

**GOOD DOCTORS, SAFER PATIENTS:**  
PROPOSALS TO STRENGTHEN THE SYSTEM TO ASSURE AND IMPROVE  
THE PERFORMANCE OF DOCTORS AND TO PROTECT THE SAFETY OF  
PATIENTS

**REPORT BY THE CHIEF MEDICAL OFFICER (JULY 2006)**

**RCGP SUMMARY PAPER 2006/02**



*Good Doctors, Safer Patients* is subject to a consultation that closes on 10 November 2006. The RCGP will be consulting with Members, Fellows and Faculties over the following months in order to inform a considered and structured response to the proposals. Whilst the background and proposals for change are discussed largely in the context of the NHS in England, an examination of the implications for each of the four countries will take place in the weeks after publication. Parts 1-9 of this document constitute a discussion of the key strands of the review, while Parts 10-11 summarise the CMO's conclusions and recommendations.

## **1. INTRODUCTION**

On 14 July 2006 CMO for England, Professor Sir Liam Donaldson, published his long-awaited review into the quality assurance and safety of doctors' practice in the UK, including the system for medical regulation. *Good Doctors, Safer Patients* responds primarily to the recommendations of the Fifth Report of the Shipman Inquiry, which examined the role of the GMC and the broader arrangements for medical regulation.

In her 2004 report, Chair of the Shipman Inquiry Dame Janet Smith, had concluded that NHS procedures for detecting and dealing with poor clinical performance were inadequate, allowing problems with a doctor's performance to extend over many years without definitive action being taken. The absence of rules on information sharing between professional, educational and regulatory bodies and NHS employers meant that concerns about a doctor were seldom collated at an early enough stage. This was coupled with a culture that lacked true patient-centredness, so that the interests of patients were often subordinated to other considerations. Dame Janet was also critical of the GMC, concluding that its culture, membership, methods of working and governance structures were too likely to support the interests of doctors rather than protect patients. The Shipman Inquiry and others' criticism of the proposed approach to revalidation of all doctors' fitness to practise is also central to the review.

Over ten chapters and 44 recommendations *Good Doctors, Safer Patients* proposes how the assessment of doctors; complaint systems; the identification and sharing of information on poor medical performance; care delivery; and the role of the GMC, could be made more effective and robust. Central to such recommendations is the concept that medical regulation should *not* be limited to the identification of poor practice but is a partnership of doctors, patients, and regulators working towards the general enhancement of quality in healthcare. Integral to these arrangements should be a universally agreed definition of a "good doctor", operationalised into an easily assessed set of standards, and systematically linked to local processes for assuring and improving care quality and patient safety. This should be facilitated by the devolution of regulation towards the regulated unit (local workplace) and away from central, statutory or governmental regulators.

## **2. QUALITY AND SAFETY IN HEALTHCARE**

Although it is not within its core terms of reference, *Good Doctors, Safer Patients* comments in detail on the effectiveness of the wider quality agenda in healthcare, and notes the recent progress made in establishing a comprehensive NHS framework in England for quality assurance, quality improvement and patient safety; according with the general approach. The quality framework now includes: the establishment of a clear set of national 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; mechanisms to ensure more patient-centred services; and national technical and support services to promote good governance and patient safety.

However, a sustained commitment to rigorous implementation is required in order to make the key elements of the quality framework a day-to-day reality for patients and staff - as currently there are few local instances where risk has been systematically reduced.

### **a) Clinical Standards and Governance**

Action has been taken within the NHS to ensure that evidence-based standards are established at national level via: Standards for Better Health; NICE guidelines; National Service Frameworks and Good Medical Practice standards for

professional practice. Additionally the quality framework for clinical services in the NHS 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.

**Key Messages:**

The structural response to the governance agenda has not been fully matched by a behavioural and cultural shift in local approaches to the issues of safety and quality. There is also a marked variation in adherence to best practice standards in different parts of the country and in different clinical services.

**b) Clinical Audit**

Clinical audit is one component of clinical governance, measuring aspects of clinical process and comparing results to predefined standards. In addition to clinical audit being carried out locally by individual practitioners and teams, various “national clinical audits” have been established over the years.

**Key Messages:**

The design and development of national audit projects is complex, and professional bodies have at times been suspicious of the activities of organisations such as the Healthcare Commission. It is important that the programme of national clinical audits builds upon its achievements, as national clinical databases have the potential to provide a wider range of information on clinical performance. Currently data from national or local clinical audits rarely feature in appraisal systems for doctors.

Whilst reflective practice through clinical audit has the capacity to improve services, it is difficult to establish the extent of local clinical audit activity or its impact upon patient care, as there are no aggregated data or mechanism for systematising findings into service improvements nationally.

**c) Inspection and Regulation of NHS services**

The Healthcare Commission has recently developed new systems of assessment, aligned to the core and developmental standards in Standards for Better Health, to replace the “star ratings” that it inherited. The new systems of assessment will devolve more responsibility to the organisations themselves and hands-on inspection will become less frequent but more targeted and focused.

**Key Messages:**

New ways of working in the NHS, with a shift in emphasis towards commissioning as a lever to ensure quality, are now taking shape. The plurality of providers demands that the quality agenda is also adopted by independent sector providers of care to NHS patients.

**d) Addressing Poor Practitioner Performance**

There have been serious deficiencies in the NHS response to doctors whose performance or conduct pose a risk to patients. PCTs have felt unable to take local action themselves and instead rely on the GMC, knowing that sometimes the Council’s high test of “proof” will mean that the doctor will not be censured in any way. There is also no effective corporate NHS ownership of doctors with performance problems who are employed on short-term, fixed-term or locum contracts.

The scale of performance problems in the medical workforce has been reported in research studies, with a five-year prevalence estimate of around 5%. However, over the last five years, the National Clinical Assessment Service (NCAS) has brought about a transformation in this situation. The Service dealt with 1,772 cases in the four years following its launch in April 2001, and has halved the number of long-term exclusions (suspensions). The NHS is now dealing with more “fitness to practise” cases than the GMC. The overlap between cases of poor performance or misconduct dealt with by the NHS in this way and those dealt with by the GMC is 3%.

**Key Messages:**

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. Cases of poor clinical performance are highly complex to investigate and require expert advice and support of the kind that has been provided by the NCAS. Doctors can be successfully retrained and rehabilitated if detected early, but this is a complex and intensive process which needs expert oversight and control.

### **e) Patient Safety: systems awareness**

The UK has been one of the first countries to give national priority to tackling the patient safety issue, and work in this area is internationally respected. The patient safety movement has grown with the increased awareness of the scale and nature of the problem and has shown a willingness to work towards tackling it.

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. 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.

The patient safety agenda in England is gaining momentum but adverse event detection systems remain in their infancy. Many events are still not reported by healthcare workers because of fear of blame, and understanding of the causes and determinants of adverse events is limited. The rollout of the National Reporting and Learning System has been slow, as has the sharing of lessons from the information collected in it. Healthcare organisations remain unfocused and therefore unable to rapidly reduce potentially fatal risks.

#### **Key Messages:**

A systems-based programme to improve patient safety by learning from mistakes and adverse events is underway, but faster progress needs to be made. 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.

## **3. THE THREE INQUIRIES**

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 - those of Clifford Ayling, Richard Neale, and William Kerr/Michael Haslam. Although the CMO's report highlights that the culture of the NHS is now more open and much less willing to accept or tolerate aberrant behaviour and unsafe practice, it identifies important areas for action that emerge from the work of the three inquiries - noting the many similarities and common conclusions drawn by those reports. It emphasises particularly the ongoing potential in individual healthcare organisations to develop the kind of inward looking "club culture" where such situations could recur.

#### **Key Messages:**

The handling of sensitive information about practitioners in the NHS has not been systematic in the past, with grossly ineffective communication between organisations. Complaints have not been valued as a source of information to drive improvements for patients, and NHS managers and clinicians have not recognised that a complaint can be addressed even if the complainant is initially reluctant to pursue it. There is a need for: greater transparency in the complaints process; an accessible and user-friendly system with more independent, patient-centred advocacy; comprehensive training in the management of complaints; more sympathetic handling of complainants; and the protection of complainants who are especially vulnerable.

Recruitment processes in the NHS have often lacked thoroughness, with an inadequate approach to the handling and use of professional references.

At times, the GMC has been reluctant to act upon information and slow to deal with practitioners about whom there are concerns.

## **4. THE GENERAL MEDICAL COUNCIL (GMC)**

The GMC is regarded as one of the better medical regulatory bodies internationally, but seems to be neither highly valued nor fully trusted by either the general public or the medical profession. For 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. Amongst members of the medical profession, some have pointed to the unsatisfactory way that the Council has dealt with minor or invalid complaints against doctors, while others have felt that it 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.

The GMC has 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. Despite their growing number, complaints are now dealt with more quickly by the GMC.

### **a) Shipman Inquiry's Criticisms of the GMC**

The Fifth Report of the Shipman Inquiry considered it unacceptable that one organisation should set the rules, investigate cases and pass judgment upon those cases. It suggested that the adjudication function should pass to another body, and also recommended changes to the composition of the Council. Dame Janet had other concerns about the functions of the GMC, notably: the absence of robust definitions, standards, criteria and thresholds to underpin fitness to practice procedures, leading to a lack of both transparency and consistency; the use of terms that are themselves inherently vague, such as "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".

One of the recent reforms proposed and introduced by the GMC was the concept of revalidation, in which all doctors' continuing fitness to practise would be checked every five years. 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. Dame Janet concluded that the GMC had lost its way in relation to revalidation.

#### **Key Messages:**

Despite recent reforms the present structure and functioning of the GMC remain unsatisfactory and the current approach to revalidation will not work effectively.

As the complexity of both medicine and the system in which it is delivered increases, the GMC 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. The other functions of the GMC, aside from fitness to practise, are challenging and varied, and more so as medicine becomes increasingly specialised. Each one of these functions should be carried out by the organisation best equipped to undertake it.

## **5. ASSESSING CLINICAL PRACTICE**

Doctors are regularly assessed until they finish training but few are formally assessed in the rest of their career, which may span 30 years. Historically seniority was often a marker of length of experience, rather than the competencies acquired per se. 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.

### **a) Professional Codes**

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. However, there is no country in which a universally agreed code of practice is meaningfully and intimately linked to a mechanism of re-licensure or re-certification via generic and specialist aspects of medical practice. In the UK, the GMC's *Good Medical Practice* 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 RCGP.

### **b) Methods and Tools for Assessment**

A wide variety of assessment tools have been developed for use in medical education and many have the potential for use in quality assurance. 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 (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.

With the commencement of the Foundation Programme several innovative forms of assessment have been introduced: multi-source feedback (MSF); direct observation of procedural skills (DOPS); clinical evaluation exercises (mini-CEX); and case-based discussions. 360-degree feedback has been used for many years in non-health sectors. The RCGP Fellowship by Assessment scheme uses a comprehensive process of peer-review against criteria that are regularly updated, undertaken within day-to-day practice, highlighting the potential link between fellowship and quality of practice.

#### **Key Messages:**

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.

### **c) Surveillance data**

Many different types of routine data collected in the NHS have the potential to provide vital information as to the quantity and quality of care administered by services or individuals. However, there is a risk that inappropriate conclusions can be drawn from such data, as it may be incomplete or potentially misleading due to 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. Information on service items can lend itself to measurement and benchmarking, for example that held by the NHS Business Services Authority summarising the prescriptions generated by GPs.

Further information is available via the reporting of negative or untoward events, for example incident reporting and incident reviews; or death certificates stating the likely causes(s) of death and the details of the patient’s doctor. A review into mortality monitoring, conducted by Professor Richard Baker at the behest of the Shipman Inquiry, recommended that systems for the monitoring of GPs should be reviewed and extended to include routine monitoring of death rates. Such information is important for reasons beyond the performance monitoring of doctors, such as identifying disease trends.

#### **Key Messages:**

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. No single source of information is adequate to assess performance – multiple strands of information are necessary.

Systems for monitoring death rates in primary care have been proposed but not systematically implemented. The various statistical systems proposed would benefit from being widely piloted. 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.

### **d) Complaints**

The NHS has a tendency to view complaints in a negative light, rather than as a precious source of customer feedback, allowing managers to see an organisation from a fresh perspective and enabling innovative and patient-centred improvements. 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 GPs; 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; and is dependent on high-quality investigation, for which some organisations lack capacity.

Complaints relating to the care provided by GPs are a particularly challenging area, as PCTs and the Healthcare Commission have limited powers to investigate them in the absence of cooperation from the individual doctor. A number of solutions have been proposed in relation to these criticisms including the ability to lodge complaints relating to primary care with the NHS PCT and not just at the level of the practice.

### **e) Ill Health and Addiction**

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 the BMA estimates that as many as one in fifteen doctors may be affected by drug or alcohol dependence at some point during their career. Sick doctors (including those with substance addiction) can pose a real threat to patient safety and they also present a difficult problem for medical regulation, as there may be a reluctance to refer a practitioner into a system that is perceived as “disciplinary”.

#### **Key Messages:**

There is some emerging evidence that the specialised treatment of addicted health professionals may offer improved results. Recently, a six-month abstinence rate of around two-thirds was reported by one group in the UK, using an innovative and intensive treatment programme with a small group of health professionals. 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.

### **f) Assessing and Investigating Poor Performance**

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. Each year, approximately 300 doctors appear for the first time before fitness to practise panels operated by the GMC.

The one-year risk of referral to the National Clinical Assessment Service (NCAS) 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. About two-thirds of referrals to the NCAS are handled through the provision of expert one-to-one advice over the telephone, with the remaining one-third requiring more intensive involvement, 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. As the work of the NCAS has matured, the proportion of referrals already known to the GMC at the time of referral has dropped and is presently only 3%. Just over 10% of referrals have involved locums.

The NCAS occasionally employs formal performance assessment procedures 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. It has built its approach to performance assessment on four key domains: clinical capability (including knowledge, skills and the ability to use clinical resources); health and well-being; behaviour; and immediate work environment (including the functioning of the clinical team and the wider organisation). The interplay between those four domains is seen as central to the understanding of performance through assessment.

#### *Key Messages:*

The assessment methods developed by the NCAS for cases of poor practice have a wider applicability to affirming safe practice. The 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.

#### **g) Is Appraisal Assessment?**

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 formative rather than summative (judgmental about the standard of an individual's performance).

In the absence of standards, or standardisation of approach, the pattern of appraisal around the country is reported as variable, especially in general practice. The appraisal process in primary care is currently heavily reliant on the GP's self-assessment because the doctor carrying out the appraisal will have little first-hand knowledge about their colleague's work or day-to-day performance. Anecdotal accounts suggest that where the management of a PCT has concerns about the standards of a general GP's care, more often than not such individuals have "good" appraisals on file.

## **6. MEDICAL REGULATION AROUND THE WORLD**

As part of the CMO's review an international assessment of medical regulation in a number of other countries was undertaken – namely Australia, Canada, Finland, The Netherlands, New Zealand and the US. Although no one model of medical regulation is internationally accepted as best practice, the primary aim of medical regulation is now explicitly focused on patient protection and safety. Other trends include common frameworks for regulating all healthcare professions and a move away from the model of "pure" self-regulation, in favour of a model of partnership or co-regulation involving the state or health services, as well as the professional regulatory body. In some countries, accountability to government has been strengthened, regular reports are required and the government has powers to audit professional regulatory bodies. There has also been a trend to separate disciplinary functions from the registration or licensing body.

Across most countries surveyed, there are moves towards periodic mandatory assessment of competence. The major role in developments aimed at maintaining fitness to practise has generally been played by medical specialty colleges or boards.

#### *Key Messages:*

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. 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.

## 7. MEDICAL REGULATION IN OTHER HIGH-RISK PROFESSIONS

Useful parallels can be drawn with other high-risk sectors where comprehensive regulatory systems have been developed and the culture has changed to manage risk to good effect. Common themes in professions such as Pilots and Air Traffic Controllers, Nuclear Power Unit Desk Engineers, Offshore Installation Managers 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”). The CMO identifies nine general themes of competence assessment in high-risk industries:

- An independent regulator, with competence assurance of personnel devolved to operators.
- Regular, formal proficiency checks.
- Clearly defined standards of competence.
- Trained and accredited assessors.
- Non-technical skills assessed formally.
- Remedial approach to failure, rather than stigmatization.
- Simulators widely employed for competence assessment.
- Mandatory health checks and drug and alcohol testing policies.
- Linkage of competence assessment to safety management.

### *Key Messages:*

Some themes and principles identified may not be readily transferable to the regulation of doctors chiefly because of the sheer scale of the task of regulating UK doctors. Any excess regulatory burden (time or cost) would be more tangible in medical regulation. Another distinction is that in the high-risk industries studied, the failure of an individual has direct safety implications for both individual and co-workers. In medicine, the consequences of failure largely befall a third party – the patient.

## 8. PUBLIC AND PROFESSIONAL VIEWS

For the purposes of this review a wide range of opinions were gathered on regulatory issues via consultation, a MORI survey of public opinion, and discussion in professional journals and meetings.

During that exercise it became 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. Patients wanted their doctors to have good clinical knowledge and skills, but also interpersonal qualities (communication, respect, dignity and involving patients in decisions). To this end the majority of the public (and of doctors) believe that there should be regular assessment, covering a wide range of professional skills, attitudes and behaviours, not merely technical competence.

The opinion-gathering exercise also identified an “ongoing debate” as to the fundamental nature of appraisal and its ability to contribute to a process of revalidation. 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 developmental tool to enhance learning, improve practice or drive continuing professional development. There is scepticism about whether it could ever on its own be the basis for discussions about re-licensing or revalidation of a doctor. Many respondents and commentators have been frustrated by the pace of progress in relation to the issue of revalidation.

## 9. REGULATION IN THE MODERN WORLD

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. Approaches to regulation have changed in recent years. Statutory regulators (governmental, arm’s-length and independent) consume significant resources, and in many fields excessive regulation is seen as stifling innovation. This has led to the concept of “risk-based regulation” whereby 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. The overall burden of regulation can thus fall whilst regulatory outcomes are maintained or improved. 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.

However, there are a number of issues pertaining to medical regulation that need to be taken into account, such as the public belief that the competence of doctors should be regularly assessed and, furthermore, that such a process is already in place. Additionally the evidence base on differential risks posed by specific groups of practitioners is poor. The reports of the voluntary sector suggest that there are some aspects of sub-optimal performance that are barely addressed by the current regulatory framework, and there is little evidence to suggest that individual medical practitioners are over-regulated at present.

### *Key Messages:*

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.

## **10. CONCLUSIONS**

### ***a) The Ethos of Medical Regulation***

There has been long-standing discordance in the threshold for determining an unacceptable standard of practice between the GMC and the NHS employer. The GMC 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 that the sanctions imposed by the GMC are so devastating to an individual doctor's livelihood and reputation that the criminal standard of proof must apply. 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.

The atmosphere for wider medical regulation in the UK is in large part set by the GMC, which is adversarial in its outlook. Procedures have not been constructed with a view to the holistic assessment of a practitioner following referral. 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.

A way needs to be found to integrate the handling of fitness to practise cases by the GMC and by the NHS, or other organisations delivering healthcare. The GMC has been inflexible, legalistic and distant, making black or white binary decisions, such as whether to investigate a complaint or not. Employers are pragmatic and require, as a minimum, doctors who are able to do the job well and within an acceptable level of risk.

### ***b) Diversity in Practice***

PCTs are not empowered to assure the quality of many of the individual doctor-patient interactions that occur within GP practices. For many principals in general practice, the concept of line management within the PCT is an extremely abstract one. This imbalance between the statutory responsibilities of PCTs and the level of influence and power that they are able to exercise in reality is notable. Additionally doctors who do not have a long-term relationship with a specific healthcare organisation represent a special challenge for regulation. 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.

### ***c) Medical Regulation to Promote Good Practice***

It is important to ensure that the concept of medical regulation is not limited to the identification of poor practice. 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. 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 do not adequately address the related but distinct tasks of assuring good practice, identifying poor practice, and acting as a vehicle for quality improvement.

### ***d) The Role of Appraisal and Revalidation***

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. No one could successfully argue that NHS appraisal is routinely addressing all these domains.

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 a skilled, trained appraiser conducts appraisal rigorously, objectively and thoroughly. 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 due to local knowledge of a doctor's reputation or complaints made against them.

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. 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. For such a process of revalidation to be effective it must be built upon more than the current system of NHS annual appraisal.

#### ***e) Once a Doctor, Always a Doctor***

Retired doctors, by definition, have ceased to have a substantive medical practice. 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.

Being a medical student is a position of great responsibility that carries the potential to do harm to patients. The profession's regulator must therefore engage students. A case has been made for a single national examination to quality-assure the graduates of UK medical schools in a uniform manner.

#### ***f) Transparency, Openness and Fairness***

At present, there are too many potential sources of information on doctors' performance. For example, a GP's name must be on the formal Medical Register and the new general practice register (both maintained by the GMC), as well as the PCT performers list (perhaps in a location distant from where they now work).

There is a large pool of less formal information, 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. 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.

The notion of free access to any, and all, information ever collected or held by the GMC is superficially attractive. However, 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 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.

## **11. RECOMMENDATIONS**

### ***a) Local GMC Affiliates***

The GMC's role in investigating concerns about a doctor's care or conduct should be extended to a local level by the creation of specially trained medically-qualified GMC affiliates within healthcare organisations. Affiliates would deal with some fitness to practise cases locally while referring more severe cases to the central GMC. Affiliates would also have the power to agree a "recorded concern" - complaints identified by healthcare organisations that raise concerns about a specific doctor.

The affiliate should inform a doctor's employer or contracting organisation and any complainant when a "recorded concern" is accepted. These would be reported to the GMC centrally for collation and routinely reviewed by a national committee with a lay majority. This will enable the responsive and timely resolution of issues close to the workplace and align any regulatory action with that of an employer.

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 GMC affiliate. Each 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.

### ***b) Complaints in General Practice***

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 PCT. Such arrangements should be publicised widely in surgeries and within patient information resources.

### ***c) Performance, Health and Conduct***

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. In serious fitness to practise cases investigation and assessment should be carried out by the GMC, but a separate and independent tribunal should undertake formal adjudication. The Healthcare Commission and the Ombudsman should be able to require the GMC to assess or investigate an individual doctor's performance, health or conduct; and the GMC should have the power to specify packages of rehabilitation and conditions

on practice following a comprehensive assessment. During its assessment of a practitioner whose fitness to practise has been called into question, the GMC should make full use of the expertise of the NCAS.

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

#### ***d) Standards for Medical Practice and Appraisal***

A clear set of standards should be created for generic medical practice as an operational definition of a “good doctor”, and placed in doctors’ contracts. Medical colleges should develop a similar set of standards for each area of specialist medical practice. 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.

#### ***e) The Medical Undergraduate Curriculum and Student Registration***

The role of the GMC in setting the content of the medical undergraduate curriculum, and to inspect and approve medical schools, should be transferred to the PMETB.

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

#### ***f) English Language Proficiency and Registration Exam***

Any NHS contracting organisation should ensure that all doctors have successfully completed an accredited assessment of English language proficiency in the context of clinical practice. This assessment will be introduced for doctors entering the Medical Register and seeking employment for the first time after a specified date.

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 GMC. 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.

Responsibility for the Professional Linguistics Assessment Board (PLAB) examination should pass to the PMETB. It is likely that the clinical components of the examination will be commissioned and delivered through UK medical schools.

#### ***g) Locum Appointments***

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.

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

#### ***h) Appraisal and Revalidation***

Revalidation will be based on two elements – 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 re-licensing process should be based on the revised system of NHS appraisal and any concerns known to the GMC affiliate. Information should be collated by the affiliate and presented to a statutory clinical governance and patient safety committee, dependent upon the doctor participating in appraisal and an independent 360-degree workplace feedback exercise. The chairman of this committee should then submit a formal list of recommendations to the GMC centrally.

Specialist certification (including general practice) 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. 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.

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 GMC, supported by the NCAS 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.

### ***j) Doctors Approaching Retirement***

As doctors approach retirement, they should be invited to a review with their GMC 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 by a working group.

### ***j) Clinical Audit and Use of Routine Data***

A 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.

The routine monitoring of significant events in general practice should be supported through the contracts of GPs. The RCGP should be asked to assess the suitability of the information held on the prescribing habits of individual practitioners for use in quality assurance; and to examine the wider role of practice profiling and the use of other routinely available data for quality assurance. This will enable reflective practice, drawing upon a wide range of clinically relevant data including information about deaths, prescribing habits and data from the quality and outcomes framework.

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 PCTs.

### ***k) PCT Access to GP Records***

Further attention should be paid to ensuring the formal and personal accountability of individual GPs to their PCT, through use of standard contracts and other mechanisms. In particular, PCTs should be guaranteed unfettered access to all patient records.

### ***l) Information for the Public, Employers and Professional Bodies***

The Medical Register should be the key national list of doctors entitled to practise in the UK and should contain tiers of information (some publicly available, others available with restricted access) about each doctor and their standard of practice. It would eventually subsume primary care performers' lists, which should cease to be a statutory requirement.

The following information should be freely available: registration status; date of expiry of licence; specialist certification or inclusion on the GP register and date of expiry of the same; 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 GMC is in progress if that is the case, and any "recorded concerns".

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 PCT.

### ***m) Structure and Governance of the GMC***

The primary role of the members of the GMC should be the appropriate corporate governance of the organisation. This role is one of accountability for the quality of services delivered 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. The role of members is a strategic one, and not an operational one.

To reflect its new responsibilities, the GMC's composition should become more "board-like" with members independently appointed by the Public Appointments Commission, and its President elected from amongst those members. It should be accountable to Parliament, to which it should be required to present a detailed annual report.

[Good Doctors, Safer Patients](#) (Full DH Document: large file)  
[Conclusions and Recommendations](#) (44 Specific Recommendations in Full)