poor performance on the part of a general practitioner in their area in a number of ways: informally, formally (including through the regulations referred to above) or by involvement of the medical regulator (the General Medical Council). The National Clinical Assessment Service will also often be involved in helping to diagnose and understand the problem and in helping the primary care trust to decide how to move forward with it.
- 56** Within a clinical governance culture, concerns about a general practitioner's conduct or performance can be dealt with informally by support, development and agreeing a plan of remedial action. In some parts of the country, primary care trusts have established groups of doctors with experience of dealing with poor performance to intervene and investigate when complaints or concerns arise. Such groups (or panels) may play a part in 'working up' cases for more formal investigation or action.
- 57** Such informal action can only really be carried out with the doctor's cooperation. If they will not cooperate or if informal solutions do not seem appropriate, or are ineffective, then the primary care trust can invoke formal action. Each primary care trust must maintain a performers list. A general practitioner must be on a performers list to practise in the NHS (although not necessarily the list of their contracting primary care trust).
- 58** Primary care trusts can act by: suspension, removal or contingent removal (i.e. conditions imposed) from its own local list, for example where there are serious concerns about the practitioner's performance or it is considered necessary to protect the interests of patients.
- 59** In very serious cases, a primary care trust that has removed a general practitioner from its performers list can apply to have the doctor disqualified nationally through the Family Health Services Appeals Authority. Around 30% of such applications for national disqualification are appealed by the doctor, and more than half of such appeals are successful.
- 60** Although these regulations give the primary care trusts much stronger powers than they used to have to deal with poorly performing general practitioners, they have only been in place for a relatively short period of time. Early experience is that many primary care trust chief executive officers find them daunting, inflexible and bureaucratic, and a relatively high hurdle to have to jump in order to take effective action against a doctor whose practice is giving rise to concern. The regulations are often described as being 'like the NHS hospital disciplinary procedures used to be

before they were reformed'. There is little doubt that many primary care trusts feel unable to take local action themselves and instead rely on the General Medical Council, knowing that sometimes the Council's high test of 'proof' will mean that the doctor will not be censured in any way. Some primary care trust chief executive officers express the view privately that they have general practitioners in their jurisdiction that they would not really want to treat patients.

Procedures in NHS hospital and community services to deal with poor practice

- 61** The procedures available to the NHS to deal with the full spectrum of failure of clinical performance remained in large measure unchanged from 1948 until the turn of the present century. Despite two revisions in 1961 and in 1990, the core principles, and much of the detail, remained intact.^{22,23} Procedures were on the one hand unwieldy, bureaucratic and unable to keep up with the pace of modernisation in the NHS, and on the other hand firmly disciplinary in emphasis, using highly adversarial quasi-judicial protocols. As a result, they were insufficiently agile to deal with the wide range of guises and circumstances in which poor performance could present. Moreover, the procedures were so daunting that poor performance was tolerated to a much greater degree than it should have been.
- 62** A long overdue reform of the disciplinary framework itself began in 2003, and consisted of three distinct elements.
- 63** The first step came with the publication in December 2003 of a framework for the exclusion of doctors and dentists employed by the NHS, *Maintaining high professional standards in the modern NHS: a framework for the initial handling of concerns about doctors and dentists in the NHS (restriction of practice and exclusion)*.²⁴ This modernised the management of what had previously been variably termed 'suspension' or 'gardening leave'. A series of protocols were set out, to be used where a concern arises about the practice of a doctor which places patient safety in doubt. For example, it provides for an immediate, temporary period of exclusion which may be needed to enable rapid investigation of the concern and the formulation of a plan to address it. It also sets out guidance and safeguards to ensure that any formal exclusion is used appropriately and only for as long as is required.
- 64** The second step came with the publication in February 2005 of *Maintaining high professional standards in the modern NHS: directions on disciplinary procedures*.²⁵ This represented a radical departure from previous, national protocols, placing the emphasis firmly on local procedures relevant to the circumstances of the case. The key feature is a need for compliance with the principles and good practice set out in the protocol, avoiding the potential difficulties which a nationally prescriptive protocol could lead to. It also means that NHS doctors and dentists are dealt with under the same disciplinary procedures as any other NHS staff member, leading to the much quicker management and resolution of some types of case than in the past.

- 65** This new framework introduced two key sets of changes.
- It brought to an end the distinction between professional and personal misconduct which had shaped the NHS approach to dealing with poor clinical performance since its inception. This change leaves local procedures in a position to deal with all the key elements of a case, rather than having to select a process to follow which, in turn, could exclude consideration of important matters.
 - It introduced procedures relating to health and capability – fields which were served poorly by the adversarial and legalistic procedures which went before.
- 66** The emphasis of the traditional procedures on disciplinary solutions meant that many concerns, where performance assessment and a re-entry and retraining programme would be more appropriate, were in fact managed through discipline. The new procedures, including the exclusions framework, require NHS Trusts to seek help and advice from the National Clinical Assessment Service:
- to help plan the management of a case;
 - where needed, to carry out targeted specialist assessment;
 - to support the development and delivery of an action plan.
- 67** The third and final element of this reform programme focuses on the ‘alert letter’ system, described in more detail in Chapter Five.

Procedures to deal with poor practice amongst doctors in training

- 68** The management of disciplinary and performance problems that arise amongst trainee doctors is complex, falling in part under the remit of the postgraduate medical deans, and in part under the procedures operating within the trainee’s employing NHS Trust. In theory, postgraduate deans focus on concerns of an educational nature, and NHS Trusts on issues of misconduct or those that pose significant risks to patient safety. In reality, this distinction is not easily made. Postgraduate deans operate in accordance with guidelines on higher specialist training published in 1998 and known as *The orange book: a guide to specialist training*.²⁶ Although these guidelines provide a framework for dealing with performance matters, individual postgraduate deaneries have developed local approaches. Most contact between trainees in difficulty and the postgraduate deanery is devolved to the programme director of the relevant specialist training committee, who usually liaises with a senior member of the postgraduate dean’s team. There may therefore be further variation in the way in which procedures are applied.
- 69** At any given time, most postgraduate deans will have several active cases of failed or failing trainees, or of trainees who are appealing against deanery decisions or taking legal action.
- 70** Trainees engaged in higher specialist training (specialist registrars) undergo an annual appraisal and an assessment process (known as a RITA – Record of In-service Training Assessment). The RITA committee may judge that a trainee’s progress has been unsatisfactory and formally record their concerns (an appeals process is possible at this point). Further unsatisfactory progress may result

in the termination of training. The RITA process allows for annual scheduled review of performance. However, the rigour and consistency with which the RITA system is applied, across deaneries and across specialties, varies.

- 71** Where performance concerns become obvious to either the postgraduate deanery or the NHS Trust, whether through the RITA process or as a result of specific adverse events, a similar range of options are available as for career grade doctors. Referral to the National Clinical Assessment Service or the General Medical Council may be appropriate. Alternatively, a particular course of remedial training may be required.
- 72** Although many individual deaneries manage poor performance well in conjunction with NHS Trusts, there are a number of challenges relating to the processes in place.
- Reliance on the chairs, programme directors and members of multiple specialty training committees makes it difficult to assure consistency in due process and may prevent the development of dedicated local expertise. Although postgraduate deans inevitably gain some experience in these matters, there may be insufficient legal expertise in this complex area at local level.
 - Despite the existence of *The orange book: a guide to specialist training*, there is a lack of clarity as to how cases should be managed.
 - Unless escalated to the level of the General Medical Council, there is no formal collation of performance procedures for trainees, nor are data captured as to the outcomes of such procedures.
 - If removed from a training programme, doctors may continue to practise elsewhere. There is no effective corporate NHS ownership of doctors with performance problems who are employed on short-term, fixed-term or locum contracts. This is a large group with, at one end of the spectrum, the entire trainee workforce and, at the other end, doctors who (for whatever reason) have made a career from short-term attachments or locum positions.
- 73** The situation for other doctors in training is similar to that in place for specialist registrars. Presently, responsibility for doctors in the first year of the foundation programme formally remains with the undergraduate (medical school) deans, although this responsibility may be delegated to the postgraduate deans.

Knowledge management

- 74** The National Programme for Information Technology (Connecting for Health) aims to equip the NHS with a modern and sophisticated system that will bring solutions to long-standing problems and facilitate the delivery of quality care.²⁷ The programme is unrivalled in its scale and is committed to spending £6.2 billion over 10 years.
- 75** Knowledge about new research findings, evidence about best practice and information on new drugs and technologies is essential for doctors to keep up to date and practise to a high standard.

- 76** In the past, the management of knowledge in the NHS, and the wider world of healthcare, has been piecemeal. There has been a reliance upon information derived from traditional texts and journals, alongside advice from peers. Whilst these sources each have their place, Connecting for Health (through the National Library for Health) aims to procure, store and deliver a wealth of quality-assured and up-to-date information, made available to clinicians, as and when they need it. The programme also provides an opportunity to embed knowledge within systems.
- 77** With changes in patterns of work and increased patient mobility, Connecting for Health, along with the Electronic Health Record, has much to offer patients in a healthcare system in which they may be the only constant. Providing clinicians with simultaneous access to accurate patient records, quality-assured knowledge and details of local care pathways is key to ensuring safe and effective healthcare in the future. Safety can be embedded within systems too: with the advent of electronic prescribing and advances in decision support software, clinicians can be guided to the best treatment and the risk of error can be reduced.
- 78** In addition to providing ‘live’ support at the time of the clinical encounter, new systems have much to offer in realising the potential of routinely available data, for example, in clinical audit.

Patient involvement and empowerment

- 79** Patients (and the citizens from whom they are drawn) are central to all that the NHS does. At times, the enormous size of the organisation has meant that this fact has been forgotten. With a more explicit emphasis on quality, there has been an appropriate focus upon clinical outcomes, patient experience and value for money. In many NHS organisations, patients are now meaningfully involved in decisions about service reorganisation and priority setting, through the relevant Patient and Public Involvement Forum. Often, internal appointment panels have lay input. NHS foundation trusts have boards of governors, made up of local people. The role of patients in the strategic management of health services is developing further, with the publication of *Creating a patient-led NHS: delivering the NHS improvement plan* and *Our health, our care, our say: a new direction for community services*.^{28,29}
- 80** Patients are becoming increasingly empowered to direct their own care. The Expert Patients Programme aims to provide training and support to people with chronic diseases to enable them to participate fully in their treatment and maintain control over their lives.³⁰

Council for Healthcare Regulatory Excellence

- 81** The Council for Healthcare Regulatory Excellence was established in April 2003. The organisation is an overarching body, maintaining oversight of the nine statutory regulators responsible for United Kingdom health professionals (one of which is the General Medical Council). Expenditure for the financial year 2004/05 was approximately £2.5 million.

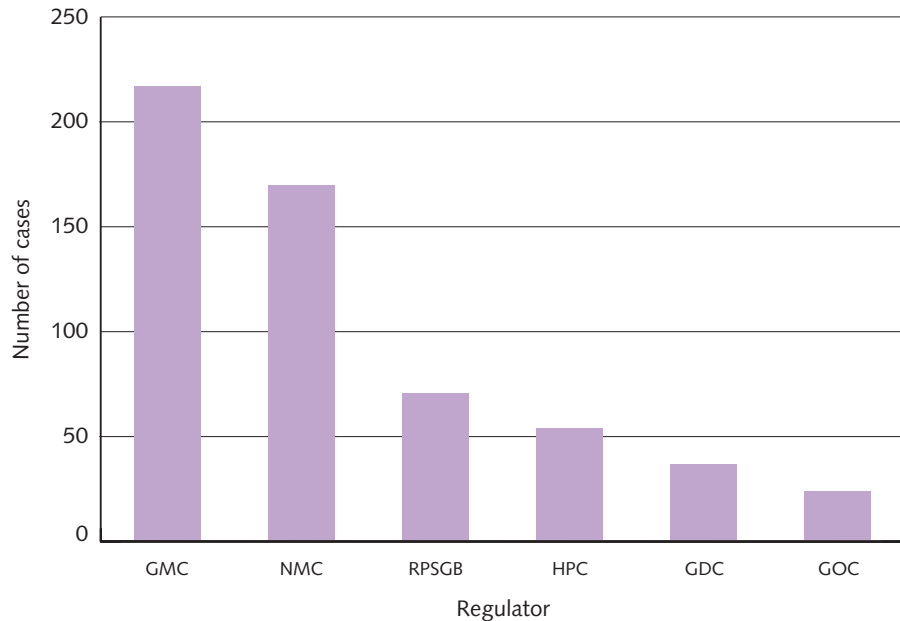
82 The Council for Healthcare Regulatory Excellence has powers to:

- monitor how regulators carry out their functions (through annual performance review);
- recommend changes to the rules of a regulator;
- refer cases of ‘undue leniency’ in fitness to practise findings to the courts;
- advise health ministers.

83 The Council for Healthcare Regulatory Excellence sees the development and spread of good practice amongst regulators as essential to its role. In order to accomplish this, the organisation encourages communication and networking between the regulators. It also supports the principles set out by the Better Regulation Task Force (outlined in Chapter Nine) and promotes dialogue with other partners.

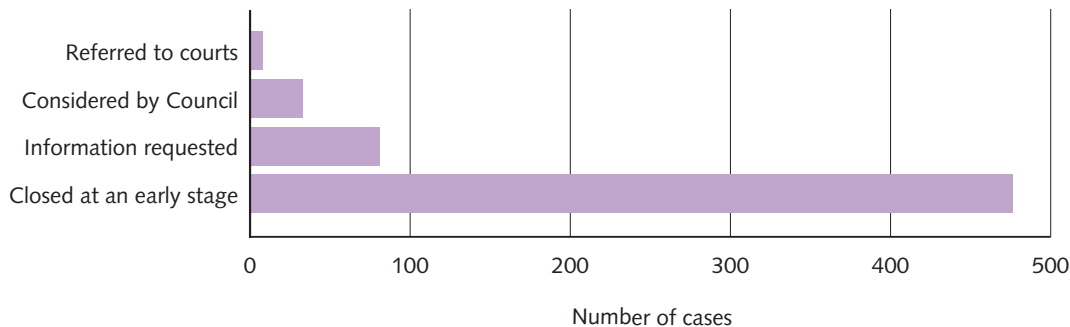
84 The Council for Healthcare Regulatory Excellence can review certain fitness to practise decisions made by individual health professional regulatory bodies, once an individual decision has reached the adjudication stage. It refers some cases to the courts on account of ‘undue leniency’. Often such referrals are made with the full cooperation of the individual regulator which may welcome clarification on a specific point of law.

Council for Healthcare Regulatory Excellence: total fitness to practise cases reviewed in 2004/05



GMC	General Medical Council	HPC	Health Professions Council
NMC	Nursing and Midwifery Council	GDC	General Dental Council
RPSGB	Royal Pharmaceutical Society of Great Britain	GOC	General Osteopathic Council

Council for Healthcare Regulatory Excellence: outcome of fitness to practise cases reviewed in 2004/05



Patient safety: systems awareness

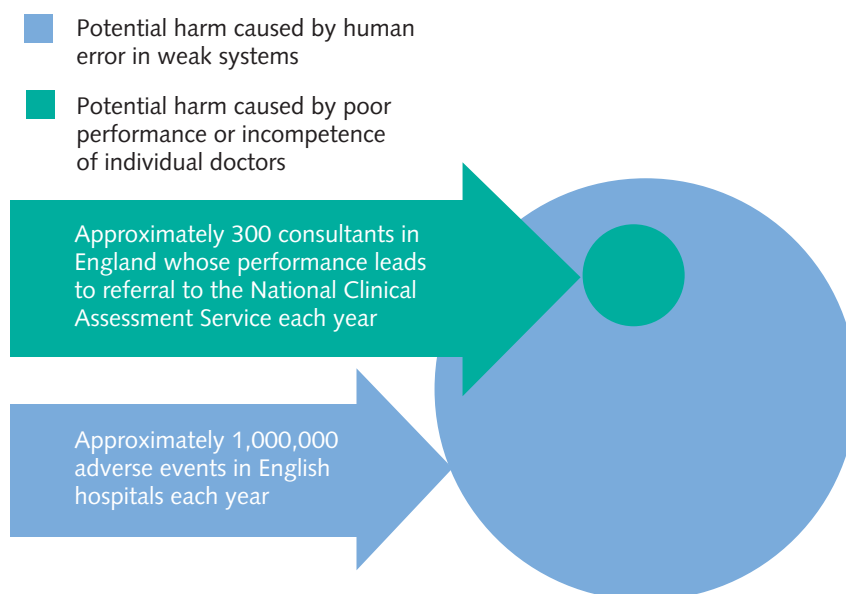
- 85 In 2004, the airline industry was able to claim its safest year ever. No European or American airline’s plane had crashed in the previous three years on account of aircraft or pilot failure. This major achievement in a previously high-risk industry had been hard won. Air safety has been a focus for the airline industry for four decades. Lessons have been learned from the major disasters, reporting systems have been developed to analyse all incidents – both big and small – that could be a source of future risk, and a culture of safety has been actively and consistently promoted. Regular and sustained improvements have been made to reduce the risk of air travel for passengers and crew.

- 86 In healthcare, the position is entirely different. It is only relatively recently that attention has been focused on patient safety as an issue. Despite the relatively high level of risk associated with healthcare – roughly one in ten patients admitted to hospital in developed countries suffers some form of medical error – systematic attempts to improve safety and the transformations in culture, attitude, leadership and working practices necessary to drive that improvement are at an early stage.³¹

- 87 The problem of adverse events in healthcare is not new.³² Studies as early as the 1950s and 1960s reported on adverse events, but the subject remained largely neglected. A body of evidence started to emerge with the publication of the results of the Harvard Medical Practice Study in 1991.^{33,34} Subsequent research in Australia, the United Kingdom and the United States of America drew attention to the scale of the problem. The 1999 publication *To err is human: building a safer health system* by the Institute of Medicine in the United States of America, and my own publication *An organisation with a memory* in 2000, provided further impetus and brought the subject of patient safety to the top of the policy agenda and the forefront of public debate worldwide.^{35,36} Although there is continued debate about the exact size of the problem, few would now disagree that it is an important source of morbidity and mortality.

- 88 Current concepts of patient safety place the prime responsibility for most adverse events on deficiencies in system design, organisation and operation rather than on the negligence or poor performance of individual providers or individual products. Indeed, the level of harm arising from error in unsafe systems versus unsafe doctors is several orders of magnitude higher (see diagram below). Countermeasures based on changes in systems of care are, therefore, more productive risk reduction strategies than those that only target individual practices or products, though both are necessary.

Risk to patient safety in hospitals: the balance between systems factors and individual performance problems^{37,38,39}



Methodology notes: Data from the National Clinical Assessment Service show that hospital doctors (excluding trainees) have about a 1% chance of referral to the Service. In 2004, there were 29,917 consultants in the NHS in England. In addition, hospital doctors may be referred solely to the General Medical Council: such cases are not accounted for here. Vincent and colleagues demonstrated that an adverse event occurred in 10.8% of hospital admissions. In 2004/05, there were a total of 9,859,133 hospital admissions in England.

- 89** A systems focus on protecting patients is very important, but it is also essential to realise that harm can be caused by incompetent or poorly performing individuals. Safe patient care also requires competent, conscientious and safety-conscious individuals at the frontline. Ensuring that patient safety is a key component of educational curricula, training programmes and induction schemes is vital.
- 90** The United Kingdom has been one of the first countries to give national priority to tackling the patient safety issue. Our work in this area is internationally respected. Patient safety is a fundamental part of the drive to improve quality in the NHS in England.
- 91** *An organisation with a memory*³⁶ highlighted a failure to learn systematically from things that go wrong, in marked contrast to other high-risk industries. The report demonstrated the importance of improved and unified mechanisms for detecting safety problems, the importance of a more open culture and the value of a systems approach to preventing, analysing and learning from adverse events.
- 92** The National Patient Safety Agency (NPSA) was created in 2001 to promote system-wide reporting, learning and action on patient safety problems. In 2004, a National Reporting and Learning System was launched, designed to draw together reports of patient safety errors and systems failures across England and Wales and help the NHS to learn from things that go wrong. The National Patient Safety Agency works with patients and healthcare professionals locally and nationally to foster a culture of learning rather than blame.

- 93** The patient safety agenda in England is gaining momentum. However, much remains to be done. Our adverse event detection systems are in their infancy. Many events are still not reported by healthcare workers because of fear of blame. Understanding of the causes and determinants of adverse events is limited. Although there are examples of successful safety policy and programme initiatives, few have been extended across the NHS. In addition, the roll-out of the National Patient Safety Agency's National Reporting and Learning System has been slow, as has the sharing of lessons from the information collected in it. This has led to criticism by the National Audit Office.⁴⁰
- 94** One way of improving patient safety is the seemingly simple process in which a national alert is sent to local NHS organisations which they are then asked to act upon. In April 2004, we established an electronic system for issuing these alerts. For the first time ever, this allows a systematic means to help assure how nationally endorsed safety guidance is being implemented across the NHS. In the first eight months of the system, around 72 alerts were issued.
- 95** In my 2004 Chief Medical Officer's annual report, I reviewed progress in implementing action on alerts in relation to national guidance published on the safe administration of intrathecal (spinal) chemotherapy.⁴¹ Unfortunately, more than four years after revised guidance was issued and widely disseminated, along with a number of other significant steps to support and indeed mandate compliance from healthcare organisations to minimise the risks of such an event ever occurring again, some NHS Trusts were still not fully compliant.
- 96** Case studies like this reveal much about the safety culture of healthcare. Unlike aviation and other high-risk industries, healthcare organisations remain unfocused and therefore unable to rapidly reduce potentially fatal risks. This challenge is not unique to this country. In my capacity as Chair of the World Alliance for Patient Safety, I have heard of many similar experiences worldwide.⁴²
- 97** Improving patient safety demands a sustained, comprehensive and multi-faceted effort to identify and manage actual and potential risks to patient safety in individual services and find broad, long-term solutions for the NHS as a whole. This involves a wide range of actions in performance improvement, environmental safety and risk management, including infection control, safe use of medicines, and ensuring equipment safety, safe clinical practice and a safe environment of care.
- 98** In the light of the National Audit Office report on the patient safety programme in England and Wales, a review is underway to address concerns and reshape the programme as necessary.⁴⁰

Conclusions

- 99** The quality framework for clinical services in the NHS has evolved over the last six or seven years and is creating a climate in which: standards for high-quality care are made explicit and assessed; poor and unsafe care is identified early and measures taken to reduce risk for patients; and the culture of NHS services is patient centred and intolerant of poor practice.

- 100** The NHS is now well aware of clinical governance, but there is substantial variation in the extent to which the concepts that it embodies have become embedded within the everyday fabric of NHS teams and organisations. In places, adoption has not progressed beyond the structures of clinical governance: such structures are necessary but not sufficient.
- 101** Some commentators have been disappointed by the output of the national clinical audit programme to date. The design and development of these national projects is complex, and professional bodies have at times been suspicious of the interest shown by organisations such as the Department of Health and the Healthcare Commission in what they sometimes regard as their data. It is important that the place of national clinical audit is now consolidated and that the output of the national programme (and national projects more broadly) grows.
- 102** The contribution made by local clinical audit is also unclear. Whilst reflective practice through clinical audit has the capacity to improve services, it must be undertaken in partnership with management, and audit loops must be closed. The wealth of activity that does occur locally is often poorly organised and the maximum benefit for patients is not reaped. Occasionally lip service is paid to clinical audit, which can be undertaken in a tokenistic way.
- 103** The NHS is an enormous organisation and this brings with it both opportunities and challenges for the quality framework. A degree of central control should help to assure minimum standards and reduce inequalities, but the challenge of performance managing an organisation of this size can be overwhelming. The quality framework must aim to embed good practice within organisations.
- 104** New ways of working in the NHS, with a shift in emphasis towards commissioning as a lever to ensure quality, are now taking shape. Plurality of providers demands that the quality agenda is also adopted by independent sector providers of care to NHS patients.
- 105** Developments in information technology within the NHS will improve access to quality-assured information. Innovative approaches to knowledge management are powerful tools through which to deliver quality care.
- 106** The significance of the problem of patient safety has grown in stature in recent years. As treatments become more complex, interventions have the capacity to do harm. It is now widely recognised that the poor design of healthcare systems, which makes them vulnerable to human error and its impact, is a major hazard to health and well-being. Understanding these issues is key to their resolution.
- 107** Elements of this framework need to be developed further. In particular, the culture of clinical governance needs to be spread to more local NHS organisations, there needs to be more consistent adherence to best practice standards and guidelines; more information on quality of care should be available to patients; and more effective and timely learning from adverse events needs to take place.
- 108** These arrangements provide the right foundations and environment to ensure that medical practice is safe, quality assured and well regulated.

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Chapter Three:

The three inquiries

Key points in this chapter

- In addition to The Shipman Inquiry, three other major inquiries have been held into the circumstances surrounding the poor performance and behaviour of doctors in recent years.
- Taken together, the reports of these four inquiries represent the culmination of many years of evidence-taking and analysis, at a cost to the taxpayer of over £28 million.
- The handling of sensitive information about practitioners in the NHS has not been systematic in the past.
- Recruitment processes in the NHS have often lacked thoroughness.
- The NHS has not valued complaints as a source of information to drive improvements for patients.
- At times, the General Medical Council has been reluctant to act upon information and slow to deal with practitioners about whom there are concerns.
- The inquiry into the conduct of Clifford Ayling highlighted a disjointed and inadequate system of complaints handling, and grossly ineffective communication between organisations.
- The inquiry into the performance and conduct of Richard Neale noted the absence of checks upon his clinical competence, the failure of the General Medical Council to put the information that it received from numerous sources to good use, and an inadequate approach to the handling and use of professional references.
- The inquiry into the conduct of William Kerr and Michael Haslam found that members of the local healthcare community remained silent, despite a building body of evidence, not as part of a conscious conspiracy, but because the pervading culture permitted such inaction. When concerns were raised, they were not acted upon and the 'whistleblower' was treated poorly. There was an absence of understanding about sexualised behaviour amongst clinicians, and of research into the grooming of vulnerable patients for abuse.

- The reports contain many similarities and often reach common conclusions, from differing approaches. Although a significant period of time has elapsed since some of the events that the reports describe, it is vital that the opportunities to learn are not lost.

- 1 My report was commissioned in the immediate aftermath of the publication of the *The Shipman Inquiry: fifth report*¹ and therefore largely addresses the issues raised by Dame Janet Smith in relation to revalidation and the General Medical Council. However, its brief is more wide-ranging.
- 2 Under the terms of reference of this review, I have been asked to advise Ministers upon further measures necessary to ‘strengthen procedures for assuring the safety of patients in situations where a doctor’s performance or conduct poses a risk to patient safety or the effective functioning of services.’ In so doing, I have considered several other well-known cases of incompetent performance or criminal behaviour on the part of doctors that have come to light in recent times: namely the cases of Clifford Ayling, Richard Neale, William Kerr and Michael Haslam.
- 3 All of these cases have themselves been the subject of a set of incisive independent inquiries, run in parallel following their launch in July 2001, reporting to the Secretary of State for Health during 2004 and 2005. Each of these cases represented a quite fundamental betrayal of trust on the part of the doctor involved, and each caused damage to the physical or mental well-being of very many patients. The inquiries focused primarily upon the NHS systems in operation at the time of the events that they examined. The role of the General Medical Council, as the independent national regulator, was excluded from the terms of reference. Nonetheless, the inquiries have revealed a great deal of valuable information about the interface between the NHS and the General Medical Council.
- 4 The three inquiries shared a number of common features in relation to their design and conduct. The shared terms of reference were as follows:

“To assess the appropriateness and effectiveness of the procedures operated in local health services: (a) for enabling health service users to raise issues of legitimate concern relating to the conduct of health service employees; (b) for ensuring that such complaints are effectively considered; and (c) for ensuring that appropriate remedial action is taken in the particular case and generally.”

- 5 The three inquiries cover an extended period of time, from 1964, when Kerr left Belfast under a disciplinary cloud, to May 2003, when his name was erased from the Medical Register. Over this period of 29 years, the systems in place, the prevailing culture within medicine and the shape of society itself have all changed quite markedly. Nonetheless, the failures demonstrated over this

period, the inadequacies that echo through each inquiry and the disturbing features of the narrative accounts all form lessons that must be learned and never forgotten.

- 6 In this chapter, I shall focus upon the lessons to be learned from these cases and, in so doing, draw out the salient features from the inquiry reports. The Department of Health is producing separately a point-by-point response to the recommendations of the inquiries.

The case of Clifford Ayling²

(Inquiry Chair: The Honourable Mrs Justice Pauffley, DBE)

On 20 December 2000, Clifford Reginald Ayling, a 69-year-old general practitioner from Kent, was convicted of 12 counts of indecent assault relating to 10 of his female patients. He was sentenced to four years' imprisonment and his name was added to the register of sex offenders.

Clifford Ayling entered medicine as a mature student and qualified from University College Hospital, London, at 32 years of age in 1963. Between 1963 and 1975, Ayling was employed in a number of surgical and obstetrics training posts at various hospitals but, having ceased to apply for promotion within the hospital medicine career structure, he was appointed as part-time Clinical Assistant in Obstetrics and Gynaecology. Ayling continued in this post until 1988. In the early 1980s, he moved into primary care and became a full-time Principal in General Practice during 1983. In addition, Ayling was also employed in Kent hospitals between 1984 and 1994, as Clinical Assistant to Mr Rodney Ledward (a consultant gynaecologist whose own poor practice and behaviour was the subject of an inquiry, chaired by Jean Ritchie QC).³

In each of these settings, Ayling attracted formal complaints. These complaints concerned only a fraction of Ayling's unsatisfactory and, at times, criminal actions. A wealth of knowledge and considerable concern about Ayling's behaviour had existed within Kent for many years: this knowledge had not been brought together and acted upon.

Ayling's misconduct related primarily to his frequent performance of inappropriate intimate examinations, amounting to indecent assault, upon his female patients. On a number of occasions, Ayling was said to have been sexually aroused at these times and he was allegedly witnessed masturbating during the course of such an intimate examination. In addition, there were a number of concerns over Ayling's clinical performance in his obstetric practice, involving the excessive use of episiotomies and rough delivery using instruments.

Matters arising from the case of Clifford Ayling

- 7** The formal written complaints about the practice of Clifford Ayling derive from only a proportion of the cases that were subsequently unearthed during the course of the police investigation and the inquiry. At all stages during Ayling's career, there was a substantial body of people, both patients and NHS staff, who harboured concerns about his behaviour. This informal or tacit knowledge, had it been brought together at an earlier stage, would have identified the extent of problems and may have resulted in actions to protect patients.
- 8** When complaints did surface, they were often dealt with on an informal basis, through discussion and not in writing. On at least one occasion, a patient was advised that pursuing an informal route of complaint would be more likely to be effective.
- 9** The existence of professional hierarchies and barriers at times hindered the appropriate transfer of information relating to Ayling's conduct.
- 10** There appeared to be a reluctance (on the part of professionals and organisations) to report Ayling to either the General Medical Council or the police, even when events came to light that would probably (even taken alone) have constituted serious professional misconduct or resulted in a criminal charge.
- 11** When other local general practitioners became aware of issues and concerns relating to Ayling's practice (generally surrounding inappropriate intimate examination), they kept their own written records but did not feel able to take matters further, a position reinforced following discussion with a medical defence organisation. In particular, another general practice (to which Ayling's patients were defecting in large numbers) recorded such concerns an average of three times per year, over a 12-year period.
- 12** There was a general feeling that only formal complaints made by patients themselves could be acted upon, even where another health professional had witnessed misconduct.
- 13** Even when more formal routes were followed, documentation was often poor and communication between key figures lacking. On one occasion, two individuals each thought that the other had discussed matters with Ayling: as a result, neither did.
- 14** Perhaps the most serious of all the issues raised in the report was the inadequacy of communication between the numerous organisations employing Ayling. At times, employers were unaware of Ayling's other appointments and therefore could not have communicated effectively, even if they had been so inclined. At other times, when rumours of disciplinary action being taken by one employer began to circulate, another took this as a reason not to undertake its own proceedings, even though information was not shared. They had no formal confirmation that another organisation had taken on the task of investigation.

- 15** Analysis of the events involving Clifford Ayling demonstrates problems with the formal complaints procedures and the absence of clear lines of accountability and responsibility. There was no system in place through which to share information, and in the absence of such a system, for many years, no organisation took the initiative.
- 16** It is also striking how individual incidents of quite extreme behaviour did not in themselves raise alarm bells. For example, there were two reported occasions on which Ayling, hearing that female patients had removed themselves from his list, had pursued them, on one occasion going to the patient's home. No effort was made by any individual or organisation to formally assess the motivation of patients to leave Ayling's practice, nor to question the doctor's extraordinary behaviour.
- 17** The examination of the role of the General Medical Council was beyond the scope of the report's terms of reference but it is clear that it was slow to respond to complaints about Ayling (when they were eventually lodged). This was acknowledged by the General Medical Council's Chief Executive in his evidence to the inquiry. Additionally, following the High Court decision to amend the conditions of bail that had initially prevented Ayling from continuing to work pending his trial, the General Medical Council did not further involve itself.

Chronology of formal actions against Clifford Ayling who remained in clinical practice until 2000

Initial complaint about Ayling to General Medical Council	March 1998
Health authority informed by General Medical Council of possible grounds for action – further investigation proposed	16 June 1998
Health authority ask General Medical Council to expedite proceedings	22 Sept 1998
Ayling's arrest	11 Nov 1998
General Medical Council state that they will await the outcome of criminal proceedings	27 Nov 1998
Conviction in court	20 Dec 2000
Preliminary Proceedings Committee of the General Medical Council	17 Jan 2001
Erasure from the Medical Register	14 July 2001

The case of Richard Neale⁴

(Inquiry Chair: Her Honour Judge Matthews QC)

On 23 August 2000, the name of Richard William Neale was removed from the United Kingdom Medical Register. He had been found guilty of serious professional misconduct in relation to the treatment of 12 of his former patients (two further charges were not proven). On 25 June 1985, a discipline committee of the College of Physicians and Surgeons of Ontario had found Richard Neale to be incompetent and had ordered that his name be erased from the Ontarian Medical Register.

Richard Neale qualified in medicine from the Westminster Hospital, London, in 1970. Following house officer posts and a short period in general practice in Cheshire, he obtained posts in obstetrics and gynaecology, at the level of senior house officer and subsequently registrar.

In 1977, Neale moved to Canada and worked in British Columbia in obstetrics and gynaecology. In 1978, Neale undertook a hysterectomy on a woman in otherwise poor health, against the advice of a senior colleague; the patient died and Neale lost his practising privileges at the hospital. The provincial medical regulator launched an investigation and following this, Neale was given the option to either cease practising or to undergo further training. He elected the latter but soon left British Columbia for Ontario. In 1981, he was involved in the mismanagement of a woman admitted in the late stages of pregnancy for the induction of labour. He administered a dangerous combination of drugs and retrospectively adjusted the case notes. The patient in question died. In June 1982, an investigation was ordered by the College of Physicians and Surgeons of Ontario, the medical regulator in that jurisdiction, and by October 1983, a decision had been made to charge Neale with misconduct. In 1984, Neale abruptly resigned from membership of the college and returned to the United Kingdom, where he took up a substantive consultant appointment in Northallerton, Yorkshire. In June 1985, the Ontario medical regulator found Neale to be incompetent and removed his name from the Ontarian Medical Register. Neale did not disclose this himself to either his next employer in the United Kingdom or the General Medical Council.

The General Medical Council was informed of Neale's erasure in Canada via two routes in 1985/86 and took no action. Neale became established in practice in Northallerton, where his surgical skill was admired by colleagues. He made three applications for re-instatement in Canada between 1987 and 1992, and misled colleagues when making his request for references: the first two applications were unsuccessful, the third abandoned. In 1988, having made an application to become a police surgeon, Neale's background in Canada was examined by the police and, as a result, further representations were made to the General Medical Council. Again, no action was taken.

In 1991, Neale accepted a formal police caution (for conduct likely to cause a breach of the peace) following an incident in public toilets in Yorkshire. He was dishonest with the police at the time of his arrest. He was given a formal warning by his employer. The General Medical Council was informed of the police caution and elected to take no action.

In 1992, Neale was appointed Clinical Director for obstetrics and gynaecology within the new NHS Trust and also took on responsibility for clinical audit and risk management.

In 1993, stories appeared in the press concerning Neale's background and his erasure in Canada. An internal inquiry was held in Northallerton and Neale's management responsibilities were removed: he was robustly defended by the British Medical Association during this internal inquiry. In 1994, he started to look for work elsewhere. Concerns began to surface about his honesty and behaviour at work. In July 1995, Neale was suspended by the Trust on the basis of alleged irregular expense claims, non-availability when on-call, inappropriate leave and poor supervision of junior staff. In November 1995, the NHS Trust that employed him made the decision to negotiate Neale's departure.

Neale subsequently applied for a locum consultant post in Leicester and was provided with references which did not make explicit mention of his past history. Neale was dismissed from his locum appointment in Leicester, after an alleged altercation with a porter in a lift. He obtained a further locum appointment on the Isle of Wight, again with a supportive reference. In May 1998, the General Medical Council began formal investigation of the case and in July 2000, Neale was found guilty of serious professional misconduct and his name was subsequently erased from the Medical Register.

Matters arising from the case of Richard Neale

- 18** Whilst the focus of the inquiry into the conduct of Richard Neale was the effectiveness of local procedures for complaint handling in the NHS, the inquiry also sought to assess the level of concern as to his technical skills and clinical competence, following his return to the United Kingdom. It is clear that the number of formal complaints lodged about him was not extraordinary and, in addition, most of Neale's colleagues in Northallerton appeared to have confidence in him as a surgeon. Once the profile of his case had developed, numerous former patients did bring forward concerns. Many of the issues raised did not primarily relate to technical skills. Rather, patients took issue with the unrealistic expectations that Neale gave them when discussing proposed surgery, and his unsatisfactory performance in gaining truly informed consent. Some said that he was rude in manner or made inappropriate personal comments. A number did allege unacceptable operative and post-operative complications (and poor management thereof). Similarly, many of the comments made by staff, largely in retrospect, related not to technical skill but rather to dishonesty, unavailability and poor communication skills. Neale denied many of the complaints made in all of these respects and maintained that a full audit of cases would be the only way properly to assess matters.

- 19 The case of Richard Neale shines a spotlight onto the area of recruitment to medical posts: advertising, application procedures, interviews and the taking up of references. Questions that arise from it include the desirability, or otherwise, of standardised application forms with questions specifically relating to prior or current complaints and disciplinary actions. Neale's source of references was questionable throughout his medical career. The appropriateness of some of those references has also been examined in depth and the potential implications for a medical referee's own professional conduct is an important theme.
- 20 The negotiation of a legal settlement involving a payment in exchange for resignation in the case of a poorly performing doctor, with a confidentiality clause, raises the risk that future employers may be unknowingly putting patients at risk. It is clear that the balance struck between the employment rights of the individual, the convenience of the employer and the right of future patients to expect a safe doctor is an area that needs to be addressed.
- 21 At several points during Neale's career, there was a lack of resolve on the part of those in positions of authority to tackle issues with him in a direct and transparent way, and an inexplicable degree of leniency was shown at times.
- 22 Although now over 20 years ago, the General Medical Council's lack of investigation when informed of events in Canada raises a number of questions as to the relationship between the United Kingdom regulator and its international counterparts, particularly regarding the exchange of information.

The exchange of information between the General Medical Council and other international regulators in 2006

Registration

The General Medical Council now requests 'certificates of good standing' from other regulators in respect of doctors from Europe or further afield who wish to register for the first time with the General Medical Council, or re-register following a break. In addition, the General Medical Council provides almost 4,000 such certificates each year for its own registrants who wish to work overseas.

Fitness to practise

The General Medical Council routinely notifies its findings to 65 regulators in 34 countries. Although there is little alternative to this 'scattergun' approach, there is a significant danger of information overload, unless appropriate systems are employed to manage the receipt of notifications. The General Medical Council also receives notifications from regulators in 10 other countries. Since 2004, such information can be treated as evidence of impairment to practise without the requirement to prove the facts of the case once again.

The General Medical Council is a founding member of the International Association of Medical Regulatory Authorities and uses this forum to further the exchange of information.

- 23 When considering the General Medical Council's involvement in the 1980s with Richard Neale, a lack of standardised procedures and sub-optimal record keeping were features. These weaknesses have been addressed subsequently.
- 24 A further point raised by Neale's case is that of the boundary between the NHS and private care, a boundary that has become increasingly blurred in recent years. That a surgeon who has become essentially 'unemployable' within the NHS can find sanctuary in the private sector, again, raises concerns about patient safety, and draws attention to the need for sharing of data between sectors.

The case of William Kerr⁵

(Inquiry Chair: Nigel Fleming QC)

On 18 December 2000, William Kerr, a 75-year-old retired psychiatrist from North Yorkshire, was convicted of indecent assault, one of 19 charges brought against him by the Crown Prosecution Service. Kerr, by now suffering from cognitive impairment, was given an absolute discharge and his name was placed on the register of sex offenders for five years. In April 2001, Kerr applied for voluntary erasure from the Medical Register, a request granted in May 2003.

Kerr qualified in medicine from Queen's University, Belfast, in 1953. He undertook house officer posts in the city after working abroad, returning to Belfast as a senior house officer in psychiatry in 1961. It is alleged that in late 1964, Kerr saw a patient in her late teens with depression and anxiety and told her that sexual intercourse with him would help her condition. After sexual intercourse with Kerr in his car, the patient complained. Old records are incomplete but a disciplinary hearing may have been held. In any event, Kerr was apparently advised that if he wished to continue to practise medicine, he ought to leave Northern Ireland at once. In late 1964, he did so, moving to junior posts in psychiatry in Yorkshire, although references were not taken up. He subsequently became a consultant psychiatrist in North Yorkshire, where he practised for 20 years. He retired from the NHS in 1988, at the age of 63 years, and a letter of thanks was sent to him for the 'valuable contribution' that he had made to health services.

The inquiry discovered that during Kerr's time in the NHS in Yorkshire, 38 former patients made disclosures to NHS staff of sexualised behaviour by Kerr. Of the 30 concerns raised prior to 1983, only one resulted in any action. In 1979, a patient's general practitioner chose to discuss the concerns that she had raised with one Michael Haslam, a colleague of Kerr (and himself the subject of a later conviction for indecent assault of patients): he did nothing. In 1983, the allegations were brought to the attention of the authorities: a nurse raised concerns. No investigation took place and the nurse in question was forced to move post – a move that she felt related to the complaints that she had doggedly championed. It was not until February 1997 that a patient made a formal complaint to police in Harrogate, that Kerr had sexually assaulted her between 1982 and 1986, and an investigation was launched. During the course of these investigations and the subsequent inquiry, many other patients came forward with allegations.

The case of Michael Haslam⁶

(Inquiry Chair: Nigel Pleming QC)

On 12 December 2003, Michael Haslam, a 69-year-old retired psychiatrist, was convicted at Leeds Crown Court of four counts of indecent assault against his former patients, and one of rape. He was sentenced to seven years' imprisonment.

On 20 May 2004, the Court of Appeal quashed the rape conviction whilst upholding the other four. Haslam was released under licence in June 2005.

On 14 April 1999, the General Medical Council had agreed to Haslam's request for voluntary erasure from the Medical Register.

Michael Haslam undertook his clinical studies at St Bartholomew's Hospital, London, and qualified in medicine in 1959. Following house officer posts in Harrogate and a period of National Service, he trained in psychiatry. He became a consultant psychiatrist in Doncaster, moving to North Yorkshire in 1970, where he set up a psychosexual medicine clinic.

In the course of his practice, Haslam made use of a number of strange techniques, including carbon dioxide inhalation, 'Kirlian' photography and full-body massage. The massage in particular has subsequently been judged to have been grossly inappropriate, in that the patient was often naked and the massage took place without a chaperone. In 1988, following an allegation of sexual assault, Haslam was encouraged to retire from the NHS. No formal investigation took place at this time. Haslam was awarded an honorary NHS consultancy and continued to practise privately and to work in medical management.

An inquiry was carried out by the regional office of the NHS Executive in 1997, when some of the original patients raised their complaints again.

During the course of the police investigation launched in 1997 into William Kerr's conduct, a number of allegations were made against Haslam. At the time, there was not judged to be sufficient evidence for a criminal charge. In early 1999, *The Sunday Times* ran a story about the sexual abuse of psychiatric patients in York, referring to Haslam by name. Haslam launched a libel suit and, at this point, one of the patients who had complained about him agreed to provide a formal statement to the police in relation to an allegation of rape. Haslam was subsequently charged and his case came before Leeds Crown Court in 2003.

Matters arising from the cases of William Kerr and Michael Haslam

- 25** The sheer length of time for which the profession, and the NHS locally, collectively ‘harboured’ serious concerns, and the allegations of patients, is remarkable. The fact that Kerr’s behaviour at one point was brought, in good faith, to the attention of Haslam is a terrible irony.
- 26** There appeared to be a number of specific explanations for this, in addition to the prevailing NHS culture of deference to the status of senior doctors that is often cited. It is clear that people could not fully accept that doctors might abuse their patients, even in the face of mounting evidence. There was certainly an attitude that complainants who had mental health problems were unreliable witnesses. There was also a belief that without the presence of a patient willing to pursue a formal complaint, there was nothing that could be done. The particular vulnerability of this patient group makes the assaults still worse, likewise the massive abuse of trust.
- 27** The complaints system in place at the time, to the extent that there was one, was clearly neither patient-friendly nor capable of delivering patient safety.
- 28** The role played by local gossip and tacit knowledge is a striking feature of the analysis in the inquiry’s report. For example, in the mid 1980s, a female doctor, new to York, was warned to ‘watch out’, on account of Kerr’s ‘reputation with women’. The inquiry chair came to the conclusion that there were rumours circulating in York as early as 1974, particularly amongst the consultant community, that ‘Michael Haslam’s behaviour with patients was less than appropriate’.
- 29** On the occasions when complaints were brought to health service management, both in the hospital and beyond, the response was inadequate. No systematic enquiries were made to attempt to establish the facts or form a judgement. The easiest way out was often chosen – including, in Haslam’s case, the facilitation of early retirement from the organisation.
- 30** The courage and integrity of one health professional stands out very clearly from the story of William Kerr: a nurse, made aware of allegations of sexual impropriety through her counselling of a patient, took the issue to management and made repeated efforts, over a number of years, to ensure that it was handled properly. Whilst Kerr was thanked for his ‘valuable contribution’ to the NHS, the inquiry found that the career progression of this nurse was hindered by events.
- 31** During the 1970s and 1980s, a picture emerges of the consultant psychiatrists as all-powerful within the institutions in which they worked. They offered treatments unbeknown to managers, and allegations against them were not pursued. Juniors worried about the detrimental effect upon their own careers of ‘rocking the boat’.
- 32** Voluntary erasure from the Medical Register and the facilitation of early retirement as a way out feature strongly in this account. This is not always a mechanism through which patient safety can be assured. With regard to the General Medical Council, the issue is a more philosophical one: permission for voluntary erasure does offer a degree of patient safety and generally brings forward the time at which the name will cease to appear on the Register. However, for some patients, the avoidance of an appearance before the General Medical Council and the opportunity that this affords to air the evidence and have a judgement delivered is a mixed blessing.

Voluntary erasure

When a doctor applies to the General Medical Council for voluntary erasure, they are required to state whether they are aware of any concerns held by others over their fitness to practise or of any referrals that are likely to be pending. Corroborative information is sought from the doctor's current, or most recent, employer.

Where there is felt to be a potential fitness to practise issue in relation to the doctor, the General Medical Council's internal guidance demands that the decision maker takes into account the public interest, along with that of the complainant and the doctor. The guidance suggests that the General Medical Council should be very slow to grant voluntary erasure in such a situation, unless there are exceptional circumstances. In practice, such circumstances usually relate to a doctor's inability to mount a defence at a public hearing through serious illness.

A worldwide problem

- 33** It is important to remember that the poor performance of medical practitioners is not a problem unique to the United Kingdom, with other countries also having to face up to this challenging issue. Two examples follow, from Ireland and the United States of America.

Our Lady of Lourdes Hospital, Ireland

In January 2006, Judge Maureen Harding Clark presented her report on events between 1960 and the present day at Our Lady of Lourdes Hospital, Drogheda, to the Irish Government.⁸

Her inquiry had been triggered by concerns raised by two midwives during 1998 into the very high number of Caesarean hysterectomies performed there by consultant Dr Michael Neary. Caesarean hysterectomy involves the removal of the womb following delivery of a baby by Caesarean section, usually because of heavy blood loss that proves impossible to stem by other means.

The Lourdes Hospital Inquiry found that between 1974 and 1998, 188 hysterectomies were carried out around the time of childbirth, 129 of them by Neary. Most obstetricians are said to carry out between two and 10 such procedures during their whole career. This represented a rate that was 10-fold higher than for other hospitals in the region, and far in excess of rates published in the academic literature. It has been said that Neary had a 'morbid sensitivity' to haemorrhage, approaching 'phobic dimensions'.

Neary was initially suspended when the concerns came to light but returned to work following a brief peer-review of selected cases. Further reviews were undertaken on behalf of the Health Board and subsequently the Institute of

Obstetricians and Gynaecologists. Neary's registration with the Irish Medical Council was suspended in February 1999 by the High Court. His name was removed from the Medical Register in September 2003.

The story in the report is not just one of errant individual practice but rather one of a dysfunctional system and a problematic culture. There are clear parallels between events in Drogheda and those uncovered within the paediatric cardiac surgery service in Bristol. Both reports demonstrate that the regulation of individual practitioners and the sound governance of healthcare systems are intimately linked. Some of the major themes raised by the Lourdes Hospital Inquiry include the following:

- a hospital that was in a 'time warp' with an 'internal and external culture of isolation';
- a period of unquestioning submission to authority, whether religious or civil, where permanent jobs were few and treasured;
- consultants worked independently (essentially in a vacuum) where 'seniority' brought privileges but no extra duties or responsibilities;
- an absence of any system of clinical governance – no formal communication or feedback between surgeons, anaesthetists, pathologists and the multidisciplinary team, and a lack of departmental audit, teaching and management meetings;
- no routine collection and analysis of data – 'it was inconceivable to the doctors and most of the midwives who assisted Dr Neary that the hysterectomies on young women were anything more than bad luck';
- administrators who left the management of the maternity unit to the matron and consultants, in part on account of personality clashes;
- premises that were characterised as 'Dickensian' (until a new maternity unit opened in 1991);
- the prohibition of sterilisation in Drogheda (on account of the hospital's religious tradition), despite the choice offered in other hospitals, and the difficulties this caused, as demonstrated by ongoing communication between the consultants, their defence organisations, the Health Board and the Irish Department of Health;
- initial informal peer-review that was flawed and motivated by compassion and collegiality;
- deficits in the training programme offered to obstetric registrars had been noted by the Royal College of Obstetricians and Gynaecologists, yet recommendations were not implemented.

The case of Dr Michael Swango: the perils of fragmented regulation

Michael Swango was born in 1954, qualified in medicine in the spring of 1983 and entered a residency programme in Ohio, in the United States of America.

A short time later, the suspicious death of a patient attended by Swango was reported by a member of the nursing staff. An investigation was launched but no charges were brought. The next year, Swango's contract was not renewed but hospital authorities did recommend that Swango should be licensed to practise medicine in the State of Ohio. Subsequently, the Ohio Medical Board facilitated his licensing in Illinois.

Swango took up employment as a paramedic in Illinois in 1984. He was arrested, charged and convicted of poisoning his colleagues with arsenic-laced doughnuts. He was sentenced to five years in prison.

A few years after his early release, Swango applied to enter a residency programme at the University of South Dakota, telling the programme's director about his previous licence suspension on account of a conviction for an incident 'unrelated to medicine', that was described in vague and misleading terms. Regulatory authorities in Ohio were not willing to divulge details to the hospital staff unless waivers were signed by all parties. Swango was taken at his word, and he was appointed to the residency programme in South Dakota.

When reports of Swango's previous activities in Ohio came to the attention of staff in South Dakota, he was dismissed.

He went on to take up another post in New York State, where two patients soon died through poisoning. Authorities in South Dakota contacted their counterparts in New York, who issued a letter warning of Swango's history to over a hundred medical schools and over a thousand teaching hospitals.

Swango obtained a post in Zimbabwe. Two patients were found poisoned and Swango was again dismissed. Using a false curriculum vitae, Swango went on to obtain a post in Saudi Arabia.

Passing through Chicago airport in 1997, Swango was arrested and was sentenced to three and a half years in prison for making a false statement. Whilst in prison, an investigation took place and Swango was tried for murder, being found guilty of three counts. He was sentenced to life imprisonment without the possibility of parole.

Sources: various

Conclusions

- 34** The three inquiries cumulatively spent many years examining evidence, hearing from witnesses and arriving at conclusions. Their collected reports to the Secretary of State for Health, at a total cost in excess of £7 million, run to over 1,600 pages.
- 35** In considering the ‘diagnoses’ of the problems posed by the misconduct and poor practice of the doctors investigated in the three inquiries, there are many similarities to other past cases and strong echoes of the analysis of the systems dysfunctions outlined in *Supporting doctors, protecting patients*.⁷ It is fair to say though, as in *The Shipman Inquiry: fifth report*, that the ‘landscape’ in respect of dealing with poor clinical performance has changed since the 1980s and early 1990s, when the doctors subject to the three inquiries were firmly ensconced in senior posts within the NHS.
- 36** Clinical governance has been established. The National Clinical Assessment Service has helped local NHS employers to identify problem doctors earlier and find definitive solutions. There have been major reforms and improvement to the General Medical Council’s ways of working and statutory procedures.
- 37** Whilst the culture of the NHS is now more open and much less willing to accept or tolerate aberrant behaviour and unsafe practice, it is always possible for an individual health organisation to develop the kind of inward looking ‘club culture’ where such situations could recur. That is why the findings of the three inquiries, The Shipman Inquiry, and the Bristol Inquiry before them, must constantly be reinforced. An adverse culture in a hospital, a general practice or a mental health service does not just create a poor environment for the quality of care, it can actively cause harm to patients.
- 38** A number of other important areas for action emerge from the work of the three inquiries.
- 39** The manner in which complaints have been, are being and should be handled by health services is a recurring subject: the importance of transparency in the complaints process; the need for an accessible and user-friendly system; comprehensive training in the management of complaints; the sympathetic handling of complainants; and the protection of complainants who are especially vulnerable. A particular concern is that NHS managers and clinicians should realise that a complaint can be addressed even if the complainant is initially reluctant to pursue it.
- 40** The use of references in health services is a recurring theme and raises a number of important issues that need to be further addressed, including: the appropriateness of referees and their relationship to an interviewee; the honesty and transparency of the reference itself; the use of a ‘gagging clause’ in agreements between employers and former employees; the concept of ‘certificates of good standing’ with other regulators and bodies; and that the taking up of references should be mandatory.

41 The whole question of how information is gathered, held, organised and shared is a key feature of the cases analysed in the three inquiries. In relation to poor clinical performance, it is important that there is a concept of ‘one NHS’. It is not acceptable for information about serious concerns in a doctor’s practice being held by one employer to remain hidden so that another NHS employer may unwittingly be placing patients at risk. The role of so-called ‘soft intelligence’ or tacit knowledge about a doctor’s problems is particularly contentious. Some say soft intelligence should play no part unless it results from a formal investigation, yet it is clear that if concerns that were below the surface about some of the doctors in the three inquiries had surfaced and been reviewed, action to protect patients might have been taken earlier.

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Chapter Four:

The General Medical Council

Key points in this chapter

- The General Medical Council – the main regulatory body for doctors in the United Kingdom – was established by Act of Parliament in 1858.
- The General Medical Council has four main statutory functions, covering: the setting of standards for good medical practice; assurance of the content and quality of basic medical education; the running of the registration and licensing system for doctors; and the handling of complaints and concerns about doctors' fitness to practise.
- Medical regulation was last comprehensively reviewed by the Merrison Committee which, having been established in 1972, reported in 1975.
- Following an initial period of calm after the Merrison Report, criticisms of the General Medical Council resurfaced through the 1980s and early 1990s as a result of high-profile failures of standards of care and the analysis of influential commentators.
- The General Medical Council led a series of reforms to its structure and functions from the late 1990s to the early 2000s, including reduction of the Council's size, an increase in the proportion of lay members, more public information and simplification of fitness to practise procedures.
- A key element of the recent reforms proposed and introduced by the General Medical Council was the concept of revalidation, in which all doctors' continuing fitness to practise would be checked every five years.
- In *The Shipman Inquiry: fifth report*, the Inquiry's Chair, Dame Janet Smith, criticised the General Medical Council for 'watering down' the original concept of revalidation, sustaining a culture that was not sufficiently patient centred, having procedures that were flawed and overly complex and maintaining too high a standard of proof in order to remove a doctor from practice.
- The debate and consultation stimulated by my review and the findings and conclusions of *The Shipman Inquiry: fifth report* make clear that the present structure and functioning of the General Medical Council remain unsatisfactory and that the current approach to revalidation will not work effectively.

- 1 The last major review of the role, structure and functions of the General Medical Council was carried out by Sir Alec Merrison.¹ His Committee of Inquiry first met in March 1973 and reported in April 1975; in 1979, following the passing of the Medical Act 1978, some (but only some) of its recommendations were implemented.
- 2 The affairs of the General Medical Council continue to attract the interest of the public and the profession. A web-based discussion forum dedicated to the General Medical Council has been said to attract as many as 25,000 visits a month from doctors.²

Early history

- 3 Between 1840 and 1886, there were over 50 legislative attempts in England and Wales to address aspects of medical regulation. The drivers of this flurry of activity were two-fold.^{3,4} Firstly, there was the arrival of a large new group of doctors, predominantly in the provincial towns and countryside: the general practitioners. Given the range of services that these doctors were expected to provide, they did not sit easily with the traditional tripartite system of physicians, surgeons and apothecaries. Secondly, the Poor Law (Amendment) Act 1834 included a provision for the appointment of medical officers (in the districts) and medical attendants (in the workhouses). A clause specified that appointees should be ‘duly licensed’. In 1842, the Poor Law Commission strictly defined a limited number of acceptable qualifications; Scottish qualifications were excluded, lending extra impetus to the movement for change.
- 4 The General Medical Education and Registration Council of the United Kingdom (known formally as the General Medical Council since 1951) was eventually established by the Medical Act 1858 with the following functions:
 - the oversight of medical education and the examinations leading to qualification;
 - the registration of qualified practitioners and the publication of the Medical Register;
 - the removal from the Register of practitioners convicted of felony (section 29);
 - the prosecution of unqualified practitioners who had presented themselves as licensed;
 - the publication of a British pharmacopoeia.
- 5 The first three of these functions remain core to the work of the General Medical Council today.
- 6 Professional conduct was referred to only in passing by the 1858 Act. Dealing with poor professional conduct was not seen as a core function of the Council, with scant reference being made to section 29 of the Act in parliamentary records (*Hansard*) for 1858.

“If any registered medical practitioner shall be convicted in England or Ireland, of any felony or misdemeanour, or in Scotland of any crime or offence, or shall after due enquiry be judged by the General Council to have been guilty of infamous conduct in any professional respect, the General Council may, if they see fit, direct the registrar to erase the name of such a medical practitioner from the Register.”

Extract from section 29 of the Medical Act 1858

- 7 There were a number of obvious deficiencies in the Act: there was no formal recognition of the general practitioners, nor was dual qualification (in medicine and surgery) a requirement for registration. With 22 different diplomas permitting registration (in addition to the numerous domestic and overseas degrees permissible for those already in practice), there was no meaningful quality assurance. The Council’s supervision of medical education was indirect, with much power retained by colleges and universities (following a last minute change to the Bill). Nonetheless, the substance of the Medical Act was generally welcomed by the profession, attracting favourable comment in the medical press.⁵

“An Act, which whatever be its shortcomings, will collect the scattered sheep of the profession into one fold, and put on them – as far as law can so do – a mark by which they may be known from pretenders.”

Source: British Medical Journal, 1858

- 8 Before long, there was evidence of dissatisfaction with the workings of the General Medical Council, centred largely upon its perceived reluctance to deal robustly with incompetent and unqualified practitioners. The Register itself was in short supply and was therefore difficult to consult: a court case in Halifax was abandoned in 1861 because a copy of the Register could not be found. On the few occasions that the new Council did attempt to flex its muscle, the results were unsatisfactory. For example, the General Medical Council produced a definition of medical education such that informal ‘apprenticeship’ would cease: the Royal College of Surgeons of England completely ignored the edict. In February 1870, a petition (containing the signatures of almost 10,000 registrants) was presented to the General Medical Council demanding wholesale reform. Amongst the more vocal critics was Archibald Jacob, who published a damning critique in 1880.⁶

“The outcry of the profession has always been for the maintenance of such a standard of education as would ensure that medical men should be gentlemen and know their business... In every town in the Kingdom, medical men are feeling the difficulty of holding up their heads as gentlemen and making a living of their profession in consequence of the competition of quacks, chemists and unqualified assistants.”

- 9 This period also saw the birth of the medical defence organisations. Initially, they were developed to bring forward prosecutions against the unregistered (before the General Medical Council or the courts) as the General Medical Council had failed to be proactive in this area. In 1885, the Medical Defence Association was founded for the personal defence of individual practitioners: the other organisations generally merged (or collapsed) into it.
- 10 Despite such concerns, and a Royal Commission in 1882, the General Medical Council remained largely unchanged until the middle of the 20th century, although the Medical Act 1886 did establish a requirement for dual qualification and stipulated that five Council members were to be elected directly by registrants. The criticism of the General Medical Council had not been without foundation, with John Marshall (the Council President in 1889) stating that ‘it should not seem to be over anxious to be at work’. His predecessor as President, Henry Acland, shared the more general frustration about the organisation’s mediocre start.

“Much fruitless labour, with loss of time to Council and Parliament, and some loss of character to the profession.”

Henry Acland (President 1874–87) of the period 1870–86

- 11 Nonetheless, the General Medical Council continued to hear a modest number of cases under section 29, some of which were more bizarre than others.

Selected charges under section 29 of the Medical Act included:

- maintaining an indecent wax anatomical museum (1864);
- kidnapping Fijian natives (1884);
- advertising secret remedies (1884);
- publication and distribution of ‘the wife’s handbook’ [on birth control] at so low a price as to bring the work within reach of the youth of both sexes, to the detriment of public morals (1887);
- wrongful detention of a female patient of unsound mind in a chicken house in Palestine for five months (1939).

- 12 With a new Medical Act in 1950, the workload of the General Medical Council expanded. The pre-registration house officer year was introduced (along with provisional registration), as well as a new power to visit medical schools (and not just inspect their examinations). In the 1960s, the General Medical Council needed more money because of higher numbers of registrants, an increase in misconduct proceedings and high levels of inflation. The Medical Act 1969 introduced the annual retention fee to meet this need. The Act also replaced the term ‘infamous conduct in any professional respect’ with the soon to be equally controversial term ‘serious professional misconduct’.

The 1970s crisis of confidence in the General Medical Council

- 13 In the early 1970s, following a decade of profound social change and at a time of marked economic difficulties, the medical profession turned decisively against the General Medical Council. A crisis in November 1972 (described in detail below), forced the then Health Secretary, Sir Keith Joseph, to set up the Merrison Inquiry, charged with considering what changes needed to be made to the General Medical Council in order to move forward.
- 14 This crisis was precipitated by the level of the annual retention fee (proposed at £3, negotiated to £2), introduced by the Medical Act 1969. However, there were more deep-seated concerns that led to a loss of confidence in the General Medical Council.
- 15 A growing body of medical opinion held that the General Medical Council did not represent its registrants. Whilst the sense of disenfranchisement was felt most acutely by the general practitioners, an increasing number of consultants were working in the regions, so there was a general antipathy towards the ‘establishment’ in London which was seen to be running the General Medical Council. Nevertheless, the establishment too was dissatisfied with events: the Royal Commission on Medical Education of 1968 (published as the Todd Report) had proposed that the General Medical Council should have oversight of specialty training, previously the domain of the colleges.⁷

- 16** The Royal College of General Practitioners led the charge. The College had long recognised the issue of poor performance and, armed with a fresh concept of professionalism, sought to formalise and raise the quality of education and training in general practice. Measures would include putting general practice in medical undergraduate curricula, quality assuring general practice trainers and establishing compulsory vocational training schemes for general practice trainees. The Royal College of General Practitioners also embraced the new concept of medical audit. The public line taken by the British Medical Association's then Chairman, James Cameron, did not help matters: "There is no such thing as a bad general practitioner."⁸ The College saw the General Medical Council as failing to support its initiatives to tackle poor practice. The General Medical Council had made recommendations to modernise the medical undergraduate curriculum, but showed no signs of implementing them. There was no seat for the Royal College of General Practitioners on the General Medical Council and no formal recognition of the College membership examination, the MRCGP.
- 17** Another important concern was the inability of the General Medical Council (as then constituted) to differentiate between sick doctors and bad doctors, 'serious professional misconduct' being the only route to deal with poor performance arising from ill health.
- 18** As a protest over these issues, substantial numbers of doctors refused to pay the General Medical Council's annual retention fee. In November 1972, the General Medical Council voted to strike from the Register the names of those who failed, following repeated warnings, to pay their retention fee. As a result of this action, the Government was forced to act and the Merrison Inquiry was commissioned.

The Merrison Committee

- 19** Merrison's 15-strong committee reported in 1975. It presented a raft of considered and varied proposals, addressing the issues of registration, education and fitness to practise. The Committee supported the concept of regulation that was largely self-directed.

Key recommendations of the Merrison Committee included:

- two-tier registration: the general register (restrictive) and the introduction of an indicative 'specialist' register on completion of higher training;
- improvements to the pre-registration year;
- the General Medical Council, and not the Government, to be the proper arbiter in assuring the quality of doctors from overseas (through limited registration);
- new health procedures to improve the fitness to practise machinery;
- marked enlargement and restructuring of the Council, with a majority of elected members.

- 20** The Merrison Committee did consider the concept of re-licensure, but concluded that it was too significant a change in approach at that time. Merrison noted that a separate inquiry had been set up by the profession to consider this very issue, and was ongoing (under the chairmanship of Sir Anthony Alment).⁹

- 21** The Merrison Committee arrived at a number of other key conclusions that had a powerful influence in the decades that followed. It rejected the development of a series of written standards or a code against which the General Medical Council would operate, fearing that a formal code would restrict the Council in its activities and create ‘loopholes’ for poor doctors to exploit. The Committee also addressed the issue now termed ‘whistleblowing’, and expressed the firm view that the introduction of a statutory duty to report the misconduct of colleagues was impracticable and undesirable, the role of the informer being described as ‘too uncongenial’. The absence of written standards at the General Medical Council has troubled many commentators over the years, and the reluctance of doctors to report their miscreant or incompetent colleagues is a recurring theme in inquiries examining the circumstances of medical scandals.
- 22** The medical profession agreed with the changes to the composition of the General Medical Council (see figure at the end of Chapter Four) but was less united on other proposals. The Government agreed in principle with the majority of the recommendations, although it was only after some time, and following some dilution, that they were presented to Parliament. Following significant strengthening and amendment in the House of Lords, the key Merrison proposals passed into law as the Medical Act 1978.

More criticism

- 23** The Merrison Committee allowed important principles about the regulation of the medical profession to be aired and largely resolved. However, partly because of its terms of reference and partly because of the prevailing culture, the work of the Committee was centred firmly upon the medical profession. The patient’s interests were largely peripheral to proceedings.
- 24** The new form of medical regulation introduced by the post-Merrison Medical Act 1978 had barely got going when the implications of changing attitudes in society came home to roost.
- 25** The death of deference was moving closer and the medical profession provided a striking illustration. Professor (now Sir) Ian Kennedy delivered the BBC Reith Lectures in 1980, under the title *The unmasking of medicine*.¹⁰ His powerful critique focused upon the secrecy with which concerns about a doctor’s performance were dealt, the resulting lack of transparency and the lack of meaningful scrutiny or accountability. Kennedy expressed concern that the scale of the General Medical Council’s disciplinary function appeared to be determined by resources, as opposed to need. He also advocated a system of ‘re-registration’ to ensure ongoing fitness to practise. Kennedy was subsequently appointed to the General Medical Council in 1984 as a lay member.
- 26** Events, too, challenged the prevailing system. A landmark case in 1982 was the death of a child, Alfie Winn, in circumstances that were the antithesis of good medical practice (see box below).
- 27** Jean Robinson published a pamphlet drawing heavily upon her nine years as a lay member of the Council.¹¹ This cast light on the inner workings of the Council, lending weight to the widely held perception of the General Medical Council as a rather secretive and mysterious organisation. It also raised a number of more philosophical questions as to the propensity of a body, elected by the profession, to protect the public interest. Kennedy, Robinson and others such as Rudolf Klein

encouraged observers, and the General Medical Council itself, to see medical regulation from the viewpoint of the consumer – the patient.¹² The Assistant Editor of the *BMJ*, Richard Smith, furthered the debate with a series of hard-hitting articles over the summer of 1989.¹³

The Case of Alfie Winn

Alfie's doctor had visited him at home at the request of his mother. Alfie was comatose and had a high fever, but when his mother suggested to the general practitioner that the boy could not hear him, the general practitioner replied: 'If he can't be bothered to open his bloody mouth, I shall not bloody well look at him.' The general practitioner did prescribe an antibiotic. However, in addition to this gross rudeness and disrespect, he failed to arrange specialist care for Alfie, who died four days later from meningitis. The General Medical Council, whilst critical of the doctor's practice, did not feel that it amounted to serious professional misconduct. Alfie's mother twice assaulted the doctor in question but was given an absolute discharge by the courts. A short time later, the same doctor appeared before the General Medical Council once again for another matter and was this time found guilty of serious professional misconduct. A public outcry followed, as did a fiercely critical Private Member's Bill, brought by Nigel Spearing MP. The House of Commons became very interested in the running of the General Medical Council.

- 28** A third lay member of the General Medical Council was integral to this powerful but constructive onslaught against the Council, spearheaded in public by Kennedy and Robinson.
- 29** Margaret (Meg) Stacey, professor of sociology at Warwick University, served on the Council between 1976 and 1984. Twenty years or more ahead of her time, Stacey recognised many of the issues that face the world of medical regulation today. *Regulating British medicine* was published in 1992.¹⁴ In it, Stacey recognised that the ability of the General Medical Council to regulate medical practitioners depended upon the unity of the profession, the belief of the profession that regulation was rightfully the business of the General Medical Council and the confidence held by the profession in the General Medical Council to perform the task. She described medicine as a 'brotherhood', displaying an unrivalled degree of solidarity despite being the most hierarchical of professions: there was an instinct to 'keep the sheep in the fold' (this remark furthered an analogy originally drawn by the *British Medical Journal* in 1858).
- 30** Stacey identified five themes:
- professional unity versus public responsibility;
 - clinical autonomy versus competence to practise;
 - control of educational standards;
 - the relationship between the General Medical Council and the Government;
 - the relationship between the General Medical Council and the profession.

- 31 These themes remain fresh and relevant a decade and a half later and are central to the deliberations of my report.

“Doctors cling to certain tenets of professionalism which blind them to the realities of contemporary medical practice.”

Stacey M. *Regulating British medicine: the General Medical Council.* Wiley, Chichester, 1992

Reforms to medical regulation in the 1990s and beyond

- 32 Following on from the criticism levelled by both the profession and lay commentators, and stimulated by the response of Government and the press to a number of emerging medical scandals, through the 1990s, the General Medical Council began to shift its emphasis. In many important ways, the organisation refocused.
- 33 The changes that took place during this period were quite fundamental, accomplished only after a fierce struggle between traditionalists and modernisers, both within the General Medical Council and outside. The General Medical Council eventually committed itself to put in place three crucial pillars, through which the organisation would deliver good doctors and thus guarantee safe care. These pillars were:
- a set of standards to define that which is expected of a doctor (*Good medical practice*, 1995);¹⁵
 - a framework to ensure that medical education delivers doctors who meet these standards (*Tomorrow's doctors*, 1993);¹⁶
 - a proactive system to ensure that doctors continue to meet these standards throughout their working lives (revalidation).
- 34 Other important reforms in this period were:
- the establishment of a new strand of fitness to practise, addressing performance in addition to serious professional misconduct and ill health (1995);^{17,18}
 - the publication of the pamphlet, *Maintaining good medical practice*, establishing links between the individual doctor and the process of clinical governance (1998);¹⁹
 - the power to suspend doctors from practice on an interim basis in order to protect patients pending the outcome of investigation (2000);²⁰
 - a further reduction in the size of the Council and changes to its composition (to increase the proportion of lay members) (approved in 2002);
 - distancing of Council members from the day-to-day work of the organisation – the Council now appearing more akin to a board of governors, wielding less executive power (approved in 2002);
 - simplification of the fitness to practise procedures (see box below) (approved in 2002);
 - enhanced public access to information about individual registrants (2005).

Changes to the fitness to practise procedures approved in 2002

The fitness to practise procedures operated by the General Medical Council were simplified by the 2002 Amendment Order. Prior to November 2004, there were three stages in the handling of complaints about doctors: screening, preliminary proceedings and appearance before a professional conduct committee. These stages occurred within any one of three streams and complaints were defined as primarily concerning conduct, health or performance. Once allocated to a stream, the complaint remained there. Now, however, there is a unified approach to fitness to practise, with one stream only and two stages: investigation and adjudication. In addition, the long-criticised term 'serious professional misconduct' has now been replaced by 'impairment of fitness to practise'.

- 35 In the late 1990s, the General Medical Council returned to the question of re-licensing of doctors and took the initiative to create a process of revalidation in order to achieve this.
- 36 The beginning of the new millennium marked an even more challenging time for the General Medical Council, with a concentrated period of adverse publicity for the medical profession and its regulator. In addition to the ongoing public inquiry into the paediatric cardiac surgery service in Bristol, the case of Shipman and other medical scandals came to light. Over the years that followed, it has been argued by some that the General Medical Council appeared to step back from the promising vision of regulation it had offered in the late 1990s.

Role, structure and functions of the General Medical Council today

- 37 In 2006, the General Medical Council continues to base its activities around the four main statutory functions defined by the Medical Act 1983 (which, as amended, remains the relevant primary legislation).

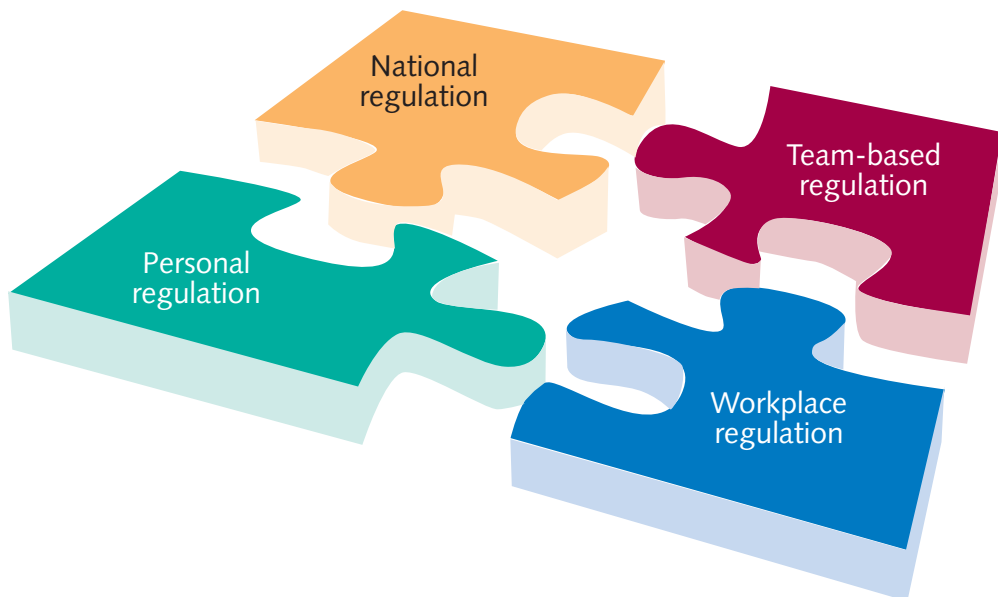
Key functions of the General Medical Council

- Setting the standards of good medical practice which society and the profession expect of doctors throughout their working lives.
- Setting the content of basic medical education and assuring its quality, promoting high standards and coordinating all stages of medical education.
- Administering systems for the registration and licensing of doctors to control their entry to, and continuation in, medical practice.
- Dealing firmly and fairly with doctors whose fitness to practise is questioned.

- 38 The General Medical Council offers two models to describe its modern approach to regulation: the four layers of regulation (relying on contributions from the individual, team, employer and regulator) and the concept of risk-based regulation, whereby the regulatory efforts of the General Medical Council are concentrated in areas where risks are higher or a supervisory framework is lacking. The illustrations below are based upon a presentation given to my advisory group by the General Medical Council.

Four layer model

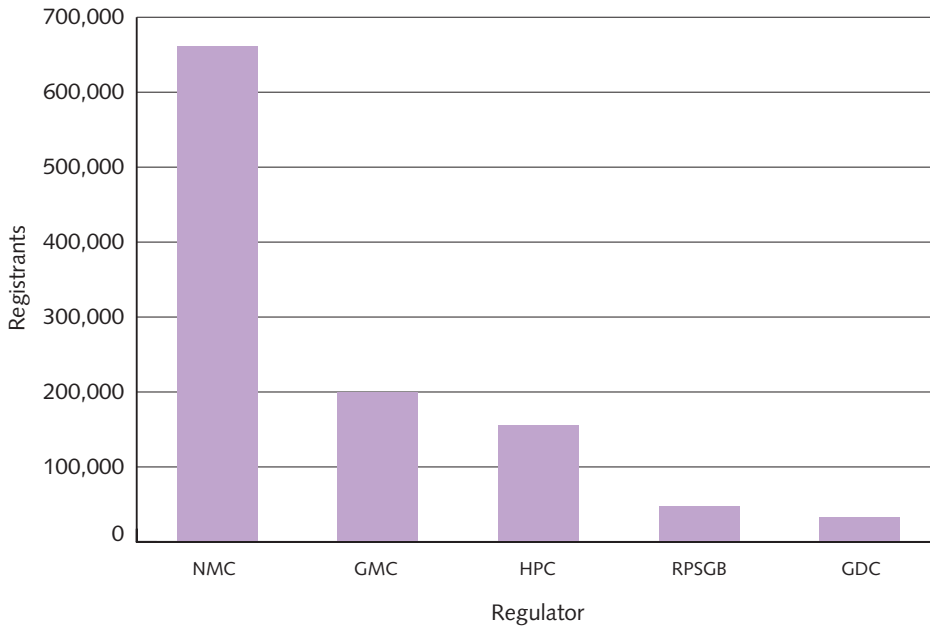
Doctor practising in a GMC approved working environment			
Personal regulation	Team-based regulation	Workplace regulation	National regulation
Collects folder of evidence	Provides 360-degree feedback	Operates a quality assured appraisal scheme	GMC generic principles (<i>Good medical practice</i>)
Reflects on practice through participation in appraisal	Patient surveys	Operates effective clinical governance systems	GMC guidance on folder content
Submits completed revalidation submission	Action when a colleague's conduct, performance or health puts patients at risk	Provides local certification	College specialty related standards and evidence
		Prompt and effective action if actual or emerging impairment	GMC approves working environments
			Prompt and effective action to deal with impairment



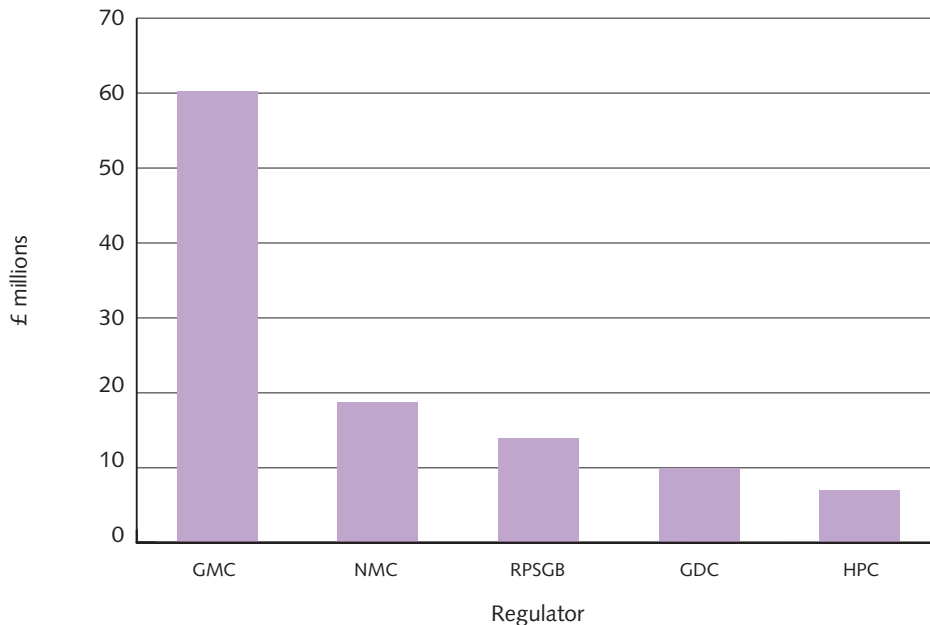
39 In its early years, the Register maintained by the General Medical Council contained the names of between 15,000 and 20,000 practitioners. The General Medical Council's recurring annual income, once the initial queue of those seeking registration had been cleared, was around £7,000.

40 The General Medical Council’s machinery has grown very substantially since the 19th century and so too has the size of the task facing the organisation. The number of doctors on the Register has increased more than ten-fold since its inception. In 2005, the organisation had an expenditure in excess of £67 million and employed around 400 staff at offices in London and Manchester. The budgets of, and the numbers of registrants handled by, some of the other health regulators are shown below.

Regulators of health professions: approximate number of registrants



Regulators of health professions: approximate budgets



Data from Council for Healthcare Regulatory Excellence Annual Report And Accounts 2004/05

Key

GMC	General Medical Council	GDC	General Dental Council
NMC	Nursing and Midwifery Council	HPC	Health Professions Council
RPSGB	Royal Pharmaceutical Society of Great Britain		

- 41 At present, the annual retention fee payable by fully registered doctors is £290. The fee for initial provisional registration is lower. The annual fees paid by other health professionals to their respective regulators in 2005 varied between £43 and £1,000.

Annual fees paid by health professionals on the register of their regulatory body

Regulatory body	Retention fee (£) (2005)
General Medical Council	290
General Dental Council (dentist)	409
General Dental Council (hygienist)	68
General Optical Council	169
Nursing and Midwifery Council	43
Royal Pharmaceutical Society (pharmacist)	267
General Chiropractic Council	1,000
General Osteopathic Council	750
Health Professions Council*	60

*Physiotherapists, occupational therapists, radiographers and 10 other professional groups.

- 42 In addition to its domestic work in relation to education, the General Medical Council administers the PLAB (Professional Linguistics Assessment Board) examination for doctors with primary qualifications gained outside the European Union who are seeking admission to the Register. The modern design of the examination is held in high regard. The £5 million spent on this enterprise is recouped from candidates.

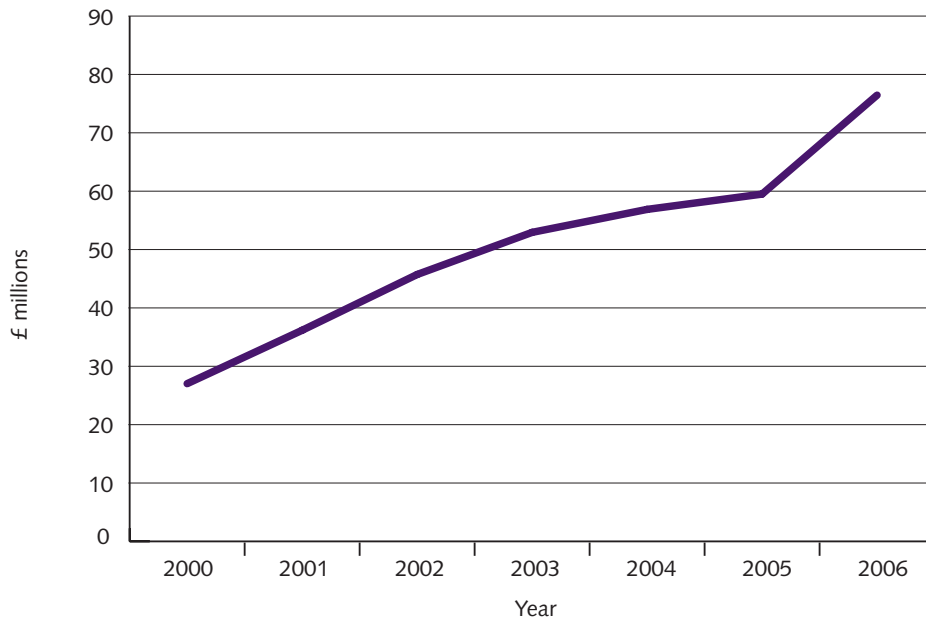
The PLAB examination

The PLAB test has been criticised in recent years on the grounds that it may give those overseas doctors who sit it unrealistic expectations of obtaining a job in the United Kingdom. In response, the General Medical Council took a number of actions to better inform potential applicants of their employment prospects. As a result, between 2004 and 2005, there was a 29% drop in the number of candidates sitting part 1 of the examination. Of those doctors passing the PLAB examination during 2004, 82% took up limited registration (and by implication, a post of some type and duration) within the next 12 months.

43 Analysis of the General Medical Council's expenditure and various activities over the last five years shows that in common with the other health regulators, it devotes a high proportion of its resources to fitness to practise proceedings (estimated at 45% for 2006). The analysis also shows that:

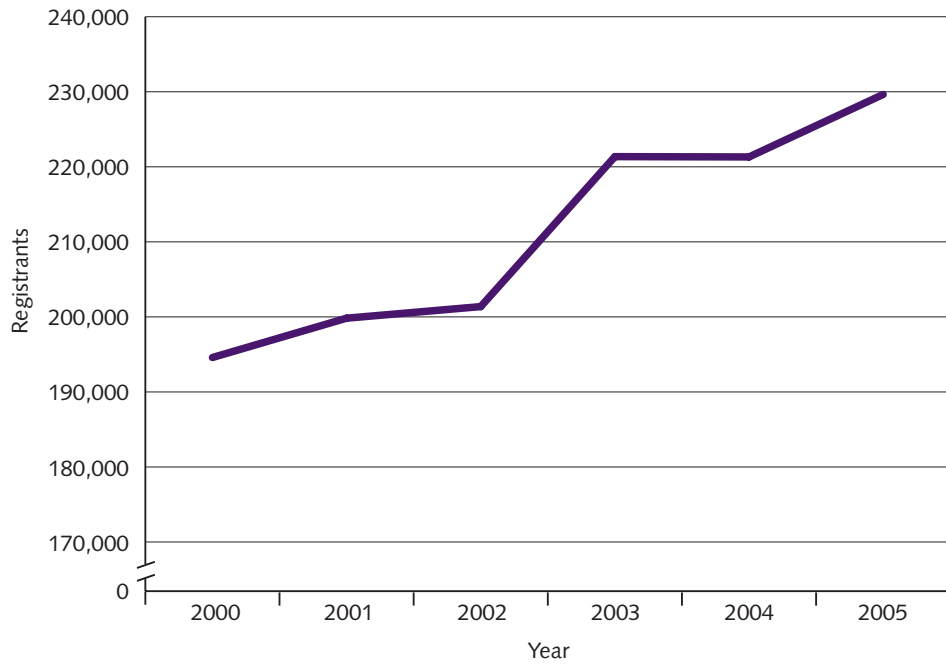
- the General Medical Council's budget more than doubled over the five-year period 2001–06;

General Medical Council budget



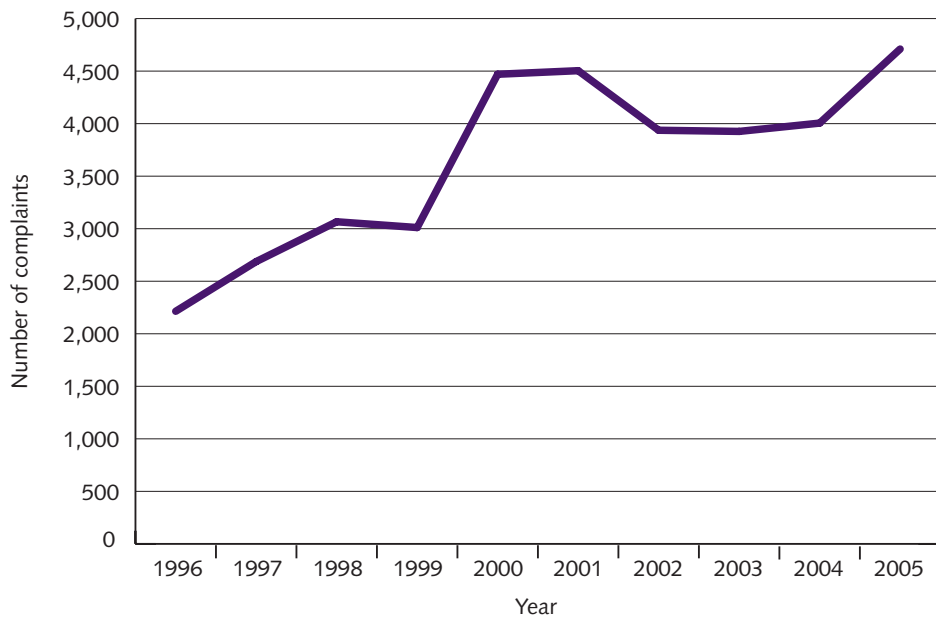
- the number of doctors graduating from United Kingdom medical schools (for which the General Medical Council is responsible) increased by 17% over the five-year period 2000–05;
- the number of doctors gaining registration for the first time increased by 16% over the five-year period 2000–05;
- the graduates of United Kingdom medical schools in 2005 accounted for 52% of new registrants that year;
- the Medical Register held the names of 229,644 medical practitioners at the end of 2005, an increase of 18% on the figure for the year 2000;

Total number of doctors on Medical Register



- the number of fitness to practise complaints received by the General Medical Council has tended to rise over the last decade and the number of complaints received in 2005 was more than double that for 1996.

Number of complaints lodged with the General Medical Council regarding fitness to practise each year



- 44 The General Medical Council also gave me access to audited figures of their fitness to practise activities. These are presented in Chapter Five.
- 45 Since 2001, the General Medical Council has adopted service standards for the time taken to reach decisions on a case. Over the years, the nature of the standards, the targets and indeed the procedures themselves have changed, making year-on-year comparison difficult. However:
- in 2001, a preliminary decision (to dismiss or proceed) was made within six months in 70% of cases (target 80%), but only 14% of cases referred on to the professional conduct committee had been heard a year later (target 100%);
 - in 2003, a preliminary decision (to dismiss or proceed) was made within four months in 88% of cases (target 90%), and 100% of cases referred on to the professional conduct committee had been heard a year later (target 100%);
 - in 2005, the aim of the General Medical Council was that the investigation process should be complete in 100% of cases by six months (achieved in 85% of cases) and that the adjudication process should be complete in 100% of cases eight months later (insufficient numbers to report).

The evolution of the concept of revalidation

- 46 To date, the maintenance of ongoing registration has been based upon having previously attained a recognised primary medical degree, having avoided suspension or erasure and (since the Medical Act 1969) having kept up to date with payments of an annual retention fee. It has long been argued that these conditions alone are inadequate to ensure continuing fitness to practise. In 1975, the Merrison Committee discussed the concept of a continual process of re-certification or re-licensure but did not recommend change to the status quo. The following year, Sir Anthony Alment's Committee, set up under the auspices of the British Medical Association, considered the same issue. They were well-disposed towards medical audit in general and towards the possibility of a voluntary system of re-licensure, but their report had little impact. Ian Kennedy revisited re-certification in his Reith Lectures.
- 47 In 1998, the General Medical Council President, Sir Donald Irvine, returned to re-certification and initiated discussion amongst Council members, with the Royal Colleges and the other leaders of the profession, about a system of intermittent revalidation. In this concept, registration would continue, but a licence to practise would be introduced. It would be this licence and not registration per se that would carry the privileges associated with being a doctor. The licence would expire after a period and renewal could only occur following satisfactory completion of a process of revalidation. In this way, continuing fitness to practise would be assured.
- 48 The original vision of revalidation, as it emerged in 1998, foresaw an assessment of the individual practitioner against defined standards (both generic and specific to the practitioner's field of work), making use of data drawn from the newly introduced framework of clinical governance. During 1999, the General Medical Council held further positive discussions about revalidation and a number of the Royal Colleges made a start in defining the standards for their specialities.

- 49** A local revalidation panel, with lay representation, was to be responsible for the assessment of each doctor. A public consultation took place during 2000. Simultaneously, it became apparent that opposition was mounting within the British Medical Association's consultants committee. In October 2001, the General Medical Council stated its intention that the revalidation groups would consider a number of documents resulting from appraisal as the prime evidence, examining the full folder only in selected cases. December 2002 saw the passage of the Medical Act (Amendment Order) enabling the introduction of revalidation.
- 50** In April 2003, following a number of piloting exercises, the General Medical Council changed tack once again, now proposing that for doctors working in 'managed environments', the fact of participation in appraisal would become the trigger for revalidation. The submission of a 'clinical governance certificate' from the employer was a later addition. By 2004, revalidation (on a five-yearly basis) would involve a statement from a doctor's employer, confirming the lack of any significant concerns and documentary evidence of participation in an annual process of peer-appraisal. The detailed work on standards had not progressed and the revalidation panels (along with their lay members) had disappeared. Furthermore, the consequences of failing to revalidate were not made explicit: would a practitioner have to cease to practise, or would they 'limp on' in sub-standard practice, through to the next revalidation cycle?
- 51** It was this incarnation of revalidation that attracted criticism from Dame Janet Smith in the fifth report of her inquiry into the murders committed by Dr Harold Shipman. The concerns of Dame Janet and others led to the postponement of the launch of revalidation and the commissioning of this review.

Revalidation over the years

1998–2001

- Assessment against the generic standards set out in *Good medical practice*, adapted for the specialties by the relevant Royal College
- Preparation and presentation of folders of evidence
- Revalidation panels with lay membership to examine all folders
- A definite linkage to registration
- Aspects of clinical governance central (audit, education and appraisal)
- Peer-review as a potential data source

2001–02

- Data gathered to inform annual appraisal as the key evidence source for the folder
- Only a sample of folders to be assessed by a revalidation panel

2003

- The mere fact of participation in the appraisal process as the only evidence source
- Disappearance of revalidation panels and lay involvement
- Implicit local certification through an 'appraisal route'

2004–05

- Addition of the clinical governance certificate – explicit local certification and the concept of 'approved working environments' (and the 'independent route' for those working elsewhere)

The Shipman Inquiry's criticisms of the General Medical Council

- 52** In *The Shipman Inquiry: fifth report*, as directed by the terms of reference, the inquiry Chair, Dame Janet Smith, undertook a highly detailed analysis of the functions of the statutory bodies, authorities, organisations and individuals with responsibility for monitoring primary care provision.²² The fifth report runs to over 1,000 pages. Whilst the report does examine local systems of clinical governance, information, complaints and appraisal, about half of it is focused upon the General Medical Council. The report contains numerous detailed criticisms of the General Medical Council over the period covering Shipman's murders and on to the present. It also examines the General Medical Council's proposals for revalidation and the changes that took place in November 2004. Dame Janet made multiple recommendations which, in her view, would further the protection of patients. The report's conclusions cover culture, structure and function and revalidation.
- 53** Dame Janet characterised the General Medical Council as a reactive organisation, responding grudgingly to external events. She did not see it as proactive or as having an ethos of patient safety at its heart.
- 54** She also observed that the General Medical Council seemed to yield to external pressure, rather than holding firm as an independent regulator. In her view, changes in direction were made for reasons not of principle, but of expediency. Dame Janet's examination of recent events led her to conclude that although the General Medical Council had made a number of beneficial changes, its culture had not altered fundamentally. She concluded that the perception of many doctors is that the General Medical Council is supposed to be 'representing' them, not regulating them.
- 55** Criticisms were also made of the structure and functions of the General Medical Council. Dame Janet considered it unacceptable that one organisation should set the rules, investigate cases and pass judgement upon those cases. She suggested that the adjudication function should pass to another body. She also recommended changes to the composition of the Council, altered as recently as the summer of 2003, so that there would be a move away from elected towards appointed doctors (although she felt that the balance of professional and lay members was appropriate).
- 56** Dame Janet had other concerns about the functions of the General Medical Council: the absence of robust definitions, standards, criteria and thresholds to underpin the fitness to practise procedures, leading to a lack of both transparency and consistency; the use of terms that are themselves inherently vague, such as 'serious professional misconduct' and, latterly, 'impairment of fitness to practise'; an insufficient level of lay involvement in the fitness to practise procedures, particularly in the early stage of screening; and the use of the criminal standard of legal 'proof' before acting on a doctor's registration (Dame Janet favoured the lower, civil, standard of proof).

- 57** When considering revalidation, Dame Janet criticised the General Medical Council's failure to translate an idea, which she saw as having been 'visionary' when first discussed in 1998, into a viable working model. Dame Janet expressed doubt that, with appraisal at its heart, revalidation as proposed could offer the public much more than false reassurance – appraisal being a variable but largely formative process. She asserted that the addition of a clinical governance report, stating the absence of significant concerns, seemed a rather negative notion and by no means constituted a positive, objective affirmation of ongoing fitness to practise. Dame Janet concluded that the General Medical Council had lost its way in relation to revalidation.
- 58** Overall, Dame Janet recognised the significance of the changes set in motion by the General Medical Council in the late 1990s, 'the three pillars' that I refer to above (see paragraph 33), with the patient central to each of them. However, she recognised also that the General Medical Council had not held to its resolve: whilst there had indeed been a fundamental break with the past and the beginnings of true engagement with the public, these steps had been followed by a reversal, a U-turn. Amongst the first casualties had been public involvement and the transparency that such involvement brought.

Conclusions

- 59** The General Medical Council has been the principal regulator of standards of medical practice for almost 150 years. For much of this time, its fundamental role and purpose remained unchanged.
- 60** Criticisms of the General Medical Council over the years have been pretty consistent. For members of the public or those taking a public interest perspective, the concern has been that medical regulatory processes have been too secretive, too tolerant of sub-standard practice and too dominated by the professional interest, rather than that of the patient. Amongst members of the medical profession, there is no single strand of opinion. Some have been concerned that the General Medical Council has too easily deferred to tabloid newspaper criticism. Others have pointed to the unsatisfactory way that the Council has dealt with minor or invalid complaints against doctors, who are kept under lengthy and stressful investigation and never truly exonerated (see box below). Other professional opinion, including that within some medical Royal Colleges, has been that the General Medical Council should have dealt more effectively with the small proportion of bad doctors and, as a by-product, have clearly and publicly supported the majority whose practice is good.

A doctor's account of being investigated by the General Medical Council in 2005

Dr Mike Shooter found himself angered by his treatment at the hands of the General Medical Council. At the time of proceedings against him, Dr Shooter was President of the Royal College of Psychiatrists: rather than raising his concerns with the General Medical Council as the process unravelled, he remained passive, so as not to prejudice matters. Following the conclusion of his case and the dismissal of the allegations against him, Dr Shooter voiced a number of concerns.

The General Medical Council did not appear to take any account of the context in which the complaint about him was made. The complainant had a long history of writing similar correspondence concerning other College officers. Failing to take this into account, prior to launching straight into a full investigation, appeared to be an enormous waste of a limited resource and also risked alienating doctors by laying them open to years of potential harassment.

At no point was the specific 'charge' under investigation made clear to him. Indeed, the subsequent conduct of the investigation led him to believe that the General Medical Council was not itself clear about this either.

From the outset, standard letters from the General Medical Council were couched in the most negative of terms with language that appeared threatening. Such letters were shared with his employer and the Department of Health. Far from helping to garner the 'fuller picture' (their purported function), such letters immediately cast the situation as adversarial and would seem to have been set against obtaining a fair and balanced view.

The verdict of the General Medical Council, when it arrived, was essentially incomprehensible. As illustrated below, the letter consisted of two parts, a direct quote from the case examiners and some 'standard' text:

'We have no hesitation in closing this wholly unsubstantiated allegation.'

'There was no realistic prospect of establishing that your fitness to practise is impaired to a degree justifying action on your registration.'

He felt that these two statements were inconsistent.

Despite the legal and administrative resources available to him as a College President, he found the whole episode very uncomfortable. He concludes that the experience must therefore be extremely distressing for more typical doctors, who are likely to be far more isolated.

- 61** Over the last 15 years or so, the General Medical Council has initiated, led and implemented serious and important reforms to its structure, processes and governance. Despite a growing volume of complaints, they are now dealt with more quickly. There is now extensive lay involvement in the complaints and disciplinary procedures and in the policy-making machinery of the Council. There is also much closer working between the General Medical Council and local NHS bodies when there are concerns about a doctor's competence, conduct or performance.
- 62** The last 150 years have therefore been characterised by cycles of consolidation followed by criticism, or crises of confidence followed by reform. The major shifts in the philosophy and practice of medical regulation have mainly taken place within the last 20 years, namely:
- a move towards more explicit standards of practice;
 - a broader scope of what constitutes acceptable practice, beyond simply technical clinical skills;
 - much greater lay involvement in the process of medical regulation;
 - closer links between medical regulation and clinical governance in the NHS workplace.
- 63** Despite these relatively recent developments, judging by the responses to my *Call for ideas* consultation, the extensive public and professional debate on these issues and the criticisms of The Shipman Inquiry, a number of important matters remain unresolved and unsatisfactory. These issues can be grouped under three broad headings.

Overall aims and purpose

- The ability of the General Medical Council to discharge its primary purpose: ensuring the safety of patients whilst also being fair to doctors.
- The level of support for the General Medical Council's two guiding models for modern regulation (the four layers and risk-based regulation).
- The ability of the General Medical Council to provide clear public assurance that the profession's members demonstrate continuing fitness to practise.
- The level of confidence in the General Medical Council's proposals for revalidation, based on participation in annual appraisal and the absence of concerns on the part of the employer.
- The privileges, if any, to be retained by retired doctors in an era of re-licensure.

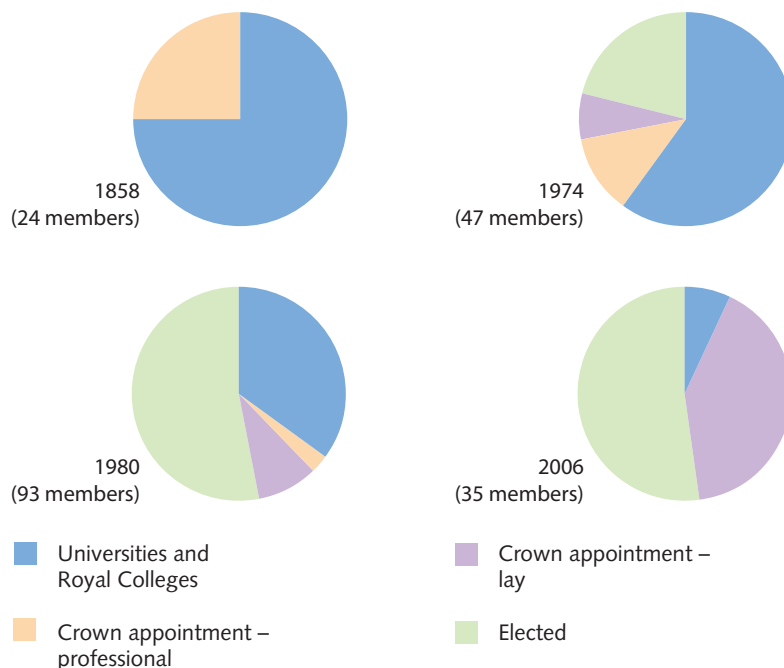
Structure and governance

- The primary purpose of the Council itself: akin to a publicly accountable board, or directly involved in exercising the General Medical Council's powers and functions.
- The importance, or otherwise, of the election of representatives by professionals in the process of professionally led regulation.
- The appropriate balance between professional and lay members, appointed and elected, within the Council.
- The arrangements for the financing of an independent regulator.
- The desirability and need for increased harmonisation between regulatory bodies and processes across the wider health professional landscape.

Mechanisms of working

- The ability of a single organisation to deliver the range of different functions currently performed by the General Medical Council.
- The appropriateness of a single organisation setting rules, investigating, adjudicating and sentencing.
- The standard of proof required, civil or criminal, when taking action upon a doctor's registration.
- The quality assurance of those aspects of regulation that rely upon the contributions of third parties.

The changing composition of the General Medical Council



General Medical Council timeline

- 1858 Medical Act establishing the General Council of Medical Education and Registration of the United Kingdom (later the General Medical Council)
- 1860 First inquiry under section 29 (conduct)
- 1882 Royal Commission into the Medical Acts
- 1886 Introduction of a small number of elected practitioners to the Council
- 1963 Annual retention fee proposed (in face of financial difficulties)
- 1969 Medical Act introducing annual retention fee and coining the term ‘serious professional misconduct’
- 1975 Report of the Commission of Inquiry into the Regulation of the Medical Profession (The Merrison Inquiry)
- 1978 Medical Act introducing the health jurisdiction
- 1983 Passage of the Medical Act 1983 which, as amended, remains the primary legislation relating to the regulation of doctors
- 1993 *Tomorrow’s doctors* published
- 1995 *Good medical practice* published
- 1995 Medical Act introducing the performance jurisdiction
- 1998 Concept of revalidation re-awakened
- 1999 Health Act 1999 provides an accelerated mechanism (section 60) for amending the Medical Act 1983
- 2000 Powers of immediate suspension introduced
- 2001 Launch of the National Clinical Assessment Authority
- 2001 Publication of *Learning from Bristol*²³
- 2004 New streamlined fitness to practise procedures
- 2004 Publication of *The Shipman Inquiry: fifth report*
- 2005 Terms of reference published for this review (revalidation postponed until conclusion)
- 2005 Ongoing General Medical Council public consultation into the revision of *Good medical practice*, student registration and the case for unified national assessment at the time of entry to the Register
- 2006 Publication of the report of the Chief Medical Officer’s review, *Good doctors, safer patients*

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Chapter Five:

Assessing clinical practice

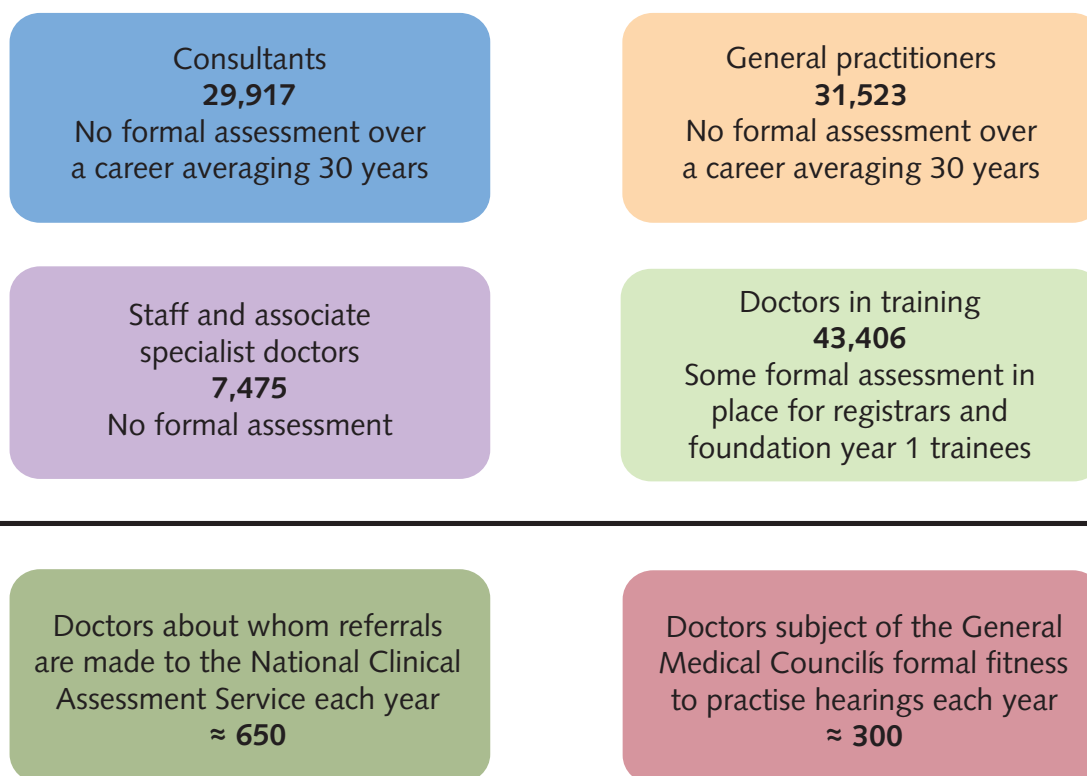
Key points in this chapter

- There is a consensus that the quality of an individual doctor's practice cannot be taken for granted and needs to be assessed; this happens in training posts but not for doctors in career grades who may have no formal assessment of their practice in their entire career.
- Well-developed systems of assessment are in use to assess doctors whose performance is causing concern but these have not been deployed more widely.
- Assessment models in undergraduate and postgraduate training have changed markedly in the last 15 years and now offer improved objectivity and transparency, and the scope for wider use (for example, the Objective Structured Clinical Examination or OSCE format).
- There are many routine sources of data that have the potential to offer an insight into practitioner performance and the quality of care but these are largely being used for purposes other than assessment.
- There is a great deal of interest internationally in developing formal codes of practice to provide a standard as to what is expected of a 'good' doctor.
- Systems for monitoring death rates in primary care have been proposed but not systematically implemented.
- Techniques for simulating actual practice situations are developing rapidly, particularly in the fields of anaesthetics and surgery.
- The true prevalence of performance problems is difficult to determine, especially where ill health and addiction are concerned.
- Sick and addicted doctors are not all recognised, and sources of help are fragmented and of variable effectiveness.
- The one-year risk of referral to the National Clinical Assessment Service is approximately 0.5% for all doctors and rises to 1% for those in the most senior posts: over 1,700 doctors were referred between 2001 and 2005.

- Over 500 alert letters have been issued since 1997, warning the NHS of practitioners who pose a threat to patient safety.
- Each year, approximately 300 doctors appear for the first time before fitness to practise panels operated by the General Medical Council.
- The assessment methods developed by the National Clinical Assessment Service for cases of poor practice have a wider applicability to affirming safe practice.

1 In the early days of the NHS, it was assumed that a strong system of education and training backed up by a broad professional code of ethics would ensure that doctors were generally good doctors. This notion of conscientious, well-trained doctors being taken on trust was hardly challenged for 30 years.

The number of doctors in the NHS in England and their assessment



2 In today's NHS, the expectations of the public and patients, as well as the standards expected of doctors as members and fellows of professional bodies, mean that the quality of a doctor's practice can no longer be taken for granted. Inevitably, this means establishing ways in which practice can be assessed fairly, reliably and objectively.

3 Assessment is usually thought of as the measurement of the performance of an individual against a predefined standard. Assessment is used in a wide variety of situations in medicine:

- in education and training;
 - in examinations to award degrees and professional qualifications;
 - in determining competence and fitness to practise;
 - in making judgements about the quality of care provided.
- 4 Although, strictly speaking, assessment must be based on a standard, whether that necessary to pass an examination or to be competent to practise, the term ‘assessment’ is often used more broadly and less formally to refer to processes through which information is used to examine, investigate, explore or compare a practitioner’s performance or the quality of care provided, without necessarily having formal standards against which to make judgements.
- 5 This chapter addresses the key themes relevant to assessing or making judgements about the quality of medical practice and the methods used to do so.

Assessment in education and training

- 6 Historically, the training of doctors followed an apprenticeship model. After selection, students learnt by observing and then copying others, before progressing to independent practice. Seniority was often a marker of length of experience, rather than the competencies acquired per se. The direction of an individual’s career and the speed of their advancement was often determined informally. Patronage played a significant role.
- 7 Over the last 30 years, the human resources function of medical schools and the NHS has developed significantly. In order to enhance equity of opportunity and to provide quality assurance, progression through a medical career is now more structured and transparent.
- 8 Examples of significant advances include the development of vocational training schemes for general practitioners, the introduction of the unified specialist registrar grade by my predecessor Sir Kenneth Calman and the frequent involvement of lay people in appointment panels for the consultant grade. A contemporary development is that of additional assessment tools prior to entry to medical school.

Admissions procedures to medical schools in England

Researchers found that in 22 medical schools in England, although there was commonality with regard to the criteria used for selection, the processes operated to determine whether or not potential students met these criteria varied widely:

- some schools do not make use of face-to-face interviews;
- some schools take account of non-academic factors (as well as an individual's academic record) in order to shortlist for interview;
- some schools pay attention to personal statements and the referee's report, others have concerns over bias;
- the interview process itself varies in format and committee composition.

Source: Parry J et al. *Admissions processes for five year medical courses at English schools: review.*

BMJ 2006 332:1005–1009.

The United Kingdom Clinical Aptitude Test (UKCAT)

The majority of university medical and dental schools in the United Kingdom will deliver a standardised aptitude test, for applicants to their courses from autumn 2007.

A computer-based test will be available at a large number of sites around the world. A means-tested fee will be payable. The test will aim to assess an applicant's innate qualities and skills. The test will be used to complement the other information available as part of the application process and will assess:

- verbal reasoning;
- quantitative reasoning;
- abstract reasoning;
- decision analysis.

- 9 The ongoing Modernising Medical Careers programme grew from my report *Unfinished business*, which made the case for further reform to the senior house officer grade.¹ In addition to improving the balance between dedicated training and ‘service’ for medical trainees, the programme makes an explicit link between the attainment of specific competencies and progression to subsequent career stages.
- 10 These reforms rely upon doctors demonstrating the attainment of specified standards in their practice. In order to do this, a number of objective assessment tools have been developed by educationalists, in association with medical schools, Royal Colleges and other bodies.
- 11 In addition to the use of assessment tools during medical school and postgraduate training, they are of vital importance as a source of objective evidence when doubts arise as to an individual’s fitness to practise.

Assessment in independent practice

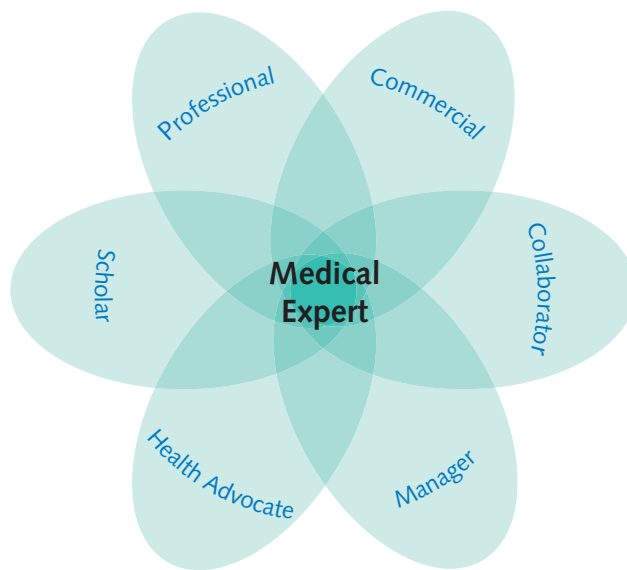
- 12 The vast majority of doctors working independently as consultants or principals in general practice do not encounter any form of formal assessment (of knowledge, skills or performance) from the time that they take up their appointment until retirement.
- 13 Although there is little in the way of formal assessment, most doctors do participate, to a greater or lesser extent, in clinical governance activities. This may involve attendance at morbidity and mortality meetings (offering an opportunity for peer-review of particular cases) and local involvement in clinical audit.
- 14 In a small number of specialties, forms of assessment have become mainstream. For example, all cardiothoracic surgeons undertaking coronary artery bypass grafting and valve replacement are expected to participate in the continuous monitoring of patient outcomes, under the auspices of the Society of Cardiothoracic Surgeons of Great Britain and Ireland (described in Chapter Two).
- 15 Although opinion remains divided as to whether or not appraisal constitutes assessment, the process was formally introduced for career grade doctors in the NHS in 2001. Participation in appraisal has formed the cornerstone of the revalidation process proposed by the General Medical Council since that time. In essence, appraisal in the NHS involves meeting with one or more peers to reflect upon prior practice, informed in so far as is possible by evidence and data, in order to identify strengths, weaknesses and areas for improvement. Appraisal concludes with the agreement of future objectives in the form of a personal development plan. Much controversy has arisen as to whether appraisal in the NHS is a formative or summative process, or a mixture of the two. Appraisal is discussed further in paragraphs 88–97, and in Chapters Four and Eight.

Professional codes

- 16** Along with the recognition of a need to demonstrate ongoing fitness to practise, there has been widespread international interest in the role and construction of codes of professional conduct for doctors.
- 17** Guidance on the behaviour expected of doctors has been published in several countries: *Good medical practice* in the United Kingdom and the *CanMEDS 2000 project* in Canada are notable examples.^{2,3}

The CanMEDS roles framework

The seven key roles of a specialist physician



© Royal College of Physicians and Surgeons of Canada

Several common domains of practice are covered by such guidance:

- technical and scientific;
- ethical;
- relationships with others (patients and colleagues).

18 There are also a number of major differences in emphasis and approach:

- standards that define expectations versus those that define aspirations;
- standards that can be generalised to all doctors versus those that are specific to doctors working in a narrow area of practice;
- standards that are vague and non-specific versus those that are tightly defined;
- the extent to which members of the public are involved in the determination of standards;
- the degree to which inevitable tensions (such as the autonomy of the patient versus the resource limitations of the wider system) are managed;

- the extent to which standards are operationalised by means of criteria (against which assessment can be made) and thresholds (of success or failure);
- the linkage of standards with licensure to practise.

- 19 There is no country in which a code of practice is meaningfully and intimately linked to a mechanism of re-licensure or re-certification. In the United Kingdom, the General Medical Council's *Good medical practice* now informs the process of medical education and provides a context against which fitness to practise decisions may be made. However, it is not yet operationalised in a manner that would permit its use in revalidation. A number of medical Royal Colleges have made encouraging progress in adapting *Good medical practice* to the circumstances in which their members operate, notably the Royal College of General Practitioners.⁴
- 20 There remains some reluctance amongst medical regulators, perhaps reflecting the concerns of the wider profession, to firmly embed good practice guidance: the General Medical Council's foreword to *Good medical practice* states:

“Serious or persistent failures to meet the standards in this booklet may put your registration at risk.”

A number of commentators would prefer the use of the term ‘code of conduct’ to ‘guidance’ and for serious or persistent failures to unequivocally put registration at risk.

Methods and tools for assessment

- 21 A wide variety of assessment tools have been developed for use in medical education and many have the potential for use in quality assurance. A common feature to all modern assessment techniques is an explicit aim of objectivity. Despite this, significant concerns remain as to the validity, accuracy and reproducibility of some of these tools.

“Examinations are formidable even to the best prepared for the greatest fool may ask more than the wisest man can answer.”

Charles Caleb Colton (1780–1832)⁵

- 22 Formal written examinations have been used by medical schools (during courses and at the time of initial qualification) and other bodies (for postgraduate qualifications) to assess knowledge for a long time. In recent years, examinations have switched their focus from an essay format to structured short answers and multiple choice papers. The reasons for this shift have been three-fold:

- the structure provided by the more focused formats allows for knowledge to be more objectively tested;

- short answers and multiple choice questions lend themselves well to questions of increased practical and clinical relevance;
- short answers and multiple choice questions allow for more efficient assessment at reduced cost (computer-aided marking).

23 In addition to written examinations, there is a long tradition of oral and practical examinations in medicine. Indeed, many examinations in medicine include a series of hurdles, both written and practical. In the past, these took the form of viva voce examinations and short and long cases, where examiners would either watch a candidate clinically examine a series of patients, or question them in detail about a case following a more prolonged interview. In recent years, the format of non-written examinations has also changed. Today, most such examinations tend to be delivered through the Objective Structured Clinical Examination (OSCE) format. Advantages to this approach include increased consistency in examination, more objective marking against predefined standards and increased opportunity to formally assess communication skills through role-play. Most medical schools, the General Medical Council (through its Professional Linguistics Assessment Board examination – see Chapter Four) and many Royal Colleges and faculties have developed modern examinations employing this format: much effort and money has been invested to ensure that these assessments are fair, transparent and valid.

24 Since the changes to specialist training introduced by Sir Kenneth Calman in the mid 1990s, specialist trainees have undergone an annual review. This review or Record of In-Training Assessment (RITA) serves several purposes:

- to ensure satisfactory progress on the part of a trainee;
- to identify any concerns about a trainee;
- to establish shortcomings in training opportunities;
- to begin to address concerns or shortcomings, where these arise.

25 This process brings the trainee together with representatives of the local NHS and postgraduate deanery, the relevant training authority and Royal College. A trainee brings with them various documents outlining their experience and progress, including a record of appraisal with an educational supervisor. Approaches to this process vary between specialties and region: the core function is to ensure that a trainee is making adequate progress.

26 With the commencement of the Foundation Programme (as part of the Modernising Medical Careers programme), several innovative forms of assessment have been introduced:

- multi-source feedback (MSF);
- direct observation of procedural skills (DOPS);
- clinical evaluation exercises (mini-CEX);
- case-based discussions.

27 A number of Royal Colleges have begun to build structured assessments of this type into their specialist training curricula. Amongst them is the Royal College of Surgeons of Edinburgh, which

has been involved in the development of surgical performance-based assessment across all nine surgical disciplines.⁶

- 28** 360-degree feedback, sometimes called multi-source feedback, has been used for many years in non-health sectors. The process, which is often computer-aided, collects the opinions of a group of individuals who have experience of the subject in the workplace. In the medical setting, this group might include peers, senior and junior medical colleagues, managers, support staff, allied health professionals and patients. These individuals rate the subject across a number of domains. There may also be an opportunity to offer free text comments. Usually, responses are not traceable. Whilst 360-degree feedback may provide useful insights, there are some doubts as to its validity: subjects often select the pool of respondents, and the exercise may provide an opportunity to give biased feedback. 360-degree feedback is discussed further in Chapter Eight.
- 29** In the medical profession, membership of the relevant Royal College is a prerequisite for higher specialist training in most (although not all) specialties. Membership is obtained through examination: having obtained membership, a doctor may choose whether or not to pay subscriptions in order to remain an active member of the relevant college and participate in its affairs. Fellowship, at least in the recent past, has been an honour bestowed upon an existing member, usually following nomination by current fellows. Fellowship is professionally prestigious and fellows have a greater say in the running of their institution. The award of fellowship is made for life.
- 30** The Royal College of General Practitioners established an additional path to its college fellowship in 1989: fellowship by assessment. Fellowship by assessment is a route open to members of five years' standing who are established as principals in general practice. This route was conceived as part of the college's commitment to maintaining the highest possible standards: assessment involves a comprehensive process of peer-review against criteria that are regularly updated, undertaken within day-to-day practice. It is estimated that between 150 and 200 hours are required on the part of the doctor to assemble the evidence required for the assessment. This innovative scheme highlights the potential link between fellowship and the objective quality of practice. Many colleges have held discussions around the concept of doctors being 'fellows of good standing' and the possible consequences upon fellowship of poor practice or behaviour.
- 31** Interest in the use of simulators for assessment has grown in recent years as their capability has increased and their cost fallen. Anaesthetics has been one area of medicine in which there has been great interest in simulator technology. Although high-fidelity simulator centres began to develop in the United Kingdom from 1997, to date simulator-based assessment has not been incorporated into the anaesthetics curriculum.⁷ The advantages of simulators in enhancing the objectivity and efficiency of training are clear, and the increased emphasis placed upon the ability to perform a task (rather than simply having knowledge of it) is also welcome. Drawbacks include the inability of simulators to take account of the experience or value systems of the individual being assessed. Furthermore, simulator training requires considerable resources, not just equipment but also the time of trainers. Despite these reservations, it is clear that high-fidelity simulators are likely to have a very important role for training (and on-the-job assessment) in a number of the more 'hands-on' specialties.

- 32** Some medical Royal Colleges have already paid considerable attention to the tools that might be appropriate for the assessment of ongoing competence in the trained workforce. Amongst them is the Royal College of Obstetricians and Gynaecologists, which has concluded that such assessment is likely to rely upon three specific aspects:
- demonstration of continuing professional development (through a college-approved programme);
 - directed 360-degree appraisal;
 - periodic objective structured assessment of clinical skills (based on those tools already in use for trainees, modified as appropriate).

Surveillance data

- 33** Many different types of data are collected in the NHS during the course of service delivery. These routine data have the potential to provide vital information as to the quantity and quality of care administered, by either services or individuals. Examination of these data, perhaps looking beyond their prime purpose, can be very informative. On occasion, they are not adequately analysed and any opportunity for learning and service improvement may be lost.
- 34** Other data are collected specifically in order to examine service quality and patient outcomes. These data and the systems used to collect them are discussed in Chapter Two.
- 35** There is a risk that inappropriate conclusions can be drawn from data. Data may be incomplete, unreliable in other ways or potentially misleading on account of complex confounding factors. Such data lend themselves best to ‘screening’, where figures are used as an entry point into a broader exploration of an area of practice, rather than to draw firm conclusions.
- 36** Information on service items can lend itself to measurement and benchmarking, for example:
- Hospital Episode Statistics (‘HES data’), recording all interactions between an individual and a hospital (outpatient appointments, admissions, specified operative and non-operative procedures);
 - information held by the prescription pricing division of the NHS Business Services Authority, summarising the prescriptions generated by general practitioners and others (over 2 million prescription items per day);
 - reports from local risk management and governance systems.
- 37** Some information is available from the reporting of negative or untoward events, for example:
- incident reporting and incident reviews;
 - death certificates, currently stating the likely causes(s) of death and the details of the patient’s doctor (of course, in some circumstances, death need not always be regarded as a negative event);
 - reports from whistleblowers;

- complaints information (both quantitative and qualitative) held by local organisations, the Healthcare Commission, the Health Service Ombudsman, the General Medical Council, medical defence organisations and others;
 - ‘alert letters’ (urgent communications regarding concerns of a serious nature about a healthcare practitioner);
 - litigation information held by medical defence organisations and the NHS Litigation Authority.
- 38** Information from the reporting of positive or primarily formative events which, as a by-product, may throw light on a potential performance problem, for example local appraisal and audit activity.
- 39** Furthermore, the sources of information about individual practitioners are widely spread across a number of sectors and include:
- the local employer or contractor, including data relating to occupational health, audit, prescribing, appraisal and continuing education, as well as any disciplinary and other negative action;
 - the regulator, including data relating to fitness to practise;
 - the medical Royal Colleges and faculties, the deans of postgraduate medicine and the Postgraduate Medical Education and Training Board;
 - the Health Service Ombudsman, the Healthcare Commission, the Family Health Services Appeals Authority and the National Clinical Assessment Service;
 - the civil, coroner’s or criminal courts, the police and the Criminal Records Bureau;
 - social services.

Complaints

- 40** The NHS has a tendency to view complaints in a negative light. An alternative standpoint is to see them as a precious source of customer feedback, allowing managers to see an organisation from a fresh perspective and enabling innovative and patient-centred improvements. Assessments made by patients following their experiences, whether positive or negative, offer information that may have a bearing on the performance of both health systems and individual practitioners.
- 41** The NHS complaints handling system is not sophisticated. Dame Janet Smith, Chair of The Shipman Inquiry, and others have made many recommendations for its improvement. At present, the NHS complaints system has three tiers:
- local resolution within the individual NHS organisation;
 - independent review through the Healthcare Commission (which does not apply to NHS foundation trusts);
 - a final level of scrutiny through the independent Health Service Ombudsman.
- 42** Two main sources of assistance are available to patients when they consider lodging a complaint. The Patient Advice and Liaison Service (PALS) is based within NHS Trusts, working alongside complaints

managers, and can provide patients with advice on how to take their concerns forward. In addition, the Patient Advice and Liaison Service is able to refer complainants on to the Independent Complaints Advocacy Service, which is able to provide a range of support, including advocacy (see box below).

Independent Complaints Advocacy Service

The Health and Social Care Act 2012 placed a duty upon the Secretary of State to make arrangements for the provision of independent advocacy services for those wishing to make complaints arising from their experiences in the NHS.

Following piloting, the Independent Complaints Advocacy Service (ICAS) was launched in all nine government regions in September 2012. In its first two years of operation, the Service (which has been provided by a variety of organisations) received almost 60,000 telephone calls and provided full advocacy services to over 20,000 patients and relatives.

The Independent Complaints Advocacy Service now has two distinct components: self-advocacy (involving information and signposting) and supported advocacy (involving specialised help, tailored to an individual's needs). Emphasis is placed upon encouraging learning from complaints, and efforts are made to obtain service improvement undertakings from NHS managers. In addition, the results of the Service's work are shared locally with NHS organisations and stakeholders including the Patient and Public Involvement Forum, and with the overview and scrutiny committees of the relevant local authorities.

43 Although some of the criticisms of NHS complaints systems pre-date the creation of the Patient Advice and Liaison Service and the Independent Complaints Advocacy Service, many remain relevant. The current system:

- is poorly publicised;
- is complex and confusing with a wide range of bodies to which a complaint might reasonably be addressed;
- is not designed to deal with complaints that fall under the remit of more than one body;
- makes it particularly difficult for patients to complain about general practitioners (where complaints are generally made at the level of the practice to the doctor themselves, or to one of the doctor's employees);
- is inaccessible to some patients from ethnic minority groups and others who are unable to frame their complaint and present it effectively because of language or literacy issues;
- is dependent on high-quality investigation, for which some organisations lack capacity.

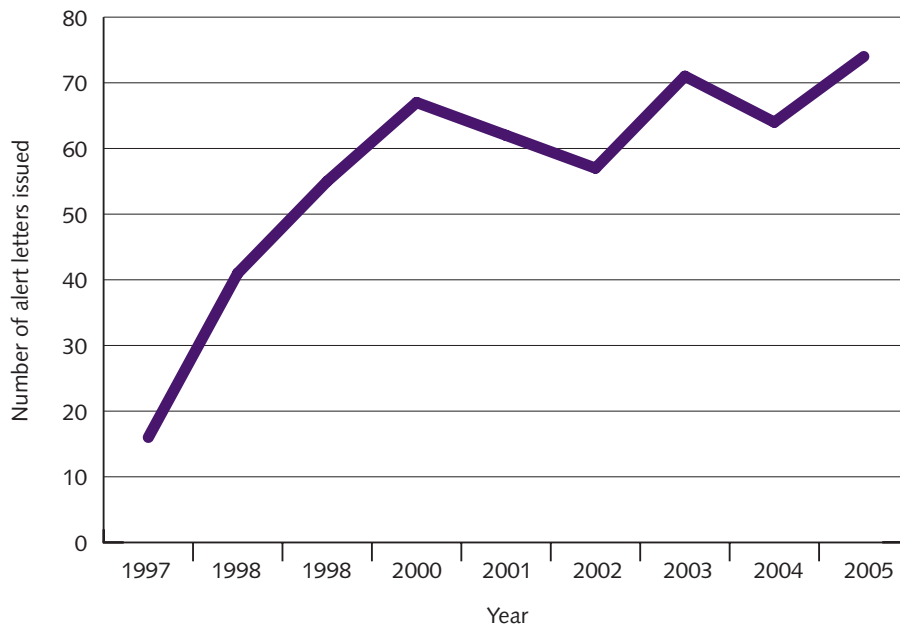
44 Complaints relating to the care provided by general practitioners are a particularly challenging area, as primary care trusts and the Healthcare Commission have limited powers to investigate them in the absence of cooperation from the individual doctor.

- 45 A number of solutions have been proposed in relation to these criticisms. These include:
- the ability to lodge complaints relating to primary care with the NHS primary care trust and not just at the level of the practice;
 - common information standards such that all potential complaint recipients have a common understanding of the wider complaints landscape and signpost complainants appropriately;
 - promotion of access for those with communication difficulties;
 - the creation of a specialised complaints investigation resource, to cover a number of NHS organisations, so that expertise is available to all;
 - further consideration to the ‘fast-tracking’ of certain complaints to the Ombudsman (with the Ombudsman’s significant powers to require evidence).

Alert letters

- 46 Alert letters provide a mechanism by which the NHS can urgently communicate concerns of a serious nature in relation to a healthcare practitioner. In summary, the alert letter system is intended for use where three criteria apply:
- the practitioner, or their practice, is thought to pose a serious actual or potential risk to patients or staff;
 - the concern leading to this assessment of risk remains unresolved (investigation is incomplete or definitive action has not yet been taken by all relevant agencies);
 - the doctor is not in a situation in which their whereabouts and scope of practice are certain.
- 47 The alert letter scheme for doctors and dentists was set up in 1997, in part because of the inevitable delays that may occur between the time at which a concern is identified and formal action is taken by the relevant national regulator to exclude the individual from practice. In addition, healthcare professionals, doctors in particular, have ample opportunity to relocate to alternative parts of the United Kingdom and continue to practise. Alert letters have been distributed to the entire NHS by a Regional Director of Public Health, following a request from senior officers of an NHS Trust. In 2003, the scheme was expanded to include other health professionals, although a large majority still relate to doctors. Approximately 70 alerts are issued in the United Kingdom each year.

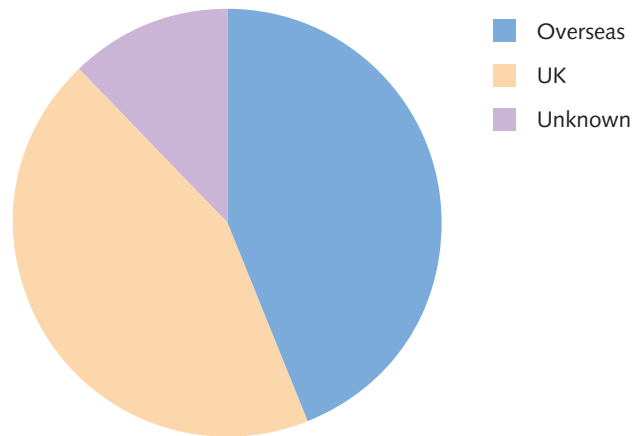
Alert letters issued in the United Kingdom each year, 1997–2005



Source: North West Regional Office audit of alert letters (1997–2005)

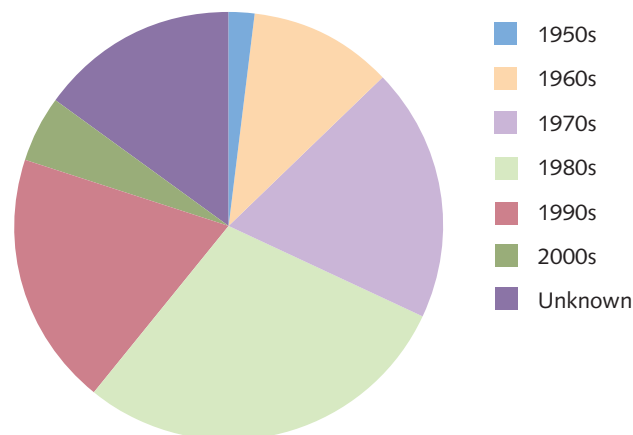
- 48 In many situations, the three criteria above will determine that referral should take place to the professional regulator – in the case of doctors, the General Medical Council. This referral is made at the same time as an alert letter is issued, or shortly thereafter. For doctors, there is therefore a significant overlap on the alert letter system between the activities of employers, the National Clinical Assessment Service and the General Medical Council.
- 49 A comprehensive audit of the alert letter system has recently been carried out in the North West Region of England.⁸ The region has been the originator of over a quarter of all alert letters issued since the system began, although it covers approximately 11% of the United Kingdom population. The reasons for this discrepancy are not clear but may reflect good clinical governance systems for detecting problems. This audit offers an excellent overview of the system and another valuable insight into the scale and nature of performance problems amongst doctors.
- 50 Since 2003, more data have been collected about the processes involved in the issuing of alert letters. These show that requests from employers do not always result in the issue of an alert letter, with approximately 20% deemed to be unnecessary. A majority of doctors lodge an appeal following the issue of a letter.
- 51 The study paints a clear demographic picture of those who had alert letters issued about them in the North West in the period 1997 to 2005: approximately half had qualified in medicine overseas and the age profile of the doctors was mixed (with a number having qualified comparatively recently). All career grades were represented, with around a third employed in the training grades.

Place of primary qualification of doctors on whom an alert letter was issued in one NHS region



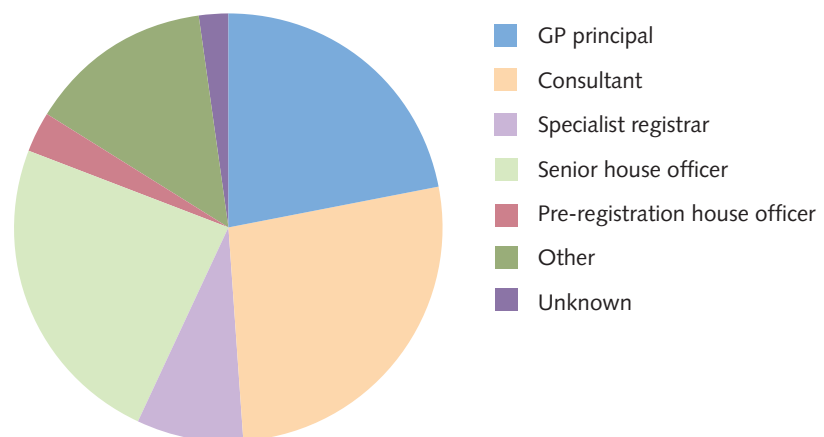
Source: North West Regional Office
(115 alert letters issued 1997–2005)

Decade of primary qualification of doctors who were the subjects of alert letters in one NHS region, 1997–2005



Source: North West Regional Office
(115 alert letters issued 1997–2005)

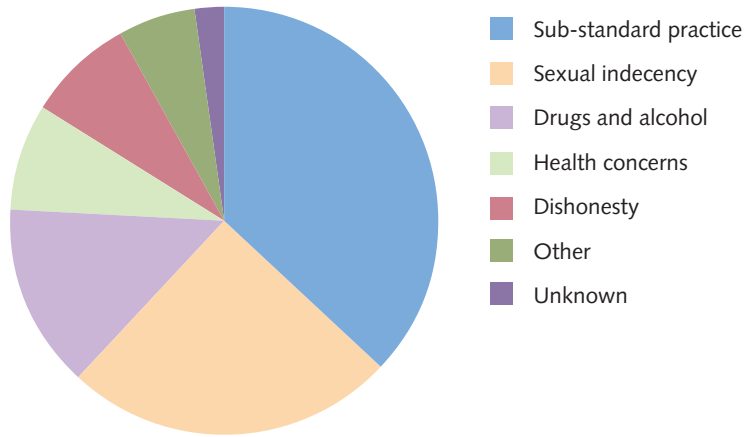
Grades of doctors who were the subjects of alert letters in one NHS region



Source: North West Regional Office
(115 alert letters issued 1997–2005)

52 Sub-standard performance, alleged sexual indecency and addiction problems together made up the majority of concerns that led to alert letters.

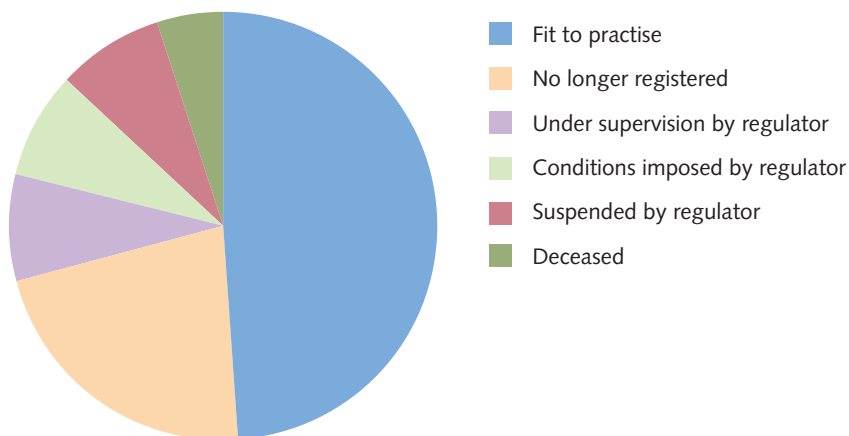
Nature of allegations prompting issue of alert letters in one NHS region (some alerts relate to multiple allegations)



Source: North West Regional Office
(115 alert letters issued 1997–2005)

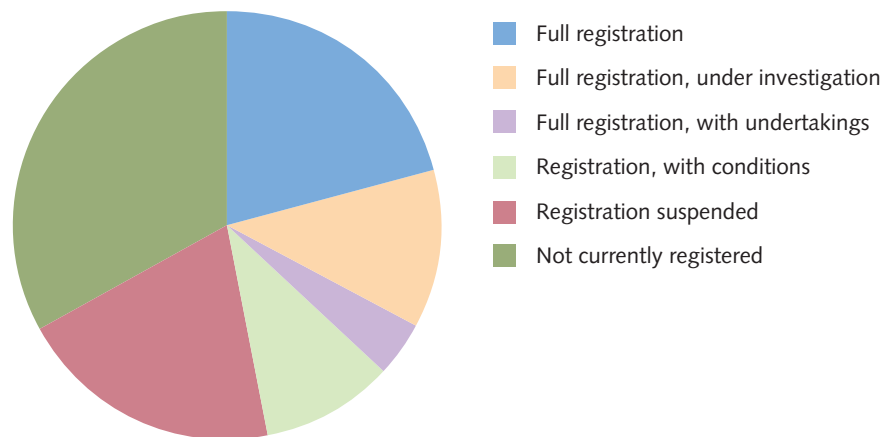
53 The appropriateness of these alerts is reviewed frequently. In the North West Region’s experience, approximately half of the practitioners remain registered with the regulator, with or without conditions to practise. Some of these cases may be due to the delay that occurs between the commencement and conclusion of formal fitness to practise proceedings. For alert letters cancelled by the North West Region, half were because the practitioner was deemed fit to practise: these findings suggest that on occasion, allegations may not be substantiated or that successful remediation is achieved.

Reasons for the subsequent cancellation of alert letters issued in one NHS region



Source: North West Regional Office
(40 alert letters cancelled 1997–2005)

Registration status of those practitioners in respect of whom alert letters, issued in one NHS region, remain in place



Source: North West Regional Office
(92 alert letters in place in 2005)

Additional sources of data

- 54** 'Dr Foster' is a private company set up to provide information on health services to the public. The organisation was launched in January 2001 with the publication of its hospital guide, in association with *The Sunday Times*. Information produced by Dr Foster may differ from that published by other sources (such as the Healthcare Commission). These differences may be accounted for by the format of presentation, or by the approach to adjustment (whereby information is weighted according to other factors such as the age profile of patients or the degree of co-morbidities).
- 55** Dr Foster has established a reputation for producing accessible information that has been well received by patients, particularly as they exercise choice in the NHS. In January 2006, a joint venture was announced between Dr Foster and the Health and Social Care Information Centre: 'Dr Foster Intelligence' aims to further the delivery of quality information to the public and empower managers, clinicians, patients and the public to improve the quality of care.

Mortality monitoring

- 56** Following Harold Shipman's conviction for the murder of 15 of his patients, I commissioned an audit of his clinical practice from 1974 to 1998, led by Professor Richard Baker.⁹ Professor Baker undertook a detailed analysis, making use of a number of data sources, as follows:
- identifying all medical certificates of cause of death issued by Shipman over this period and comparing their number and demographic distribution with those issued by a control group of local general practitioners;
 - tracking all of those patients registered with Shipman for any period after 1987 and comparing their mortality (from the NHS central register) with that of all patients in the local district, in a group of similar districts and in England and Wales as a whole;

- examining clinical records for all of those patients for whom a medical certificate of cause of death had been issued by Shipman (or by those in the control group of local general practitioners);
- analysis of data provided by the then Prescription Pricing Authority and controlled drug registers at local pharmacies.

57 Professor Baker's analysis concluded that there had been an excess of 236 deaths, occurring at home or on practice premises, amongst Shipman's patients, a similar figure to that arrived at by Dame Janet Smith. Professor Baker's detailed work and the enormous scale of the deaths that he uncovered led him to make a number of recommendations, including:

- systems for the monitoring of general practitioners should be reviewed and extended to include routine monitoring of death rates;
- a system for collecting information about the number of deaths of patients of, and medical certificates of cause of death issued by, general practitioners should be investigated and a practical system introduced as soon as possible;
- in a revised certification system, brief information about the circumstances of death and the patient's clinical history should be recorded in the case of both cremations and burials.

58 Since the publication of Professor Baker's work, debate has been ongoing as to how such a system should be designed and whether it could fulfil the dual purposes of detecting illegal behaviour and also helping general practitioners to plan improved methods of care.^{10,11}

59 The challenge in designing a system for mortality monitoring revolves around the identification of an appropriate comparator, against which the death rate of a given practice can be compared. Whether such a comparator should be defined at a national level or more locally is not clear: certainly, it must take account of the demographic features of the local population.

60 The monitoring of mortality rates is complex and there is still much debate about how best to achieve it. However, such information is important for reasons beyond the performance monitoring of individual doctors, or groups of doctors (e.g. identifying disease trends and scope for the prevention of disease). The various statistical systems proposed would benefit from being widely piloted, and the results of these exercises evaluated to inform the development of a consistent approach to mortality monitoring nationally.

61 There may be many valid reasons for which the mortality of one practice appears to be higher than that of another. A process of mortality monitoring would identify significant divergence from expected rates in a number of practices that would then need to be examined in an inquisitive rather than adversarial manner.

III health and addiction

62 The interplay between work, health and well-being in a high-stress profession such as medicine is complex. The work of the National Clinical Assessment Service, particularly in its approach to

detailed performance assessment, has yielded important information. The most prominent aspect of this, however, is the impact of ill health on ability to practise safely.

- 63** Sick doctors (including those with substance addiction) can pose a real threat to patient safety and they also pose a difficult problem for medical regulation:
- the insight of sick doctors into their condition and the impact that it has upon their performance may be severely compromised;
 - illness in doctors may be poorly managed and appropriate assistance may not be sought for a variety of reasons (including low rates of registration with a general practitioner);
 - doctors may be able to disguise their illness from others (perhaps through self-prescription);
 - where illness is recognised to adversely affect performance, there may be a reluctance to refer a practitioner into a system that is perceived as ‘disciplinary’ and a lack of knowledge as to alternatives;
 - an excessively stressful work environment may have a significant and negative impact on a doctor’s health and well-being.
- 64** For these reasons, it is very difficult to put an accurate figure upon the number of doctors whose performance may be adversely influenced by physical illness, mental health problems or addiction. Doctors addicted to drugs constitute a particular challenge as performance issues are likely to overlap with misconduct and perhaps criminality. Estimates as to the prevalence of substance abuse amongst doctors are variable but the literature includes the following assessments:
- as a professional group, doctors are particularly likely to experience alcohol-related death;¹²
 - the incidence of drug dependence amongst physicians in the United States of America is estimated at 1–2% and when alcohol abuse is considered, this figure increases to 10–14%.¹³
- 65** Even when using more conservative estimates, the size of the problem is significant: the British Medical Association estimates that as many as one in fifteen doctors may be affected by drug or alcohol dependence at some point during their career.¹⁴ The experience of groups and organisations including the Sick Doctors’ Trust, CHITS (Clinicians’ Health Intervention, Treatment and Support) and the Royal Pharmaceutical Society of Great Britain (which previously operated a specialist inpatient treatment facility) confirms that addiction is a serious problem amongst doctors in the United Kingdom. It also seems likely that employers, the National Clinical Assessment Service or the General Medical Council know about only a minority of these cases.
- 66** The treatment of identified drug and alcohol addiction is not straightforward. Success rates with intervention (for alcohol addiction in all comers) are generally very modest, even when looking at more subtle indices than total abstinence.¹⁵ Where total abstinence is the aim, some trials suggest that this may only be achieved on between 2% and 14% of occasions, depending upon the type of intervention used. Given these disappointing figures and the threat to patient safety posed by addicted doctors, a number of professionals advocate a dedicated specialist assessment and treatment service. Recently, a six-month abstinence rate of around two-thirds was reported by one group in the United Kingdom, using an innovative and intensive treatment programme with a small group of health professionals (personal communication).¹⁶ The international literature on the

outcomes of treatment for addicted physicians (generally through impaired physicians programmes in the United States of America) is growing but further research would be valuable.¹⁷ Some treatment programmes for chemical dependency estimate that up to 70% of affected healthcare professionals successfully return to medical practice.¹⁸

Assessing and investigating poor performance – the size of the problem

67 Poor performance may occur for a variety of reasons. It may arise from problems stemming directly from the practitioners themselves, but also from the interplay between the different aspects of an individual's practice or between the practitioner and their working environment. These reasons include:

- inadequate education and training;
- poor motivation;
- physical or psychiatric ill health;
- behavioural misconduct;
- an excessively stressful working environment or poor relationships within the clinical team.

68 Poor performance may be obvious but sometimes it is more difficult to identify, particularly where there have been attempts at concealment or the poor performance relates to psychiatric disturbance. Because of these difficulties, estimating the scale of the problem is a challenge. Historically, many cases of poor practice have been dealt with informally, and this situation likely persists. The General Medical Council and the National Clinical Assessment Service (now part of the National Patient Safety Agency) are two important sources of information, although all such national figures are likely to be underestimates.

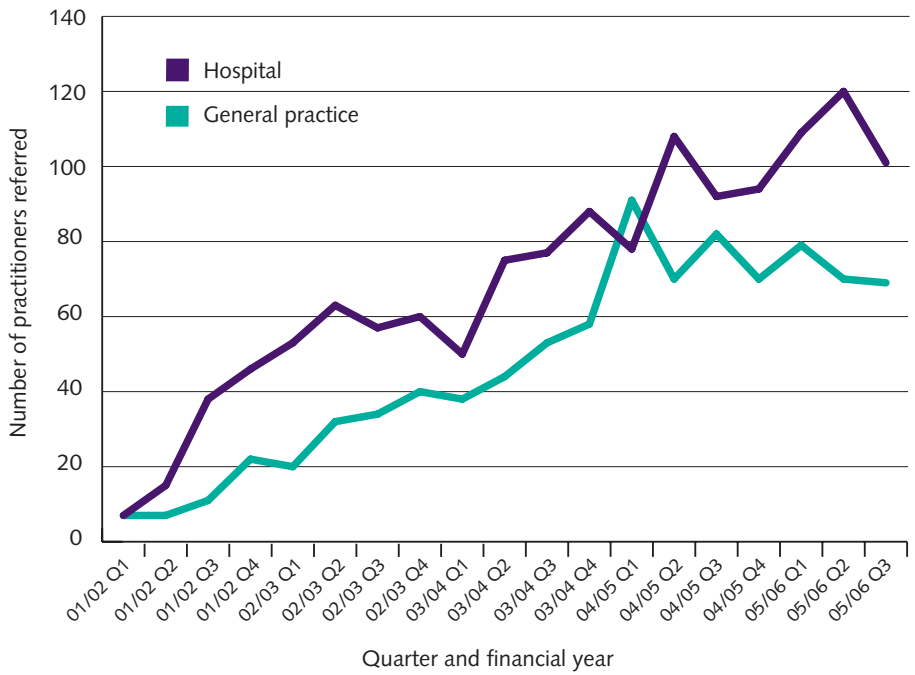
69 My own experience as Director of the Northern and Yorkshire Regional Health Authority during the 1990s gives me a particular insight. Over a five-year period, during which time the authority employed approximately 790 consultants and 60 associate specialists, serious concerns were raised in relation to the conduct or performance of 49 doctors, equating to a five-year period prevalence of 6%. Poor attitude, commitment or knowledge accounted for the majority of these cases, with dishonesty and sexual misconduct occurring in a smaller but significant proportion.¹⁹

70 Data relating to the number of doctors appearing before the General Medical Council between 2001 and 2005 provide a starting point when considering the national picture. Due to the procedural reforms that took place in November 2004 and the transitional arrangements that were in place around that time, figures for 2005 are presented separately.

71 Between 1 January 2001 and 31 October 2004, 545 doctors appeared (for the first time upon a given matter) before a professional conduct committee, 86 doctors appeared before a professional performance committee and 526 doctors appeared before a health committee.

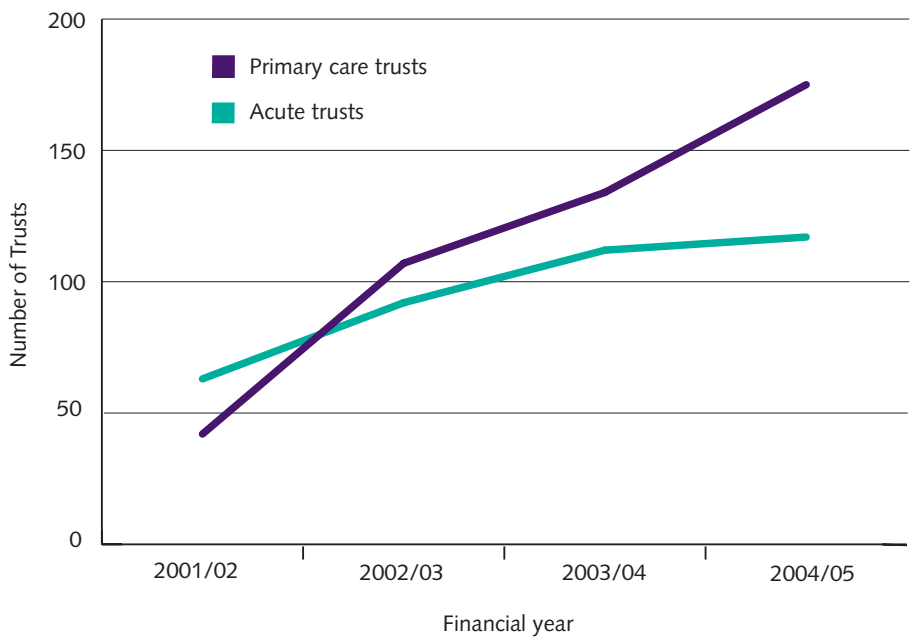
- 72 It is not possible to account for those cases that spanned more than one year, in order to match the cases with their own outcomes. However, the actions taken by the General Medical Council over the same period (three years and 10 months) were as follows:
- 129 doctors were forcibly erased from the Register;
 - 10 doctors took voluntary erasure (following performance or health procedures);
 - 331 doctors were suspended (following health procedures on 70% of occasions) and 39 of these suspensions were for an indefinite period of time;
 - 382 doctors had conditions imposed upon their registration;
 - 74 doctors received reprimands (following conduct procedures);
 - 153 doctors were found not guilty of serious professional misconduct (following conduct procedures).
- 73 During 2005, when the procedural transition meant that several different processes were in operation, 46 doctors were forcibly erased from the Medical Register, 136 were suspended and 121 had conditions imposed upon their registration. In total, 80 new cases were managed in accordance with the General Medical Council's reformed fitness to practise rules.
- 74 The National Clinical Assessment Service becomes involved with doctors when employers, or contractors in the case of general practitioners, have concerns about performance which they feel require external help to tackle, but where those concerns have generally not led them to refer the doctors in question to the General Medical Council. About two-thirds of referrals to the National Clinical Assessment Service are handled through the provision of expert one-to-one advice to a manager over the telephone. The remaining one-third require more intensive involvement, mostly in the form of detailed support from a team of staff from the National Clinical Assessment Service, aimed at enabling local resolution of the problem. Only in a subgroup of cases (up to 10% of all referrals each year) will a detailed performance assessment be undertaken.
- 75 The National Clinical Assessment Service has recently published data describing referral patterns over a four-year period.²⁰ An external release policy is in operation to protect the privacy of individuals and details are not released where case numbers are very low, or where the population of doctors from which cases are drawn numbers under a thousand doctors. The data afford a unique insight into the problem of poor performance:
- 1,772 doctors were referred to the National Clinical Assessment Service over the four-year period.

Quarterly referrals to the National Clinical Assessment Service by sector



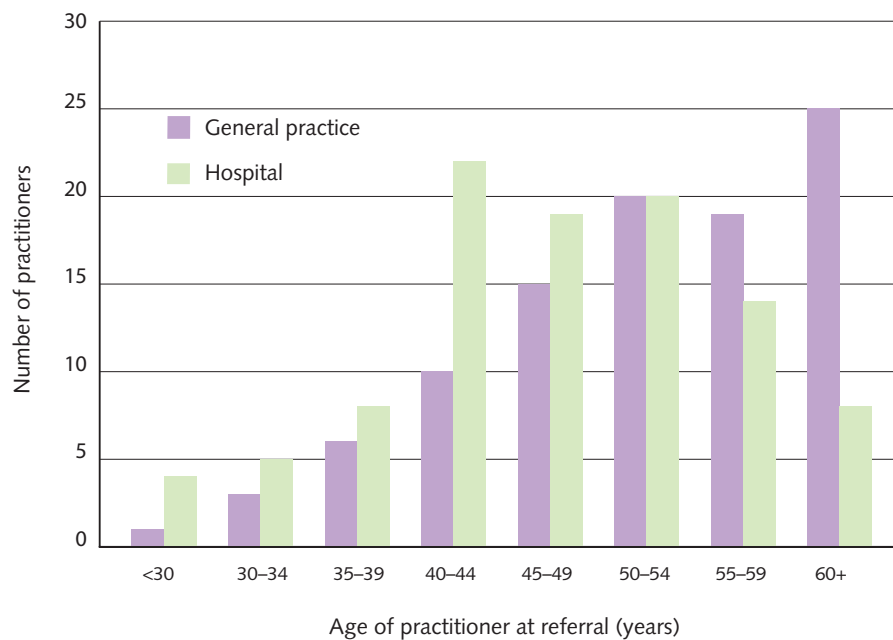
- Up to 10% of referrals each year went on to undergo a full assessment procedure, although the rate appears to be rather lower for psychiatrists.
- More than 90% of NHS Trusts in England have used the National Clinical Assessment Service on at least one occasion, and, at any one time, around half of all NHS organisations have a case open with the National Clinical Assessment Service.

Number of NHS Trusts that have used the National Clinical Assessment Service (cumulative)

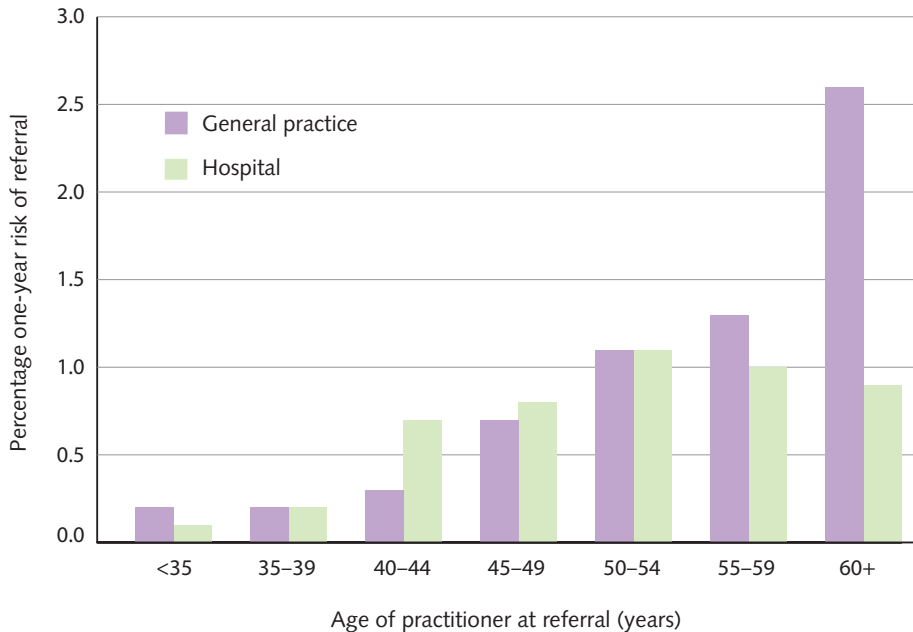


- Behavioural issues alone precipitated referral in 29% of cases, and when concerns were taken collectively, more cases related to behaviour (67%) than clinical capability (61%).
- The majority of referrals made in 2004/05 related to concerns that had come to light within the previous year. This contrasts with 2002/03, when more than 60% of referrals related to more long-standing concerns. About 3% of referrals have related to concerns first identified more than 10 years prior.
- Concerns are more common in men than women and the reasons for this are not readily apparent (nor explained by differences in age structure and specialty distribution).
- Isolated behavioural concerns are more common amongst younger practitioners, whereas concerns relating to clinical capability increase with age. In general practice, the frequency of referral increased markedly with age.

Referrals to the National Clinical Assessment Service by workplace and age, April 2001 – March 2005



Annual risk of referral to the National Clinical Assessment Service by workplace and age, April 2001 – March 2005



The performance of older doctors

The experience of the National Clinical Assessment Service is consistent with the findings of a study involving a systematic review of 62 papers evaluating the impact of age on performance:

- 32 studies reported decreasing performance with increasing years in practice for all outcomes assessed;
- 13 studies reported decreasing performance with increasing years in practice for some outcomes, but no association for others;
- 2 studies reported an initial improvement in performance with increasing experience, followed by a decline;
- 13 studies reported no association;
- only 2 studies reported improving performance with increasing years in practice.

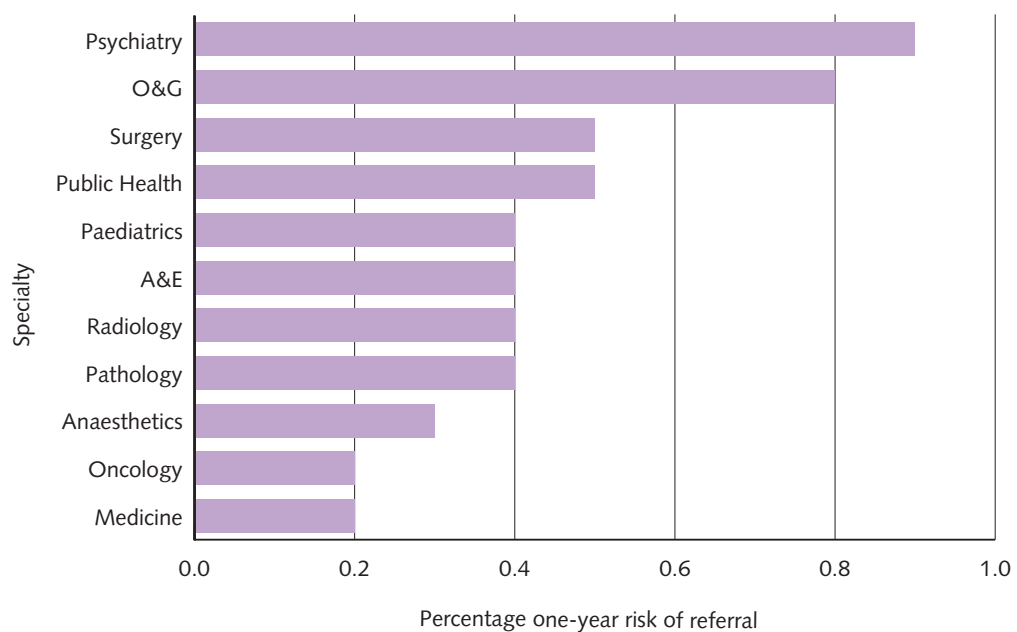
These results challenge the frequent assumption that performance improves as knowledge and skills accumulate over time. Performance may actually decline in older physicians (or a subset of older physicians).

Source: Choudhry N et al. *Systematic review: the relationship between clinical experience and quality of healthcare.*

Ann Intern Med 2005 142:260–273.

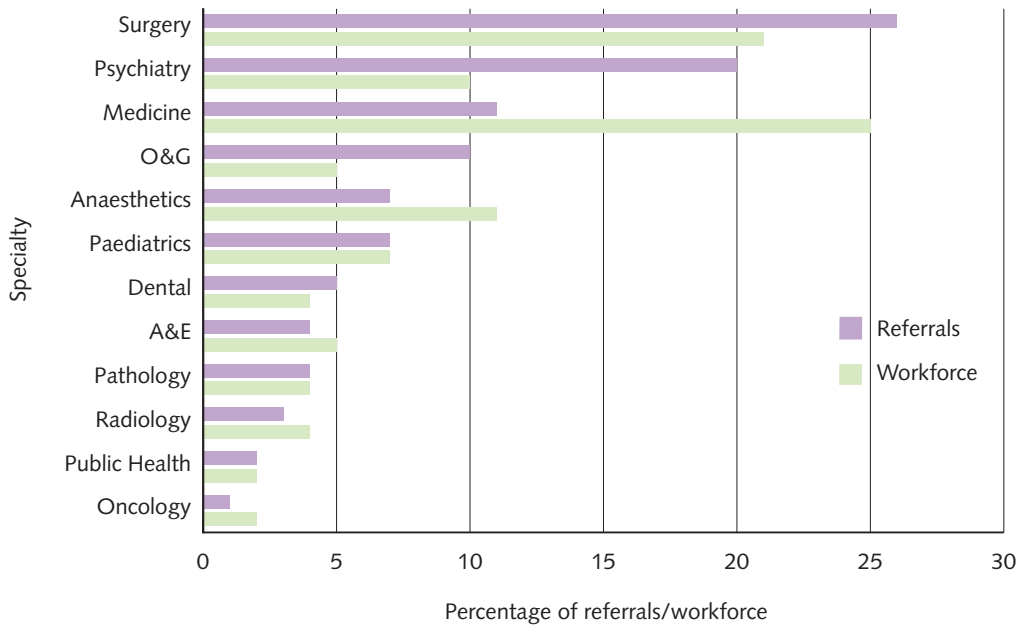
- Non-white practitioners are more likely than white practitioners to be referred to the National Clinical Assessment Service. However, a deeper analysis to include country of primary qualification suggests that this may be a more significant association.
- As the work of the National Clinical Assessment Service has matured, the proportion of referrals already known to the General Medical Council at the time of referral has dropped and is presently only 3%.
- Just over 10% of referrals have involved locums.
- The one-year risk of referral to the National Clinical Assessment Service is approximately 0.5% for all doctors, rising to 1% if doctors in training are excluded.²⁰ This corresponds closely with my own figure from some 10 years previously.

Annual risk of referral to the National Clinical Assessment Service by specialty, April 2001 – March 2005



- There is substantial variation in the number of hospital referrals arising from each specialty which is not accounted for by the numbers of practitioners. Psychiatry, obstetrics and gynaecology, and surgery are over-represented. Medical specialties are under-represented. It is unclear whether this discrepancy relates to the behaviour itself or the perceived risks posed by it.

Referrals to the National Clinical Assessment Service in relation to workforce composition, April 2001 – March 2005



76 The National Clinical Assessment Service also undertook a detailed audit of the first 50 cases where a full assessment was conducted.²¹ Twenty-two of these 50 doctors worked in primary care; the remainder worked in the hospital sector. In the majority of cases, there had been concerns about performance for in excess of two years, perhaps in part due to the novelty of the National Clinical Assessment Service.

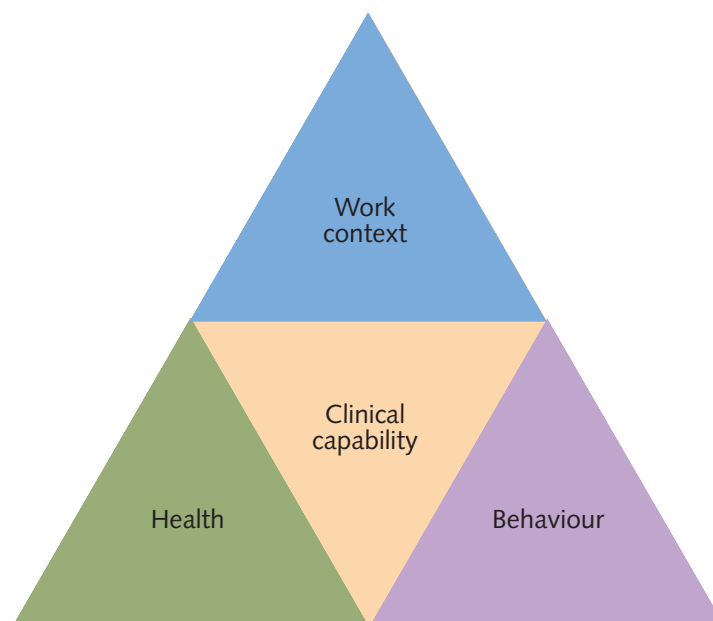
Key findings of a detailed audit into the first 50 full assessments carried out by the National Clinical Assessment Service

- Clinical performance problems were found in 94% of cases.
- Physical and/or mental health problems (including cognitive impairment) were found in 28% of cases.
- Communication with colleagues was sub-optimal in 76% of cases.
- Insufficient training or poor engagement with continuing professional development was found in 48% of cases.

77 The concerns raised at referral to the National Clinical Assessment Service were often not substantiated by assessment. However, in many cases, assessment identified other areas of concern, supporting the concept of broad-based assessment of problems that are usually multi-faceted.

Assessing and investigating poor performance – assessment methods

- 78** The National Clinical Assessment Service and the General Medical Council each employ formal performance assessment procedures from time to time. The cooperation of the practitioner is of course vital if such assessments are to be worthwhile.
- 79** Up to 10% of the doctors referred to the National Clinical Assessment Service undergo a full performance assessment. The purpose of this assessment is to clarify what areas of practice provide cause for concern, to understand causation and to make recommendations as to how these concerns might be resolved. This task is a demanding one as the mechanism employed must be credible, resistant to legal challenge, practicable and affordable.
- 80** Modern approaches to performance assessment recognise that performance has a wider base than simply knowledge and skills alone. The National Clinical Assessment Service has built its approach to performance assessment on four key domains, derived from work in Quebec developing the Monitoring and Enhancement of Physician Performance (MEPP) system, through which the province conducts its competence assurance programme.²² The four domains are as follows:
- clinical capability (including knowledge, skills and the ability to use clinical resources);
 - health and well-being;
 - behaviour;
 - immediate work environment (including the functioning of the clinical team and the wider organisation).
- 81** The interplay between those four domains is seen as central to the understanding of performance through assessment.



- 82** This broader concept of performance (and therefore its assessment) extends to the field of appraisal and individual performance review as part of governance structures, particularly in the field of independent practice. A full and meaningful public assurance that a practitioner is delivering all that is required of them will need evidence in three broad areas:
- education and training (the doctor must be taking a full and successful part in educational appraisal and continuing professional development, as led and assured by the relevant college or faculty);
 - regulation (the doctor must be in possession of a continuing licence to practise in their chosen field, as assessed and granted by the regulator);
 - delivery of care (the doctor must be taking a full and successful part in continuing appraisal by local management and individual performance review, as led by their employers or the organisations to which they provide services).
- 83** These three areas have quite distinct requirements and drivers, and it is possible to provide assurance in one or two of the areas, without satisfying all three. These three areas of evidence, across four domains of practice, provide important context to the ideas contained in my report.
- 84** The National Clinical Assessment Service uses recognised methods, proven in other settings and adapted for the specific purpose. Its approach has been to develop its role as an independent objective assessor of performance in the vocational setting – sometimes called ‘fitness for purpose’ – rather than the ‘fitness to practise’ setting familiar to many regulators. It focuses firmly upon practice (what the practitioner actually does), as opposed to solely competence. Assessment is therefore holistic and is not confined to knowledge and skills. It is an intensive process for all involved. This is reflected in the structure of the assessment team, which is chaired by a lay assessor, and includes an occupational health physician, an occupational psychologist and at least two clinical assessors in the relevant area of practice.

National Clinical Assessment Service: performance assessment

- Occupational health assessment
- Behavioural assessment by an occupational psychologist
 - Questionnaire
 - Interview
- On-site clinical assessment (usually over two days)
 - Review of data provided by practitioner and referring body (employer or contractor)
 - Clinical record review
 - Review of multi-source feedback from colleagues and patients
 - Direct observation of practice
 - Assessment of clinical decision making, using case-based assessment (sometimes termed 'chart-simulated recall')
 - Site review
 - Clinical simulations (if necessary)
 - Interview with the practitioner

85 When a doctor is referred to the General Medical Council in relation to their performance, a formal assessment may be deemed necessary. Where a doctor agrees to such a process, an assessment team is appointed by the General Medical Council, comprising of a medically qualified team leader and additional medical and non-medical performance assessors. Although the precise form of the assessment varies according to the issues in question, it almost invariably involves peer-review and a test of competence.

General Medical Council: performance assessment

- Peer-review
 - A visit to the doctor's place of work
 - Interviews with the doctor
 - Interviews with third parties (including complainants)
 - Review of medical records
- Test of competence
 - Formal tests of knowledge and skills required for the area of practice in which the doctor is engaged

- 86** Both organisations share the results of their assessments with the practitioner concerned and allow an opportunity for comment.
- 87** During 2003, I held a series of meetings with the medical Royal Colleges, the General Medical Council, the British Medical Association and others to agree a set of principles that should underlie all assessment in medicine.²³ These still hold true as a benchmark for good practice.

Is appraisal assessment?

- 88** The requirement for there to be an annual appraisal for every NHS doctor in a career grade post was proposed in my report *Supporting doctors, protecting patients*²⁴ and implemented for hospital and public health doctors in 2001, and for general practitioners the year after. Arrangements differ for doctors employed in the private sector but many are involved in some system of annual appraisal.
- 89** The idea of appraisal and its underpinning philosophy has proved particularly contentious. By and large, doctors have valued the opportunity that annual appraisal provides to reflect on their practice and identify scope for professional development but only in so far as it is a formative (i.e. developmental) process. Suggestions that appraisal could ever be summative (i.e. judgemental about the standard of an individual's performance) is an anathema to some medical professional bodies and individual doctors. Yet Dame Janet Smith in *The Shipman Inquiry: fifth report*²⁵ condemned the NHS system of annual appraisal because it failed to carry out any assessment or make any judgements.
- 90** Even leaving aside the underpinning philosophy of appraisal (assurance versus improvement), the emphasis on different aspects of content and the way it is carried out are themselves flaws in the present arrangements.

- 91** Having empirically identified best practice, the methodologies for carrying out appraisal (contained within the national guidance for appraisal) were arrived at through negotiation with the main trade union, the British Medical Association, rather than being firmly rooted in research evidence.
- 92** In the absence of standards or standardisation of approach, the pattern of appraisal around the country is reported as variable. In some NHS Trusts, annual appraisal was already in place and the policy decision to make it a requirement strengthened this practice. In other NHS Trusts, it was started from scratch and some of the early anecdotal accounts were alarming. For example, one leading doctor described how, in the first year of the scheme, and facing a deadline for completion of all appraisals in the organisation, he was asked by the human resources department to sign a blank appraisal form. Such practice, apart from having no value, undermines a process intended to benefit the quality of care.
- 93** Feedback suggests that such events do not now happen and that appraisal in hospitals is well established, though its quality undoubtedly varies. The experience is also that in some hospitals too much of the time set aside for appraisal is taken up with detailed negotiations of job plans.
- 94** Annual appraisal for doctors in primary care has evolved somewhat differently, mainly because of the absence of the managerial hierarchy of medical and clinical directors which exists in hospitals. In primary care, general practitioners are appraised by peers (usually other general practitioners working in the area). Increasingly, the local system of appraisal for general practitioners is organised under the auspices of the medical director of the primary care trust. However, the latter's role is often restricted to ensuring that appraisals are carried out each year and, in some parts of the country, to establishing a good training programme for appraisers.
- 95** Essentially, the appraisal process in primary care is currently heavily reliant on the general practitioner's self-assessment because the doctor carrying out the appraisal will have little first-hand knowledge or information about their colleague's work or day-to-day performance in the job. Anecdotal accounts suggest that where the management of a primary care trust has concerns about the standards of a general practitioner's care, more often than not, such individuals have 'good' appraisals on file.
- 96** Before the advent of the current General Medical Services contract, many general practitioners were paid specifically (usually upwards of £150, sometimes much more, for preparation time and the cost of locum cover) for taking part in the appraisal process. This seemed anachronistic given the element of professional development.
- 97** The Clinical Governance Support Team has done much to enhance the quality of annual appraisal for NHS doctors, including the publication of a set of standards (see box below), though there is clearly much more to do.

High-level indicators to assure the quality of appraisal of NHS doctors

Organisational ethos

There is unequivocal commitment from the highest levels of the host organisation to deliver a quality-assured system of appraisal that is fully integrated with other systems of quality improvement.

Appraiser selection, skills and training

The host organisation has a process for selection of appraisers, and appraiser skills are continually reviewed and developed.

Appraisal discussion

The appraisal discussion is challenging and effective; it is informed by valid and verifiable supporting evidence that reflects the breadth of the individual doctor's practice and results in a personal development plan (PDP) prioritising the doctor's development needs for the coming year.

Systems and infrastructure

The supporting systems and infrastructure are effective and ensure that all doctors linked to the host organisation are supported and appraised annually.

Source: Clinical Governance Support Team. *Assuring the quality of medical appraisal. Report of NHS Clinical Governance Support Team Expert Group.* Clinical Governance Support Team, Leicester, 2005.

Conclusions

- 98** The need for transparent and objective assessment of clinical performance during training is now well established. The means by which to deliver such assessment are evolving but need to develop further.
- 99** Many promising tools have been designed in order to produce assessment that is more objective and structured: these include high-fidelity simulators. Assessment can cover both technical and non-technical aspects of performance.
- 100** The place of assessment for doctors established in career posts is currently less well defined, but many professional bodies have made a promising start in determining how best to assess practitioners to ensure continuing competence.
- 101** The place of professional codes is an area that has been much discussed: although there are several examples of sets of standards for doctors, these have not been effectively operationalised for day-to-day use as formal codes of practice.
- 102** Numerous existing sources of data have the potential to aid the assessment of individual practitioners. Many of these data are currently collected for another prime purpose.
- 103** The degree to which ill health adversely affects the performance of doctors is uncertain. Specialised treatment programmes may offer improved outcomes: further research and audit would be helpful.
- 104** An audit of the alert letter system in one of the NHS regions, presented here for the first time, reveals important details about the processes and the outcomes of this system. This information is key to understanding the whole field of medical regulation.
- 105** The exact extent of poor performance is difficult to determine but the work of the National Clinical Assessment Service has been extremely informative in describing the scale and nature of the problem. Both the National Clinical Assessment Service and the General Medical Council operate performance assessment procedures.

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Chapter Six:

Medical regulation around the world

Key points in this chapter

- There is no one model of medical regulation which is internationally accepted as best practice.
- Medical regulation is developing rapidly in the countries examined in research for this report.
- The trend is for medical regulatory bodies to demonstrate more transparency in their processes and ways of working and to become more accountable to external authorities.
- There is a trend away from placing standard setting, the maintenance of the Register, investigation, prosecution and adjudication all under the remit of one organisation.
- Many codes of good practice for doctors do not specify the standards expected and are more aspirational than indicative.
- Across most countries surveyed, there are moves towards periodic mandatory assessment of competence.
- No single model of re-accreditation or re-certification has been evaluated and costed so that it could be used to design a system of revalidation.
- A greater range of stakeholders is involved in dealing with poor practice than in the past.

- 1** The need to regulate the medical profession is not peculiar to the United Kingdom, nor are the challenges inherent in the design and operation of a regulatory system. As part of my review, I commissioned a research report on medical regulation in an international context from Professor Judith Allsop of the University of Lincoln.¹ Much of the content in this chapter is based on Professor Allsop's findings.
- 2** Many of the countries reviewed in the research report (Australia, Canada, United States of America, Netherlands, New Zealand and Finland) have introduced revised legislation on medical regulation comparatively recently.
- 3** The emphasis in medical regulation in most of these jurisdictions has changed in recent years. The traditional form of professional regulation based on self-regulation and characterised by

collegiality, informality and confidentiality has given way to further transparency, more formal rules and stronger accountability to external authorities.

- 4 Medical regulation is evolving rapidly in the countries reviewed, although there is no single model to follow that has been evaluated and costed.
- 5 This chapter summarises the methods used for medical regulation in six jurisdictions. I have then drawn out some common themes and trends across the world.

International case studies

Australia

- 6 In Australia, responsibility for healthcare is shared between the national government (the Commonwealth) and the state governments. The Commonwealth develops policy and provides funding primarily through a public health insurance scheme that gives universal coverage for free public hospital treatment, out of hospital services and pharmacy services. Private health insurance plays a prominent role and those who pay for private insurance are given a partial rebate. Since the early 1990s, the Australian national government has placed strong emphasis on the quality and safety of healthcare through the establishment of the Australian Council for Safety and Quality in Health Care (this has recently been superseded by a new quality body).
- 7 State, territorial and local governments are responsible for the delivery and management of health services. The registration of doctors is the responsibility of State Medical Boards.

New South Wales, Australia

In New South Wales, the State Governor appoints a Medical Board which is the statutory regulator of doctors in the state. Many of the appointees are nominated by other bodies. There are fifteen professional and five lay members. The board submits an annual report to Parliament through ministers, detailing complaints encountered, performance assessments conducted and actions taken. Information held on the state register must be made available to members of the public who enquire about conditions imposed upon a doctor's practice. Matters solely relating to the health of a practitioner are not disclosed.

Since 2000, all doctors in New South Wales must demonstrate annually their continuing fitness to practise. They do this by submitting a wide-ranging self-declaration. Information required includes: current qualifications and experience, health status, criminal charges and convictions, disciplinary actions and 'professionalism'. 'Professionalism' may include self-certification of continuing medical education or participation in a professional standards programme operated by one of the national specialty medical colleges. This process relies upon membership of the relevant college, which is not mandatory for specialists, although many employers insist upon it. There is currently no direct link between compliance with the annual return and continuing state registration

(i.e. re-certification or revalidation). Nor, with the exception of one specialty, is participation in a professional standards programme explicitly linked to ongoing specialty certification. The specialty medical colleges in Australia have played a major part in setting pragmatic standards and in establishing professional development programmes (including the domains of clinical expertise, risk management and professional values) to keep doctors up to date.

The Medical Board in New South Wales plays a key role in the management of poor performance, the detection of which is complaint-driven. The handling of complaints is a responsibility shared by the Medical Board and the Healthcare Complaints Commission: irrespective of which body receives the complaint, there is a requirement to consult on all individual complaints and to assess them jointly. If it is deemed that investigation is required, the Healthcare Complaints Commission takes on this task, employing lay staff, drawing on medical expertise as necessary. Where appropriate, the Healthcare Complaints Commission may prosecute a practitioner before the Medical Tribunal.

The Medical Board, once aware of concerns relating to a practitioner's performance or conduct (usually following a complaint), makes a decision as to whether that complaint relates to actions that are reckless, unethical, wilful or criminal. In such instances, the complaint may result in definitive action upon a practitioner's registration and the case is referred to the Medical Tribunal, often via the Healthcare Complaints Commission (where investigation can take place). In other situations, a non-disciplinary route is followed. If, during the course of conduct proceedings, the Medical Board forms the view that suspension or removal from the register may be warranted, proceedings are terminated and referred to the Medical Tribunal for a complete rehearing.

Where the Medical Board chooses to follow a non-disciplinary route, it frequently makes use of a performance assessment programme: this programme is intended to be educative, focusing upon early intervention and remediation for the doctor. Assessments are broad based, conducted by peers and usually involve observation of the practitioner in the workplace. Following assessment, a performance review panel will consider the practitioner's case and will recommend educational or protective actions: the practitioner will usually be monitored whilst such actions are ongoing and reassessed at a later date. When the practitioner does not agree to the recommended actions or conditions, they may appeal to the Medical Tribunal, or the Medical Board may itself 'recommend that a complaint be made'. A similar system of assessment and panel review is operated for physicians with health problems, through the Impaired Physicians Health Programme.

There are a number of routes through which the Medical Board may dispose of a complaint:

- require no action;
- refer for direct resolution;
- refer to Healthcare Complaints Commission;
- refer to Health Conciliation Registry (with consent of all);
- refer on to a panel of the Medical Board (private and informal);
- refer to the Medical Tribunal.

The panels of the Medical Board have a wide range of sanctions and tools available, including conditions on practice and educational remediation. Practitioners have a right of appeal to the Medical Tribunal.

The Medical Tribunal is a separate and independent body. The Tribunal is made up of a legally qualified chair, an additional lay member and two medical practitioners. It has the ability to de-register a practitioner. Practitioners may appeal to the State Supreme Court.

- 8 The Australian system differs from that in the United Kingdom because the federal structure of government creates a division of functions between bodies at the Commonwealth (i.e. national) level and those in the states. At the state level, medical boards license doctors to practise and deal with complaints and poor performance. A doctor licensed in one state can practise in others.
- 9 In New South Wales – chosen here as an example of the state system of regulation in Australia – there is a strong emphasis on thorough investigation of complaints to identify situations where patients are at risk from a practitioner's conduct or performance. There is a strong system of joint working on complaints between the Medical Board and the Healthcare Complaints Commission. The latter is an independent statutory body established following a series of inquiries into poor practice.

Canada

- 10 In Canada, the federal government requires that provincial and territorial health insurance plans are comprehensive in order to qualify for full federal transfers. Such plans are publicly funded, through general taxation. Three provinces charge additional healthcare premiums. In addition, provincial and territorial governments provide some supplementary benefits (such as prescription drugs, ambulance services, dental care, home care and occupational therapy) to certain groups. Charges may be made to patients for non-insured services. Most medical practitioners are in group or private practice, remunerated on a fee-for-service basis.

- 11 Provincial and territorial governments have the authority to regulate health providers, leading to a degree of complexity across Canada. Typically, they delegate control over medical practitioners to professional ‘colleges’, whose primary duty is to set standards and license practitioners.

Ontario, Canada

Within Ontario, there is a common framework for the regulation of all the health professions. There are a number of legally defined professional acts and a practitioner must be registered and licensed by a relevant professional college in order to carry these out. The regulatory college for doctors is the College of Physicians and Surgeons of Ontario, and licensing by this body allows doctors to perform 12 of the 13 defined professional acts (the exception relates to dental procedures).

The powers of the provincial government are essentially delegated to the college. Where debate arises in relation to decisions made by the college, the Health Professions Appeal and Review Board is able to decide whether or not the correct procedures have been followed (and if not, direct a re-hearing). Where the validity of a decision itself is in question (rather than procedural technicalities), appeals can be made to the Ontario Divisional Court. In addition, there is an arm's-length governmental agency, the Health Professions Regulatory Advisory Council, which maintains an oversight role.

The College of Physicians and Surgeons of Ontario is a membership body and 16 of its Council are elected by members. Three physicians are appointed by the provincial government, along with between 13 and 15 lay members. The college controls access to the register, which is accessible to the public via the internet. The college also plays a role in maintaining professional standards in Ontario, although to a large extent this relies upon continuing membership of the college following initial registration: this is not mandatory and fees may act as a disincentive to some, particularly general practitioners.

In order to maintain standards, the college operates a peer-assessment scheme. Practitioners may undergo assessment for a number of reasons: random selection, being aged over 70 years, following self-referral or the identification of concerns by the college. The assessment process is conducted by a doctor from a similar professional field, trained specifically for the task. The assessor reports to both the practitioner and the college. The report may confirm good practice, suggest specific educational remediation or indeed onward referral for an in-depth assessment (both generic and specialty-specific). Around 700 peer-assessments are carried out through the college each year.

In addition to registration with the college in Ontario, a number of specialist certification or fellowship schemes are operated by the national specialty medical colleges. These schemes generally involve records of continuing medical education and self-reflection exercises: they are entirely voluntary.

The College of Physicians and Surgeons of Ontario is developing plans for a process of re-certification or revalidation. This will be based on a three-layer system for monitoring and evaluating physician performance, with only a proportion of practitioners passing through to the more detailed layers. These plans are not yet finalised and over the last six months, the Ontario Medical Association has declared its opposition to the process, based largely on concerns over the validity of the system and the additional burden that will be placed on practitioners.

Ontario has a developed system to identify, help and manage sick doctors. The Ontario Medical Association Physician Health Programme collaborates with the College of Physicians and Surgeons of Ontario in this area. The programme deals mainly with doctors with psychiatric illness and addiction problems. The college is represented on the programme and makes a financial contribution towards it. The majority of doctors refer themselves to the service.

The College of Physicians and Surgeons of Ontario has a complex committee structure with separate fitness to practise, complaints and discipline panels (with onward referrals from complaints to discipline). Complaints received by the college are investigated by a health professional, who is trained and employed for this purpose. Efforts are made to obtain resolution without recourse to the complaints committee where possible. The discipline and fitness to practise committees have a number of sanctions at their disposal, including the imposition of conditions, fines, suspension or erasure. There are plans afoot for judges and senior lawyers to chair a number of the college's discipline committees.

- 12 The Canadian system, as illustrated by practice in Ontario, is similar in a number of respects to that in the United Kingdom. The powers of government, including the control of access to the register, are delegated to a body made up of elected and appointed members. There is a relatively complex committee structure and the processes employed in fitness to practise procedures are less transparent than in some of the other jurisdictions examined. As in the United Kingdom, fitness to practise procedures, by design, tend to be adversarial in nature.
- 13 The College of Physicians and Surgeons of Ontario operates a system of peer-assessment. Whilst usually prompted by complaints or concerns, the process can be triggered on a random basis. In addition, the college plans to introduce a system of intermittent revalidation: as in the United Kingdom, the design of the process (rather than the concept itself) continues to be the subject of debate and disagreement.

Finland

- 14 Healthcare in Finland is available to all through a system of compulsory sickness insurance. It is funded through taxation at both the national and municipal level. Supplementary private medical care is also available, particularly in larger towns.
- 15 The regulation of medical practitioners in Finland is a function of the state. The National Authority for Medico-legal Affairs (an executive agency of the Ministry of Social Affairs and Health) is responsible for the registration and licensing of doctors. In addition, the agency has a wider role in assuring patient safety, setting policy around ethically challenging areas (such as abortion, sterilisation, human tissue and forensic psychiatry) and investigating deaths following complaints.

Finland

The National Authority for Medico-legal Affairs regulates doctors and all other health professionals. A combined register is maintained and this can be accessed by the public in a number of ways. For over 40 years, there has been collaboration between the Nordic countries in relation to the regulation of health professionals and, in particular, with regard to specialist training.

Unusually in Europe, specialist societies in Finland do not have the right to grant specialist certification to doctors, this function being undertaken instead by the universities, upon successful completion of an examination.

The main mechanism for the maintenance of standards is participation in continuing medical education, strongly supported by the doctors' trade union. In 2004, the Finnish Government placed responsibility for providing, funding, monitoring and evaluating continuing medical education with employers. It is too early to judge how effective these mechanisms are. There is no process of re-certification.

The handling of complaints is an important mechanism by which medicine is regulated in Finland. Complaints may be dealt with by the employer, a State Provincial Office or the National Authority for Medico-legal Affairs. A patient liaison officer is involved locally in drawing up the complaint and directing it to the most appropriate destination. The most serious complaints, and those involving death, tend to be managed by the National Authority, which is empowered to act upon a doctor's registration (although a range of other sanctions are available to the other bodies). The National Authority also has the right to formally assess the performance of a doctor, and refusal to cooperate may result in the cancellation of a licence to practise.

Decisions concerning fitness to practise are made by a supervision board, formed by the National Authority and made up of five health professionals.

- 16** The most striking feature of the system for medical regulation in Finland is that it is operated unequivocally by the Government. Some remote rural communities in Finland experience shortages of key workers, including doctors. Commentators have suggested that the dual role of government as provider and regulator produces a conflict of interest and may have an adverse impact upon quality.
- 17** The Finnish system places significant responsibilities in the hands of employers, both in complaint handling and in the mandatory provision of continuing medical education.

The Netherlands

- 18** Since the beginning of 2006, healthcare in the Netherlands has been funded by compulsory basic insurance, with voluntary supplemental schemes. Local tax revenue and government subsidy is used to top-up the income from insurance premiums. Insurance schemes tend to involve some cost sharing, in the form of co-payments and deductibles.
- 19** Medical regulation occurs via two parallel routes in the Netherlands. The Central Information Centre for Professional Practitioners in Healthcare maintains a register of all healthcare professionals entitled to practise in the country, on behalf of the Government. In addition, the Central College of Specialists (a professional body) operates a registration scheme for specialist doctors: this system encompasses compulsory intermittent re-registration, although the details continue to evolve.

The Netherlands

The Minister of Health, Welfare and Sport is responsible for the regulation of health professionals through the Central Information Centre for Professional Practitioners in Healthcare. The centre maintains a register that is readily accessible online (although details of expired conditions upon practice are not included).

In addition, there is a separate registration scheme for specialist doctors, run by the Central College of Specialists on behalf of the Royal Dutch Medical Association (a federation of specialist associations), that also has a remit covering the quality assurance of postgraduate training. The Central College of Specialists has operated a mandatory system of re-registration for all specialists (not general practitioners) since 1991. The exact form of this system has varied over the years but currently involves three elements, on a five-yearly basis: a minimum number of hours per week practising in the given specialty, at least 40 hours of accredited continuing medical education and, from 2005, participation in a 'visitatie' programme.

The 'visitatie' programme, having developed from a system set up in 1966 to quality assure postgraduate training, now involves visitation of specialty practices and systematic peer-review of individual doctors (and the wider team), across four domains: patient care, patient perspective, professional development and specialist group functioning. The 'visitatie' programme, operated by the specialist

associations (including the Dutch Association for General Practitioners), has been funded by the Government in recent years, although this arrangement is scheduled to end in 2007: there is an expectation that funding is likely to become the responsibility of specialists themselves. The 'visitatie', in general a positive process of quality assurance, can result in a number of sanctions, including a further visit at a reduced interval, mandatory improvement progress reporting, educational undertakings, onward reporting to another body or termination of a doctor's membership of the specialist association. Membership of the relevant specialist association is not currently compulsory across all specialties.

In order to deal with poor performance, the Netherlands operates a structured system of complaint handling. Each local provider has a statutory requirement to operate a complaints committee with an independent chair. There is a national telephone helpline to signpost complainants through the system. The complaints committees may refer a complainant on to the Dutch Healthcare Inspectorate or to a disciplinary board. Statutory disciplinary procedures are in place for all health professionals. For doctors, these are operated through a system of six Medical Disciplinary Colleges. Each college operates a disciplinary board made up of five members, a mixture of legally and medically qualified. There are a number of sanctions available to these boards, including deletion, suspension or 'suspended' suspension from the national register of healthcare professionals: in addition, conditions on practice or financial penalties can be imposed.

- 20 The system in the Netherlands is notable for the way in which it combines a restrictive register (operated by the state) with an indicative specialist register (operated by the professional bodies).
- 21 There are two cornerstones to the Dutch approach: 'visitaties' and the independent, local handling of complaints. The 'visitaties' offer an interesting model for revalidation.
- 22 Currently, the system of 'visitaties' is heavily subsidised by government. The true costs of medical regulation in the Netherlands are difficult to identify.

New Zealand

- 23 The New Zealand healthcare system is financed through general taxation. Funds are distributed via district health boards. A very broad range of services is provided. For some services (including primary care and non-hospital prescriptions), a significant proportion of the population makes means-tested co-payments. Around one-third of New Zealanders have private insurance to cover the costs of co-payments, elective surgery and specialist outpatient consultations.
- 24 The Minister of Health is responsible for medical regulation and discharges this duty by appointing a Medical Council. The Council defines scopes of practice, sets standards and maintains a register. Specialist colleges have a role in the design and delivery of continuing professional development

programmes, participation in which is a prerequisite for maintenance of registration. A separate tribunal is responsible for adjudication, where the civil standard of proof is applied.

New Zealand

The Medical Council of New Zealand is composed of seven professional and three lay members. Since 2003, a common framework for the regulation of all healthcare professionals has been in place. The Health Practitioners Disciplinary Tribunal is an independent body responsible for adjudication in relation to matters that may impinge upon registration.

The Medical Council defines three 'scopes of practice': general, vocational (specialist) and special purpose. A doctor may register in more than one of these areas. Part of the registration process, where applicable, includes the submission of certificates of good standing from all the authorities with whom a practitioner has been registered over the preceding three years. The register is accessible online.

In addition to maintaining the register, the Medical Council also sets standards and professional codes, based in part on the General Medical Council's *Good medical practice*. In order to maintain their place on the register, a doctor must submit an annual declaration to the Medical Council. The declaration covers ongoing competence, adequate health and participation in a programme of continuing professional development. Each year, 10% of returns are audited. If it is found that a doctor has not participated in 10 hours of clinical audit activity, 20 hours of peer-review and 30 hours of continuing medical education, a 360-degree feedback exercise will be carried out. If this indicates any cause for concern, the practitioner will be referred for formal assessment of competence.

The specialist colleges have an important role, often exercised in conjunction with their Australian counterparts, in standard setting and the provision of accredited continuing professional development. The New Zealand College of General Practitioners operates a scheme involving the accumulation of points over a three-year cycle (resuscitation training is a compulsory component), designed to satisfy the requirements of the Medical Council.

Concerns about poor performance can come to the Medical Council from a number of sources, and many bodies have a statutory responsibility to inform the Medical Council of any concerns. Complaints from patients about doctors must be referred on to the Office of the Health and Disability Commissioner in the first instance, for investigation as required. The Medical Council is empowered to direct a registrant to undertake a 'performance assessment for competence' at any time, although usually this would be in response to concerns raised. Assessment, funded by the Medical Council, is carried out by a panel of three members, including two

appropriate medical professionals. During an assessment, the panel typically spends a day in practice, with one professional observing the practitioner, the other inspecting records. Standardised assessment techniques are used where possible. The assessment panel prepares a report for the Medical Council and the practitioner. The Medical Council can pursue a number of avenues, including mandating participation in educational activities, after which a further assessment of performance will take place.

Where concerns about a practitioner relate predominantly to a health matter, a health committee is convened to assess the health of the doctor. The overriding priority of the committee is patient safety. The usual outcome is a negotiated agreement with the doctor as to what measures or restrictions may be necessary. The Medical Council regards the health committee as a 'soft mechanism' but notes that it is usually effective, with progress to disciplinary proceedings or formal action upon registration being rare.

Professional conduct committees of the Medical Council comprise two physicians and a lay panellist, none of whom are Council members. Professional conduct committees may decide to pursue a charge against the practitioner.

An important element of the New Zealand regulatory landscape is the presence of the Accident Compensation Commission (a system of no-fault compensation covering medical injury) and the Office of the Health and Disability Commissioner. The Health and Disability Commissioner receives all patient complaints and some others: all are analysed, examining the role of both individuals and systems to promote an atmosphere of learning. The Commissioner may direct either the investigation of a complaint (as is the case with all complaints of a clinical nature) or referral back for local remediation. If an investigation concludes that a professional has breached their obligations, the Commissioner makes recommendations, which are usually taken up by the practitioner. The Commissioner may, however, decide to charge the practitioner before the Health Practitioners Disciplinary Tribunal (bypassing the Medical Council).

The Health Practitioners Disciplinary Tribunal adjudicates upon charges brought either by the Medical Council of New Zealand or by the Health and Disability Commissioner. The Tribunal is independent with a legal chair and a panel maintained by the Minister of Health. Hearings are usually held in public and the civil standard of proof is applied, not the higher criminal standard. The Tribunal is able to take a range of actions against the practitioner's registration with the New Zealand Medical Council: cancellation, suspension or imposition of conditions. It may also censure a practitioner, impose a fine or make an award of costs. Appeals can be made to the High Court, or the Human Rights Review Tribunal.

- 25** Medical regulation in New Zealand follows a very similar model to that operating in Australia. An appointed Medical Council is responsible for registration, with an independent tribunal taking on the adjudication function. A well-developed system of performance assessment is available to aid the Medical Council in its proceedings. The existence of a separate adjudicator may permit the Medical Council to take on a remedial, rather than adversarial, role.
- 26** Complaint handling in New Zealand is thorough and all aspects of a complaint, whether relating to an individual or the wider system, are examined and managed together. This affords significant opportunities for learning and continuous improvement.

United States of America

- 27** Health services in the United States of America are financed through a mixture of public and private health insurance, although 45 million Americans were uninsured in 2004. Health benefits and services vary according to the insurance scheme, as do cost-sharing arrangements. Medicare is an insurance scheme covering the elderly and some younger people with chronic diseases, administered by the federal government and financed through a combination of payroll taxes, general federal revenues and premiums. The scheme has recently expanded to cover outpatient prescription charges. Medicaid is an insurance programme administered by the states, within federal guidelines: it covers some of the most vulnerable groups in society and is often a vital source of cover for the frail elderly and the disabled. Private insurance is provided by approximately 1,200 independent organisations. A number of managed care plans have been developed in an attempt to contain spiralling costs.
- 28** The regulation of medical practitioners is carried out at the level of the state, although the Federation of State Medical Boards issues guidance encouraging a degree of harmonisation. The American Board of Medical Specialties plays an important role in specialty certification (and re-certification). Although specialist certification is not mandatory as such, insurers and other providers often insist upon the maintenance of certification.

New York State, United States of America

Doctors in the United States of America may hold a licence to practise in more than one state. Federal and national bodies are concerned with the setting of nationwide criteria and standards. The National Board of Medical Examiners regulates medical schools, providing a level playing field in terms of standards at the point of initial state licensure for graduates of American schools. The Federation of State Medical Boards has several functions. It operates:

- an assessment system (for re-entry following removal of a licence, or if state disciplinary procedures require);
- a data centre (to share disciplinary information);
- an accreditation service for continuing medical education;
- a federal credential verification service.

The Federation issues guidance to state boards as to licensing and discipline. It advocates mandatory periodic assessment of continuing medical education and continuing professional development for re-licensure.

The National Practitioner Data Bank holds information (both positive and negative) on all physicians, from multiple sources. The data bank is accessible to the state boards, and hospital employers are also required to check with the data bank when awarding privileges. In addition, there is a Healthcare Integrity and Protection Data Bank, recording information on adverse incidents involving practitioners. There is concern about the quality of national data due to under-reporting. Commercial enterprises also record and collate data on individual physicians and disclose this to patients or others for a fee.

The American Board of Medical Specialties has a significant national role in specialty certification across 24 different specialties. Although re-certification is nominally voluntary, certificates are now time-limited, and the maintenance of certification is vital for retaining privileges and obtaining fees at a higher rate – health insurers and providers therefore make a substantial indirect contribution to medical regulation. The various specialties each operate a 'maintenance of certification programme'. Typically such programmes are computer based and involve prescribed reading and multiple choice questions (that can be taken again if failed). Different specialties take different approaches and programmes are at varying stages of maturity.

In New York State itself, the New York State Medical Board holds the register of physicians. The board is made up of 24 nominated members, including two lay people. There are two responsible bodies for medical regulation: licensure and registration are the remit of the Office of the Professions, part of the State Department of Education. It is this office that appoints the State Medical Board. Disciplinary functions, however, reside with the Office of Professional Medical Conduct, part of the State Department of Health.

Initial registration and licensure requires proof of an eligible degree, lawful residence and completion of an appropriate education, examinations and experience. In particular, the State Medical Board requires the completion of specific training in child protection and infection control. In order to maintain standards, there is a requirement for re-licensure every two years after initial registration. Whilst there is an expectation that a physician will participate in continuing medical education, there is no explicit link with re-licensure. Since 2000, the State Medical Board has been considering ways of mandating continuing medical education and looking at other mechanisms for assuring continued fitness to practise, including programmes of peer-review. There has been no decision to date.

The State Board for Professional Medical Conduct (separate from the State Medical Board) investigates and adjudicates on complaints. The Board has 168 appointed members, of whom 107 are nominated physicians. The Commissioner for Health appoints the Board members, on behalf of the State Governor. It is this Board that has the power to act upon a licence. There are 46 defined categories of offence, one of which is the failure to report concerns about a colleague. Complaints are initially screened, then investigated and put before an Investigation Committee (two professional and one lay member). The Investigation Committee may dispose of a complaint, refer it to another body (such as the Committee of Physician Health of the Medical Society of the State of New York) or on to the Disciplinary Committee. It is the Disciplinary Committee (same composition) that may instruct the New York State Medical Board to act upon a doctor's registration: in addition to taking various actions upon a licence, the Committee can also issue censure, fines or, indeed, require a practitioner to undertake up to 500 hours of community service. New York State is obliged to inform the two national data banks of any action taken on a licence to practise.

- 29** Medical regulation in the United States of America contrasts with that in the other jurisdictions. In addition to the marked variability across the individual states, the role of organisations such as healthcare providers and insurers is important: real pressure to maintain certification is exerted via this route. The challenges posed by medical regulation across state borders are apparent. There are interesting parallels with regulation across the enlarged European Union.
- 30** In New York State – chosen for more in-depth analysis – the separation of investigation and adjudication from the body responsible for the register is notable.

Common themes and trends

- 31** Even in countries previously operating the more traditional model of self-regulation, there has been a decisive shift over recent years towards ensuring patient safety as being the core purpose of the regulator. The concept of self-regulation has become one of professionally-led regulation, with forms of co-regulation, or partnership regulation, becoming more common.
- 32** In an era when healthcare is often delivered by teams rather than individuals, a number of jurisdictions have developed a common framework of regulation for different groups of health professionals. This may operate at the institutional level, with the organisations holding the register having a similar structure and jurisdiction. It may involve setting specific standards for regulators or the establishment of a separate adjudicatory body, operating across all the health professions. Overall, there is a discernable trend away from the placing of standard setting, the maintenance of the register, investigation, prosecution and adjudication all under the remit of one organisation.
- 33** The level of independence of regulators from government varies between countries, although there are usually fairly clear lines of accountability back to government. Many regulators are obliged to

submit annual reports, with a specified content, to government. The financing of medical regulation appears to be fairly consistent around the world, with registrants themselves meeting most of the costs incurred, through payment of an annual fee. A notable exception is Finland, where the state has a central role in regulation. In the Netherlands, the costs of assessing continuing competence through the ‘*visitatie*’ programme is, during the present development phase, covered by government subsidy.

- 34** All the regulators examined seek to assure the public that doctors are maintaining their competence to practise. A wide range of different techniques has been adopted in order to demonstrate this, including participation in continuing medical education, computer-based tests of knowledge, 360-degree feedback and peer-review. Such plans remain in the early stages of development in many jurisdictions and it is rare for re-certification, and certainly re-licensure, to be contingent on such activities.
- 35** The role of specialist societies and colleges in the maintenance of competence is widely recognised. In some cases, such schemes may be accredited by the regulator. Problems arise when ongoing membership of a society or college is not mandatory for individual practitioners, a particular issue for general practitioners. In several countries, employers and insurers have essentially mandated specialty certification (and membership of the relevant society or college, if required, for re-certification) by making it a requirement for privileges or reimbursement.
- 36** A number of different models of regulation of the medical profession exist, from systems aimed at the improvement of standards across the board, to systems concerned primarily with the identification of poor practice, to regulators that have a more punitive ethos, to those that foster learning and rehabilitation. Models that encourage learning and facilitate improvement across the board seem to be becoming more common, although in most countries, the imposition of conditions on registration tends to remain a fairly adversarial and legalistic process.
- 37** A handful of jurisdictions now employ the civil standard of proof rather than the criminal standard, and when taken together, an imaginative range of sanctions is in operation across the world.
- 38** Another common theme in medical regulation is the development of procedures aimed at objectively assessing competence. Many countries now have such systems in operation, although there is variation as to their prime purpose. In some, the majority of practitioners may go through these procedures (such as the ‘*visitatie*’ programme in the Netherlands). In other countries, registrants are assessed because of a concern about some aspect of their practice, or because they are deemed to be in a risk group (such as older age in Ontario, Canada).
- 39** Whilst almost all of the fitness to practise procedures examined are primarily complaint-driven, a number of countries stand out on the basis of the careful and systematic approach taken to complaint management and the efforts made to ensure that lessons are learnt and widely disseminated.

- 40 Examples of good practice encountered in this research include: the ‘visitatie’ programme of peer-review that feeds into specialist re-certification in the Netherlands, the progressive handling of complaints seen in New Zealand and Australia, and the sensitive joint-management of sick doctors by the regulator and the professional body in Ontario, Canada.

Conclusions

- 41 In the countries studied, the primary aim of medical regulation is now explicitly focused on patient protection and safety.
- 42 Other trends are clear and include common frameworks for regulating all healthcare professions and a move away from the so-called Anglo-American model of ‘pure’ self-regulation. The latter is being replaced by a model of partnership or co-regulation involving the state or health services, as well as the professional regulatory body. Tables 1 and 2 summarise a number of key features across the jurisdictions.
- 43 In some countries, accountability to government has been strengthened, regular reports are required and the government has powers to audit professional regulatory bodies.
- 44 There has also been a trend to separate disciplinary functions from the registration or licensing body.
- 45 In all the countries reviewed, there are developments aimed at maintaining fitness to practise and generally it has been the medical specialty colleges or boards that have played the major role in this.
- 46 The systems for medical regulation tend to emphasise one of two philosophies:
- a ‘learning’ approach based on trust, cooperation and peer-review aimed at raising standards of practice;
 - the ‘performance assessment’ approach focusing on assessment mechanisms to ensure that doctors are competent across different domains of practice.
- 47 No single method of ongoing assessment for doctors has been developed that is wholly satisfactory. Doctors tend to become more specialised in their practice over time, and the main body of a doctor’s work may have a very narrow focus. For this reason, it is generally the specialist societies and colleges that have made the most progress in the design of assessment processes. This raises the question across all jurisdictions as to how best to handle those doctors who are not members of such a group.

48 There is no single, evaluated and costed model of re-certification (revalidation) that can be used to compare United Kingdom proposals against. The elements of such a system that need to be addressed include:

- identifying which aspects of practice should be assessed;
- defining the standard in particular areas of practice and how it should be tested and with what methods;
- deciding on a threshold for competence;
- recruiting and training assessors;
- dealing with doctors who fall below the standard (including retraining and remediation);
- logistics and overall resource requirements.

49 The pattern of medical regulation required reflects the origins and traditions of the country concerned and also the structure, funding and accountability of the healthcare system of that country. Nevertheless, there are some remarkable similarities in the trends in medical regulation. Especially marked are the moves to greater public accountability, a dilution of the purely professional self-regulation model and the governance arrangements for complaints and fitness to practise cases (separation of investigation and adjudication). The greatest differences are in the model of re-certification and whether this should apply to all doctors (or more selectively), whether it should have statutory force and the standards set and methods to be used.

Table 1: International comparison of systems of medical regulation

Place	Licensing body (and jurisdiction)	Adjudication undertaken by body holding register?	Body responsible for specialist certification	Re-licensing in operation	Method of assessment (re-licensing)	Fitness to practise procedures	Comments
New South Wales, Australia	New South Wales Medical Board (State)	No (separate independent Medical Tribunal)	National Colleges (non-mandatory)	Annual self-report of ongoing fitness to practise but no explicit link to registration or specialist certification	Participation in continuing medical education or a National College Professional Standards Programme	Complaint-driven and handled in association with Healthcare Complaints Commission. Medical Tribunal adjudicates	Annual fee of Aus \$275
Ontario, Canada	College of Physicians and Surgeons of Ontario (Province)	Yes	National Colleges (non-mandatory)	Planned but faced with substantial opposition from Ontario Medical Association	Three-layer model, with only a proportion needing to progress to higher layer	Complaint-driven. College Council members involved in adjudication	Annual fee of Can \$895 for college membership (voluntary after initial registration). Use of peer-assessment
Finland	National Authority for Medico-legal Affairs (National)	Yes	Universities	No	n/a	Complaint-driven. Handled by state-appointed supervision boards	High level of harmonisation across health professions. Maintenance of professional standards largely the responsibility of employers

Table 1: International comparison of systems of medical regulation – continued

Place	Licensing body (and jurisdiction)	Adjudication undertaken by body holding register?	Body responsible for specialist certification	Re-licensing in operation	Method of assessment (re-licensing)	Fitness to practise procedures	Comments
The Netherlands	Central Information Centre for Professional Practitioners in Healthcare (National)	No (system of Medical Disciplinary Colleges)	Component associations of the Royal Dutch Medical Association	Compulsory specialist re-certification in place	Continuing medical education and participation in 'visitatie' programme of peer-review	Specialist re-certification provides assurance for specialist practice. Complaint-driven disciplinary boards, appointed by government	Annual fee of €59. Specialist re-certification currently subsidised by government. Strong model for specialist accreditation and cooperation between profession and government
New Zealand	Medical Council of New Zealand (National)	No (separate independent Medical Tribunal)	National Colleges (non-mandatory for general practitioners)	Annual declaration required from all doctors	Self-declaration of continuing professional development (checked in a sample of returns)	Adjudication by an independent body. Two bodies can bring charges	Annual fee of NZ \$485. Role for Health and Disability Commissioner. Separate adjudication

Table 1: International comparison of systems of medical regulation – continued

Place	Licensing body (and jurisdiction)	Adjudication undertaken by body holding register?	Body responsible for specialist certification	Re-licensing in operation	Method of assessment (re-licensing)	Fitness to practise procedures	Comments
New York State, United States of America	New York State Medical Board (State)	No (two different departments of state government involved)	American Board of Medical Specialties	State re-licensing but no explicit link to continuing medical education or continuing professional development. Specialty re-certification required by many employers and insurers	State re-licensing presently fee based. Discussion about other methods of ensuring continuing fitness to practise. Specialist re-certification may involve computer-based education and exams	Complaint-driven in New York State. A separate body is responsible for the adjudication of disciplinary matters. Sanctions include fines and community service	Annual fee of US \$735. National standards for registration but diverse range of approaches between states as to how this, and disciplinary activities, are carried out

Table 2: International comparison of medical regulators

Place	Elected or appointed board or council	Common regulatory framework for all health professionals?	Primary aim of the regulator
New South Wales, Australia	Appointed	Yes	Protect the health and safety of the public
Ontario, Canada	Elected	Yes	Achieve best quality healthcare for people of Ontario
Finland	Operated by government	Yes	Monitor and promote security of patients
The Netherlands	Operated by government	Yes	Promote and monitor quality in field of healthcare
New Zealand	Appointed	Yes	Protect the health and safety of the public
New York State, USA	Appointed	Yes (for physicians and physician assistants)	Protect the public

Reference

- 1 Allsop J and Jones K. *Quality assurance in medical regulation in an international context*. University of Lincoln, 2006. Link to report to be made available on Chief Medical Officer's website (www.dh.gov.uk/cmo).

Chapter Seven:

Regulation in other high-risk industries

Key points in this chapter

- As medicine becomes more complex, its risks increase.
- There are useful parallels in other high-risk sectors where comprehensive regulatory systems have been developed and culture has changed, often following a seminal tragedy, to manage risk to good effect.
- Common themes in such industries include: some devolution of responsibility for the competence of employees to the employer; safety as a protective (rather than adversarial) jurisdiction; the use of multiple strands of evidence; and the positive demonstration of competence (rather than the default of 'competent unless proven otherwise').
- Competence checks (six-monthly) and licence renewal (annual) are far more rigorous for pilots than for doctors.
- The stigma of failing an assessment and being 'off service' for retraining is much less in other high-risk professions than in medicine.
- Trained and accredited assessors (inspectors) are a key feature of other high-risk industries.
- Other high-risk industries are stronger than medicine and healthcare in a number of significant areas, for example: having clearly defined standards of competence; more rigorous training and accreditation of assessors; focusing on non-technical as well as technical skills (teamwork, communication); using simulators; conducting regular health checks; and linking competence assessment to safety management systems.

- 1 The practice of medicine is risky and it is becoming increasingly so as technology marches on and the impossible becomes possible. As the potential to do harm rises, measures must be taken to contain and minimise this potential: systems in their widest sense, regulation amongst them, have a crucial role to play (a theme discussed fully in Chapter Two).

“In the past, medicine was simple, relatively safe, and ineffective. But today, medicine is complicated – we regularly perform miracles – which has made it less safe...”

Dr Lucian Leape, Harvard University, 2004

2 The same may be said of many other areas of modern life. Air travel, for example, has developed the potential to kill many more passengers now that aeroplanes have greater capacity and the skies are busier.

3 Many have a fear of flying and for some this is based on the perceived danger. In fact, this fear is largely unfounded: 2004 was the safest year on record for air travellers.

“2004 was the safest year in history for commercial air travel. With 1.8 billion passenger flights completed, 428 lives were lost: a similar figure to 1945, when around 9 million passenger flights took place.”

Giovanni Bisignani, CEO, IATA, 2005

4 At the same time, it is estimated that for one patient in every 300 entering hospitals in the developed world, medical error results in, or hastens, death.¹

5 Other industries, just like aviation, have been forced to tackle the risk accompanying technological advance, often in response to a seminal disaster: the explosions on the Piper Alpha oil platform (1988) and at Chernobyl (1986) provide just two examples.

6 Only in recent years has work on patient safety become mainstream. It is not clear why such levels of risk and danger went unnoticed for so long in medicine; perhaps it is because adverse incidents in medicine are so spread out in time and place.

7 More effective regulation is just one tool that has been used in other industries to turn around a poor safety record, tackling both incompetence and misconduct, and raising quality across the board. In this chapter, I examine the regulatory systems operating for individual practitioners in four occupational groups where the potential for risk is, or has been, high: commercial pilots and air traffic controllers, nuclear power desk operators and offshore installation managers.

8 The material in this chapter has largely been drawn from research on licensing and competence in high-risk industries that I commissioned from Professor Rhona Flin of the Industrial Psychology Centre, University of Aberdeen.²

Civil aviation – pilots

- 9 The civil aviation industry internationally has well-developed systems to assure competence, based on training, qualifications and licensing for pilots and engineers.
- 10 In the United Kingdom, the Civil Aviation Authority establishes and monitors the regulations for civil aviation and these are harmonised with European requirements.
- 11 The Civil Aviation Authority issues operating licences to airlines that are then required to adhere to certain standards derived from the regulations. The Civil Aviation Authority monitors compliance and its personnel licensing department oversees the system of pilot licensing, although some aspects can be devolved to airlines.
- 12 Every pilot must hold a licence that includes a rating for a particular type of aircraft. The ratings in a licence can only be awarded or revalidated by a so-called type rating examiner, who is a licensed pilot with relevant flight experience, appointed by the Civil Aviation Authority.
- 13 Commercial pilots are subject to the following regular competence checks:
 - operator's proficiency check – a twice-yearly assessment by the airline using a type rating examiner and involving extensive testing in an approved full-fidelity simulator as well as examination of non-technical skills (e.g. communicating with a co-pilot);
 - line check – a yearly assessment by a trained and approved assessor who travels on the flight deck during a normal public transport flight undertaken by the pilot;
 - licence proficiency check – an annual licence revalidation undertaken in an aircraft or simulator and lasting several hours;
 - analysis of flight recorder data and incident reports relevant to the pilot;
 - fitness to fly certification involving medical assessment.
- 14 If a pilot fails a check, they will not be allowed to fly, will be referred for retraining and will be checked again.
- 15 Many airlines also have random drug and alcohol testing programmes in place.

Licensing and competence assurance in airline pilots

- The regulator (Civil Aviation Authority) manages a long-established international system of pilot licensing and revalidation for particular types of aircraft and specific operating conditions.
- Pilots have competency checks every six months where their flying skills are observed and rated.
- Pilots also have an annual licence check involving observed task performance.
- Standards of performance are clearly stipulated and are the foundation for training and assessment.
- Rigorous systems of training and accreditation for assessors are in place.
- There is a focus on non-technical (cognitive and social) skills as well as technical.
- High-fidelity simulators are extensively used.
- Other complementary safety monitoring systems (e.g. analysis of flight recorder data and incident reports) are also used.

Civil aviation – air traffic controllers

- 16** The Civil Aviation Authority has operated a competency scheme for air traffic controllers since the mid 1990s. It also determines the curriculum at the small number of approved colleges that are able to award the relevant primary qualification.
- 17** Following qualification, trainees join an employer (such as National Air Traffic Services) and undertake a period of highly supervised workplace training in a given role at a specific site. An examination then takes place to validate the trainee as an air traffic controller and to license them to practise in that role, at that location.
- 18** Examinations are conducted by a senior local air traffic controller, along with an external examiner from a pool maintained by the Civil Aviation Authority. Assessment occurs against predefined standards and involves observed practice and an oral examination.
- 19** Following initial licensure, there are ongoing in-house competence checks that may include random reviews of recorded performance. In addition, there are standardised debriefs following any untoward incident and a mandatory annual oral examination, focusing upon new developments in air traffic control.
- 20** If an air traffic controller wishes to change post, either job role or location, a further period of supervision is required before licence validation and independent practice.

- 21 The Civil Aviation Authority maintains a central record of all air traffic controllers and the licences in place. More comprehensive documentation is held by the employer.
- 22 The Civil Aviation Authority is able to inspect and audit the competency assurance schemes operated by employers, along with their wider safety and risk management systems.

Licensing and competence assurance in air traffic controllers

- The regulator (Civil Aviation Authority) oversees a system of initial licensing for air traffic controllers and subsequent revalidation, for particular tasks in specific locations.
- Controllers have an annual oral examination to ensure that they are up to date with developments in air traffic control.
- Debriefing occurs following any untoward incident.
- Other complementary safety monitoring systems are used such as the random review of recorded performance.

Nuclear power unit desk engineers

- 23 The Nuclear Installation Inspectorate of the Health and Safety Executive regulates the nuclear industry under the terms of the Nuclear Installations Act 1965 and issues site licences to operators. Some of the conditions of these licences relate to the necessary competence of personnel. The approach to regulation is one of goal setting, rather than prescription. Guidelines as to how regulatory processes might be designed and operated are issued both by the regulator and by the International Atomic Energy Authority.
- 24 The competency-based approach to the regulation of personnel covers both technical and non-technical aspects, and periodic reassessment is regarded as an integral component. A number of safety-related roles are designated, including those of ‘suitably qualified and experienced person’ and ‘duly authorised person’.
- 25 Unit desk engineers work in nuclear power control rooms and must obtain both of these designations. The licensee (for example, British Energy) conducts assessments to demonstrate the required competencies, following a rigorous training programme lasting 18 months:
 - performance on a full-fidelity simulator during three scenarios, observed by a senior colleague and an independent assessor, to become a ‘suitably qualified and experienced person’;
 - formal authorisation interview before a panel, to become a ‘duly authorised person’.

- 26** Following appointment as a unit desk engineer, an employee undergoes a multi-faceted revalidation process, including:
- annual simulator training;
 - annual company appraisal;
 - 360-degree feedback exercise;
 - occupational stress questionnaire;
 - formal biennial simulator assessment and panel interview.
- 27** In the case of any adverse plant incident, the relevant unit desk engineer's status as a 'duly authorised person' may be revoked pending investigation.
- 28** The regulator employs around 170 inspectors who have full access to all relevant facilities, with warrants if necessary. These inspectors may be either site based or specialist. The function of the inspectors is to ensure that operators meet licence requirements, including those relating to the competence of personnel.

Licensing and competence assurance in unit desk engineers

- The regulator (Health and Safety Executive) oversees a system of initial authorisation for unit desk engineers and subsequent revalidation.
- Controllers have biennial simulator checks and panel interviews to ensure ongoing competence.
- Authorisation may be removed pending investigation following any untoward incident.
- Other complementary safety monitoring systems are used, such as safety audits, risk assessment exercises, 'reverse briefing' and the use of human error tools.

Offshore installation managers

- 29** The Offshore Safety Division of the Health and Safety Executive has regulated the oil exploration industry since the early 1990s, using an approach that is goal setting, rather than prescriptive: there is no statutory requirement for the certification of those in safety-critical positions, with legal responsibilities placed upon employers, rather than employees.
- 30** Oil companies submit documentation to the Health and Safety Executive outlining the risk assessment and safety management systems in place for each installation. These systems include arrangements for the competency assurance of offshore installation managers. A hundred inspectors are employed to ensure that operators comply with licence requirements, making site visits as necessary.

- 31** Each offshore installation has a duty manager at all times who doubles up as incident commander in emergencies. Although specific to the operator, competence assurance systems have a number of common features across the industry, including the demonstration of a number of generic and site-specific competency standards. These competencies must be demonstrated prior to, or in the case of the non-safety critical standards shortly after, appointment as an offshore installation manager.
- 32** Following appointment, competency assurance schemes are employed to ensure that offshore installation managers remain fit for purpose. Although components vary, schemes typically involve:
- computer-aided self-assessment tools (with results accessible to line managers);
 - peer-assessment;
 - regular training and refresher courses (as suggested in industry guidelines);
 - annual rig-based safety exercises;
 - a comprehensive rig-based safety exercise without briefing every three years (in the presence of an independent assessor);
 - use of dedicated simulator installations.

Licensing and competence assurance in offshore installation managers

- The regulator (Health and Safety Executive) oversees a system of employer-operated competence assurance.
- Installation managers are encouraged to make regular use of computer-aided self-assessment tools.
- Installation managers undergo annual rig-based safety exercises.
- Once every three years, there is a more comprehensive exercise which occurs in the presence of an independent assessor.
- Some companies make use of simulator rigs for training and assessment.
- Regular medical checks take place.
- Drug and alcohol testing policies are in operation.
- Safety has a high profile within a target-driven performance management culture.

General principles

- 33** Having reviewed the systems used for competence assessment and assurance in these four industries, nine general themes have been identified that are relevant to the licensing and revalidation of doctors.

Nine general themes of competence assessment in high-risk industries

I	An independent regulator
II	Regular, formal proficiency checks
III	Clearly defined standards of competence
IV	Trained and accredited assessors
V	Non-technical skills
VI	Remedial approach to failure
VII	Simulators
VIII	Health checks
IX	Linkage of competence assessment to safety management

- 34** In each of the industries reviewed, the award of a licence to operate a site is managed by an independent regulatory body. The competence assurance of personnel is generally devolved to operators, whose licence then becomes contingent upon the satisfactory performance.
- 35** Regular formal proficiency checks of some description occur in all four industries. The frequency and intensity of assessment is highest for pilots. In all groups, assessment occurs not just for the purposes of regulation but also to provide constructive feedback to improve individual performance.
- 36** Clearly defined standards of competence are used in assessments that are carried out by a combination of licensed examiners (employed by the operator) and independent assessors (employed by the regulator). Assessments are made on the basis of proficiency and outcomes, rather than input data (such as training courses completed or hours of experience accumulated).
- 37** Trained and accredited assessors are key to satisfactory assessment in these high-risk industries. The arrangements for pilots in particular are notable on account of the importance given to the selection and training of assessors. A very significant investment and commitment is made by airlines to competence assurance and training by senior staff.
- 38** There is universal recognition that non-technical skills are critical to safety. In some industries, skills such as situation awareness, leadership and teamwork are assessed formally.

- 39 Clear procedures are in place for those who fail in assessment. In general, such individuals are removed from frontline duties for remedial training. The stigma of failure is minimised in so far as is possible. Individuals tend not to return to the role in the case of repeated failure.
- 40 Technology is widely employed for competence assessment in the industries examined and in some cases, full-fidelity simulators are in use.
- 41 Close attention is paid to the health of individuals in safety-critical roles, with mandatory health checks and drug and alcohol testing policies in place in some industries.
- 42 Schemes for the assurance of competency amongst individual employees tend to be fully integrated with the wider risk management and safety systems in place. In some situations (such as in oil exploration), the safety issues are pervasive within the general target-driven performance management culture.

Transferability

- 43 There are of course a number of reasons as to why some of the themes and principles identified may not be readily transferable to the regulation of doctors.
- 44 The most obvious is that the scale of the task of regulating doctors in the United Kingdom is greater by several orders of magnitude than that of some of the other professional groups studied. Certainly, any excess burden (time or cost) would be more tangible in medical regulation.

Numbers of professionals employed in various high-risk industries in the United Kingdom

Occupational group	Number employed in United Kingdom
Doctors	≈177,000*
Pilots	17,000
Air traffic controllers	2,000
Unit desk engineers	≈300
Offshore installation managers	250

* ≈230,000 registered with GMC, ≈177,000 working in the NHS

- 45 Another distinct difference relates to the consequences of poor performance for the individual practitioner. In many of the industries studied, the failure of an individual in a safety-critical task may have direct implications for the safety of themselves and, indeed, their co-workers. In medicine, the consequences of failure largely befall a third party – the patient.

Conclusions

- 46 In each of the safety-critical industries examined, there is a statutory regulator, the governance of which is independent of both the industry and government. In many cases, the regulator operates a goal-setting approach, delegating many of its operational functions to employers.
- 47 The delegation of regulatory tasks to the level of the employer is facilitated by the existence of defined and unambiguous standards, against which an organisation can assess its employees.
- 48 In each of these industries, continuing fitness to practise is intermittently demonstrated. This process involves a positive and objective affirmation of competence, rather than the adoption of a default position of ‘competent until proven otherwise’.
- 49 The assurance of an employee’s ongoing fitness to practise is explicitly linked to safety (rather than productivity more generally).
- 50 The competence of the assessor to assess is given appropriate weight: thorough training and revalidation schemes exist for examiners, just as they do for the primary practitioner.
- 51 The regulatory schemes operating in these highly technical environments all take account of non-technical skills such as communication and leadership.
- 52 In some cases, practitioners are licensed solely for a specific role and a particular geographical location. Any variation in the scope of the work undertaken is likely to require fresh assessment.
- 53 Regulatory activity is taken seriously by employers, with many organisations exceeding the strict requirements of the statutory body. There seems to be a genuine appreciation of the long-term savings accrued through the quality improvement to which regulation can contribute.
- 54 Regulatory activity is seen as operating within a ‘protective jurisdiction’. Any doubts about performance result in the removal of an employee from safety-critical duties until such a time as competence can once again be demonstrated. Proceedings rarely take on an adversarial flavour and the standard of proof, where such a concept is valid, is low.
- 55 One common feature of these systems is that each uses more than just one procedure, or strand of evidence, to ensure ongoing competence.

Routine formal assessment of competence in two professional groups in the United Kingdom

Area of practice	Pilots (captain)	Doctors (consultant or general practitioner)
Technical skills	<ul style="list-style-type: none"> ● Simulator-based proficiency check every six months, lasting several hours ● Licence check annually lasting between two and five hours, including objective assessment of some prescribed manoeuvres 	<ul style="list-style-type: none"> ● No routine objective assessment of technical skills explicitly linked to licence to practise or ongoing specialist certification ● Annual appraisal provides a mandatory annual opportunity to reflect upon performance and identify development needs
Non-technical skills	<ul style="list-style-type: none"> ● Annual line check with in-flight observation of 'crew resource management' skills ● Crew resource management component of proficiency checks 	<ul style="list-style-type: none"> ● Annual appraisal provides a mandatory annual opportunity to reflect upon performance and identify development needs
Physical and mental condition	<ul style="list-style-type: none"> ● Regular medicals according to age and risk profile (including stress testing where appropriate) ● Policies for random drug and alcohol testing 	<ul style="list-style-type: none"> ● Requirement for occupational health clearance on taking up a post, usually limited to infectious diseases ● No regular assessment ● No random testing for drugs or alcohol
Other relevant systems	<ul style="list-style-type: none"> ● Mandatory European reporting system and additional in-house schemes ● Operational flight data monitoring ● Airline flight audits ● Black box analysis following incidents 	<ul style="list-style-type: none"> ● Non individual-specific quality assurance activities (e.g. local clinical audit, clinical governance reviews, morbidity and mortality meetings) ● Databases (e.g. national audits, incident reporting systems) not usually linked to individuals

References

- 1 Based on calculations by Dr Lucian Leape, Harvard School of Public Health, United States of America (unpublished, used with permission).
- 2 Flin R. *Safe in Their Hands? Licensing and Quality Assessment for Safety-critical Roles in High Risk Industries*. University of Aberdeen, 2006. Link to be made available on Chief Medical Officer's website (www.dh.gov.uk/cm0).

Chapter Eight:

Public and professional views

Key points in this chapter

- A wide range of views were gathered on the current issues and problems in medical regulation along with ideas for the future.
- The sources of these views were: a survey of the public and doctors, a *Call for ideas* consultation which preceded the review, and commentary in professional journals and meetings.
- Few members of the public know anything about the current assessment of doctors after qualification but most believe they must already be regularly assessed.
- The public, as well as doctors, believe doctors should be assessed regularly.
- The public want to see emphasis on checking whether a doctor is up to date, examining information on success rates of treatments and providing ratings from the doctors' recent patients.
- The survey of the public also emphasised that whilst patients wanted their doctors to have good clinical knowledge and clinical skills, they also placed a high value on interpersonal qualities (communication, respect, dignity and involving patients in decisions).
- The *Call for ideas* paper attracted 167 thoughtful responses from a range of individuals and organisations.
- Responses to the *Call for ideas* paper reflected the diversity of opinion on medical regulation and the complexity of the subject.
- Many respondents were concerned about the balance between the costs of a system of medical regulation and the benefits derived.
- There is a broad consensus that the positive demonstration of ongoing fitness to practise is a worthy and necessary goal but little agreement as to the route by which to achieve this.
- There is ongoing debate as to the fundamental nature of appraisal and its ability to contribute to a process of revalidation.

- Many respondents and commentators have expressed dissatisfaction with the workings of the General Medical Council and others have been frustrated by the pace of progress in relation to the issue of revalidation.
- Many different assessment tools have been discussed and championed in the *Call for ideas* paper and professional journals, but few are developed and validated.
- A new model of medical professionalism has been described by a working party of the Royal College of Physicians and is relevant to the consideration of medical regulation.

1 A research study was commissioned from MORI to examine the attitudes of the general public and doctors towards medical regulation and assessment. The responses to a *Call for ideas* paper which was put into the public domain as the review started provided further important insights into opinion and experience of the areas covered by my review. Also, the main themes underlying the debate on the future of medical regulation have been extensively discussed in professional journals and meetings. This chapter describes these views.

Research amongst doctors and the general public

- 2 Full details of the research carried out by MORI and the methods used can be found in a report published in July 2005.¹
- 3 The key findings of this research were:
- Few members of the general public know anything about the current system of assessment of doctors after qualification.
 - Almost half of the sample of the general public assume that regular assessments are already taking place, with over one in five thinking they already happen annually.
 - There is widespread support for regular assessment amongst the general public and doctors.
 - Nine in ten members of the public and more than seven in ten doctors thought it important that doctors' competence was assessed every few years.
 - Nearly half the public thought that these assessments should be done on an annual basis whilst doctors favoured doing it less frequently.
 - Hospital doctors seem to favour more frequent assessments than their colleagues in general practice.
- 4 The current system of medical regulation is not visible to the general public. It is striking that many people believe that regular assessment of doctors is already taking place. Moreover, almost all wished it to take place frequently, and half said that there should be annual checks. This public view is in marked contrast to commentators who hold that regulation should be a 'light touch' process (see Chapter Nine).

Good doctors, safer patients

- 5 The public surveyed here was remarkably insightful about the areas of a doctor's practice that were important and should be assessed:
 - Highest rated as requiring assessment was evidence that the doctor is up to date, followed by information on the success rates of their treatments and whether they receive high ratings from their patients.
 - When asked what aspects of their doctor's performance they would like to comment on, the top characteristic was their communication skills followed by whether they are up to date, how much they involve patients in treatment decisions and whether they show their patients dignity and respect.
- 6 These findings emphasise that, whilst patients want their doctors to have good clinical knowledge and technical skills, they also rate the interpersonal aspects of care as equally, if not more, important. This accords very strongly with other research that has been conducted into public attitudes and patient experience. For example, the work of Mechanic and colleagues in the United States of America has examined the concept of trust in the doctor-patient relationship.² He found that five components of a doctor's practice were important to patients: competence (both technical and interpersonal), that the doctor had their interests at heart, compassion and dedication, confidentiality, and whether there were any conflicts of interest.
- 7 Traditional medical attitudes towards these matters would tend to place lower importance on the non-technical aspects and practice, regarding them as 'softer' or less significant elements of quality of care. Moreover, it is believed that they are difficult if not impossible to assess properly.
- 8 To some extent, the research study reflected these professional attitudes in that doctors placed more importance on a good doctor being someone who kept up to date with medical developments (85% of hospital doctors and 81% of general practitioners thought this). However, there were some marked differences between hospital doctors and general practitioners: for example, 74% of hospital doctors thought feedback from patients important compared with 36% of general practitioners.
- 9 When asked who should regulate and assess doctors, most hospital doctors (62%) and general practitioners (58%) thought that assessment of doctors should be carried out solely by other qualified medical professionals. The majority of the general public (52%) favoured a mixture of qualified medical professionals and expert lay people (only a third of doctors favoured this option).
- 10 The findings of the MORI poll are consistent with surveys carried out elsewhere. In the United States of America, a 2003 Gallup poll found: 80% of adults believed that it was important for doctors to be re-evaluated periodically, to have high success rates for the conditions they treat most often, to periodically pass a written test of medical knowledge and to receive high ratings from their patients.³

Responses to the *Call for ideas*

- 11 The *Call for ideas* paper attracted 167 responses. They came from professional bodies, NHS bodies, other organisations and individuals. Some were structured according to the questions posed in the

Call for ideas document, others did not follow this structure. Some were formal and extensive, others were short and much more personal.

- 12** The responses reflected a great deal of interest in the current state of medical regulation and what was necessary for the future. Not surprisingly, some very strong views were held and expressed about the adequacy of the present system of medical regulation, the findings of The Shipman Inquiry, the performance of the General Medical Council, the role of NHS employers, and the cost and logistics of any expansion of the present system of medical regulation.
- 13** Some very passionate, seemingly polarised, views were received from respondents. Whilst these represented a minority of the responses, they should not be dismissed as they confirm strong anecdotal impressions of substantial bodies of opinion. Such views included:
- doctors who regarded themselves as overworked and loaded with paperwork, and who viewed the prospect of any extension of regulation as a burden likely to be ‘the straw that would break the camel’s back’;
 - patients who regarded professional bodies as purely orientated to protecting bad doctors from scrutiny or exposure;
 - doctors whose own experience of the General Medical Council was of being subjected to unfair, lengthy, stressful and hostile investigations with no form of exoneration even though the complaint against them was not upheld (see account in Chapter Four).

The responses to the key themes

- 14** The collected responses to the *Call for ideas* provide a rich source of information on opinion and experience relating to medical regulation. The majority of the responses drew attention to weaknesses and dysfunction in the present system of medical regulation. The majority also drew attention to the principles or the philosophy that should be adopted in taking things forward. Some gave important evidence or related experience in one aspect of dealing with poor performance or trying to assure good practice. Relatively few pointed to a detailed design for medical regulation in the future.
- 15** In the following sections, some of the main points that came out in the *Call for ideas* exercise are summarised in relation to the main themes of my review.

Principles of good regulation

- 16** In addressing the role of regulation in society or the principles of good regulation, respondents were often more pragmatic than philosophical. Comments addressed:
- the balancing of the burden of regulatory activity and the benefits that may be derived from regulation;
 - the importance of the independence of the regulator from government;
 - the necessity to use objective data and the application of valid tools in assessment and regulation;

- the extension of regulation (in some form) beyond entry to a profession so that it is pervasive throughout a professional's career;
 - the early years, suggesting that professionalism starts at the point of admission to medical school (with knock-on to the selection and regulation of medical students).
- 17** A number of interesting and thoughtful contributions proposed aspects of professionalism to be regulated. One response suggested that competence, performance and integrity were the three cornerstones of professionalism, whilst another saw knowledge as a subset of performance, not needing to be formally assessed in its own right.
- 18** Some responses did go into the fundamentals of regulation, discussing the parallels with other sectors, the specific needs in medicine and the modern outlook on regulation more generally. The main points made in these submissions were:
- Recent initiatives across the whole field of regulation in this country have been directed towards reducing the burden of regulation so as not to stifle innovation, opportunity and productivity.
 - Thinking in professional regulation has not come to grips with the multiprofessional nature of modern healthcare: medicine is increasingly practised in a team setting, yet no major formal process of regulation focuses on assessing the effective functioning of multidisciplinary clinical teams (of which an individual doctor is part).
 - Medical practice is increasingly being conducted in very diverse settings: some doctors practise in highly structured organisational environments (e.g. hospitals); others in more isolated situations (e.g. single-handed general practitioners); still others offer their services to health organisations on a more peripatetic basis (e.g. locums) or use their facilities (e.g. private hospitals).

Appraisal and assessment

- 19** The introduction of compulsory annual appraisal for all NHS doctors (originally proposed in my report *Supporting doctors, protecting patients*⁶) was the subject of a great deal of comment in the *Call for ideas* responses. Respondents were interested in whether the current system of appraisal – in hospitals and primary care – was working, whether it was a robust basis on which to make revalidation decisions, and, indeed, what the link should be between annual employer appraisals for doctors and their periodic revalidation.
- 20** A strong strand of reaction to this aspect of the *Call for ideas* drew attention to the philosophy and purpose of the processes of appraisal and assessment. This is a debate that has become something of an ‘old chestnut’ in the eight years since they were first mooted as methods to be applied to quality assurance of medical practice in the United Kingdom.
- 21** Essentially, this debate turns on whether the processes are, or should be, ‘formative’ or ‘summative’. In the ‘formative’ model the processes together with the analysis and conclusions that are associated with them are used for learning, development and improvement. In the ‘summative’

approach the results of assessment are used to make judgements about, for example, competence, achievement of standards, conduct and performance.

- 22** Many views on this important area were very polarised but can be summarised:
- Many believe that annual appraisal can only be ‘formative’ and to use it for ‘summative’ purposes is an abuse of trust between employer and doctor.
 - Many others believe that annual appraisal must involve ‘summative’ assessment and whilst it may not do so currently, it should be developed so that it does.
 - Many believe that a periodic process, whether of appraisal (annually) or revalidation (five-yearly), is an unsatisfactory way of spotting poor performance and a third, more continuous form of monitoring is needed for this.
- 23** Other strong themes coming out of the *Call for ideas* responses in this area included:
- the importance of the appropriate selection and training of assessors and appraisers;
 - the identification (or development) of a suitable set of standards against which to appraise or assess;
 - the role of the medical Royal Colleges and other professional bodies as the setters and owners of standards (others felt that only the General Medical Council could be the rightful arbiter here);
 - the appropriate standard against which to assess doctors, with some asserting that all doctors should be ‘acceptable’ and others preferring ‘good’ or ‘excellent’.
- 24** Many respondents focused upon the tools that might be used for appraisal or revalidation. Objectivity and validity were seen as vital. Many pointed to the financial investment that would be required, others to the centrality of information technology. Amongst the techniques advocated were:
- knowledge tests;
 - 360-degree feedback;
 - patient surveys;
 - observation of consultations (direct or video-assisted);
 - simulators;
 - analysis of clinical audit data;
 - regular compulsory checks on physical and psychological health.
- 25** Many respondents chose to comment upon their early experience of the appraisal system in the NHS. Some felt strongly that it needed more time to ‘bed down’. It is clear that there are a number of exemplar sites, where appraisal has been embraced with enthusiasm. There are also parts of the country where it is perceived as ‘tokenism’ with few persuaded of the benefits. Some pointed out that appraisal is only as good as a health organisation wants it to be. Bitterness was expressed by some doctor respondents that an individual’s development needs, identified through appraisal, were

often not then addressed by NHS employers because of the low local funding priority given to postgraduate medical training, continuing education and professional development.

Revalidation

- 26** Most respondents viewed positively the concept of revalidation. They saw it as a way for patients, employers and practitioners to ensure that a doctor is ‘fit for purpose’ and therefore felt that doctors should be assessed against the role they currently perform and not that for which they qualified or that which they could theoretically perform.
- 27** Overall, the majority view was that revalidation should be primarily about raising standards and securing public trust by ensuring that any patient’s doctor is consistently a good doctor. The public protection side of revalidation was also seen as very important and therefore it was felt that the processes that made up revalidation should be capable of detecting impaired performance at an early stage. However, it was repeatedly pointed out that a five-yearly check (the extant proposed interval for revalidation) was not adequate to detect and address poor performance.
- 28** These points are reinforced by views on revalidation which consistently came through in the *Call for ideas* responses:
- that evidence about, and experiences of, a doctor in their day-to-day workplace(s) must be integrated into any system for the future;
 - that NHS annual appraisal, in its present form, should not be the sole basis for revalidation;
 - that the focus should be on attitudes and behaviour of doctors as well as knowledge, skills and aspects of technical competence;
 - that an agreed common data set for use in revalidation does not exist though there are many valuable sources of information currently available or being developed.
- 29** Amongst the *Call for ideas* submissions were many substantial documents produced by professional bodies (including medical Royal Colleges), researchers and individuals who had looked at the technical and practical requirements for revalidation in considerable depth. A number of points stand out from these submissions:
- Detailed practice standards and criteria for assessing them have been developed but almost all relate to specialist, rather than generic, aspects of practice.
 - A universally agreed definition of what comprises a ‘good doctor’, operationalised in a way that is widely understood and could be assessed, is not available.
 - There is a relatively small evidence base of research or evaluation studies showing whether the particular methods that have been proposed for revalidation would achieve the desired outcome.
 - Many of the ideas that have been developed so far have progressed as a result of first principles thinking, apparent commonsense assumptions, professional opinion or negotiation rather than rigorous review of evidence-based interventions in the fields of medical education, training, competency development, professional development or quality improvement.

- 30** When considering the revalidation process itself:
- Many were fearful about the devolution of responsibility away from the General Medical Council to employers.
 - Others recognised that the size of the task would require a partnership approach, with the General Medical Council as ‘conductor of the revalidation orchestra’.⁵
 - Some, both individuals and organisations, wrote in strong support of a local revalidation panel and the vital presence of lay input.
 - Most respondents identified the need for multiple sources of data and the avoidance of over-reliance upon any one source.
- 31** A number of more specific points were also put forward: that revalidation would push senior doctors into early retirement; that trainees should be exempt from the process (on the assumption that training programmes already provide an adequate quality assurance framework). Some respondents wanted healthcare managers to be subject to a thorough and challenging revalidation process too (given that poor managerial practice could damage NHS services).
- 32** A point made powerfully by several patients’ organisations, and resonating with a number of professional bodies, was that revalidation has now been under discussion for more than seven years. Contributors were frustrated at best, angry at worst, that many of the same arguments continued to perpetually ‘go round in circles’. They characterised revalidation as ‘a nettle that needs to be grasped’. Furthermore, they were adamant that the culture and attitudes found within the medical profession has changed significantly: revalidation would likely be accepted, indeed embraced.

Complaints systems

- 33** Amongst the responses to the *Call for ideas* were those that expressed strong views on the complaints system. Many of these reflected long-standing concerns and frustrations with the way that the NHS responds to complaints including those about doctors’ standards of care. A particularly insightful submission was received from the Parliamentary and Health Service Ombudsman. The points made in relation to complaints included:
- The current complaints system is not well publicised and is complex for the public to use.
 - It is particularly difficult for the public to understand the role of many different bodies (e.g. foundation trusts, NHS Trusts, primary care trusts, the General Medical Council, the police, the Healthcare Commission, the Ombudsman) in dealing with complaints.
 - It is often difficult and inappropriate to separate out elements of a complaint into administrative, clinical and organisational because they are often interlinked and require a single rather than separate investigative process.
 - There is little evidence of systematic learning from complaints either to improve the quality of clinical practice or of NHS services.

- 34 There were a number of proposals for a so-called ‘common portal’ for complaints, or some other way in which a patient or member of the public with a complaint about healthcare could be helped or directed to the appropriate quarter.

Fitness to practise

- 35 There was broad agreement in the responses to the *Call for ideas* that when there was a concern about a doctor’s competence, conduct, performance or standards of care then early action was necessary to protect patients, to investigate and to take appropriate action. However, views were more diverse on the effectiveness of the present system:

- There was an acknowledgement that local clinical governance systems had improved greatly and together with the National Clinical Assessment Service this meant that poor practice was identified and dealt with much earlier by local NHS services.
- Some scepticism was expressed about the effectiveness of retraining when doctors’ fitness to practise fell below the required standard.
- There was concern about the publication of disciplinary or fitness to practise allegations before the investigation had concluded and they had been upheld.
- There should be a single national database for the collation of information on concerns about a doctor’s practice.

Respondents also addressed detailed fitness to practise issues:

- Doctors asserted that even when there was found to be no case to answer, they by no means felt exonerated by the General Medical Council’s procedures.
- The general consensus, to the extent that there was one, appeared to support the tiered disclosure of information, with a certain amount openly available to all, and more distant or sensitive information being available to those specifically requesting it or to some other parties (such as employers) on a ‘need to know’ basis.

- 36 Another theme in the responses to the *Call for ideas* in relation to fitness to practise was a concept of increased harmonisation amongst regulators of health professionals. Some felt this should centre on common standards underlying decision-making processes, others wished to see a single adjudicatory body for all fitness to practise cases involving health professionals. One of the arguments advanced in favour of a harmonised framework was that the divisions between traditional roles appear, at times, to be blurring.

The General Medical Council

- 37 Very strong and differing opinions were received about the future shape, role and direction of the General Medical Council:

- Some respondents (doctors and the public) appeared to have no faith in the organisation and advocated its abolition.

- Others argued forcefully that the institution had undergone major reform and that these changes must be allowed to ‘bed down’.
- Others addressed the composition of the Council, wishing to see greater lay representation.

- 38** Another point raised in response to *Call for ideas* was that of the nature of the relationship between employers, the General Medical Council and the National Clinical Assessment Service. A number of responses suggested that closer links and partnerships were needed in order to secure patient safety.
- 39** Several alternative points of view were put in relation to the accountability of the General Medical Council. A majority of the respondents who addressed this suggested that parliamentary accountability (and intermittent interrogation by the National Audit Office) would be desirable.

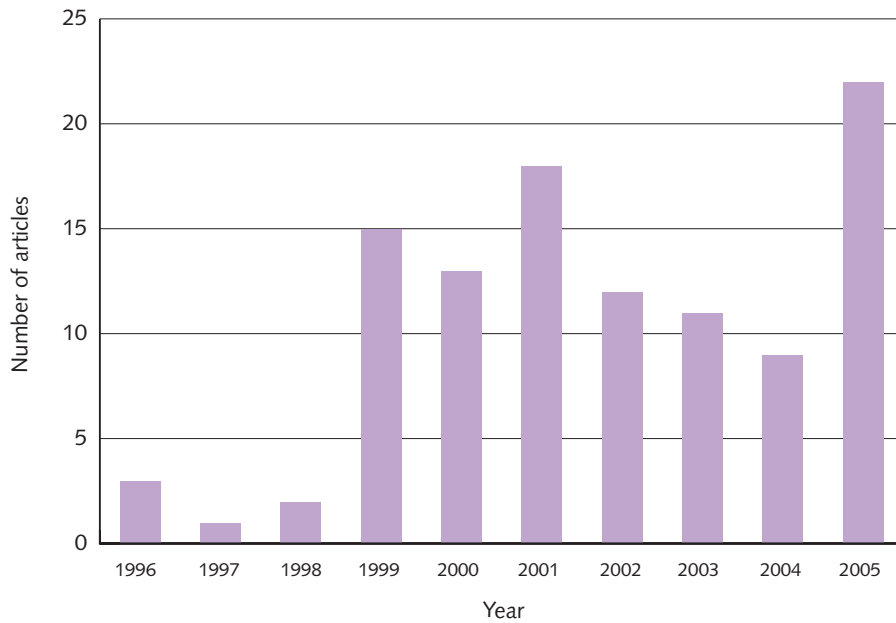
Other issues

- 40** Several other interesting ideas were fed in through the *Call for ideas* exercise. Although not fitting in with any of the broad themes identified above, they each deserve consideration:
- the role of mentorship in assuring the quality of practice;
 - the adequate provision of facilities for remedial training;
 - conflicts of interest if ongoing membership of a faculty or college is to become a prerequisite for specialist revalidation;
 - the needs of the independent sector and doctors working outside ‘clinical’ medicine;
 - the needs of locum doctors;
 - the issue of retired doctors and their prescribing rights;
 - the use of questionnaires to gain insight into the reasons why patients may move from a doctor’s list.

Professional commentary and reflection

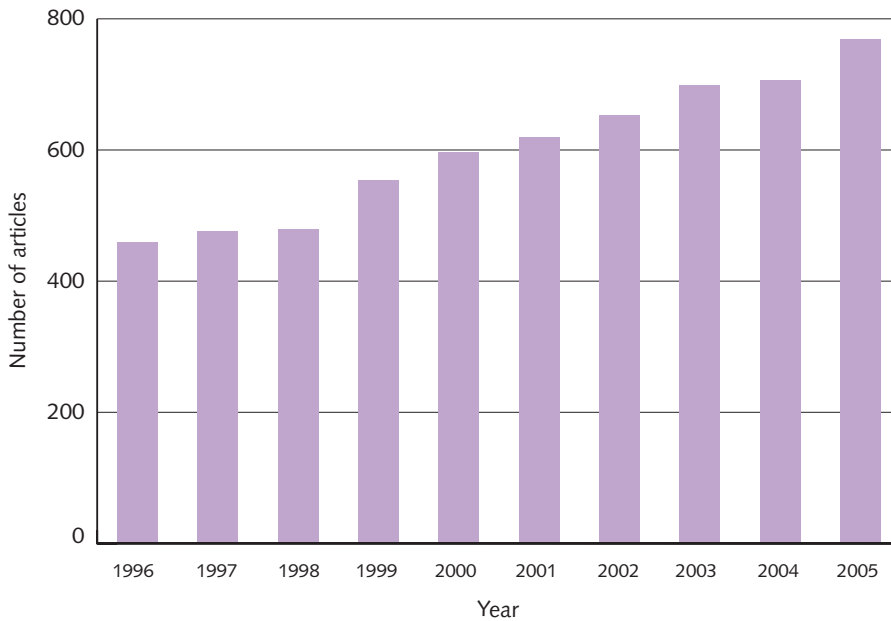
- 41** Another important source of information has been the discussion of revalidation and related issues outside the confines of my advisory group. The high level of interest in medical regulation over recent years has been reflected in lectures and papers published in professional journals. A Medline search shows an upward trend in the number of articles specifically addressing revalidation and a slower but sustained increase in the number of articles mentioning appraisal, revalidation, re-licensure and re-certification more broadly (see graphs below). Revalidation is a term mainly used in the United Kingdom whereas the other terms are used internationally.

Appearance of the term 'revalidation' in the title of medical articles



Source: Medline database

Appearance of the terms 'revalidation', 're-licensure', 're-certification' or 'appraisal' in the text of medical articles



Source: Medline database

42 The *British Medical Journal* (which has a large and broad readership) and the *British Journal of General Practice* have published high-quality editorials and papers, reflecting the evolution of opinion. Other perspectives have appeared in a diverse range of publications. In addition, Professor Michael Pringle's John Fry Fellowship Lecture and work on the concept of professionalism (by a working party of the Royal College of Physicians of London and others) have been important contributions to the debate.

43 The *British Medical Journal* has a long tradition of addressing medical regulation. I have drawn attention, in Chapter Four, to the 1858 editorial marking the arrival of the General Medical Council and Richard Smith's series of powerful articles in the summer of 1989. The *British Medical Journal* has continued to provide a home for the ideas and opinions of the profession on the subject of medical regulation and revalidation specifically. A further editorial by Smith in 2001 suggested that the difficulties raised by revalidation for the General Medical Council, compounded by problems in clarifying future governance arrangements, were insurmountable: would it not be easier to start again from scratch?⁶ The response to this editorial was swift, with letters appearing the following week in robust defence of the General Medical Council, from a group of professional members, a group of lay members and the Chairman of the Academy of Medical Royal Colleges.^{7,8,9}

"The General Medical Council is the crucible of our professionalism and without it, doctors in this country would become mere technicians. Any alternative to professionally-led regulation is unthinkable."

Dr Brian Keighley, elected member of the General Medical Council, and others, 2001⁷

- 44 Contributions published in the *British Medical Journal* have questioned the cost of revalidation and the sources of funding; reported on a 360-degree assessment pilot and calculated that a large hospital might consume annually 1,000 hours of staff time and 50,000 pieces of paper; and doubted the rigour of appraisal as the sole basis of revalidation.^{10,11,12}
- 45 Van Zwanenberg interviewed 18 'opinion leaders' about revalidation.¹³ Three strands emerged: securing public trust, promoting continuing professional development and detecting poor performance. Most of those interviewed foresaw tension and difficulty in addressing all three in one process. This study reinforced a common view of commentators, that is agreement in principle with revalidation but marked differences in opinion on implementation.
- 46 Discussion of revalidation in the *British Journal of General Practice* began in earnest as early as 1999. In an editorial, the then Chair of the Royal College of General Practitioners Council recognised the need for a process that would, above all, be credible with the public, and drew attention to the potential to adapt processes for assessing standards already begun by the college, including a programme of fellowship by assessment.¹⁴ During the last year, the debate amongst general practitioners has been more heated. Keighley, casting revalidation primarily as a tool to raise standards across the board, defended the General Medical Council's 2004 proposals for revalidation, raised concerns about the logistics of the local revalidation panels sought by some and pointed out that any system would need to evolve once in place and would not be perfect at its inception.¹⁵ Neighbour, the President of the Royal College of General Practitioners, countered that the 'detection of bad apples' had to be a priority for a profession wishing to hold on to self-regulation.¹⁶

“The GMC’s proposals, prior to Dame Janet, much as we might wish them to have been adequate, were more appropriate to a golf club’s membership committee.”

Dr Roger Neighbour, President, Royal College of General Practitioners, 2005¹⁶

- 47 Credibility in dealing with poor performance has been seen by many as central to judging a system of revalidation, with failure to address those who are unfit for practice being described as ‘retracting into paternalism’.¹⁷ Others, whilst expressing reservations as to the ability of appraisal to identify poor practice, have strongly defended the role of both appraisal and clinical governance in the revalidation process (potentially ‘complementary and powerful tools’).¹⁸
- 48 The technical aspects of the revalidation process have been given considerable attention in journals. In a study of perceptions towards appraisal amongst general practitioners in Northern Ireland, there was general support for the professional development aspects, but significant reservations about the linkage with registration through revalidation.¹⁹ A study of the views of general practitioners in Scotland on appraisal by peers (as opposed to practice partners) suggested that peer-appraisal (and the inherent lack of local knowledge) permitted a ‘strategy of avoidance’. Appraisal by a partner was less likely to occur when scheduled, giving way to the other demands upon their time.²⁰ Another group evaluated the use of a (multidisciplinary) peer-assessment questionnaire in primary care in Wales.²¹
- 49 Articles in other publications have also caught the eye.

- A heated debate filled the pages of the *Journal of the Royal Society of Medicine* on the impact of revalidation upon retired doctors and, specifically, their ability to prescribe for friends and family.²²
- *Rheumatology* examined the application of 360-degree feedback in the setting of a multidisciplinary team within secondary care. Some team members found the process threatening and emerged hurt, others doubted its value and relevance. Overall, the authors felt that 360-degree feedback was a powerful tool that must be ‘handled with care’.²³
- *Surgeon* looked at the possibility of using anonymised peer-review of an individual surgeon’s mortality data in appraisal. A report of a two-year pilot suggested that the approach was feasible and acceptable. Furthermore, it enabled the identification of common ‘system failures’ simultaneously.²⁴
- *Medical Education* featured an interesting piece entitled ‘Continuing medical education in a district general hospital: a snapshot’. The vast majority of the 80 consultants questioned managed to undertake the amount of activity suggested by their college. Much of the activity focused on sub-specialist training, rather than updates in specialty (or indeed general) knowledge and skills. Prompts encouraging doctors to engage in educational activities appeared to be internal and personal, little influence coming from the employer or the relevant college.²⁵

The view from the top of the General Medical Council

- 50 Those with direct high-level experience of the General Medical Council have made important contributions to the ongoing debate. Sir Donald Irvine, immediate past-President of the General Medical Council, has written widely on the necessity for a transparent process of revalidation. In the *Medical Journal of Australia*, he presented a typically clear and persuasive account of such a process, underpinned by a new model of professionalism, defined standards and robust clinical governance.²⁶ He also drew attention to the gap between the standard set by the General Medical Council (*Good medical practice*) and that used by them in determining fitness to practise, which according to Irvine's successor (in his evidence to The Shipman Inquiry) is 'remarkably low'. Irvine 'sets the bar' when he states that all patients are 'entitled to a good doctor'.²⁷ Sir Graeme Catto (the current General Medical Council President) has reflected upon The Shipman Inquiry's recommendations in the medical press. He outlined the actions already taken and ongoing work to build upon the General Medical Council's achievements and develop an effective system of revalidation.²⁸
- 51 Professor Michael Pringle delivered his John Fry Memorial Lecture in June 2005 at the invitation of the Nuffield Trust. He chose as his title, *Revalidation of doctors: the credibility challenge*.²⁹ He spoke with authority and passion on the subject, borne of his experience in general practice, at the helm of the Royal College of General Practitioners and as a member of the General Medical Council. He set his discussion in the context of the 'two powerful ideologies currently fighting for the soul of medicine', the tradition of medical paternalism versus the patient-led healthcare system. Pringle notes with regret the reversal in both the detail and ethos of revalidation in the spring of 2001. He goes on to describe an alternative model, analysing the roles of various parties en route, and describing the General Medical Council as 'conductor of the revalidation orchestra'. Lay involvement is the central plank, not an optional add-on. He finishes with a case study, describing the interaction of a hypothetical doctor and his proposed system of revalidation. Commenting on the way forward, he states:

"The alternative is a system of revalidation that is fit for purpose. It will be painful. If it isn't identifying poor performance then there is either no poor performance – a hardly credible proposition – or all poor performance is being dealt with locally, or some doctors have their licence to practise curtailed. If revalidation is transparent to the public, objective, fair but firm, and designed to protect patients, the public and all of us will benefit."

Professor Michael Pringle⁵, *John Fry Memorial Lecture*, 2005

Modern professionalism

- 52** In December 2005, the Royal College of Physicians of London published *Doctors in society: medical professionalism in a changing world*.³⁰ The report summarised the deliberations of a working party set up to revisit the concept of medical professionalism and arrive at a set of underpinning values, attitudes and behaviours, appropriate for the 21st century. The report sees medicine at the interface between science and society and makes note of the rapid advancements in technology and the simultaneous alterations in societal attitudes that have occurred in recent decades. Given these real shifts, coupled with an ever-changing landscape in terms of the management and delivery of healthcare, the old construct of professionalism deserved examination afresh. Through consultation, interviews, questionnaires, focus groups and a thorough literature review, the group assembled a large body of evidence. The working party rejected a number of the traditional dimensions of professionalism, such as mastery, privilege, autonomy and self-regulation. Instead, the report focuses on a model that puts the patient unequivocally first and is delivered through partnership with those patients and members of the wider healthcare team. The report goes on to consider the application of medical professionalism in various spheres and to make recommendations. The working party regard their report as the beginning of a process rather than the end: modern medical professionalism and its component parts now need to be harnessed and fostered. The working party make a persuasive argument as to the ongoing validity of the concept of ‘professionalism’, extending above and beyond any contract of employment.
- 53** Just weeks after the Royal College of Physicians of London launched their report, a personal viewpoint entitled ‘Surgical professionalism in the 21st century’ was published in the *Lancet*.³¹ In this essay, perceived problems in surgery are conceptualised as challenges and opportunities. The author highlights the role of training, communication and clinical audit in ensuring continuous quality improvement and achieving the overarching objective of delivering good outcomes for patients. One key aspect of professionalism is the willingness and ability to adapt to circumstances, such that this overarching objective remains central.

Conclusions

- 54** The views of the public, professional bodies, individual professionals and consumer organisations have been a very valuable part of my review coming as they have in response to the *Call for ideas* exercise, as unsolicited submissions, in published commentaries on the issues, and from the research that I commissioned.
- 55** It is clear that the general public believes that doctors are subject to routine and regular assessment of their practice and performance even though they are not.
- 56** Notwithstanding this, the majority of the public and of doctors believes that there should be regular assessment.
- 57** The public and doctors believe that the assessment should cover a wide range of professional skills, attitudes and behaviours, not merely technical competence.
- 58** Annual appraisal of NHS doctors is now an important part of the quality landscape but is still seen to be in its early days, lacking rigour and consistency of application in many parts of the country. Moreover, there is disagreement about whether it should ever have a ‘summative’ element (an assessment of standards of practice or performance) or it should remain as a ‘formative’ (or developmental) tool to enhance learning, improve practice or drive continuing professional development.
- 59** Even if more assessment was built into annual NHS appraisal, there is scepticism about whether it could ever on its own be the basis for discussions about re-licensing or revalidation of a doctor.
- 60** There is little disagreement with the assertion that in 2006 every patient is entitled to a good doctor. Yet, there is no universally agreed and widely understood definition of what a good doctor is. Nor are there standards in order to operationalise such a definition and allow it to be measured in a valid and reliable way. More work has been done to develop such standards in specialist areas of medical practice.
- 61** There are concerns to get the philosophy of revalidation right, with a consensus emerging that it should be patient centred, promote improvement of standards, root out bad or sub-standard practice and be rigorous.
- 62** It is good that these points of principle have emerged but they do not move from the ‘what’ to the ‘how’ of revalidation. Many potential sources of information have been pointed to as being of value in assessing a doctor, but little consensus has emerged on the approach to be used. Nor has there been much reliance on evidence or experience of what works in devising frameworks so far.

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Chapter Nine:

Regulation in the modern world

Key points in this chapter

- Approaches to regulation have changed in recent years.
- Statutory regulators (governmental, arm's-length and independent) consume significant resources.
- The Better Regulation Task Force has established five principles for good regulation.
- In many fields, excessive regulation is seen as stifling innovation.
- Regulators are expected to consider the worth of the measures that they impose.
- Although mindful of these principles, there may be a number of areas relating to medical regulation where increased activity is required: the net burden of regulation takes account of both costs and benefits.

1 Over the last 10 years or so, much thought has been devoted to the place of regulation in modern society and how to strike the right balance between the costs and the benefits of regulatory activity. An independent body, the Better Regulation Task Force, was established in 1997 and has produced several significant reports in this area. In this chapter, I draw heavily on the published work of the Better Regulation Task Force, along with that of Philip Hampton, in order to summarise the wider regulatory context.^{1,2,3,4}

Defining regulation

- 2** Regulation is any measure or intervention carried out by (or on behalf of) government, or some other statutory body, that seeks to change the behaviour of individuals or groups. It may be prescriptive or proscriptive.
- 3** As societies become more developed, there are constant demands for more regulation to protect the environment, employees or consumers. Although these goals are worthy, poorly designed and inappropriately applied regulation is expensive, reduces productivity and hampers innovation. Complying with the information requirements of United Kingdom regulations is estimated to cost the business sector £20–40 billion each year. It is neither possible nor desirable to remove all risk.
- 4** In its 2003 report, the Better Regulation Task Force could not identify all of the independent regulators. Duplication in function, and overlap in purpose, between those bodies that do exist

means that the regulatory landscape should be examined thoroughly before establishing the case for a new regulator.

Approximate annual costs of independent regulators (2002/03)²

Regulator	Cost
Audit Commission	£214m
English Nature	£166m
Sport England	£58m
General Medical Council ⁵	£45m
Commission for Racial Equality	£19m
Competition Commission	£16m
Equal Opportunities Commission	£8m

Better regulation

- 5 In its first year, the Better Regulation Task Force devised five principles, which should result in regulation that is necessary, effective, fair, affordable and supported by the public. These principles are:
 - proportionality;
 - accountability;
 - consistency;
 - transparency;
 - targeting.

- 6 Some of the foundations to these five principles for better regulation are particularly relevant in the context of medical regulation:
 - Enforcers of regulations should consider an educational, rather than a punitive, approach where this is possible.
 - Regulators should have clear lines of accountability.
 - Regulators should be consistent with one another and, where possible, work in a joined-up way.
 - Regulation should be predictable in order to give stability and certainty to those being regulated.
 - Where appropriate, regulators should adopt a 'goals-based' approach, with those being regulated deciding how to meet clear, unambiguous targets.

Good doctors, safer patients

- 7 Prescriptive regulation is one tool at the disposal of government and regulators as they try to implement policy objectives. There are a number of alternatives:
- doing nothing;
 - advertising and education;
 - using the market;
 - financial incentives;
 - voluntary codes of practice.
- 8 There are several other markers of good regulation:
- regulation that is balanced and avoids ‘knee-jerk’ reactions;
 - regulation that has broad public support;
 - regulation that is enforceable;
 - regulations that are reviewed on a regular basis to make sure that they remain necessary and relevant.
- 9 In order to ensure that regulation accords with the five principles, it has been recommended that whenever there is a major alteration in the direction of a regulator’s activity, a thorough regulatory impact assessment should be conducted. Such an assessment should examine both the effect on regulatory costs and also the practicalities of implementation and enforcement.
- 10 Other findings from this body of work pertinent to independent regulators include recommendations for:
- a code of practice that commits to a 12-week process of consultation with stakeholders when changes are proposed;
 - a robust mechanism of appeals rather than proceeding directly to judicial review;
 - a commitment to the sharing of best practice;
 - a commitment to at least one open meeting per year where the leaders of the regulatory organisation can be questioned by the public and other stakeholders.

New approaches

- 11 In 2005, the Better Regulation Task Force reported to the Prime Minister on two specific proposals aimed at reducing the regulatory burden. Although specifically looking at business, the conclusions have some transferability to the public sector:
- reducing net administrative burdens through their measurement and the imposition of central targets;
 - a ‘one in, one out’ approach to new regulations.

- 12** The ‘one in, one out’ approach is about prioritising and emphasises that choices must be made if regulatory activity is to deliver. It is recommended that regulation is simplified through a combination of deregulation, consolidation and rationalisation.
- 13** Those that are regulated must also play their part in improving regulation by communicating effectively with policy makers and the regulator. Generic complaints about ‘red tape’ are not constructive and this conversation must become more sophisticated.

Risk-based regulation

- 14** The concept of risk-based regulation has come to the fore in recent years. The idea is sound. Regulatory attention should be focused on those areas where the chances of something going wrong are high and the consequences of such an event are grave. By doing this, the overall burden of regulation can fall whilst regulatory outcomes are maintained or even improved.
- 15** A related concept is that of earned autonomy: where an individual or organisation has been seen to perform well, they are visited or inspected on a less frequent or intrusive basis.

Medical regulation in a modern context

- 16** Many of the wider regulatory themes are entirely consistent with a modern system for the regulation of doctors including: accountability, transparency, joined-up working, consistency, the use of educational remediation, some devolution of regulatory authority, and attention to the impact of regulation upon cost and productivity.
- 17** However, there are a number of issues pertaining to medical regulation (discussed in depth elsewhere in this report) that need to be taken into account:
- The public believes that the competence of doctors should be regularly assessed and, furthermore, that such a process is already in place.
 - There have been many high-profile failures in the regulation of doctors (and healthcare organisations) over the last 15 years, which have damaged public confidence in healthcare systems. Public confidence is essential for a service that cost the taxpayer approximately £87 billion during 2005/06.⁶
 - This review has taken place against a backdrop of some dissatisfaction with medical regulation, and specifically the proposals for revalidation.
- 18** It is generally accepted that doctors should, in the future, demonstrate continuing competence to practise – it is the method that must be determined:
- The reports of the voluntary sector (and indeed the anecdotes of many individual doctors) suggest that there are some aspects of sub-optimal performance that are barely addressed by the current regulatory framework. There is a problem that needs to be fixed.
 - There is little evidence to suggest that individual medical practitioners are over-regulated at present.

- Whilst risk-based regulation is an attractive concept, there are considerable difficulties in implementing it within medical regulation. The evidence base on differential risks posed by specific groups of practitioners is poor.

19 Some of these issues are reflected in the ‘10 principles of professional self-regulation in the health field’, which I presented in my report *Supporting doctors, protecting patients* in 1999.⁷

Modern principles of professional self-regulation in the health field: 10 tests

- Regulatory bodies are accountable to the public and Parliament for their actions and performance. The Government must, and will, act to put right any deficiencies.
- Regulatory bodies must set clearly expressed standards of the knowledge, skills, experience, attitudes and values necessary for continuing practice.
- Regulatory bodies must demonstrate that their activities are conducted in an open and clear manner.
- Regulatory bodies must concern themselves with the competence and conduct of practitioners at all stages in their careers.
- Regulatory bodies must not delay in taking action to protect patients from serious adverse outcomes of care when such circumstances arise.
- Regulatory bodies must demonstrate their objectivity in making assessments and forming judgements about performance.
- Regulatory bodies must show that their procedures are free of racial and other forms of bias or discrimination.
- Regulatory bodies must take proper account of the health service context when making interventions.
- Regulatory bodies involved in education must produce clearly stated standards for professional education and training by which the providers of education and training can be monitored and held to account.
- Regulatory bodies must operate clear and independent disputes procedures.

Source: *Supporting doctors, protecting patients*, 1999.⁷

Conclusions

- 20** Modern thinking on the role and shape of regulation in society is very relevant to the design of future systems in medicine. However, there are a number of features, specific to medical regulation, that will inevitably make some of the conclusions of my review appear to be contrary to some of the principles which are applied in a ‘better regulation’ context more generally.
- 21** In the design of a system for medical regulation, it is crucial to take account of the starting point and the goal. Failure in medical regulation equates not only to increased costs but also to lives damaged and lost: it cannot be left solely to professionalism, market forces or luck.

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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 themselves 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).



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