

**Revalidation:  
The way ahead**

## **Publication of proceedings**

International Revalidation Symposium:  
Contributing to the evidence base

London | 2 & 3 December 2010





The International Revalidation Symposium, held in December 2010 in London, brought together experts from around the world to share their experiences, and build the evidence base for systems of assuring that doctors are clinically competent and fit to practise throughout their careers. This process is variously termed as revalidation, 'maintenance of licensure', or recertification.

The aim of the Symposium, which was co-hosted by the GMC, the Health Foundation, and the Federation of State Medical Boards, was to capture and draw on good practice in this endeavour and to learn from expertise, research, evidence and experiences of professional regulators and others from around the world.

Many of those involved in the event have already developed different ways of assuring the ongoing competence of doctors while others are in the early stages of implementation.

The wide ranging discussions at the event highlighted a clear international consensus that a formal system of assurance plays a vital role in raising professional standards and improving patient care. In the UK, the ambition is that revalidation will further encourage and embed good clinical governance, which time and again has been shown to be the foundation of high quality care.

On the first day of the Symposium, we heard about professional medical regulation in different countries and across a range of regulators. The systems being developed in each country are different, with some using examinations and assessments while others rely more on continuing professional development and multi-source feedback or a combination of all of these activities. But the goal is always the same: to ensure patient safety and drive the further development of good quality care.

The second day focused on patient and public involvement, the effectiveness of continuing professional development in keeping doctors up to date, and the role of audit as part of good clinical governance.

Although some assume having a process for assuring competence is simply a process for 'weeding out bad

apples', there was agreement that this should not be the sole or even the principal focus. A good system of clinical governance, and a culture which encourages doctors to review their practice and performance, should assist in the identification of problems or potential concerns at an early stage. By fostering self-reflection and professional development, revalidation can directly support continuous quality improvement in the provision of medical care.

Above all, it was clear from the Symposium that a system of regular checks for doctors, however this is delivered, is not an 'add-on'. Attendees agreed that revalidation for doctors, or whatever term is used to describe that process, must be a crucial element in any system that aspires to provide safe, effective and improving healthcare for patients.

The papers included in this publication reflect the good practice and lessons learned from the research, evidence and expertise of professional regulators and others from around the world. It was agreed that we should consider repeating the symposium at some point in the future – perhaps in late 2013 – to review progress and further learning. In the meantime, we look forward to building on relationships forged with colleagues at the Symposium as we continue to learn from, and share good practice with, one another on the design and implementation of this major reform in professional regulation.

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<http://www.flickr.com/photos/generalmedicalcouncil/sets/72157625843050270/show/>

# Regulating doctors: Finding the optimal balance between professionalism and self-regulation

**Professor Ron Paterson, University of Auckland**

## Summary

This paper, by a former health ombudsman and patient advocate from New Zealand, considers patient and public expectations of the competence of doctors. It notes that in most modern health systems in 2010, patients still have to take the competence of doctors on trust. A case study of a failing, elderly general practitioner is presented to illustrate how poor care and documentation can harm a trusting patient; to show that the patient had to take 'pot luck' in seeking medical care; and to critique the unfulfilled responsibilities of the GP, his colleagues, and the registration authority. A balance needs to be found between relying on medical professionalism (insufficient on its own to protect patients) and external regulation (which, if excessive, risks undermining professionalism). Co-regulatory models from New Zealand and Australia are highlighted. The challenge posed is how to give patients and the community the assurance they seek – and which legislators say is their entitlement – that any registered doctor is competent and fit to practise; yet do so in a way that supports doctors in their own efforts and is not bureaucratic, expensive and protracted.

## Introduction

The purpose of this symposium is 'to review the evidence to support different models and approaches to revalidation and recertification for doctors in various jurisdictions around the world'. The subtitle to our meeting is 'Contributing to the evidence base'.

But I think we need to stand back and ask ourselves *why* we consider it important to revalidate doctors, before we focus on *how* we go about revalidation. And since Harry Cayton and I have little experience in the how of revalidation, but a lot of experience

in mediating patient views about doctors, and in regulating health professionals, it seems sensible that we should talk about the case for revalidation, and give you our views of what the public expects.

## Background and philosophy

I need to declare, as best I can, the background and biases I bring to this task. I am trained in law, not medicine. I spent the first half of my working life as a university law lecturer in Canada, the United States, and New Zealand, and the second half in health policy and regulation in New Zealand. Over the decade 2000 to 2010, I was New Zealand Health and Disability Commissioner, responsible for handling thousands of complaints about healthcare and disability services, including hundreds about doctors whose care or communication was alleged to be substandard. I also had a 'public watchdog' role, charged with promoting and protecting patients' rights in New Zealand.

This unique perspective confirmed my healthy respect for the skills and dedication of the vast majority of doctors. But time and again, I saw cases where it must (or should) have been obvious to colleagues, may well have been suspected by patients, and would probably have been detected by external checking by a medical regulator, that a doctor was performing below par. Equally concerning, I saw cases where even reactive checking (following complaints and concerns) led to very limited assessment of a doctor's performance.

Too often, the end result of such cases is that a patient receives substandard care and may be harmed, the doctor suffers the shame and ignominy of external investigations and, in extreme cases, there is a loss of trust in the medical profession and in the regulators charged with protecting the public.

We are all familiar with the fallout from the Bristol and Shipman inquiries in England, and the Bundaberg inquiry in Queensland. They have been important catalysts for reform of health professional regulation.

The failing general practitioner or specialist in private practice is less often subject to the scrutiny of public inquiries, yet these tend to be the doctors who most often come to the attention of complaint commissions and medical regulatory bodies, as a result of complaints or concerns. I want to tell you about one such case which came to my attention as the New Zealand Commissioner. It never came to media attention and did not lead to public scandal, but I found it scandalous in ordinary but significant ways.

### **Case study – the failing elderly doctor**

Dr B was in his mid-70s and had been in general medical practice for over 50 years. By 2002, he was in semi-retirement working three half days a week for a medical centre, as an independent contractor paid on a 'fee-for-service' basis. He was described by a colleague as 'a humble and careful man with a deep concern for his patients'. When Dr B joined the practice in 2001, he was reluctant to change his life-long practice of keeping handwritten notes of his consultations. He had no prior experience of computers and although he learned to navigate the system, the input of notes into the computer required typing which 'on a part-time basis he did not feel worth learning'. He therefore did not enter patient information in the practice's computerised system, but he could access electronic records on his desk computer, and his colleagues knew to check the manual records if seeing one of Dr B's patients.

### **The loyal patient**

Ms A, aged 62, had been a patient of Dr B for 20 years. She had multiple pre-existing conditions. In January 2002, Ms A consulted Dr B complaining of dysuria and tenderness high in her abdomen, front and back, and kidney area. Over the next five months, Ms A consulted Dr B on five more occasions with urinary and abdominal symptoms, until he finally discovered that she had a pelvic cyst. His handwritten records noted only one physical examination, although he claimed to have

undertaken three. He initially diagnosed 'urethral irritation' due to sexual activity, and prescribed medication. When her symptoms did not resolve, he prescribed further medication at three consultations, and twice more in response to telephone requests. Dr B did not record his working diagnoses, and did not document any test requests or results.

An ultrasound scan and gynaecological review confirmed the presence of a large pelvic mass 'the size of a 24 week pregnancy'. By August 2002 Ms A had been hospitalised with an ischaemic right leg and, following a CT scan, was found to have cancer of the uterus. Ms A's leg was amputated. She suffered a stroke while in a rehabilitation unit, and died of inoperable cancer in September 2002.

### **Complaint**

Ms A's sister complained to the Health and Disability Commissioner (HDC) that Dr B had failed to diagnose Ms A's cancer, and that his care had been substandard. An independent expert general practitioner advised HDC: 'Dr B's care was deficient due to his failure to adequately examine and investigate Ms A's urinary and abdominal symptoms' (although the outcome would probably not have been different) and his notes were 'inadequate in content with Ms A's symptoms poorly recorded, examination findings lacking and management plans deficient'.

HDC upheld the complaint and ruled that Dr B had breached his patient's rights by not meeting the legal standard of 'reasonable care and skill' in his management of Ms A, and falling well below professional standards in his record-keeping. The decision was published on the HDC website (03HDC03134, 28 June 2005, [www.hdc.org.nz](http://www.hdc.org.nz)). I recommended that the New Zealand Medical Council review Dr B's competence and consider whether any conditions should be imposed on his intended occasional future practice (having retired from general practice).

### **Who was responsible?**

Dr B's lawyer submitted that the complaint and subsequent proceedings had had a devastating impact on the doctor and had affected his health.

Naturally, it is hard to be unmoved by the plight of a doctor who, in the twilight years of his practice, endures investigations because of lapses in his care for a single patient. Yet patients are entitled to good care, and proper records, irrespective of the age and experience of their doctor. There can be no sliding standard of care depending on the reputation and seniority of the practitioner. Dr B was personally responsible for failing to maintain his professional competence.

But Dr B was not a sole agent. What responsibility did the medical centre have for Dr B's poor care and records? In its own submission, very little: 'I have no knowledge of any steps usually taken by medical centres to ensure that locums or doctors are competent other than informal inquiry with their peers and casual overview of their notes at work. Dr B has been in practice for 50 years without a complaint. ... We did not 'audit' his notes. It did not occur to us to take steps to satisfy ourselves that he was competent. ... [T]his is the job of the regulatory authorities.' Dr B's colleagues did not see themselves as their 'brother's keeper'.

What responsibility did the 'regulatory authority' (the New Zealand Medical Council) bear in this situation? The Council's role was not investigated, but there was no evidence it had taken any steps to check Dr B's ongoing competence, nor that it had any rigorous system in place to do so. It is unlikely that Dr B's performance would have been scrutinised as a condition of ongoing practice in other parts of the world – though the Quebec system of more intensive reviews of 'at risk' practitioners (including doctors first registered more than 35 years previously) may have detected and sought to remediate his failings before a problem arose.

### Lessons

What lessons can we learn from this case? I draw the following lessons. Ms A had to take 'pot luck' in seeking medical care. She had no way of knowing whether Dr B was doing his job properly. Like most members of the public who do not have family connections with the medical fraternity, she had to take it on trust that Dr B was competent. If asked, she would probably have said, 'Well, he's a professional.' And she would have assumed that he

needed a 'warrant of fitness' to keep practising.

### Professionalism

I want to say a few words about professionalism. It is not a term that resonates with patients, but it is an article of faith for doctors. In 2001, physician societies on both sides of the Atlantic launched a new charter entitled, 'Medical Professionalism in the New Millennium'. Ten professional responsibilities are listed in the charter. The first is a strong statement of the importance of maintaining professional competence:

*'Physicians must be committed to lifelong learning and be responsible for maintaining the medical knowledge and clinical and team skills necessary for the provision of quality care. More broadly, the profession as a whole must strive to see that all of its members are competent and must ensure that appropriate mechanisms are available for physicians to accomplish this goal.'*

This is the clearest possible statement that professionalism supports maintenance of competence. It is the checking part that leads to a divergence of opinion. In relation to doctors (and indeed other time-honoured professions, such as lawyers and accountants), self-regulation generally holds sway. Thus, it is left to the medical profession, via its governing bodies, to 'strive to see that all of its members are competent'.

Dr B's professionalism was not enough to keep Ms A safe. The professionalism of Dr B's medical colleagues was not enough to protect her. The self-regulatory mechanism of oversight by the New Zealand Medical Council was no help to her. The fine words of 'Good Medical Practice' (endorsed in New Zealand before these events) did not avail.

### Finding the optimal balance

My talk is rather grandly titled, 'Finding the optimal balance between professionalism and regulation to ensure patient safety'. Onora O'Neill warned, in her 2002 BBC Reith lectures, that we risk undermining trust and professionalism by excessive accountability. My New Zealand colleague Charlotte Paul has written that we cannot put all our eggs in the basket of external regulation in our desire to keep

patients safe. But equally, we cannot simply leave it to the 'internal morality of medicine'. History tells us that the medical profession and its governing bodies are not sufficient to ensure that practising doctors remain competent.

In all the countries represented here, doctors enjoy high levels of public trust. Here is the latest data from New Zealand. It is generally accepted that the vast majority of doctors are well intentioned and practise safely. But good intentions and generally adequate care are not enough. As a member of the public, and a potential patient, I want to know that I can rely on the public medical register as assurance that any listed doctor is competent. I accept that within any profession, there will always be outliers: the gifted and the ordinary. I want to know that even the mediocre practitioner will meet minimum standards. Recent research for the Medical Council found that 75% of 523 survey respondents said their confidence in doctors would be increased if they knew that doctors' performance was subject to a regular review.

### **Reforms of self-regulation**

Across all the countries represented here, legislatures have responded to inquiry reports and public pressure with a suite of medical regulatory reforms, some of which directly challenge the concept of self-regulation. They include independent appointment processes to appoint members of regulatory bodies, greater lay participation in governance, policymaking, and assessment procedures, and separation of disciplinary functions from registration and standard setting.

Some health systems have explicitly adopted co-regulation, with dual roles for a medical council (with registration and quality assurance functions for doctors) and a complaints commission (with functions of adjudicating patient complaints and acting as a public watchdog). The New Zealand Health and Disability Commissioner, the New South Wales Healthcare Complaints Commission, and the Queensland Health Quality and Complaints Commission are noteworthy examples of co-regulators with a specific statutory mandate to delve into what has traditionally been the business of

the medical regulator.

There has also been sustained pressure on medical regulators and disciplinary bodies to become much more transparent about their processes and decisions. There is a mood of public dissatisfaction with the 'veil of secrecy' that shrouds much of the work of medical councils and tribunals, and calls for greater transparency from consumer groups and legislators.

Revalidation remains largely aspirational, 12 years after a very substantial majority of the GMC agreed to introduce it at a special conference in February 1999; and 7 years after the New Zealand Parliament passed the Health Practitioners Competence Assurance Act 2003, with the express purpose of 'protect[ing] the health and safety of members of the public by providing for mechanisms to ensure that health practitioners are competent and fit to practise their professions' (section 3(1)).

In most modern health systems in 2010, we still have to take the competence of doctors on trust. Our trust is probably well placed, since most doctors do keep their skills up to date. But independent verification is seldom undertaken. Once entered on the medical register and licensed to practise medicine, doctors are subject to few, if any, checks on their continuing competence.

The challenge – and the reason for this symposium – is to find a 'way forward'. How can we give patients and the community the assurance they seek – and which legislators say is their entitlement – that any registered doctor is competent and fit to practise; yet do so in a way that supports doctors in their own efforts and is not bureaucratic, expensive and protracted.

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# Right-touch regulation

Harry Cayton, Council for Healthcare Regulatory Excellence

## Introduction

- 1.1 This paper outlines CHRE's thinking as we explore the role and value of regulation. Common themes have emerged through our oversight of the health professional regulators and in our advice and recommendations to Government on areas of regulatory policy. In this paper we explain these in greater detail and define more clearly our concept of right-touch regulation.
- 1.2 Right-touch regulation describes the approach we adopt in the work we do. It is the approach that we encourage our regulators to work towards, and it frames the contributions we make to wider debates about the quality and safety of healthcare and the development of regulation.
- 1.3 This paper argues that this approach is the right one to take. It explains right-touch regulation in practice and outlines the benefits it offers for professional regulation and to wider healthcare delivery, as our area of expertise and experience. However, we believe that the application of this approach would be valuable in other sectors and to other areas of regulation and we would welcome responses and debate in this respect.

## What is right-touch regulation?

- 2.1 The concept of right-touch regulation emerges from the application of the principles of good regulation identified by the Better Regulation Executive in 2000<sup>1</sup>:
  - **Proportionate:** regulators should only intervene when necessary. Remedies should be appropriate to the risk posed, and costs identified and minimised

- **Consistent:** rules and standards must be joined up and implemented fairly
- **Targeted:** regulation should be focused on the problem, and minimise side effects
- **Transparent:** regulators should be open, and keep regulations simple and user friendly
- **Accountable:** regulators must be able to justify decisions, and be subject to public scrutiny.

These principles provide the foundation for thinking on regulatory policy in all sectors of society.

- 2.2 To these five CHRE has added agility as a sixth principle. This was first proposed in our advice to the Department of Health and the Pharmacy Regulation and Leadership and Oversight Group on aspects of the establishment of the General Pharmaceutical Council.<sup>2</sup> Our advice reflected on the context of rapid change expected over the next ten years in pharmacy practice and the appropriate regulatory response to this.
- 2.3 Agility in regulation means looking forward to anticipate change rather than looking back to prevent the last crisis from happening again. We consider that an agile regulator would foresee changes that are going to occur in its field, anticipate the risks that will arise as a result of those changes, and take timely action to mitigate those risks. At the same time, an agile regulator would not react to everything as changes may occur which do not need a regulatory response. In their 2009 report on *Themes and Trends in Regulatory Reform*, The House of Commons Regulatory Reform Committee agreed with us that 'agility' is an important objective for the regulatory agenda.<sup>3</sup>

<sup>1</sup> Better Regulation Executive, 2000. Five principles of good regulation.

<sup>2</sup> CHRE, 2008. Advice to the Department of Health and the Pharmacy Regulation and Leadership Oversight Group on aspects of the establishment of the General Pharmaceutical Council.

<sup>3</sup> House of Commons Regulatory Reform Committee. 2009. Themes and Trends in Regulatory Reform.

Available at: [www.publications.parliament.uk/pa/cm200809/cmselect/cmdereg/329/329i.pdf](http://www.publications.parliament.uk/pa/cm200809/cmselect/cmdereg/329/329i.pdf) [accessed 29 June 2010]

**2.4** We see the concept of right-touch regulation emerging naturally from the application of these six principles: bringing together commonly agreed principles of good regulation with understanding of a sector, and an accurate and quantified assessment of risk. In practice this means we work to identify the right level of regulation that is needed to achieve a desired effect. Our analogy is a set of scales. You put the weight on one side and start to pour flour into the bowl. Nothing happens until you reach the desired weight at which point the scales tip over. If you continue to pour flour into the bowl nothing more happens as the scale has already tipped. So the right amount of regulation is exactly that which is needed for the desired effect. Too little is ineffective; too much is a waste of effort.

**2.5** Our thinking is in line with what others have called smart regulation,<sup>4</sup> or common sense or rational approaches to regulation. For us, right-touch neatly describes the role that regulation should play. It is smart in that it builds on an accurate and informed assessment and analysis of the sector and the risks in it; it is common sense in that it is the role regulation should be playing, building on its strengths, staying true to its objectives, given the tools and levers it has at its disposal.

**2.6** Right-touch regulation recognises that there is usually more than one way to solve a problem and that regulation is not always the best answer. It may be more proportionate, for instance, to promote greater cooperation and sharing of good practice. Today, more than ever given the economic circumstances, the challenge is to find the most efficient, common sense solutions to problems. Right-touch regulation is the minimum regulatory force required to achieve the desired result.

## Right-touch regulation in healthcare

**3.1** In our work with the health professional regulators we formally define right-touch regulation as follows:

*Right-touch regulation is based on a proper evaluation of risk, is proportionate and outcome focussed; it creates a framework in which professionalism can flourish and organisations can be excellent.*

**3.2** For CHRE the outcome is clearly articulated in our legislation: 'the health, safety and wellbeing of patients and other members of the public'. Many healthcare organisations share this aim in the work they do, either explicitly or implicitly. They have a role to play and a contribution to make to achieve this wider benefit.

**3.3** The quality of healthcare received by individual patients and members of the public is the end result of a wide range of different decisions. For example:

- Self-management decisions taken or not taken by people
- Health professionals' education, training and continuing professional development
- Employers' policies and guidance, and local clinical governance arrangements
- Commissioners' contracting arrangements
- Good practice identified by advisory groups, such as professional organisations, royal colleges, arm's-length bodies
- National legislation, for example, human rights, equality, data protection, consumer protection, health and safety.

<sup>4</sup> European Commission. April 2010. Stakeholder Consultation on Smart Regulation. Available at: [http://ec.europa.eu/governance/better\\_regulation/smart\\_regulation/docs/smart\\_regulation\\_consultation\\_en.pdf](http://ec.europa.eu/governance/better_regulation/smart_regulation/docs/smart_regulation_consultation_en.pdf) [accessed 28 June 2010]

**3.4** Regulation is part of a set of possible solutions to risks in the healthcare sector. This is captured for example in the GMC's four layer model of regulation which highlights the roles and responsibilities of regulators, employers, teams and individuals in public protection. All policy development should be seen in this context, and regulation will only be effective if this wider perspective is taken. Right-touch regulation provides a means of tackling an issue in such a way that an appropriate balance of the responsibilities of individuals, employers and regulators can be achieved.

**3.5** We believe that it is primarily the professionalism of doctors, osteopaths, pharmacists, nurses, physiotherapists and the other 25 regulated professions that deliver quality care. Regulation is working in the public interest when it supports professionalism and allows it to flourish. It can do this through promotion of standards of competence and conduct, by taking action where these standards are breached, and through quality assuring the education of professionals. It does not seek to address all aspects of risk, and regulation (of health professionals or in its other forms) is not the solution to prevent every possible thing that could go wrong. Indeed over-regulation could give a false level of assurance and lead to increased risk.

**3.6** Patients and the public also have responsibility for managing risks, becoming involved in discussions about their treatment options, the different levels of risk involved, and the possible consequences for their health. For vulnerable people, this responsibility is shared and extended to family, carers and advocates. People have a fundamental and essential contribution to make to high quality healthcare. The concept of right-touch regulation recognises the value and importance of the involvement of patients and the public in assessing risks for themselves and making appropriate choices. Right-touch regulation requires the active participation of citizens.

**3.7** There is an inherent risk in all interventions in healthcare and nothing can be said to be completely safe. For example there is no such thing as an absolutely safe medicine, since there will always be someone who will suffer an adverse reaction or side effect. Given the wide range of influences on healthcare, it is neither proportionate nor targeted to expect regulation to act on every safety or quality concern (potential or actual) that may arise. Ultimately, the responsibility for managing risks in healthcare are shared between all parties.

**3.8** Figure 1 provides an illustration of these shared responsibilities for high quality healthcare. 'People' refers to patients, service users, carers and families, advocates and representative organisations. 'Professionals' refers to individual health professionals, peer groups, teams, and professional organisations and representative bodies. 'Law' refers to case law, common law and legislation. Lord Darzi, in *High Quality Care for All*,<sup>5</sup> defined quality as care that is 'clinically effective, personal and safe'. Each of these exerts a greater or lesser force in the delivery of high quality care. In this example the sectors are not to scale. They would vary in size if we wished to illustrate the respective contributions of each group of agencies to managing different problems. An example of this can be seen in Annex 2.

**Figure 1:** Agencies which contribute to delivering high quality healthcare



<sup>5</sup> Darzi, A. 2008. High quality care for all: NHS Next Stage Review final report. DH: London.

## Right-touch regulation in practice

**4.1** Through our work we have identified the following eight elements that sit at the heart of using the concept of right-touch regulation in practice. Built into these elements are commitments to using evidence and data to identify and understand problems, and to draw on the roles and responsibilities of different parts of the system to deliver the best solution. The consequences of adopting this approach may be less regulation or may be more regulation, but will certainly mean better regulation.

### Identify the problem before the solution

**4.2** We need to identify the problem before we can determine whether any particular policy solution is the right one. Often in policy development the need for regulatory change, as a solution, is identified before the problem is properly described and understood. This can lead to inefficiencies as resources are spent developing a regulatory solution when the problem itself may be better dealt with in other ways.

### Quantify the risks

**4.3** Once the problem has been identified we need to understand it fully and quantify the risks associated with it. Without this evaluation it is impossible to judge whether regulatory action is necessary or whether other means of managing issues are better used. Regulation should only be an option when it clearly provides the best solution. Simply identifying a real or potential risk is not sufficient. We have to understand whether the problem will create new risks to patient safety and public protection.

**4.4** A proper evaluation and understanding of risk is essential if we want to describe regulation as 'risk-based'. The term 'risk-based regulation' should only be used when such an evaluation has taken place. Describing regulation as 'risk-based' in the absence of proper evaluation of the risk is, in our view, misleading and can undermine wider confidence and trust in regulation. There is no justification for

regulation when a risk has merely been identified but not quantified. In particular we should be cautious of justifying regulation on the basis of potential rather than real risks.

### Get as close to the problem as possible

**4.5** Once the problem has been described and we have quantified the risks, it is necessary to consider where and how the problem occurs. In healthcare this means understanding the impact on patient care and the different levers and tools that may be available to tackle the issues. Targeted regulation needs to understand the cause of risk. Regulatory action is distant and removed from the point of care and problems are best solved near to where they occur. This means we consider options that are the responsibility of organisations and individuals rather than regulators. It may be appropriate for a change to be made that affects the whole profession, regardless of the environment they work in. In this case it may be right to consider a regulatory solution.

### Focus on the outcome

**4.6** Adopting a right-touch approach means it is essential to stay focused on the outcome that we are looking to achieve rather than being concerned about process, or prioritising interests other than public safety. Health professional regulation provides a useful illustration of the need to identify and focus on an outcome. Recent reforms have put public protection and patient safety at the heart of health professional regulation. This was in response to concerns that a self-regulatory approach put the needs and interests of the profession ahead of patients and the public. We may still see evidence of this today in some of the debates around extending regulation to 'aspirant groups' or calling on regulators to recognise elements of professional career enhancement that do not pose extra risks to patient safety and public protection. Staying focused on the outcome helps to identify the most appropriate solution.

## Use regulation only when necessary

**4.7** Once the problem, the risks and the context have been considered, we may begin to examine whether a regulatory change is the right proposal, evaluating this against the options of doing nothing and the risks and benefits of intervening. Making changes to regulation, especially statutory regulation, can be a slow process, so regulation should only be used as a problem solver when other actions are unable to deliver the desired results. A right-touch regulatory solution must keep to the six principles of good regulation and should build on existing approaches where possible.

## Keep it simple

**4.8** Patients and the public – the intended beneficiaries of this regulatory activity – have told us they find the current system of regulation confusing and difficult to navigate. We also know that it is important for health professionals to have clear boundaries and to be confident that they know where they are. In healthcare, with such a wide variety of agencies and individuals involved, avoiding additional complexity will lead to a better functioning system. That being so, it is essential that nothing is done that leads to a more complex approach, and where possible steps should be taken to simplify how the outcome is currently achieved. This also means using existing tools more effectively rather than inventing entirely new approaches. Where there is a choice between simple and complex solutions, the simplest is likely to be best.

## Check for unintended consequences

**4.9** Assessing the impact of a particular solution is an essential step to help us avoid unintended consequences.<sup>6</sup> In a system as interconnected and complex as healthcare, it is inevitable that proposing a change in policy and practice will have consequences for other parts of the system. It is likely that regulatory solutions will have consequences and these should be

considered in assessing the overall benefit of any change in regulatory (or other) approaches. Regulating to remove one risk without a proper analysis of the consequences may create new risks or merely move the risk to a different place, creating a new problem.

## Review and respond to change

**4.10** We should be building flexibility into regulatory strategy to allow regulation to respond to change in healthcare. All sectors evolve over time, as a result of a range of different influences. Regulators must not be seen to be managing past crises while being ignorant of new evidence that should call for change. This is what we mean by agility. A programme of regular reviews, post-implementation evaluation and sunset clauses can all help here.

**4.11** A framework of questions that captures these essential elements of the right-touch approach is shown in Annex 1. Annex 2 describes an example from our recent policy work, demonstrating how this concept and the question framework influence our approach and guide our analysis and recommendations.

## The benefits of right-touch regulation

**5.1** Right-touch regulation focuses on the problem, the outcome and the roles and responsibilities assumed by different agencies. It uses an evidence-based assessment of issues. It allows for an inclusive debate, not dominated by expertise about process, but informed by experience and evidence relevant to the outcome. The right-touch approach can be summed up as 'more insight, less oversight.'

**5.2** In practical terms, the benefits are seen in a number of ways:

- Outcomes are described in terms of the beneficiaries of regulation rather than the needs of others involved in delivery of healthcare, and policy development is devoted to achieving this aim

<sup>6</sup> NAO. 2010. Assessing the impact of proposed new policies. London: National Audit Office.

- It builds in the need for regular reviews to ensure that regulatory approaches and frameworks remain up to date and fit for purpose
- It provides a coherent framework for tackling a range of regulatory issues, such as managing new areas of practice, extending regulation to new groups
- Policy making is well informed, reflecting realities and the wider context, building on evidence and risk assessment.

**5.3** We believe that this approach would also yield broader benefits. The analogy we drew above with weighing scales demonstrates the impact we want regulation to have. At the balancing point, regulation is having its most efficient impact on the problem being tackled. Right-touch regulation forces us to be certain that the costs of regulation are worth the benefits they also bring. We recognise that over regulation is ineffective, and professional regulation must always be aware of its duty to be cost effective. While patients and the public have the right to expect high quality healthcare, the cost of regulation is ultimately passed onto the public. Adopting the right-touch approach will help regulation maximise the benefits.

**5.4** If regulation is to add real value, it needs to be ready to cooperate and collaborate for the health, safety and wellbeing of patients and the public. Allowing all parts of the system to play their full part can provide a more appropriate response to a problem. Alongside the regulators, employers, educators, individual professionals and their peer group, and patients themselves have particular roles and responsibilities to fulfil, as Figure 1 demonstrates.

**5.5** Right-touch regulation is agile. Regulation works well when it is in touch with and up to date with experiences and real world practice. Regulatory approaches need to remain focused on delivering their objective in the light of

change and in this respect wide-ranging strategic reviews are as essential as regular updates of standards of conduct and training. This position is inherent in our view that agility is a principle of good regulation and the need for review is built into our right-touch approach.

**5.6** The right-touch approach can enhance trust and confidence. The impact of recent well-publicised 'failures of regulation' emphasise the value of public confidence in regulation. We need to make sure regulation remains relevant to the needs of today's society, and that it reacts appropriately to issues as they arise. We should also not exaggerate claims for regulation, implying that everything can be safe and nothing will go wrong. Adopting right-touch regulation will allow people to feel confident that regulation is acting in the best way it can.

## Conclusion

**6.1** Right-touch regulation means always asking what risk we are trying to regulate, being proportionate and targeted in regulating that risk or finding ways other than regulation to promote good practice and high quality healthcare. It allows the development of the appropriate contribution of the regulatory regime to the delivery of wider aims.

**6.2** For CHRE, this aim is described in terms of the health, safety and wellbeing of patients and other members of the public, and through the work we do, the role we fulfil and the debates we engage in, we seek to promote right-touch regulation as a means of achieving regulatory excellence.<sup>7</sup> We believe this approach provides a valuable set of guiding principles to help regulation work efficiently.

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<sup>7</sup> We define excellence as the consistent performance of good practice combined with continuous improvement.

## Annex 1: Right-touch regulation decision tree

1. What is the problem? 2. Is the problem about risk?		
No – Stop, don't regulate. If the problem is not about risk there's no need to regulate	Yes – go to 3	
3. What are the risks? 4. How great are the risks? 5. Are the risks currently managed?		
Yes – Stop, don't regulate, use the existing solution to manage the problem	No – go to 6	
6. Where and why is the problem occurring? 7. Can the problem be solved locally?		
Yes – Stop, don't regulate, use targeted local approaches	No – go to 8	
8. Is there a regulatory solution in line with the principles of good regulation?		
No – consider other regulatory options - go back to 8	Yes – go to 9	
9. Are there any new risks or unintended consequences?		
Yes – Stop, consider other regulatory options - go back to 8	No – regulate. Review regularly and respond to change	

## Annex 2: Case study on managing extended practice

### What is the problem?

There are occasions when registered health professionals extend their practice. This may be into areas overseen by other regulators, such as podiatrists undertaking surgery, or into currently unregulated areas, such as nurses performing acupuncture. A model of 'distributed regulation' was proposed to us to provide oversight of professionals in these circumstances. Under this approach professionals who extend their practice would be subject to a set of standards agreed by all the regulators.

The premise behind this proposal was that current methods of oversight for professionals who extend their practice are inadequate, and the distributed model could provide a form of assurance as an alternative to statutory regulation.

### Is the problem about risk?

The model of 'distributed regulation' could appear to be shaped around the convenience of health professionals – as a means of avoiding costly dual registration – rather than about risk. We concluded that when a professional is operating in two distinct fields (for example, a nurse/physiotherapist, or a doctor/dentist), dual registration remains necessary. The remaining potential risks are outlined below.

### What are the risks?

We identified two main areas of risk that might be associated with registered professionals extending their practice:

- Professionals might be unclear about the standards of practice that they should be working to
- Regulators might not be equipped to manage fitness to practise issues in areas of extended practice.

### How great are the risks?

It is difficult to quantify these risks as they were not reported to us and we had no evidence to support them. Interrogation of CHRE's fitness to practise data did not reveal any specific issues, or a disproportionately high number of cases, for professionals in extended roles. We were provided

with evidence of how regulators currently manage the risks as they arise. These are outlined below.

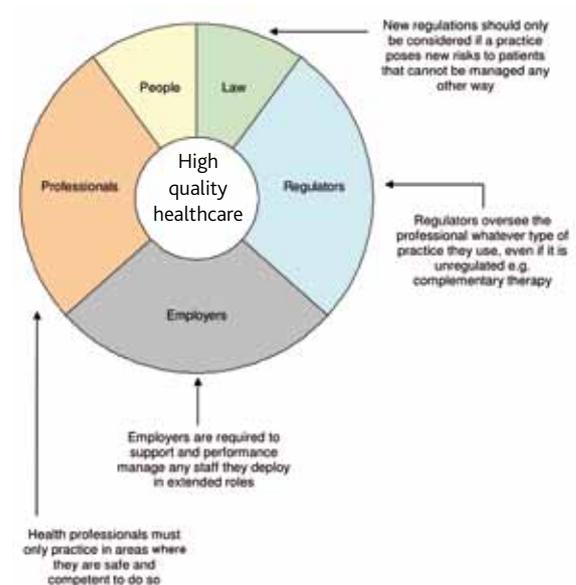
### Are the risks currently managed?

We concluded that the broad areas of risk identified above can be managed with the tools already at the regulators' disposal, and there is no need to introduce additional regulation:

- Regulators currently seek expert advice in fitness to practise cases that involve areas of extended practice
- Regulators' codes stress that professionals must only practice where they are competent to do so. The codes still apply, even when professionals are using treatments in an unregulated area of practice.
- Regulators may create specialist lists or annotations to the register if there are extra risks to patient safety.

These mechanisms are complemented by the role of employers to support and performance manage staff in extended roles, and importantly by professionals who should only practice in areas they are competent to do so. Therefore we concluded that there was no need to introduce additional regulation.

Figure 2: Relative contributions of agencies to provide high quality healthcare when professionals extend their practice



# Harry Cayton



***Harry Cayton was appointed Chief Executive of the Council for Healthcare Regulatory Excellence in August 2007.***

Harry was formerly National Director for Patients & the Public at the Department of Health. From 1992 to 2003 he was Chief Executive of the Alzheimer's Society and from 1981-1992 Director of the National Deaf Children's Society.

Harry is Chair of the National Information Governance Board for Health and Social Care, Chair of National Voices Advisory Panel, an advisor to The Health Foundation and to Macmillan Cancer Support and a trustee of Comic Relief. In 2009, he was co-Chair of the World Health Executive Forum.

Harry has written many articles and book chapters and his co-authored book for carers and people with dementia has been published in eight languages. He is a regular speaker at national and international conferences.

He was awarded the OBE in 2001 for services to people with dementia. He received the Alzheimer Europe Award in 2004, and was Distinguished Graduate of the University of Ulster 2005. In 2007 he received a Lifetime Achievement Award from the Royal College of Psychiatrists and a Fellowship through Distinction from the Faculty of Public Health.

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# Maintenance of Licensure: Protecting the Public, Promoting Quality Healthcare

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**The authors describe a system in which physicians periodically demonstrate ongoing clinical competence as a condition of licence renewal.**

## Introduction

The practice of medicine in the United States, according to the 2010 edition of *A Guide to the Essentials of a Modern Medical and Osteopathic Practice Act* of the Federation of State Medical Boards (FSMB), is 'a privilege granted by the people acting through their elected representatives.'<sup>1</sup> Citing public health, safety and welfare, and the need for protection of the public from the 'unprofessional, improper, incompetent, unlawful, fraudulent and/or deceptive practice of medicine,' the Essentials document – formally adopted by the FSMB's House of Delegates – acknowledges the historical and constitutional role of the state medical and osteopathic boards 'to provide laws and regulations to govern the granting and subsequent use of the privilege to practice medicine.'

While the granting of the initial privilege to practise medicine is generally viewed as a robust process along a rigorous continuum of medical education encompassing both undergraduate and graduate training, with multiple assessments and decision points that must be cleared along a prescribed pathway, the process for the subsequent use of that privilege has been the focus of increasing commentary and suggestions for improvement. This article summarises the background and history by which the FSMB adopted, in April of 2010, a seminal policy recommendation outlining a framework by which state medical and osteopathic boards could require physicians with active medical licences to periodically demonstrate their ongoing clinical competence as a condition for licensure renewal.

## Medical Regulation in Service to the Public

While the earliest instance of medical regulation in the Americas dates to 1649,<sup>2</sup> and the first local government licence to practise medicine was adopted in 1760 in New York City,<sup>3</sup> the authority of state governments to regulate healthcare in the United States dates to the adoption, in 1791, of the 10th Amendment to the Constitution: 'The powers not delegated to the United States by the Constitution, nor prohibited by it to the states, are reserved to the states respectively, or to the people.'

Some states initially gave local medical societies the power to examine and license prospective doctors,<sup>4</sup> while others bestowed such a right to medical schools. The notion that medical licensure and discipline should best be regulated by state-appointed licensing boards, the majority of whom today include public members on their voting bodies, rather than medical societies (which ostensibly represent the interests of practising physicians) or medical schools took several decades to gain traction. It has been postulated that what ultimately caused medical regulation, alongside coincidental public health legislation, to flourish between 1850 and 1900 was a combination of two factors: a failure of pure free-enterprise theory and the contribution of science.<sup>5</sup>

While 'good' goods, like 'good' doctors, should have ultimately driven out 'bad' ones in a free market, a better informed public was no longer willing to wait that long; people also became aware of the fact that danger lurked in bad food and bad water, an awareness prompted by the discovery of germs, that prompted calls from many corners for better protection from poor sanitation as well as from 'bad' doctors.

The FSMB, since its establishment in 1912 as the umbrella organisation for all state medical and osteopathic licensing boards in the United States and its territories, has actively promoted or supported during its long history such activities as stronger entrance criteria for medical schools, improvements in undergraduate medical education, closure of underperforming medical schools following the 1910 Flexner Report, passage of state medical practice acts, the formation of the American Board of Medical Specialties (ABMS) and the Educational Commission for Foreign Medical Graduates and, in 1991, the creation — in partnership with the National Board of Medical Examiners (NBME) — of the United States Medical Licensing Examination (USMLE). Physicians with the D.O. (doctor of osteopathic medicine) degree typically take the Comprehensive Osteopathic Medical Licensing Examination (COMLEX-USA) of the National Board of Osteopathic Medical Examiners (NBOME).

The FSMB, as stated in its current mission statement, seeks to lead by 'promoting excellence in medical practice, licensure, and regulation as the national resource and voice on behalf of state medical boards in their protection of the public.' The FSMB has more recently served the public and its 70 state medical and osteopathic boards through the development of a national database of licensed physicians and physician assistants, a disciplinary alert service, a Federation Credentials Verification Service (FCVS) and a Uniform Application to speed state processing of licensure applications and facilitate licence portability without infringing the states' autonomy or rights. Adoption of a Maintenance of Licensure (MOL) framework by the FSMB, within this context, is consistent with state medical and osteopathic boards' desire to protect the public and promote quality healthcare with robust standards for physician licensure.

### Medical Regulation to Promote Healthcare Quality

Significant technological and scientific advancements have been pioneered by physicians and scientists in the United States but there are several reasons why we do not have the very best healthcare system in the world (eg, insufficient access to primary care

services, a lack of coordination of healthcare delivery, defensive medicine practices) despite all of our expenditures.<sup>6,7</sup> The quality of the healthcare that is delivered is an area of inquiry that has garnered great attention in the last two decades. These analyses have sometimes offered specific recommendations to medical educators, healthcare leaders, medical regulators and federal and state government officials to help reform the healthcare workforce, decrease medical errors and promote best practices among healthcare providers. Many of these reports have also made specific recommendations about the standards and practises for renewal of medical licences.

In 1995, the Pew Charitable Trust Health Professions Commission recommended that states 'require each licensing board to develop, implement and evaluate continuing competency requirements to assure the continuing competence of regulated healthcare professionals'.<sup>8</sup> In 1999, the Institute of Medicine (IOM) said that consumers generally believe they are protected within the healthcare arena because 'licensure and accreditation confer, in the eyes of the public, a 'Good Housekeeping Seal of Approval,' and suggested greater assessment of the physicians' performance of skills after initial licensure.<sup>9</sup> Two years later, the IOM observed that in a profession with 'a continually expanded knowledge base,' a mechanism was needed to ensure that practitioners remain up to date with current best practices.<sup>10</sup> It also noted that medical regulation, when properly conceived and executed, 'can both protect the public's interest and support the ability of healthcare professionals and organisations to innovate and change to meet the needs of their patients.'

### Rationale for Enhanced Medical Regulation

In the United States and United Kingdom, according to a survey of 18 countries conducted last year, more than 80% of the public consider physicians to be trustworthy.<sup>11</sup> To continue to earn such high regard in a climate of greater accountability and regulation, consistent with their own professional obligations to remain competent and up to date, physicians need to demonstrate to their patients and peers what most are already doing. The rationale to do so, however, is multifaceted and not limited

to well-intentioned policy reports or professional obligations. While unequivocal, comprehensive and robust research in support of a multi-component program for maintenance of licensure is not yet available, simply because no medical regulatory authority has fully implemented such a plan, there is growing evidence in the medical literature about 1.) the practice of physicians over time, and 2.) the value of enhanced continuing medical education or continued professional development. Both of these categories are addressed by the FSMB's MOL framework.

Several studies over the years have found, for instance, that practising physicians who perform a lower volume of clinical or surgical procedures, or who have less experience with specific conditions or diseases, have higher rates of complications compared with their physician colleagues. As one researcher and his colleagues hypothesised in 1987, in the treatment of disease it would appear that practice makes perfect.<sup>12</sup> Kimmel and colleagues in 1995 studied more than 19,000 patients undergoing coronary angioplasty procedures by interventional cardiologists at cardiac catheterisation laboratories across the United States and Canada and, after adjusting for case mix, found an inverse association between cardiac catheterisation laboratory procedure volume and major complications.<sup>13</sup> An inverse association between the number of coronary artery bypass graft surgeries performed by cardiac surgeons and subsequent mortality rates, after adjustment for clinical risk factors, has also been described.<sup>14, 15, 16</sup>

In a 1996 study of 403 adult male patients with the Acquired Immunodeficiency Syndrome (AIDS) who were cared for by 125 primary care physicians, after controlling for the severity of illness and the year of diagnosis, patients cared for by physicians with the most experience had a 31% lower risk of death than patients cared for by physicians with the least experience.<sup>17</sup> Nash and colleagues found a lower mortality rate from acute myocardial infarction among patients of both primary care physicians and cardiologists who had higher patient volumes than those physicians who provided care for this condition less frequently.<sup>18</sup> A study by Tu and colleagues in 2001 found that patients with acute myocardial

infarction who are treated by 'high-volume admitting physicians' for that condition are comparatively more likely to survive at 30 days and at one year.<sup>19</sup> And Freeman and colleagues found a substantial variation in the clinical outcomes of gastrointestinal endoscopy based on the ongoing case volume of the gastroenterologist.<sup>20</sup>

Choudhry and colleagues conducted a systematic review of the relationship between clinical experience and quality of healthcare in 2005 and found that physicians who have been in practice longer may be at risk for providing lower quality care and that this subgroup of physicians may benefit from quality improvement interventions.<sup>21</sup> While under performance among physicians is neither very well studied nor defined, it has been suggested that age-related cognitive decline, impairment due to substance use disorders and other psychiatric illness may contribute to underperformance, diminishing physicians' insight into their level of performance as well as their ability to benefit from an educational experience.<sup>22</sup>

As for enhanced continuing medical education (CME) and continued professional development (CPD), the Johns Hopkins Evidence-based Practice Center for Healthcare Research and Quality conducted a systematic review of the effectiveness of such education and reported in 2009 that multimedia, multiple instruction techniques and multiple exposures to content were associated with improvements in physician knowledge.<sup>23</sup> There is also evidence that such CME/CPD practices are effective in changing physician performance,<sup>24</sup> though more research is needed that focuses on the specific types of media and educational techniques that lead to the greatest improvements in performance. In a Cochrane database review of 81 trials looking at continuing medical education, Forsetlund and colleagues concluded that strategies to increase attendance at educational meetings, using mixed interactive and didactic formats, and focusing on outcomes that are likely to be perceived as serious may increase the effectiveness of educational meetings.<sup>25</sup>

State medical and osteopathic boards have occasionally struggled with a subset of physicians with active licences who are no longer clinically active, and have looked at how clinical inactivity should be defined, identified, monitored and communicated or shared with the public. In a 2007 telephone survey of 64 state medical and osteopathic boards in the United States, excluding its territories, Freed and colleagues found that only 22 state licensing boards (34%) query physicians regarding clinical activity at both initial licensure and licensure renewal, with the majority of boards permitting physicians to hold or renew an unrestricted active licence to practice medicine, although they may not have cared for a patient in years.<sup>26</sup> A comprehensive program for maintenance of licensure, if adopted by all state medical and osteopathic boards, could logically and objectively demonstrate which physicians are engaged in clinical activity and how much — a derivative benefit that would be useful for healthcare workforce analyses and predictions. A special committee commissioned this year by Freda Bush, M.D., FSMB Board Chair, to look at physician reentry and related issues on behalf of state medical and osteopathic boards should be helpful in framing the context and offering guidance.

A rationale for a more robust or enhanced programme of medical regulation is not only predicated on the need to protect the public and promote quality healthcare delivery. It has been argued that profligacy in the care of one patient within an increasingly cost-contained healthcare system or organisation could lead to less adequate care for another patient.<sup>27</sup> A programme to promote the ongoing clinical competence of actively licensed physicians could support the adoption, or awareness, of best practices in the management of all patients and their illnesses. A less obvious impetus for state medical and osteopathic boards to embrace changes and improvements in medical regulation is the concern that if they don't, others may. Medical regulation outside the bounds of state licensing authority could in turn, as one observer notes, lead to damaging effects to patients and society.<sup>28</sup> As representatives of the people of the state, usually appointed or elected by state officials (eg, governor), state medical and osteopathic boards are sworn

to protect the public and promote quality medical licensure and discipline. Any improvements or changes in licensure renewal should logically and appropriately be led, and guided, by state medical and osteopathic boards. The FSMB can assist by facilitating the development of policies and procedures, encouraging common practices while respecting states' autonomy and collaborating with healthcare organisations with expertise in physician assessment, public safety and practice performance.

### Evolution of Maintenance of Licensure

All actively licensed physicians in the United States and its territories are required to renew their licence every one to three years, depending upon the requirements of their state medical or osteopathic board.<sup>29</sup> Most state boards use a variety of information sources to document and verify the competence of physicians seeking licensure renewal: prescribed hours of accredited continuing medical education (CME), information that is usually self-reported but sometimes verified by random audits; hospital privilege reports; disciplinary data banks — such as the Federation of State Medical Boards' (FSMB) Board Action Data Bank or the National Practitioner Data Bank; patient complaints; and medical malpractice reports.

In May of 2003, following discussions centered around the need to improve the capability of state medical and osteopathic boards to protect the public and promote quality healthcare, the FSMB, under its Board Chair, Thomas D. Kirksey, M.D., convened a special committee to make recommendations about the possibility of a system for the periodic assessment of the ongoing clinical competence of actively licensed physicians, what came to be known as 'maintenance of licensure' (MOL).<sup>30</sup> Following discussions and review of existing practices, the committee recommended a substantive policy statement that was adopted the following year by the FSMB's House of Delegates: 'State medical boards have a responsibility to the public to ensure the ongoing competence of physicians seeking relicensure.'<sup>31, 32</sup>

Beginning in 2005, the FSMB sought input and commentary from leaders and representatives of

major healthcare organisations and federal and state governmental agencies to consider options and programmes by which state medical and osteopathic boards should or could implement maintenance of licensure. During the last seven years, multiple discussions, meetings and conferences have been held, with periodic surveys of state medical and osteopathic boards to continuously gauge their concerns and interests. To perform a comprehensive review and to make final recommendations to the Board of Directors about maintenance of licensure, the FSMB, under then Board Chair, Martin Crane, M.D., convened an Advisory Group on Continued Competence of Licensed Physicians in 2009. The Advisory Group was charged to issue an opinion to the FSMB Board of Directors concerning FSMB's Maintenance of Licensure initiative and, more specifically, whether the framework proposed in the report of the Special Committee on Maintenance of Licensure was feasible, reasonable, consistent with a series of guiding principles adopted by FSMB's House of Delegates in May 2008, and suitable for use by state medical and osteopathic boards in ensuring the continued competence of licensed physicians.

The Maintenance of Licensure framework adopted by the FSMB House of Delegates in 2010 notes that as a condition of licence renewal, physicians 'should provide evidence of participation in a programme of professional development and lifelong learning that is based on the general competencies model: medical knowledge, patient care, interpersonal and communication skills, practice-based learning, professionalism and systems-based practice.' One of the framework's guiding principles is that 'maintenance of licensure should not compromise patient care or create barriers to physician practice.'

Discussion and analysis is now under way with an FSMB-sponsored MOL Implementation Group that is guided by the framework and that receives regular input from an advisory council of chief executives from a range of healthcare organisations. A draft report from the MOL Implementation Group that outlines specific options for state boards will be reviewed this summer by the FSMB's Board of Directors, then by state medical and osteopathic boards and then by other stakeholders in healthcare

and in government. It is anticipated that a starter (pilot) plan for MOL may be initiated by interested state medical and osteopathic boards as early as the end of the calendar year.

### Components of Maintenance of Licensure

While the specific details, methodologies and options by which state medical and osteopathic boards could implement a programme for Maintenance of Licensure are being formulated at press time, several themes have emerged around the three specific components identified in the MOL framework document adopted by the FSMB's House of Delegates.

The first component of MOL, reflective self-assessment, addresses physicians' professional obligation to commit to lifelong learning to maintain their skills and acquire updated knowledge affecting their practice. This could involve the use of an assessment tool such as an accredited continuing medical education (CME) pre-test, as one example, to identify needs or opportunities for improvement, followed by a tailored improvement activity based on those outcomes. State licensing boards will likely need to modify or enhance, where appropriate, their existing CME requirements.

While the second component of MOL, the assessment of knowledge and skills, does not mandate the passage of a secure or proctored examination as part of its second component, it notes that physicians enrolled in the ABMS' Maintenance of Certification (MOC) programme, or the American Osteopathic Association Bureau of Osteopathic Specialists' Osteopathic Continuous Certification (OCC) programme, could substantially comply with a state licensing board's expectations for MOL. Because more than 30% of actively licensed physicians are not specialty board certified,<sup>33</sup> most physicians with time-unlimited ('grandfathered') specialty certificates have chosen not to become recertified,<sup>34</sup> and a plurality of physicians with time-limited specialty certificates are not seeking renewal of specialty board certification,<sup>35</sup> state licensing boards will need to consider additional options (eg, computer-based clinical case simulations, hospital procedural privileging)

for physicians to demonstrate ongoing clinical competence. The FSMB's MOL Implementation Group, guided by the adopted framework and its advisory council, is reviewing those options now.

For the third component, performance in practice, physicians could use data derived from their own practices supplemented by practice improvement activities already being implemented by specialty societies, hospitals, physician groups and quality improvement organisations. As this component is similar to the fourth part of MOC and the 'Practice Performance Assessment' part of OCC, state boards may elect to substantially qualify licensees engaged in such activities. According to Kathleen Sebelius, Secretary of Health and Human Services, 20% of doctors and 10% of hospitals currently use basic electronic health records.<sup>36</sup> As 'meaningful use' regulations to promote electronic health records and health information technology advance,<sup>37</sup> and data-driven changes in physician practice gradually take hold, component three of MOL is also the most likely to evolve over time. Regina Benjamin, M.D., M.B.A., U.S. Surgeon General and Past Chair of the FSMB's Board of Directors, recently wrote of her prior experience with health information technology and how 'practising medicine became easier for the clinicians and better for the patients' following the adoption of electronic health records in her private practice setting.<sup>38</sup>

As the MOL Implementation Group deliberates the specifics of how the states could proceed with MOL adoption, the group's members have agreed that the overall process of implementation by the states should be evolutionary, not revolutionary, while recognising the need to be anticipatory.

### International Perspectives on MOL

The same year that the FSMB's House of Delegates adopted its statement of responsibility in relation to the ongoing clinical competence of physicians, the Federation of Medical Regulatory Authorities of Canada (FMRAC) adopted its framework for maintenance of licensure, a programme called revalidation by some Canadian provincial authorities. The FMRAC announced in 2004 that all licensed physicians in Canada must participate in a recognised revalidation process in which they

demonstrate their commitment to continued competent performance in a framework that is fair, relevant, inclusive, transferable and formative. The Revalidation Working Group that studied the issue said, 'The demonstration of ongoing competence and performance of physicians is a pillar of professional self-regulation.'<sup>39</sup> Several Canadian provinces have mandated that physicians participate in an educational programme, such as the Royal College of Physicians and Surgeons' Maintenance of Certification programme or the College of Family Physicians' Maintenance of Proficiency programme, to maintain licensure.<sup>40</sup> Physicians in these programmes report their participation in educational activities annually, with random audits of the documentation by the colleges and/or a peer review process involving office visits by physician colleagues.

In England, where the administration of Henry VIII passed legislation in Parliament aimed at regulating and licensing medical practitioners that endured without any amendments for 300 years,<sup>41</sup> the General Medical Council began in 1998 to develop a means by which doctors' practices could be appraised and objectively assessed annually over a five-year period as a mandatory condition for what it also calls revalidation.<sup>42</sup> While formal implementation of such a system has now been delayed by a year under the newly elected government in the United Kingdom, when it gets underway it is expected to include as part of its appraisal of physicians several elements: colleague and patient feedback, continuous professional development (CPD) records and a clinical audit, all within a quality assurance process overseen by Medical Royal Colleges and Faculties and various health systems regulators. It is expected to be a single process for both general practitioners and specialists, regulated by the General Medical Council and implemented within local hospitals with specialist standards set by the individual Royal Colleges.<sup>43</sup>

Other nations, such as Australia, New Zealand and Ireland, are in various phases of implementation of similar programmes for maintenance of licensure. All international medical regulatory authorities will differ in the details of how they implement ongoing clinical competence assessment of physicians,

but it will be helpful and appropriate for these nations to share best practices, lessons learned, and research emanating from implementation of such programs, perhaps supported by the International Association of Medical Regulatory Authorities, for which the FSMB serves as Secretariat. While the medical regulatory laws may be different around the world, notions of medical professionalism, quality healthcare, and protecting the public are substantially aligned.

### Concluding Thoughts

A system by which physicians with active licences to practise medicine in the United States will be required over time to periodically demonstrate ongoing clinical competence in their area of practice as a requirement for renewal of licensure is going to become reality in the near term. As Cyril Chantler notes with respect to the growing global movement within the medical regulatory community to establish assessment programmes for ongoing clinical competence, 'Physicians need trust more than regulation, but it is up to them to introduce systems that are comprehensive and fit for most purposes but not too bureaucratic or burdensome.'<sup>44</sup>

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# Dr Humayun J. Chaudhry



***Dr Humayun 'Hank' Chaudhry is the President and CEO of the Federation of State Medical Boards (FSMB) of the United States.***

The FSMB is a national non-profit organisation founded in 1912 that represents the 70 state medical and osteopathic licensing boards of the United States and its territories and co-sponsors the United States Medical Licensing Examination (USMLE).

Dr Chaudhry graduated from New York University and the New York College of Osteopathic Medicine (NYCOM) of New York Institute of Technology, where he received a doctor of osteopathic medicine degree. He completed residency training in Internal Medicine at Winthrop-University Hospital in Mineola, New York, where he was Chief Medical Resident.

He has a Master's degree in Anatomy from NYU and a Master's degree in Health Care Management from the Harvard School of Public Health. Prior to joining FSMB, he was Commissioner of Health Services for Suffolk County, New York, home of the ninth largest health department in the United States.

Dr Chaudhry served in the United States Air Force Reserve, rising to the rank of Major, and serving as a flight surgeon with the 514th Aeromedical Staging Squadron at McGuire Air Force Base, New Jersey. He is a member of the AMA, the AOA, the American College of Physicians, the Medical Society of the State of New York and the Harvard Club of New York City.

He is a former President of the American College of Osteopathic Internists, the Association of Osteopathic Directors and Medical Educators and the New York College of Osteopathic Medicine Alumni Association. He has served on the Journal Advisory Board of *The New Physician*, a publication of the American Medical Student Association.

Dr Chaudhry is the author of *Fundamentals of Clinical Medicine*, a medical textbook published by Lippincott Williams & Wilkins in 2004.

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# Janelle A. Rhyne, MD



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She was in private practice in infectious diseases and internal medicine for 18 years in Wilmington, North Carolina. Dr Rhyne earned a BA from the University of North Carolina at Chapel Hill, MA from Arizona State University, and MD from Wake Forest University School of Medicine.

She is a Clinical Associate Professor of Medicine at the UNC School of Medicine. Dr Rhyne is board certified both in the specialty of internal medicine and the subspecialty of infectious diseases and is enrolled in MOC. She is a fellow of the Infectious Disease Society of American and the Society of Healthcare Epidemiology of America and a master of the American College of Physicians.

Dr Rhyne has served as president of the North Carolina Chapter of the American College of Physicians, president of the North Carolina Society of Internal Medicine, chief of staff at New Hanover Regional Medical Center, governor of the North Carolina chapter of the American College of Physicians, and President of the North Carolina Medical Board. She currently is Chair-Elect of the Federation of State Medical Boards, and a member of the Healthcare Division Advisory Board of the Kate B. Reynolds Charitable Trust and the North Carolina Institute of Medicine.

# Frances Cain



***Frances Cain is Director of the Post-Licensure Assessment System (PLAS) for the Federation of State Medical Boards (FSMB) of the United States.***

The FSMB is a national non-profit organisation founded in 1912 that represents the 70 state medical and osteopathic licensing boards of the United States and its territories and co-sponsors the United States Medical Licensing Examination (USMLE). The Post-Licensure Assessment System is a collaborative initiative of the FSMB and the National Board of Medical Examiners (NBME) to provide services for use by medical licensing authorities in assessing the ongoing competence of licensed or previously licensed physicians.

Ms Cain began working at the FSMB in 1997 and has served in a variety of administrative and managerial positions since that time. In her current duties as the director for PLAS, she is responsible for overseeing policy and governance aspects of the program, as well as day-to-day operations. In addition to her PLAS duties, she provides organisational support to executive staff at the FSMB, specifically in areas related to report writing, committee support, research and project management. She has been involved with FSMB's Maintenance of Licensure (MOL) initiative since its inception in 2003.

Ms Cain received a Bachelor of Arts degree with honors from the University of Texas at Arlington in 1996.

# Aaron Young, Ph.D.



***Senior Director,  
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Federation of  
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Dr Young received his Doctor of Philosophy from Baylor University in 2002. While completing his PhD he worked for the Baylor Center for Community Research and consulted for the Perryman Group, an economic analysis firm. During this time, Dr Young specialised in survey research, needs assessments, programme evaluation and the impact of regulatory changes. He also provided litigation support to Fortune 500 clients and conducted economic development studies for Texas communities.

Dr Young worked for six years in Marketing Research for Reliant Energy, one of the largest power providers in the United States. He joined the Federation of State Medical Boards in August 2008. As Senior Director of Research and Analytics, Dr Young provides research support and expertise to state medical and osteopathic boards, works with federal agencies to compile data and analysis for reports to Congress, and collaborates with affiliate organisations to achieve mutual objectives.

# Dr Martin Crane



***Dr Martin Crane is Immediate Past Chair of the Board of Directors of the Federation of State Medical Boards of the United States.***

He has been active with the FSMB's Board of Directors since 2004, serving on the Executive Committee since 2006, as Chair-elect 2008-2009 and as Chair 2009-2010. In 2005, he chaired the FSMB's Patient Safety Workgroup and is currently Board Liaison to the FSMB's Maintenance of Licensure initiative.

From 2000 to 2008, Dr Crane served on the Massachusetts Board of Registration in Medicine, which regulates the more than 30,000 physicians licensed to practice in the state. In addition to leading the board as chair for five years, Dr Crane chaired the board's Patient Care Assessment, Licensing and Data Repository committees.

Dr Crane has been involved in a wide array of quality assurance and improvement programmes for more than 30 years and has spoken extensively on patient safety and adverse event reporting systems. In 2007, he was appointed to the Step 3 Committee of the United States Medical Licensing Examination, the three-step examination used for medical licensure in the United States co-sponsored by the FSMB and the National Board of Medical Examiners and in 2009 he was appointed to the USMLE Composite Committee. In 2006, U.S. Secretary of Education Spellings appointed Dr Crane to the National Committee on Foreign Medical Education and Accreditation, which reviews the standards used by foreign countries to accredit medical schools and determines whether those standards are comparable to standards used to accredit U.S. medical schools. He has recently been appointed chair of this committee.

A board-certified obstetrician/gynaecologist with special interests in endoscopy and the menopause, Dr Crane is a graduate of Princeton University and Harvard Medical School with residency training in general surgery at the University of Colorado Medical Center and a residency in Obstetrics and Gynaecology at the Boston Hospital for Women. He is a Diplomate of the National Board of Medical Examiners and has also participated in endocrine research in at the Royal Karolinska Institute in Sweden. Dr Crane has recently retired from active private practice and is on the courtesy staff at South Shore Hospital in South Weymouth, Mass.

In addition to medical regulation, Dr Crane has also been involved in other aspects of public service. He served his home community of Hingham, MA as a member of the Board of Health and the Board of Selectmen, which he also chaired. In 2005, he was appointed as the Governor's representative to the Martha's Vineyard Commission, a regional land use planning authority.

He presently holds the rank of Commander in the Medical Corps of the US Navy Reserves and has served as a member of the Executive Committee for the Medical and Dental Staff of the US Navy from 2004 – 2006. In December of 2005, Dr Crane was awarded the Navy and Marine Corps Commendation Medal for his superior service.

Dr Crane is married to Kathleen Marie Crane and they have four children, Brandon (27), Heather (26), Ryan (25), and David (23).

# Dr Freda McKissic Bush



***Freda McKissic Bush, M.D.,  
FACOG is Chair of the  
Board of Directors of the  
Federation of State Medical  
Boards (2010-11).***

Dr Bush has served as Treasurer of the FSMB, a member of the United States Medical Licensing Examination (USMLE) Step 3 Committee and currently serves on the USMLE Composite Committee. She has served on the Mississippi State Board of Medical Licensure for 12 years. She is Senior partner with East Lakeland OB-GYN Associates in Jackson, Mississippi, and a Clinical Instructor in the Department of OB-GYN and Department of Family Medicine at the University of Mississippi Medical Center. She graduated from the University of Mississippi Medical School in 1983 and completed her residency training at the University of Tennessee in Memphis in 1987.

Her health career began graduating from the University of Arkansas School of Nursing in 1967. Subsequently, she graduated from Columbia University, New York, with a Masters in Nursing and Certificate in Nurse Midwifery (CNM) in 1970. In 1974 she became Director of the Nurse Midwifery Program at the University of Mississippi. Dr Bush was President of the Central Mississippi Medical Society in 2005. In 2006, she received the Community Service Award from the Mississippi State Medical Association.

Dr Bush served as a Presidential appointee to the Presidential Advisory Council on HIV/AIDS from 2006-2009. Freda is currently a Board Member of The Medical Institute for Sexual Health and co-authored the book, *HOOKED, New Science on How Casual Sex is Affecting Our Children*, with Joe S. McIlhaney, MD.

# Revalidation in Canada 2010

Dr Bryan Ward, College of Physicians and Surgeons of Alberta

## Context

Canada had 68,101 active physicians in 2009 for about 33.5 million people across 10 provinces and three territories.<sup>1</sup> Unlike in previous decades, the last several years have seen the number of physicians growing faster than the population (150 MDs/100K in 1979 → 201 MDs/100K in 2009). Mal-distribution of the physician workforce, with relative shortages in rural and remote communities remains a challenge, however.

The average age of GPs is 49.1 yrs; and of other specialists is 50.3 yrs and they are retiring later. The average self-reported retirement age for physicians in the 1980s was 67.8 yrs. and by the 2000s it was 69.2 yrs. Another trend of relevance to revalidation efforts is the narrowing of scopes of practice of family physicians and specialists after graduation, shrinking the size of cohorts remaining competent across the full spectrum of their disciplines.

Canada has a fully publicly-funded healthcare system with publicly-administered hospitals and privately-administered community practices. Prescription drug plans are free for seniors and are widely subscribed by the remainder of the population through employers or privately.

Hospital privileges are not a requirement for community practice in most jurisdictions. Physicians with hospital privileges are accountable to institutional administrations for their conduct and performance but the typical processes for review and renewal of privileges are not yet rigorous enough for revalidation purposes.

## Medical Regulation and Revalidation

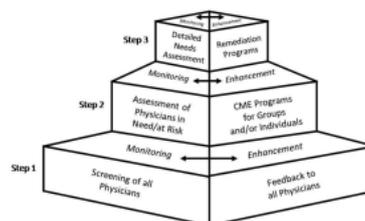
There are 13 medical regulatory jurisdictions in Canada with similar requirements for medical licensure but dissimilar requirements for maintenance of licensure.<sup>2</sup>

Commencing in 1994, Canada's medical regulatory authorities began development of a model for the

revalidation of physicians in Canada.<sup>3</sup> The resulting Maintenance and Enhancement of Physician Performance (MEPP) model for revalidation activities articulated a step-wise approach to the revalidation process.

**Step 1** applies to all physicians, is intended to be formative and educational, and to identify physicians at risk for performance problems. Tools include analysis of databases (prescribing, billing, utilisation and others), mandatory requirements for continuous professional development, and surveys of patients and colleagues about the practice.

## Monitoring and Enhancement of Physician Performance

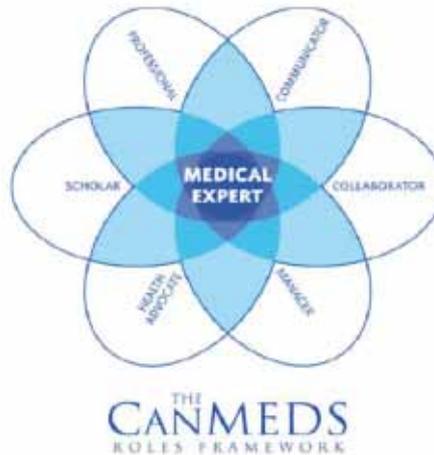


**Step 1** activity has been conducted by the medical regulator in Quebec on select groups of physicians using prescribing and other databases to identify and investigate patterns of practice that might represent substandard care. The regulators in Alberta and Nova Scotia, on the other hand, require all physicians to participate in a multi-source feedback (surveying patients, medical colleagues and non-physician co-workers) every five years in a program called Physician Achievement Review (PAR in Alberta, NSPAR in Nova Scotia).<sup>4</sup> Those physicians receive aggregated feedback from each set of respondents alongside the results of their peer group for comparison. 20% of participating physicians are then interviewed and a third of those will participate in an audit of their practice by a peer. Other provinces are considering adopting this multi-source feedback programme.



## Survey tools

- 25 Patients
- 8 Coworkers
- 8 Colleagues
- Self



**Step 2** involves face-to-face assessments of knowledge, skills and attitudes for physicians identified through findings in Step 1. Audits of hospital and/or office records and discussions with the physician about cases are the usual methods of assessment. Interviews of colleagues and observations of patient encounters are occasionally employed, as well.

Since the 1980s, several jurisdictions have conducted random and targeted visits of physicians' practices. Although generally educational for the physicians audited, random practice audit is acknowledged as an expensive process that finds >80% of practices having no significant deficiencies.

**Step 3** is reserved for a very small fraction of physicians about whom concerns are raised in Step 2 about knowledge, skills and/or fitness to practise. There are four multi-dimensional assessment programs in Canada conducting these in-depth assessments on referral from regulatory authorities.

The range of competencies assessed at each level of the revalidation process generally follows an agreed range of desirable attributes of the ideal physician. Those attributes are expressed by the CanMEDS® model of competencies developed by the Royal College of Physicians and Surgeons of Canada (the accrediting body for specialists in Canada),<sup>5</sup> and adopted also by the College of Family Physicians of Canada. Those competencies are similar in scope to expectations outlined in *Good Medical Practice* documents of the General Medical Council and other national medical regulatory bodies.

Action on revalidation in Canada has been slowed by a lack of finances, technical and human resources and by insufficient legislative authority in several jurisdictions.

However, in 2006, the Federation of Medical Regulatory Authorities brought all 13 jurisdictions together on a renewed commitment and an agreed set of principles for a Canadian revalidation process.<sup>6</sup>

## Federation of Medical Regulatory Authorities of Canada

### Position Statement on Revalidation

*All licensed physicians in Canada must participate in a recognised revalidation process in which they demonstrate their commitment to continued competent performance in a framework that is fair, relevant, inclusive, transferable and formative.*

**'Fair'** means the process is transparent to the physician, uses fair and standardised tools, and is considerate of cost and administrative burden to the physician.

**'Relevant'** means the process of revalidation is designed to confirm a physician's competence within the scope of his or her practice.

**'Inclusive'** means that revalidation applies to all licensed physicians.

**'Transferable'** means that the process of revalidation will be mutually recognised by each Canadian jurisdiction and will not inhibit mobility in Canada.

**'Formative'** means that the process of revalidation is a constructive educational quality assurance process, independent and distinct from the disciplinary processes of the regulatory authorities.

Since then, participation in continuous professional development as a condition of continued licensure has been adopted in most jurisdictions. The quality and content of CPD given credit is currently managed by the two national certifying bodies. Increasingly, however, that content will be influenced by the expectations of the licensing bodies. Regulators have recently expressed their desire that CPD will:

- (i) be aligned with each physician's practice profile,
- (ii) address all CanMEDS competencies,
- (iii) include monitoring of quality indicators in practice, and
- (iv) include documentation of improvement activities addressing performance gaps and the expectations of patients and colleagues.

### Future considerations

Although revalidation cannot wait for improvements to technology, it is expected that electronic medical records and healthcare databases will improve sufficiently within the next decade to become a routine component of professional performance review.

As the rigour of performance assessments improves in institutions and by community-based networks, it may become possible to delegate some of the proof required for revalidation to authorised entities.

So far, Canadian regulators and accrediting bodies express no desire to move in the direction of required tests of knowledge.<sup>7-8</sup> As one writer put it (Craig Campbell of the Royal College of Physicians and Surgeons of Canada): 'Rather than promoting the development of a testing culture that is based on summative examinations, [we] are advocating for the creation of a learning culture characterised by

practice reflection, inquiry, peer review and rigorous formative assessment of knowledge, competence and performance that reflect the entire spectrum of roles and competencies associated with the CanMEDS framework.'

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# Dr Bryan Ward



***After completing an MD at the University of Calgary in 1976 and family medicine residency at the University of Western Ontario, Bryan Ward practised family practice in rural Alberta.***

Dr Ward joined the staff of the College of Physicians and Surgeons of Alberta in 1993 where his current duties as Deputy Registrar include the Physician Achievement Review (PAR) Program, the College's accreditation programmes, and regulations for the medical profession in Alberta.

He recently completed a term as President of the Federation of Medical Regulatory Authorities of Canada.

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# Revalidation: The UK Experience

**Professor Malcolm Lewis, General Medical Council**

## Introduction

The way in which doctors are regulated is changing. The General Medical Council (GMC) is proposing a new process to assure patients and the public, employers and other healthcare practitioners that licensed doctors are up to date and fit to practise. This process is called revalidation.<sup>1-3</sup>

Revalidation is a new way of regulating the medical profession that will provide a focus for doctors' efforts to maintain and improve their practice; facilitate the organisations in which doctors work to support them in keeping their practice up to date; and encourage patients and the public to provide feedback about the medical care they receive from doctors.<sup>4</sup> In these ways, revalidation will contribute to the ongoing improvement in the quality of medical care delivered to patients throughout the UK.

Although it is widely understood that the delivery of medical care to patients will always involve an element of risk, revalidation will help doctors, employers and the GMC to provide further assurance to patients and the public that doctors working in the UK are fit to practise. The successful introduction of revalidation is a shared responsibility involving the GMC, the health departments in England, Northern Ireland, Scotland and Wales, the medical Royal Colleges, the NHS and other employers and the medical profession.<sup>5</sup>

## GMC registration and the license to practise

Patients trust doctors with their lives and wellbeing. They need to have confidence that doctors are competent and abide by high ethical standards. One of the ways in which the GMC ensures that trust is through the registration and licensing of doctors in the UK. All doctors who wish to practise medicine in the UK must be both registered and licensed with the GMC<sup>6</sup>. This applies whether they practise full-time, part-time, as a locum, privately or in the NHS, or whether they are employed or self-employed.

Being registered and licensed with the GMC shows that a doctor has the necessary qualifications for medical practice and that he or she is in good standing. However, at present, registration is essentially an historical record of qualification. It provides no information about the sort of practitioner a doctor has become or whether they remain competent and fit to practise.

When revalidation is introduced, doctors who wish to keep their licence to practise will need to demonstrate to the GMC every five years that they are up to date and fit to practise.

## How will revalidation work in the UK?

### A continuing evaluation of a doctor's performance in the workplace

Revalidation must be relevant to doctors' day-to-day medical practice and build upon systems that already exist in the workplace to support high quality care. It must not create unnecessary burdens which hamper doctors in fulfilling their main concern of caring for their patients. For this reason revalidation will be based on a continuing evaluation of a doctor's practice in the place in which the doctor works. It will not involve a point-in-time test of knowledge and skills.

Revalidation will be based on local systems of appraisal. Doctors will need to ensure that they have an annual appraisal and that at least part of that appraisal involves a discussion of their practice and performance in relation to the principles and values set out in the core professional guidance,<sup>7</sup> by the GMC. The *Good Medical Practice* framework for appraisal has been developed for these purposes. The framework will form the basis of a standard approach for all appraisals, in which licensed doctors must take part in order to revalidate and ensure that there is a consistent approach across the UK. The framework consists of four domains, which cover the spectrum of medical practice. They are: knowledge, skills and performance; safety and quality; communication, partnership; teamwork and maintaining trust.

Doctors will need to maintain a folder or portfolio of supporting information drawn from their practice to show how they are meeting the required standards. The information collected in their portfolio will provide the basis for discussion at their annual appraisal.

### **Revalidation recommendation to the GMC by the 'Responsible Officer'**

In order to be revalidated, doctors will link to a Responsible Officer who will usually be based in the organisation in which the doctor works or with which he or she is contracted to provide services. For the majority of doctors in clinical practice, the Responsible Officer will be a senior licensed doctor.

The post of Responsible Officer is a statutory role.<sup>8</sup> The Responsible Officer has statutory responsibility for evaluating the fitness to practise of doctors associated with their organisation. They are also responsible for ensuring that clinical governance systems (including appraisal) in their healthcare organisation are fit for purpose, and supporting doctors in meeting the requirements of revalidation.

The Responsible Officer will make a recommendation to the GMC about a doctor's revalidation, normally every five years. The Responsible Officer will review the outcome of a doctor's annual appraisals over the course of five years, combined with information drawn from the clinical governance systems of the organisation in which the doctor works.

Where there are concerns about a doctor's practice these should be identified as early as possible and, where possible, addressed through appraisal and the relevant local clinical governance processes.<sup>9</sup> We do not expect action on known concerns to wait until a doctor is due to be revalidated by the GMC since early action at a local level will reduce the risk of problems escalating and of harm to patients. Where serious concerns about a doctor's fitness to practise are brought to the GMC's attention they will be investigated through our existing fitness to practise procedures and may result in action against the doctor's registration.

It will be for the GMC to decide in each case whether individual doctors should be revalidated. We need to be confident that the recommendations we receive

are robust, fair and consistently applied. As such, the RO recommendations will be subject to appropriate quality assurance arrangements.

### **Supporting Information for revalidation**

A key element in the revalidation process is the supporting information that doctors will provide from their day-to-day practice in order to demonstrate that they are complying with the professional standards. The GMC has developed a core set of supporting information that all doctors will be expected to provide at appraisal over the course of the revalidation cycle.<sup>10</sup> The specific information will vary depending on the nature of the doctor's practice, but includes evidence of participation in CPD, a colleague and patient feedback process and a quality improvement activity or audit. This information should be brought together with other relevant clinical governance information, such as complaints and significant events, to the annual appraisal. Feedback from colleagues and patients will be gathered by asking colleagues and patients to complete questionnaires on the doctor's practice and performance.

### **Challenges of revalidation**

There are a number of challenges in developing and implementing revalidation. There has been a level of scepticism that revalidation might become a bureaucratic burden to doctors and employers, resource intensive, and take doctor's time away from healthcare service provision.<sup>12</sup> The GMC recognises that widespread professional acceptance and support of revalidation is most likely if the process is not unduly burdensome, utilises the information and data that doctors already collect and proves relevant to the improvement of the quality of practice and patient care. The challenge for the GMC is to keep revalidation as simple and streamlined as possible.

A further challenge for the GMC is quality assurance – providing confidence to both the public and to doctors that the systems in place to support revalidation recommendations are sufficiently robust.

The successful revalidation every five years of approximately 226,000 licensed doctors presents a huge logistical challenge. Such numbers mean that

it will not be practical for the GMC to review every single revalidation recommendation that it receives during each revalidation cycle. Nor would it be practicable, or a good use of resources, for the GMC to attempt to review local processes in hundreds of healthcare organisations employing or contracting with doctors across the UK, especially since such organisations are already subject to regulation and monitoring by systems regulators.

### Next steps

The GMC is in the process of finalising the model for revalidation for all doctors. On 1 April 2011 the *Good Medical Practice* Framework for appraisal and revalidation and the supporting information for revalidation were published on the GMC's website.

The GMC is currently working with our partner organisations to develop a single set of quality assurance criteria and a generic self-assessment toolkit based on those criteria for use in primary, secondary, independent and private practice settings. This, together with an annual programme of sampling and audit of the supporting information that underpin Responsible Officer recommendations, would provide a level of assurance as to the robustness of organisational support and the validity of revalidation recommendations being made by Responsible Officers.

Local processes such as clinical governance, including appraisal, will need to be 'ready' and able to deliver specific outputs for revalidation. The four delivery boards in each of the countries within the UK will use a Readiness Dashboard developed by the GMC to report on their states of readiness in the lead up to roll out. The Responsible Officer legislation has been in place throughout the UK since 1 January 2011 and designated organisations, within the legislation, are appointing Responsible Officers.

The GMC is formulating a roll out plan for the UK, which will describe and plan the sequence in which recommendations should be submitted by Responsible Officers from the end of 2012. This roll out plan will be based on the assessment of readiness.

The GMC is responsible for developing the necessary legislation and statutory guidance to support revalidation. This is currently being prepared for a public consultation in late 2011.

### Conclusion

The vast majority of doctors already practise medicine to a high standard. Most doctors routinely engage in personal and quality developmental activities to improve patient care. Regardless of the key drivers of the process, any form of revalidation is unlikely to be more than an exercise unless it is seen as useful and relevant by the profession.

Revalidation has been designed to achieve a modern system of registration and licensing that is acceptable to patients and the public. If implemented carefully and correctly, revalidation will assure patients and the public that licensed doctors are up to date and are practising to the appropriate professional standards, enable doctors to identify areas needing improvement and contribute to the ongoing improvement in the quality of medical care delivered to patients throughout the UK.

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# Professor Malcolm Lewis



***Malcolm Lewis has been a General Practitioner in Swansea, South Wales for 23 years and is Honorary Professor of Primary Care at Swansea Medical School.***

He has been a member of the General Medical Council since 1999, having been elected twice (1999 and 2003) and more recently appointed by the Appointments Commission for the 2008-12 term, which will conclude his service to the GMC. He was formerly Chair of the Registration Committee and is currently Chair of the Continued Practice, Revalidation and Registration Board.

Professor Lewis has been the Director of Postgraduate General Practice Education in Wales since 2002 and immediate past-Chair of the UK Committee of GP Directors of Postgraduate Education (COGPED). He has significant experience of GP appraisal and clinical governance and for eight years has led the development of a single web-based appraisal and revalidation system for all GPs in Wales, which is also currently being tested in hospital specialty practice. In 2010 Professor Lewis was seconded to the Welsh Assembly Government as Advisor on Medical Education, Professional Standards and Revalidation.

# Recertification of general practitioners (and specialists) in the Netherlands

**Dr Renée Weersma**

**General practitioner and member of the registration committee (HVRC)  
Royal Dutch Medical Association (KNMG)**

## Introduction

Postgraduate training for general practice and family medicine began in the Netherlands in 1973 and a register of qualified general practitioners was introduced to reflect this. Since 1973 it is only possible to register as a general practitioner or family physician in the Netherlands after completing the official postgraduate training scheme, which takes three years.

Physicians who, in 1973, were already practising as general medical practitioners were able to gain entry to the register through acquired rights. Since the introduction of the list of qualified general practitioners, doctors must be registered in order to work within the Dutch social security system as it is in effect a license to work as a general practitioner. In addition, insurance companies can only contract with licensed general practitioners/family physicians.

## Legal system

The Minister of Health is responsible for the registration of doctors and other healthcare professionals, including holding the medical list as a register of doctors. Postgraduate training for general practice and family medicine is covered by the Individual Healthcare Professions Act which regulates the medical professions.

In addition to national legislation, the legislation of the European Union also applies in the Netherlands. The Medical Directive gives a number of directions for basic medical training, specialist training programmes and the mutual recognition of diplomas and certificates by the member states of the European Union (EU), other European countries within the European Economic Area (EEA) and Switzerland.

Postgraduate training, registration and recertification of specialists are the responsibilities of the Royal Dutch Medical Association (KNMG). The KNMG has a Department of Postgraduate Training and Registration to oversee these processes, with one legislation board and three registration committees who oversee registration, arbitration of training, recognition disputes, and appeals regarding registration and recertification. The legislation board issues the rules and regulations on specialist postgraduate training, registration and recertification, including registration of overseas doctors. These rules and regulations are enforced and approved by the Minister of Health. The registration committees implement the rules and regulations and are responsible for the supervision of postgraduate training programs, recognition of trainers, training hospitals and training institutes, and the registration and recertification of specialists.

In 2009 the government directed that these separate functions be joined together, so it is planned that from 2012 these committees will merge into one committee, called the HVRC (Huisarts (general practitioners), Verpleeghuisarts/specialist ouderengeneeskunde (geriatricians) en arts voor verstandelijk gehandicapten (doctors specialising in special needs), Registratie Commissie). The HVRC will be responsible for the same areas as the current three boards for general practitioners and family physicians, with the addition of two other specialties – geriatricians and doctors specialising in special needs.

## Registration and recertification

Registration as a general practitioner or family physician is, as for all specialists in the Netherlands, limited to five years. After five years doctors are

able to renew their registration so long as they meet the conditions set out for recertification. These conditions are compulsory and without them you cannot practise as a general practitioner or family physician. Doctors must have professional experience in their specialist area and take part in continuing medical education (CME) and audit activities. Doctors are required to prove that they have worked in their specialty for an average of at least 16 hours per week and 50 hours out of office cover per year, and that they have taken part in an average of at least 40 hours CME and audit per year over a five year period. CME and audit activities are accredited by the specialist colleges.

Doctors use a computerised system to record their CME activity in order to be able to track their activities and identify further development needs. This is designed to enable an individual doctor to take a more proactive and self-reflective approach to their CME.

The requirements are flexible in relation to the different stages of a doctor's career. If a doctor has been practising for more than 25 years, they are only required to do 25 hours out of office cover per year. The requirement for out of office cover is only for general practitioners in response to the needs of the health service for out of hours doctors.

A new requirement is that doctors should participate in a peer review and feedback group, run by one of a number of providers, for ten hours every five years. In addition, as of 1 January 2011, all doctors should be participating in a visitation quality assurance programme. This is designed to be a simple system where a doctor is audited once every five years and receives feedback about their practise and the quality of their individual performance. These elements are part of a move towards quality improvement and feedback for doctors on their practice, and away from the current system which is based on finding 'bad apples'.

If a doctor is unable to meet the requirements for recertification, registration may be renewed for a shorter period of time (for example, if the doctor has managed to attain most or more than half of

the hours). However, they will be erased from the specialist register if they have only attained half or less than half of the hours required.

Where doctors are erased from the specialist register they are able to revert to being a general practitioner trainee for up to a year or they are able to work in general practice under supervision, also usually for a year. After this period of retraining it may be possible for them to be restored to the register. The decisions of the registration committees, HVRC, MSRC (Registration Committee for Specialists) and SGRC (Registration Committee for Community Doctors) on registration and recertification can be appealed.

# Dr Renée Weersma



***Renée Weersma has been member of the registration committee of the Royal Dutch Medical Association since 2007.***

Starting her membership as a GP trainee and then from January 2009 as a registered GP. During her vocational training she was president of the Dutch GP trainee association. It was here that she became interested in registration and recertification because according to her it's part of the 'circle of quality'.

She is also co founder of an organisation called Generation Next, which was founded in 2008. It's an initiative of a group of young GPs in the Netherlands that would like to see the existing medical organisations to admit younger professionals to their organisations and to think together about the future of the GP profession and primary health care in the Netherlands.

Now she works as an registered GP in Haarlem and as a GP trainer at the VU University of Amsterdam.

# Supporting information for revalidation: evaluating the evidence base – colleague questionnaires

## Professor John Campbell

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Scientific lead, GMC project on multi-source feedback for revalidation

### Background

Previous systematic review research evidence has identified the availability of only a small number of psychometrically robust instruments which might be suitable for peer assessment of physicians.<sup>1</sup> In particular, these relate to the professional associate rating,<sup>2</sup> the peer assessment questionnaire,<sup>3</sup> and the peer review evaluation form.<sup>4</sup> Instruments reviewed suffered from the shortcomings that their development focussed only on reliability and feasibility, lacked a theoretical framework and clarity of purpose, and were considered to be of doubtful validity. More recently, an international review undertaken by Lockyer and Fidler summarised the mapping of items in a range of colleague focussed survey feedback instruments to the duties of a doctor and attributes of care outlined in the GMC's authoritative publication *Good Medical Practice*.<sup>5-6</sup> In undertaking colleague feedback, previous authors have identified the potential for participation for a range of medical, non-medical, administrative and managerial colleagues to provide feedback.

### Current project

Our present research was commissioned by the GMC, started in April 2008, and has recently reported findings to the GMC. An initial target of 1000-1200 participant doctors was set. This was attained following an approach to 2454 doctors (with two reminders). Participants were drawn from a range of clinical settings encompassing acute care, primary care, and the independent and mental health sectors across England and Wales. Feedback was obtained using the GMC's colleague survey, an instrument we have previously investigated and reported on in the scientific literature.<sup>7-8</sup> Each doctor provided details of up to 20 colleagues, half

of whom, it was suggested, should be medical peers. The survey was largely undertaken as a secure online survey of the colleagues of index doctor participants. The colleague questionnaire addresses 18 core components of professionalism, with responses reported using 5-point scales, including options for 'don't know' or 'does not apply' as appropriate. Our earlier work reported on the internal consistency,<sup>7</sup> generalisability, and validity (factor analysis) of a similar, but earlier, version of the colleague questionnaire.

An overall participation rate of 43% of index doctors was observed, with in excess of 17,000 questionnaires being returned by medically-qualified colleagues, non-medically qualified clinical colleagues and health service administrators/managers/support staff associated with the 1,067 index doctor participants. Some preliminary data was presented to the workshop, but this has recently (June 2011) been updated and is now submitted for independent peer review and scientific publication (see below). Pending publication, detailed results are not reported in this paper.

### Conclusion

Colleague feedback provides a valuable means of capturing information on a doctor's professionalism. We have provided evidence in respect of the validity, reliability and potential utility of the GMC's colleague questionnaire. We believe it to be a robust, defensible instrument suitable for use in capturing information from a doctor's colleagues regarding their professionalism. We advise that the feedback obtained should be primarily used for formative purposes, especially in the early years of revalidation.

## Outputs

A number of research papers are currently in the process of submission. Interested readers might wish to contact us regarding the status of the following papers:

**Campbell JL, Roberts M, Wright C, Hill J, Richards S, Greco M, Taylor M**

*Modelling the professional practice of UK doctors; data obtained using the GMC's patient and colleague questionnaires*

**Wright C, Hill J, Roberts M, Richards S, Hobart J, Norman G, Greco M, Taylor M, Campbell JL**

*Using multisource feedback to assess the professional performance of doctors: the acceptability, reliability and validity of the GMC; Colleague Questionnaire*

**Richards SH, Hill J, Roberts M, Wright C, Hobart JA, Norman G, Greco M, Taylor M, Campbell JL**

*Obtaining patient views when assessing the professional performance of doctors: the acceptability, reliability and validity of the GMC; Patient Questionnaire*

**Hill J, Asprey A, Campbell JL**

*A qualitative analysis of the use of multi-source feedback in appraisal and for revalidation*

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# Professor John Campbell



***John Campbell is Foundation Professor of General Practice and Primary Care at Peninsula Medical School, one of four new undergraduate medical schools founded in recent years in the UK.***

A clinician, Professor Campbell leads a growing team of researchers with interests in access to care, inequalities of health status and experience, whole-person care and the implementation of new technologies in primary care settings. With colleagues from Manchester, he was involved in the development and validation of the General Practice Assessment Questionnaire, one of two instruments currently approved for use within the Quality and Outcomes Framework of the 'new' GP Contract.

More recently, he has led the development of the Out-of-Hours patient questionnaire, currently being considered for use in capturing out-of-hours users' experiences of health care. In addition, he leads the HTA-funded ESTEEM trial of triage systems in primary care and is joint scientific lead in developing the UK's National GP Patient Survey and in holding a NIHR programme grant investigating the potential of this instrument in informing developments in UK primary care.

Along with colleagues from CFEP-UK, he is leading the next phase of piloting of the GMC's patient and colleague questionnaires. The UK is currently embarking on the most substantial change in the regulation of medical practice since the establishment of the UK General Medical Council in 1858.

All UK doctors have currently been issued with a licence to practise medicine. The revalidation of doctors will involve a process, probably on a five-yearly cycle, of providing evidence to support the relicensing of that doctor.

This revalidation process has both generic and specialty-specific components. In common with other international models, feedback from patients and colleagues forms a central component of all models of revalidation currently being considered in the UK.

This study aims to describe the potential utility of patient and colleague targeted questionnaires developed by the GMC and considered for wide-scale rollout in UK health care settings.

# Patient and Public Engagement within Revalidation

**Peter Cross**

**Picker Institute Europe**

## Summary

This paper contextualises, develops and updates my presentation to the symposium, which focused on the rationale for gathering feedback from patients within medical revalidation and the various means of data collection.

As revalidation is piloted in the UK, Picker Institute Europe remains concerned that the role, value and effective use of patient feedback is not yet properly located within regulatory frameworks and requirements. Patient feedback provides data about the quality of care and information on which to base remediation and practice development initiatives; it should not be positioned only as a means of engendering public confidence in revalidation.

The doctor-patient partnership is central to the safety, effectiveness and patient experience of healthcare. The GMC's guidance document *Good Medical Practice* provides the necessary criteria for measuring and monitoring the quality of that relationship. Robust, reliable and meaningful feedback from patients therefore could and should be a core component of medical appraisal, revalidation and continuing professional development.

The General Medical Council should give an unequivocal lead to the medical profession, in line with the duties it promotes in *Good Medical Practice*, that the patient experience is a core indicator of doctors' performance and should be appraised annually.

Using properly developed instruments and methodologies, clinician-level feedback is achievable and practicable within clinical settings. A case study developed with a team of NHS consultants is included as a demonstration of what is possible.

## The doctor-patient partnership: the cornerstone of quality in healthcare

In the UK, quality in healthcare is measured on three dimensions: safety, clinical effectiveness and a positive patient experience. This triad was established by the NHS Next Stage Review,<sup>1</sup> and has been explicitly accepted by the coalition government.<sup>2,3</sup>

The relationship between doctor and patient remains the cornerstone of medicine and is fundamental to the patient experience of healthcare. Expectations of this relationship have of course changed substantially over time, and continue to evolve. Few patients are now content with 'doctor knows best' – most expect clinicians to listen to them, inform them, take account of their preferences, involve them in treatment decisions, support their efforts in self-care and respect their autonomy.<sup>4</sup>

Likewise, professional guidance and good practice codes increasingly emphasise a duty to provide genuinely patient-centred care and to work in partnership with patients. The General Medical Council sets out its expectations of the doctor-patient relationship in its *Good Medical Practice* guidance document, where the latest edition states that:

'Relationships based on openness, trust and good communication will enable you to work in partnership with your patients to address their individual needs.'

To fulfil your role in the doctor-patient partnership you must:

- (a) be polite, considerate and honest
- (b) treat patients with dignity
- (c) treat each patient as an individual
- (d) respect patients' privacy and right to confidentiality

- (e) support patients in caring for themselves to improve and maintain their health
- (f) encourage patients who have knowledge about their condition to use this when they are making decisions about their care.<sup>15</sup>

Within the doctor-patient partnership, *Good Medical Practice* requires doctors to communicate effectively with patients. This is characterised as:

- listening to patients, asking for and respecting their views about their health, and responding to their concerns and preferences
- sharing with patients, in a way they can understand, the information they want or need to know about their condition, its likely progression, and the treatment options available to them, including associated risks and uncertainties
- responding to patients' questions and keeping them informed about the progress of their care
- making sure that patients are informed about how information is shared within teams and among those who will be providing their care
- making sure, wherever practical, that arrangements are made to meet patients' language and communication needs.

*Good Medical Practice* thus provides a robust set of criteria for assessing an individual clinician's performance within the doctor-patient relationship, and one which can readily be translated into tools for gathering patient feedback about a clinician's interpersonal, communication and partnership skills. The challenge now is to ensure that these elements of *Good Medical Practice* are properly represented and assessed with medical revalidation.

### Proposals for medical revalidation: locating patient feedback

Picker Institute Europe has contributed substantively to medical revalidation task groups, consultations and development work over the years. We were represented in the high level group established by the Chief Medical Officer (CMO), whose work led to the 2007 *Trust, Assurance and Safety White Paper*.<sup>6</sup>

We were also a member of the CMO's working group on medical revalidation, which reported in the document *Medical revalidation: principles and next steps*,<sup>7</sup> and established that the purpose of revalidation is to create continuous improvements in quality – not only to identify unsafe doctors.

Our focus and ongoing concern is the way in which patient feedback is located within medical revalidation – how its purpose and value are described, how it is integrated with evidence from other sources, and how it is used to improve doctor-patient relationships.

To date, patient feedback within medical appraisal and revalidation runs along two distinctly different tracks of 'fundamental in theory' but 'too difficult in practice'. At the launch of *Trust, Assurance and Safety*, the then minister for health and the CMO confirmed that revalidation and its associated appraisals would include direct feedback from patients. The CMO's working group report also affirmed that patient feedback would form part of the evidence base for appraisal and revalidation. Throughout subsequent discussions and developments, patient feedback is characterised by all parties as a necessary and important element of assessment, appraisal and revalidation, contributing valuable evidence to appraisal and revalidation processes, right alongside feedback from professional colleagues. Taken together, the discourses imply a real commitment to collecting and using patient feedback – routinely, in the right way and for the right reasons.

In the development of proposals for implementation, au contraire, there is no substantive commitment to the systematic collection and use of patient feedback. Patient and public involvement 'is expected, and will be included in revalidation', yet it has typically been positioned only as 'critical to ensuring confidence in revalidation'.<sup>8</sup>

The Picker Institute's position is that the patient experience is a core dimension of 'quality' in health and should explicitly be located within revalidation as a core dimension of doctors' competence and performance. In this regard, the GMC's April 2011 guidance on patient questionnaires is encouraging, locating patient feedback as an opportunity for patients to reflect on 'the professional skills and behaviour of a doctor'.<sup>9</sup>

However, in our view, the requirement for doctors who have direct patient contact to seek patient feedback 'at least once in every revalidation cycle' remains wholly inadequate. As national policy demands greater, wider and more detailed use of patient experience measurement across the NHS,<sup>3</sup> revalidation risks falling further and further behind the curve of patient, public and political expectations.

From the outset, Picker Institute Europe has argued that medical revalidation should fully and effectively integrate patients' experiences into doctors' appraisals and performance assessments, and that revalidation should do this in a way that drives and supports continual improvement in the quality of care provided. Patient feedback should be gathered at least annually, considered at each appraisal and reviewed as a body of evidence within revalidation. Where patient experience data give cause for concern, a remedial action plan for improving performance and monitoring patients' experiences of care should be agreed and implemented. Doctors should be required to submit real-time evidence of compliance with the plan to their appraiser and Responsible Officer until subsequent patient experience data demonstrates satisfactory performance.

For the future, there should be formal consideration of establishing more frequent, perhaps continuous, collection of patient feedback data, tailored to the doctor's service settings and patient characteristics where relevant. Appraisal and revalidation processes should ensure early identification of poor or deteriorating patient experience and provide ongoing evaluation of the impact of remedial interventions.

As revalidation rolls out, the Picker Institute will work to support doctors, appraisers, Responsible Officers and employing organisations in collating, interpreting and effectively using patient feedback about their interactions with doctors. We must however look to the GMC for commitment and clarity in locating the doctor-patient partnership at the heart of revalidation.

The way in which the GMC positions patient and public involvement, and particularly the value

it places on patient feedback, will be critically important. In developing its proposals for revalidation, the GMC should counter resistance by clearly and consistently communicating – in line with the duties set out in *Good Medical Practice* – the centrality of the doctor-patient partnership. Resistance to clinician-level patient feedback as a source of evidence is perhaps understandable, but it should not be endorsed by appraisal and revalidation frameworks.

### Reconciling theory and practice: a case study of what is possible

In the Picker Institute's experience, resistance to integrating patient feedback into appraisal and revalidation divides, very broadly, into two categories:

- 'ideological' resistance
- 'practicality' resistance

Ideological resistance reflects a lack of confidence in patient feedback as a valid source of evidence and a useful basis for quality improvement. Only 67% of respondents to the GMC's 2010 revalidation consultation supported the involvement of patients through questionnaires,<sup>8</sup> and 57% of GP respondents in a recent survey of GPs by the King's Fund thought that patient surveys were the least effective approach to quality improvement.<sup>10</sup> This is perhaps understandable – poorly designed patient feedback initiatives, done in the wrong way and for the wrong reasons, consume resources while providing data of limited value, reliability and comparability.

Doctors may also be resistant to the concepts and language of patient-centred healthcare and related concepts like working 'in partnership' and shared decision-making. More bluntly, patient feedback may be regarded as irrelevant – pertaining to 'touchy-feely' things that nurses can do but doctors don't need to worry about. Otherwise, patient feedback might be perceived as threatening – particularly where there are misperceptions about patients 'rating' clinical competence rather than describing their experience of the doctor-patient relationship.

Practicality resistance typically centres on the belief that designing and implementing surveys to collect robust and reliable patient feedback is hard to do and impractical in clinical settings, along with a strong preference for not collecting new data. Responses to the GMC's consultation, for example, showed a clear preference for basing appraisal on information that is already routinely collected.<sup>8</sup>

Picker Institute Europe's position, backed by decades of experience, is that collecting robust, reliable and useful clinician-level patient feedback is really not hard to do. As for clinical outcomes, it just takes properly designed instruments and approaches, plus the will to collect data in the right way and for the right reasons. Demonstrating what can be done, the Society for Cardiothoracic Surgery in Great Britain and Ireland has broken ground by publishing clinician-level data on clinical outcomes.<sup>11</sup> We are now working with the cardiothoracic surgeons to explore the comparable publication of patient feedback data.

That is for the foreseeable future. For now, the case study below describes a patient feedback collaboration that combines NHS consultant surgeons' ambitions with the Picker Institute's expertise. This document summarises a not yet published paper, so is anonymised.

Picker Institute Europe was approached by a consultant surgeon working within an NHS Foundation Trust that values regular patient feedback and is committed to continuous improvement of services in the future. The consultant contacted us with a view to developing a robust method for gathering patient feedback at an individual clinician level, focusing initially on all consultants within a surgical specialty. Such feedback would be used for individual performance evaluation and to ultimately improve patient experience. The Trust's wish was to focus specifically on the consultants' communication skills.

It was therefore agreed that Picker Institute Europe, in partnership with the Trust, would formulate and conduct a pilot test to:

- develop and test robust patient experience measures specifically pertaining to consultants' communication skills
- investigate various methods of data collection in order to understand each method's efficacy, validity, logistical ease
- provide analysis of results at an individual clinician level
- examine and test how the results can identify areas for personal development and training
- facilitate development of a performance improvement and support framework with clinicians
- develop and test a tool that could potentially be used to gather patient feedback for revalidation purposes
- progress the drive for patient-centred care amongst individual clinicians and professional bodies.

This pilot test was developed and conducted between January and September 2010 and was funded wholly by Picker Institute Europe. This consisted of five separate methods of surveying patients, and self-assessment of clinicians' and colleagues' feedback.

## Outcomes

This pilot test has shown that it is possible to obtain a robust measurement of a consultant's communication skills as seen through the eyes of patients in an outpatient setting.

A set of patient-experience measures examining consultants' communication skills has been developed. The tool has been found to be statistically robust and analyses have shown that it is capable of differentiating consultants' communication skills. The tool is highly reliable (Cronbach's alpha >0.9) and unidimensional.

Some minor adjustments to the pilot questionnaire were recommended, although its current length

is not a barrier to completion and there were no significant difficulties with skipped questions.

The minimum number of questionnaires required to achieve a physician-level reliability of at least 0.8 is 32 per consultant. Consultants should not be assessed based on fewer than this number of ratings.

Results demonstrate high levels of consultant performance overall, although one consultant had a significantly lower communications score in comparison to the others.

### **Comparison of data collection methods**

There were differential effects due to questionnaire administration mode, patient age and whether the consultation was a first or subsequent encounter with the consultant as well as how long the patient had to wait for their consultation.

Whilst data collection on-site with hand-held computers yielded the highest response rate (97%), it was not the method of feedback most preferred by patients (21% preference amongst the methods offered) and results differ statistically from those collected via the two main paper-based modes of delivery.

Taking a questionnaire home for completion and freepost return was the option most preferred by patients (66% preference amongst the methods offered) and yielded a high response rate overall (62%) and consistently high response rates from men, women and different age groups (when compared to the other off-site data collection methods).

The postal method with no reminders also brought a high response rate (45%). (In comparison, national inpatient and outpatient surveys usually achieve a response rate of around 50% with two reminders.) This is probably due to the questionnaire being sent very shortly after the outpatient appointment (maximum 11 days later).

Preference for online completion was low (8% preference amongst the methods offered) and the response rate was also low (24%). Results were also

found to differ statistically from those collected via the two main paper-based modes of delivery (although the low sample size overall may contribute to this). This suggests that this method of data collection does not add any particular value to the data collection process.

Preference for completing a paper questionnaire on the spot was so low that it cannot be considered a viable data collection option (6% preference amongst the methods offered) despite the high response rate (93%).

### **Outputs and future developments**

Consultants will be provided with their own reports showing patient feedback on their individual communication skills in comparison to the combined feedback for the eight consultants in the urology team.

Feedback will then be sought from all the consultants on their feelings about the results given: are they credible, useful and actionable? How would they wish to use the information collected to reflect on their own communication skills and/or take steps to make improvements? What type(s) of support would they seek in doing this? Who would they like support from - line manager, team, Trust, Picker Institute, other organisations?

The intention is to bring this feedback to a meeting between staff from Picker Institute Europe and the Trust's executive team in order to explore how best to use the findings of this research to progress the drive for patient-centred care amongst individual clinicians (in line with the likely requirements of revalidation) and, where appropriate, develop a performance improvement framework that is owned and driven by the individual clinicians.

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# Peter Cross



***Picker Institute Europe is a leading not for profit health research organisation that specialises in researching and improving the experience of patients.***

With degrees from the University of Wales and the University of the West of England Peter joined the Picker Institute in 2005. This followed five years working as NHS manager with responsibility for patient and public engagement as well as commissioning services from voluntary and community sector organisations. Prior to this he had had a number of roles within voluntary sector organisations.

Peter's role at Picker currently divides between assisting individual organisations to make sense (and use) of patient experience data in order to improve the experience of patients and presenting at conferences, workshops and other events across the UK, Europe and North America.

From a family of doctors and engineers (to whom he is a terrible disappointment) Peter has dual UK/New Zealand citizenship, a grown up daughter and lives in the Cotswolds with his wife and camper van.

# The Effectiveness of Continuing Professional Development Project

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## Introduction

Between 2006 and 2009 the General Medical Council funded a study into the effectiveness of Continuing Professional Development (CPD). The study aimed to involve representatives of the whole range of career grade doctors, from staff grades to consultants in a wide variety of specialties - including some with purely clinical roles and others primarily involved in CPD provision and assessment, as well as institutional officials from Deaneries, Colleges and universities.

The goal of the study was to determine these doctors' understanding of their own learning and the learning of other doctors within their organisation, and their perception of how this learning relates to conceptions of CPD, its provision and its uptake. We further sort to establish what constituted effective CPD in their eyes.

The study design involved interviewing doctors in the various roles already outlined regarding their experiences from their particular points of view and the drawing out of common themes from those interviews – which were then contrasted with more quantitative data collected from questionnaires and surveys.

## Background

There is no single (or singularly correct) way of doing CPD – and it is considered that CPD goes beyond what doctors do. In organisational terms, principles of transparency and justification, in combination with a pragmatic flexibility are of vital importance in the development and provision of CPD. Major contributing factors to effective CPD included active modes of learning, integration of knowledge with everyday practice and linking of CPD to a learning needs analysis. The boundary between CPD and

quality assurance can be indistinct and the range of providers of CPD is extensive and diverse, but flexibility in CPD raises difficulties for assessing and accrediting the very same CPD.

## Design & Methods

There were five broad objectives in the exploration of what promotes and inhibits effectiveness of CPD.

1. Compare and contrast the **experiences** of CPD across the range of specialties
2. Identify and describe the range of **different models** of CPD employed across different specialties and clinical contexts
3. Consider the educational potential of **reflective practice** in CPD and its impact
4. Explore how different professionals judge the **effectiveness** of current CPD practices
5. Consider how **action research** might be employed as a means of developing effective CPD strategies

Study design was mindful of the need to focus on what happened in the clinical setting and to cover the range of specialties and the variety of posts within them. Data was collected through questionnaires (online and email via College websites and newsletters and paper-based at clinical conferences), letters to College and Deanery CPD leads, interviews and shadowing. Key insights from the literature review were able to inform the questions asked in the interviews, letters and questionnaires.

## Results

Highest scoring CPD experiences were conference attendance, local events and *journal reading*. *Interest*, *knowledge/skills gap* and *reflection on practice* were

all determinants of that highest scoring CPD. The majority of respondents agreed that the greatest impact of CPD was in the contexts of *knowledge acquisition*, changing practice and *learner satisfaction*. The attitudes towards CPD most commonly reported were a *natural part of professional life*, *rewarding* and *necessary for patient safety*, although most people felt that consultants learn best from *experience*. Most respondents felt that *Colleges and Faculties* should be responsible for CPD provision and its content. The most valuable contributors to CPD were felt to be *College conferences*, *Medical Society conferences* and *specialty associations*, and the highest-scoring barriers to CPD participation were *study leave availability*, *cost* and *work-life balance*.

### Letters to CPD Leads & Interviews

Guidance and advice given about CPD was varied – ranging from recommendations on blended learning and reflection to technical explanations of the credit points systems. This information was sometimes made available online, sometimes by post and sometimes by personal contact with designated people from Colleges/Faculties. Rather than guiding fellows towards particular CPD topics, CPD Leads talked more in terms of signposting, kite-marking and flexibility, but some also mentioned the allocation of specific CPD points to specific topics or activities. If uptake was measured, it was described through a variety of audit-type measures of annual CPD returns.

Organisations variously reported the methods used to evaluate the effectiveness of CPD ranging from none or an open culture encouraging feedback in general to a formal audit of members' activities. The most frequent method by which members recorded their CPD was diary entries or online eportfolio entries. All respondents replied in the negative when questioned about whether their organisation had any literature pertaining to the effectiveness of CPD.

### Discussion

The discussion of the results has been constructed around questions which are derived from the research objectives.

## Doctors' understanding of the term 'learning' and its effect on CPD

### Learning and CPD

It is felt that learning has two forms: the addition of something new, and verifying that practice is the same (or similar enough) to what everyone else is doing. CPD can systematise learning by deliberately providing a range of different approaches, variations in practice, and changes in viewpoint in order to enrich the experience, practice and knowledge of professionals involved. This can be developed further into a more systematic, rigorous and robust 'tool' for 'validity' checking. CPD and learning were both reported as being inextricably linked to doing the job, and methods for keeping up to date and confirming practice ranged from interactions with colleagues, through shared theatre sessions to attending workshops and conferences. It was noted that professionals may chose to stay within their comfort zone when choosing CPD. Perhaps this would change if the scoring system by which CPD is assessed were to change – alternatives to the current scoring systems should be identified and explored. It is regarded as important that professionals should be able to appraise and critique their own practice.

### CPD as learning

It is key that CPD providers recognise the heterogeneous nature of the medical profession and formulate learning designed specifically for each part of this significant variety. CPD is often linked to appraisals in our findings and associated with personal learning needs and seen as a way of gap-filling. CPD is essential to reflective practice and to an individual's development within the profession – whether or not it leads to career progression, with the Continuing component of CPD often articulated as moving on or continuing to develop.

### Distribution of CPD – institutional v personal

'Shop Floor learning' or learning there and then is seen to provide significant valuable learning experience, but the language to describe it is not developed and the question remains how to assess this rigorously and robustly. External CPD events were perceived as providing more diverse learning opportunities, but national provision tends to favour

those who live in London and the South East, for financial and personal reasons – job demands, time pressures and work-life balance make it harder for those from further afield to access London-based CPD.

#### What counts as CPD?

There were some clear differences between what users of CPD considered it to be and the view of some of those with a role in quality assurance. Being fit to practise is different to being a good doctor, and this distinction leads to questions of whether the purpose of CPD is to raise everyone to a minimum standard or whether its purpose is to allow individuals to pursue learning interests more generally. In the context of quality assurance, CPD counts if it is identifiable and claimable. However, networking and peer review both provide clinicians with ways of comparing the quality of their practice. Feedback and dialogue in the workplace could be developed as a basis for CPD, but the complexity of situated workplace learning outcomes mean they resist quantification – and this complexity would need to be reflected in the CPD system.

#### What counts as effective CPD?

Effective CPD involves *learning* and knowing both the *why* and the *how*, and putting that learning into practice. Effectiveness is facilitated when professionals are able to determine their own learning needs through reflection across the totality of their practice. This inevitably means going beyond that which is quantifiable.

It is clear that medical knowledge shapes the conception and conduct of doctors' interactions; how people talked about their ways of learning shaped their strategies for learning. This presents a culturally-embedded challenge for learning, where expressions, metaphors and modes of articulation used by professionals provide insights into their ways of seeing, thinking, speaking and doing – and how these link into developing medical concepts and the conduct of professional interactions. Consequently, changing the metaphors used in describing CPD may change the way doctors think about and undertake learning.

Providers of effective external CPD are seen as needing to attract large audiences, offer a wide range of events of high quality to attract a broad spectrum of professionals and ensure that the audience keeps returning, whilst balancing those factors against costs in terms of money and staff availability. The annual study leave budget was considered too small in the context of the costs incurred by attending an external CPD event.

The organisational perspective favours CPD activities that are recordable in some measurable and quantifiable way in order to be seen to be conducting a transparent and rigorous assessment procedure.

Online learning and CPD opportunities have become very popular with clinicians and organisations, because it tends to have fewer associated costs, and (superficially at least) learning can be demonstrated in terms of number of questions answered correctly or minutes spent online.

CPD is understood differently by those who see it as part of their professional development to those with organisational responsibilities. Learner-led CPD is most successful because it *encourages engagement and acknowledges professionalism* and is most valid from an educational perspective. For CPD to be effective overall, it must address the needs of the individual clinicians, the patients they serve and the organisations within which they work – as well as broader, system-wide, national policies. There is perception that formal CPD provision is undergoing changes in line with the implementation of revalidation – producing *industrial* CPD to make it more uniform. It is important to remember that the different roles and contexts of doctors in different posts and specialties means that they demand different things from CPD and when the complexity of medical decision making is further taken into account it is clear that an algorithmic approach to CPD will not work.

#### Differences between specialties

*For the most part, what doctors do is talk* and so communication, in all its complexity, is core to the entire medical profession. But some specialists talk only to colleagues and rarely to patients

(histopathology), some have *very clear behavioural objectives (anaesthetics)*, whilst others adopt approaches which are better adapted to enabling a *vast array of intellectual tying together (psychiatry)*. Behavioural objectives are 'visibles' and can be easily measured, whereas qualitative judgements and decision making processes are less easily measured.

#### CPD and revalidation

Many predicted that CPD assessment would inevitably become more quantifiable – with some believing that this would represent a positive move towards greater accountability, but many others spoke negatively of an accountability which would reduce the flexibility they value in their current CPD system.

#### Conclusion

There are tensions between perceptions of CPD as a learning phenomenon and the imperatives deriving from decisions to implement revalidation. The potential costs are difficult to predict but, on the basis of this study, it is probable that doctors will continue to engage in CPD at levels established up until this point because of their orientation towards their own learning. However, the 'lowest common denominator' approach risks turning CPD into a fitness to practise assessment tool, rather than a vehicle for true learning and development. The extent to which modern CPD needs can be met by more workplace-based activities is a ripe arena for further exploration.

# Dr Nick Jenkins



***After graduating from Imperial College, London, Nick trained in Emergency Medicine in Oxford, before taking up his current appointment in Poole, Dorset in 2010.***

During his training, he developed an interest in education and the ways in which healthcare professionals learn – particularly doctors' 'shop floor' learning.

He has a postgraduate diploma in medical education, and was the College of Emergency Medicine's first research fellow – working on the GMC-sponsored Continuing Professional Development (CPD) project.

As an Emergency Physician, Nick's particular interests are in critical care, resuscitation, stroke medicine, ultrasound, paediatrics and emergency medicine research. As an educationalist that clinical enthusiasm is mirrored by interests in 'shop floor' learning, skills acquisition and reflective practice.

Outside medicine, a love of foreign languages, culture, food and wine means that Nick and his wife have travelled extensively – including some lesser-known destinations in Asia, Africa, Australasia and South America – and Nick still travels as much as life with three small children permits!

# The Role of Examinations in the Quality of Patient Care in the United States

**Rebecca S. Lipner, PhD American Board of Internal Medicine**

## History of Certification

With the growth of medical specialties in the United States prior to 1900, physicians recognised the need to establish formal organisations to support these emerging fields and competencies.<sup>1</sup> The first specialty board, the American Board of Ophthalmology, was founded in 1917 and other specialties soon evolved. In 1933 the Boards organised as a federation called the Advisory Board of Medical Specialists and in 1970 was renamed the American Board of Medical Specialties (or ABMS). Today the ABMS consists of 24 member boards. There is considerable variability in the number of physicians associated with each board – the largest being the American Board of Internal Medicine (ABIM) representing one-fourth of all physicians in the United States. Each board offers a primary certificate and many also offer subspecialty certificates.

To achieve primary certification each board requires physicians to complete graduate training (ranging from three to six years) that is accredited by the Accreditation Council for Graduate Medical Education (ACGME), to possess a valid and unrestricted medical licence, and pass a rigorous secure cognitive examination in their discipline. Some boards require satisfactory programme director evaluations on six competencies (patient care, medical knowledge, interpersonal and communication skills, professionalism, practice-based learning and systems-based practice) while others require oral exams or review of case logs.<sup>2</sup>

While specialty board certification remains a voluntary process and only an undifferentiated medical licence is required to practise in the United States, practically speaking, most physicians choose to certify with the American Board of Medical Specialties upon completion of training. Certification publicly recognises a physician's specialty area.

Hospitals often require board certification to be granted privileges so that certification functions as a minimum standard to practise independently.

The ABMS boards are self-regulating independent medical bodies – purposely separate and independent from the educational arm of the physician membership organisations – led by physician directors who define the standards for the discipline. Traditionally, self-regulation has been the model used in the United States to hold the profession accountable to the public. Changes over the last decade due to a variety of reasons including the call for more patient-centred care and rising medical errors and cost of care have challenged the concept of professional self-regulation.<sup>3</sup>

## Maintenance of Certification

Multiple reports by the Institute of Medicine on concerns of quality of patient care and patient safety in the United States,<sup>4,5</sup> and some evidence that skills of physicians decay over time motivated the ABMS to develop Maintenance of Certification (MOC) programs (also known as recertification) and to limit the duration of certificates.<sup>6,7</sup> The goal of MOC is to ensure that physicians are maintaining competence over their career and in doing so demonstrate appropriate cognitive and clinical problem solving skills, professional attitudes and behavior, and quality patient care. The MOC programme is geared to be a comprehensive performance measurement of patient care by including the following four components: evidence of good professional standing through an unrestricted licence and multi-source feedback by patients and peers, participation in lifelong learning and periodic self-assessment, passing a secure exam of cognitive and clinical problem solving skills, and measurement of performance in the actual practice setting.<sup>8-9</sup> In more recent years the need for continuous physician

assessment by a regulatory body has become more evident. First, a physician's ability to independently and accurately self-assess is poor.<sup>10, 11</sup> Second, the amount of clinical experience a physician has does not necessarily lead to better outcomes of care so that just being in practice longer does not imply better care.<sup>12</sup> And third, fewer than 30% of physicians examine their own performance data and try to improve on their own.<sup>13</sup> Consequently, the profession has chosen MOC as a means of ensuring public accountability and transparency about physician performance.<sup>14</sup>

To better understand the role of examinations in ensuring public accountability in the United States this paper describes the theory and science involved in exam development, administration, and use by describing specifically ABIM's process.

### Cognitive Theory

Recognising that multiple sources of evidence are needed to establish a fair assessment of physician performance, examinations are used specifically to evaluate whether a physician can use their fund of medical knowledge and experience to successfully solve clinical problems that will lead to providing quality patient care. The exam is administered in a secure computer-based test centre and therefore also serves as a way to verify that the observed performance belongs solely to the particular physician. The exam itself cannot test all facets of patient care but its focus is to demonstrate that the physician is maintaining professional competence as it relates to clinical problem solving – an important element in both the United State's Physician Charter 15 and the United Kingdom's *Good Medical Practice*.<sup>16</sup>

But why is measurement of clinical problem solving skills seen as an important element in the programme and why is measuring the outcomes of patient care seen as insufficient? First, patients expect physicians to not only be certified but specifically undergo a periodic re-examination of their cognitive skills.<sup>17, 18</sup> Second, in general, physicians are inaccurate at identifying their own skill gaps.<sup>11</sup> Therefore, a periodic re-examination which assures the public that physicians possess the requisite competency and, at the same time, helps identify gaps in their skills should help

improve clinical care. Third, as a subset of cognitive theory, 30 years of research in the study of clinical problem solving demonstrates that in order to arrive at a correct diagnosis the physician needs to create an appropriate representation of what he/she thinks is the patient's problem.<sup>19</sup> This process is complex. The physician needs both a broad working memory that contains well-organised knowledge with readily accessible habits of problem solving and efficient information gathering skills through patient interviews, a complete physician exam and medical history, and valid medical references,<sup>20</sup> since most diagnostic errors are due to faulty synthesis of clinical findings.<sup>21</sup> If we were to only examine patient outcomes of care to determine clinical competence we might still be unsure about the level of a physician's clinical problem solving skills to arrive at a diagnosis for rare and complex situations.

### Examination Development Process

To establish robust exams that meet the public's expectations with reasonable certainty (that is, are reliable and valid), ABIM follows the *Standards in Testing* – guidelines established by the American Psychological Association, the American Educational Research Association, and the National Council on Measurement in Education.<sup>22</sup> Exams that do not test pure factual recall but clinical problem solving and diagnosis use clinical vignettes that describe challenges seen in everyday practice.<sup>23</sup> These types of questions provide basically a low-fidelity clinical simulation that is quite feasible to deliver and can easily be accompanied by different stimuli such as x-rays, lung sounds, moving images or videos of real patients. Thus, testing a physician's clinical problem solving ability in this artificial setting makes it feasible for the examiner to adequately sample the breadth of the field in an efficient manner.

The questions that comprise an exam should be relevant to clinical practice so the exam development process begins with a job analysis for a particular discipline followed by the construction of a blueprint (or table of specification).<sup>24</sup> The blueprint is based on the frequency with which various diseases are seen in practice as well as on its importance or criticality. For example, a rare disease that may have serious consequences to the patient if not diagnosed properly may be included. Expert physicians certified

in the field write testing points of questions that get transformed into full-text questions. The questions are field tested (i.e., pre-tested) to ensure they are of high quality before including them in an examinee's score. Physicians who are not associated with the Board processes ensure its relevance to clinical care by reviewing the blueprint content.<sup>25</sup>

To guarantee that the exam questions are fair, performance data is reviewed before the scores are finalised. If questions are not performing as expected they are reviewed by the experts who determine whether to – give all examinees credit, make more than one answer correct, or leave the question as is. An automated test assembly process is used to build the exam and to ensure that it is a fair balance of content from the blueprint and statistical criteria (eg, exam difficulty and discrimination) over time and forms of the exam.

### Examination Standard Setting

A passing standard for achieving certification is set using credible experts, widely accepted standard-setting approaches, and agreement from the public and profession that the standard is realistic.<sup>26</sup> The use of an absolute standard means that pass/fail decisions are made by comparing how much an examinee knows to specific content rather than to other examinees. Absolute standards are more credible since they ensure that passing or failing is based on how much one knows and not based on who else is taking the exam at that point in time.

### Examination Measurement Criteria

Van der Vleuten's utility model highlights five components – reliability, validity, educational impact, cost effectiveness, and acceptability – all important criteria to be considered when selecting and creating an exam.<sup>27</sup> Because the exam is a high stakes summative assessment reliability and validity are very important criteria. The exams are constructed to maintain high reproducibility of test scores (a Cronbach alpha >0.90) as well as high reproducibility of the pass-fail decision (a Huynh coefficient > 0.90). The risk of false-positive decisions (i.e., classifying a physician as competent when he or she is not) and false-negative decisions (i.e., classifying a physician as not competent when he or she is) then is low. Exam performance feedback based on both

absolute and relative performance is provided to physicians to improve cognitive deficits on overall exam performance as well as in specific medical content areas. Although the pass-fail decision is not based on relative performance to other examinees, this information is provided as feedback so that examinees can understand their performance relative to their peers. Other forms of feedback that are currently under consideration include efficiency of care, performance by site of care, and type of task. The multiple-choice questions portrayed as clinical vignettes are the most cost-effective, efficient, and feasible method for assessing a broad domain area. Patients value and accept certification. Patients expect physicians to demonstrate their skills periodically and most report that they would change physicians in order to be treated by a certified physician. Employers also value certification and many require it for employment or reward physicians at a higher rate if certified.<sup>28</sup>

Examinee performance is continuously analysed to ensure that the scores and pass rates are meaningful and related to other measures of physician competence. Researchers, including those outside of ABIM, continuously examine validity to show whether exam scores and certification decisions are related to other external measures as well as extrapolate to real-world.

### Validity: Relationship with Other Variables

As part of assessing validity the relationship of exam scores with the quality of physician's prior educational experiences and with their peers and supervisors' opinions of clinical competence are examined. Research studies have shown that exam results are correlated with the type of medical school training. Specifically, early research has shown that those trained in US medical schools perform better than those trained in international medical schools followed by graduates of Caribbean medical schools and that the examinees' native language is not correlated with exam performance.<sup>29-31</sup> More recent research has shown that US citizens trained internationally do not perform as well as any other group and that with the growth of international medical graduates in internal medicine their performance is now equivalent to US medical

graduates entering internal medicine.<sup>31,32</sup> The nature and amount of graduate medical education training (formal residency and fellowship training) is related to better exam performance so that those with more training in geriatric and critical care medicine do better than those without formal training or with less time in formal training.<sup>29,33-36</sup>

Exam performance is also related to peer or supervisor ratings of clinical performance. The Resident's Evaluation Summary is a standardised global rating form of clinical competence which programme directors are required to submit annually to the ABIM. Each element has descriptive anchors and is rated on a nine point scale: 1-3 ratings define unsatisfactory, 4-6 ratings define satisfactory, and 7-9 ratings define superior. At the completion of residency training, a satisfactory rating for all components is required for the resident to take the exam. Ratings of clinical competence correlate with exam scores.<sup>37-39</sup> Physicians who change programmes more frequently or have lower ratings of overall clinical competence typically have lower exam scores.<sup>31,35,40,41</sup>

Additionally, exam scores are predictors of peer assessments of clinical performance.<sup>42,43</sup> Complexity of the patient panel and patient volume are related to exam performance for geriatrics, critical care and cardiovascular disease.<sup>33,44-46</sup> Exam scores are also related to professionalism in that higher scores predict a decreased risk for future disciplinary action.<sup>47</sup>

In summary, exam performance is related to many other variables that measure different aspects of physician competence and we take comfort that the relationships are in the expected direction. Yet, the ultimate goal of physician assessment, as described in Miller's pyramid, is to determine whether a physician not only is able to provide the appropriate clinical care but also actually does so in practice.<sup>48</sup>

### **Validity: Relationship with Quality of Patient Care**

Although measurement of clinical problem solving skills is an indirect measure of patient care, the two theoretically should be related. That is, those with better clinical problem solving ability should be

better able to manage patient problems and arrive at correct diagnoses and, in turn, provide better patient care. Research that attempts to demonstrate the relationship between exam performance and patient care is difficult since evidence-based guidelines for patient care do not exist in all areas of medicine and those that do exist are subject to measurement error (i.e., there are not always enough patients per physician to get a reliable and valid measurement). In addition, the methodology is fraught with issues of physician attribution and lack of good risk adjusters to control for differences in patient health and adherence. Since there currently is no universal electronic health record in the US, acquiring the clinical data to do the necessary studies is challenging and costly.

Despite these limitations, some evidence exists to support the link between board certification (sometimes specifically board scores) and quality patient care. A meta-analysis of the literature prior to July 1999 found that of those studies that used appropriate methodology there were 16 findings that showed a positive association between board certification and quality of patient care.<sup>49</sup> Examples include that board certified physicians were more likely to provide preventive care services and show improved outcomes for some measures (eg, lower mean glycosylated haemoglobin levels for diabetics). Board certified surgeons had lower mortality rates for peptic ulcers, but for ruptured abdominal aortic aneurysm the findings were less clear.<sup>50-51</sup> Board certified physicians were more likely to provide recommended prenatal treatments for pregnant women and infants had fewer low birth weights.<sup>52</sup>

Research findings after July 1999 show another 17 studies with positive relationships between certification and quality. A series of studies in the early 2000s in cardiac care in Pennsylvania showed mortality was lower for patients with acute myocardial infarction if cared for by certified physicians in general but in particular if cared for by certified cardiologists; more recently, a very similar study demonstrated a link between board certification and significant reductions in mortality and length of stay in the hospital.<sup>53-56</sup> In paediatrics, board certified physicians had better immunisation rates for poor children seen in private practices.<sup>57</sup> For family physicians in Quebec, board

scores were positively related to some preventive, acute and chronic disease management indices like mammography screening and consultation rate.<sup>58</sup> For midcareer anaesthesiologists, the lack of board certification was related to higher mortality rates.<sup>59</sup> For surgeons, board certification was related to lower mortality and complication rates for colorectal surgery.<sup>60</sup> For geriatric patients with heart-failure and left ventricular systolic dysfunction, certified physicians had a lower rate of questionable prescriptions.<sup>61</sup> For both family medicine and internal medicine, a positive association was found between board certified physicians and rate of preventive care services for Medicare beneficiaries.<sup>62</sup> For cardiac patients hospitalised for acute myocardial infarction, those treated by board-certified internists and cardiologists were more likely to receive appropriate processes of care such as aspirin and beta-blockers at admission and aspirin at discharge than those treated by non-board certified physicians.<sup>63</sup> For patients being treated for high blood pressure, the closer in time to a physician's last board certification the better the quality of care.<sup>64</sup> For internal medicine, board scores were positively correlated with quality indicators for diabetes and mammography screening in Medicare beneficiaries.<sup>65</sup> Likewise, for patients seen in internal medicine practices, better overall chronic care and preventive services for comprehensive care were provided by physicians with higher board scores.<sup>66</sup> For diabetic patients, physicians who provide better care as defined by evidence-based guidelines score higher on exams.<sup>67,68</sup> Data from 23 subspecialty areas for commercial health plans in Massachusetts showed that board certification was related to better performance on 124 quality measures.<sup>69</sup>

### Threats to Validity

Since the ultimate goal is to ensure that a valid interpretation of the scores can be made testing organisations must manage common threats to validity. These include cheating, review courses that 'teach to the test', bias in exam questions that are unrelated to an examinee's knowledge and inadvertently favour one group of test takers over another (eg, males over females), non-standard accommodations, and time constraints. Data forensics helps find aberrant patterns of question responses to discern whether cheating has occurred

and differential item functioning is a type of analysis that can determine whether questions are biased. Computer-based testing centres have become quite good at standardising the testing experience such that the computer equipment and test centres are uniform but situations do arise like unexpected noise or power outages that affect that standardisation and must be dealt with fairly.

### Examination Benefits and Limitations

Additional research is needed to better understand the link between quality of care and exam performance and ultimate board certification. However, the exam's function is to test a physician's cognitive skills and clinical problem solving ability and does not assert to testing technical, procedural, or communication skills. The exam as an assessment tool is meant to complement other assessments that target more directly other competencies such as interpersonal communication skills and practice-based learning and improvement. One of the major benefits of the exam for assessing clinical problem solving skills, as opposed to direct observation or chart audits of the practice, is that the questions on the exam are able to adequately sample the breadth of a discipline in a limited amount of time and examine rare critical problems that do not present in a physician's practice with any regularity.

Physicians express much anxiety related to taking and possibly failing a high-stakes exam and preparation for it is time consuming. Yet, the majority of physicians who have taken ABIM exams report that the content is fair and the testing experience is quite reasonable.<sup>8</sup> Eventually, 95% of those who take the exams pass.<sup>70</sup> In addition, the public expects that physicians undergo periodic examinations,<sup>17</sup> and physicians are obligated through the physician charter to maintain professional competence. The exam helps serve both these purposes.

### Conclusion

Although controversy over taking an exam continues to be voiced, progressive initiatives exist for addressing the concerns (eg, questions are not relevant to 'my' practice or access to medical references during the exam are needed).<sup>71,72</sup> Certifying boards have traditionally defined the discipline areas

in medicine but as physicians tailor their practices the scope of these areas may in fact be changing. Focused recognition in narrower areas may be a way for certifying bodies to publicly recognise this change. Addition of medical references to the exam in a controlled way is a reasonable option as long as the exam can still measure whether a physician has an accurate representation of the clinical problem and can arrive at a correct clinical diagnosis.<sup>72</sup> Other progressive initiatives that are under development include enhancing the fidelity of the exam to mimic real practice by using more audio and video clips, authentic lab reports, and formula calculators.

Changes and enhancements to the examination will continue to adhere to the measurement standards that govern examinations that have so far led to rigorous and fair assessments of clinical problem solving skills. Certification boards should continue to evaluate the role that the examination plays in the quality of patient care and in integrating it into the broader landscape of measuring physician competence.

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# Dr Rebecca Lipner



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She oversees the scoring, statistical analysis, standard-setting, equating, security and evaluation of measurement properties for ABIM assessment products including innovative items types such as procedural simulation.

She also oversees quantitative research analysis ranging from internal medicine workforce trends to health outcomes research. In her previous role as Director of Psychometrics for ABIM, she was involved in the implementation of new programmes in maintenance of certification and computer-based testing.

Dr Lipner was Director of Psychometrics at the Institute for Clinical Evaluation from 1999 – 2001, where she was responsible for managing all psychometric activity for standard setting, scoring, statistical analysis and reporting of examination results. Prior to joining ABIM, she held a variety of teaching and faculty positions at Drexel University, St. Joseph's University and the University of Pittsburgh, where she taught undergraduate and graduate courses in statistics, tests and measurement, experimental design, systems analysis and design, and expert systems.

Dr Lipner received the Research in Medical Education T. Hale Ham Award for New Investigators in 2003. She was also awarded a Sigma XI Research Grants-in-Aid of Research award and The Drexel University Chapter of Sigma XI: First College of Information Studies Prize in 1993.

Her research interests include computer-adaptive testing, Bayesian methodology, high-stakes testing and assessment, univariate/multivariate statistical modeling, experimental design and the use of simulators in medical education. Dr Lipner is a frequent speaker on these subjects and is widely published in professional journals, including the Journal of the American Medical Association, Annals of Internal Medicine, Academic Medicine, Applied Measurement in Education and the Journal of Educational Measurement.

Dr Lipner received a doctorate in Information Systems from Drexel University and a master's degree in Quantitative Psychology from the University of Pittsburgh. She graduated summa cum laude from City College of New York, where she received a bachelor's degree in Mathematics and Psychology. She is a member of the American Educational Research Association, the Association of American Medical Colleges, Generalists in Medical Education, National Council on Measurement in Education and the Association of Test Publishing, where she served as Program Committee Chair and Vice-chair from 2006-8. She currently chairs the American Board of Medical Specialties Psychometric Advisory Group.

# Clinical Audit and Revalidation

## Mr Robin Burgess, HQIP

Clinical Audit is an essential part of being a doctor; hence it is an essential source of evidence for the effectiveness of medical practice through revalidation and related processes. Audit has a long history as the primary means by which doctors and others can assess the quality of their work. Whilst other quality improvement methodologies have appeared the central value of clinical audit has been confirmed by successive requirements issued by the GMC and professional bodies as part of their confirmation of what is required to practice medicine. An overview of the history of audit and its application in the UK is contained in chapter one of Burgess (ed).<sup>1</sup>

Because of this central historical role, when revalidation was first proposed, a requirement that clinical audit activity by the doctor should be a suitable source of evidence for assessment of a doctor's work was immediately suggested. The GMC required a position statement on exactly how audit could be used as such evidence, and they asked the Academy of Medical Royal Colleges to prepare a position paper to set this out. The Academy, as a partner in HQIP, the Healthcare Quality Improvement Partnership, the body commissioned by the English Department of Health to reinvigorate clinical audit, asked HQIP to prepare this paper.

HQIP gathered together representatives from all the medical Royal Colleges and this group, working with HQIP staff, defined the terms on which they felt clinical audit could be used to evidence effective medical practice for the purposes of revalidation. They used a document created by HQIP, itself drafted with the involvement of various clinical leads and experts in audit, 'Criteria and Indicators for Best Practice in Clinical Audit' as the basis for their work,<sup>2</sup> as this sets out a consensus view of best practice in clinical audit and markers of effective audit work.

The group accepted the model of clinical audit set out in that document, which emphasises that clinical audit is explicitly a dynamic quality improvement

process, not simply a measurement exercise. This approach to clinical audit is accepted by nearly all those active in audit policy and practice. The cycle involves four stages:

- Defining the issue and the standards to be assessed
- Measuring current practice
- Acting upon the results
- Re-measuring and assessing continuing adherence to good practice.

See **figure 1**



Having agreed the basic model of what clinical audit should involve, and acutely aware that too much audit practice fell short of this, the group went on to define what good practice really meant, because such definition was essential to make the use of audit work in revalidation a credible source of evidence against objective criteria. The group was agreed that engagement in audit needed to be marked by certain standards and processes, not simple participation or generalised responsibility for audits actually carried out by others. Similarly, taking part in only one part of this cycle was not enough.

Before moving on to define what engagement meant, beyond these first principles, several key issues presented themselves immediately; the first that not all doctors carry out clinical work; the second that much audit work is not individual, but collective; and thirdly that audit results, both positive and negative, did not necessarily reflect the work of the individual doctor and thus could not be used as appropriate evidence for an individual assessment process.

The first issue applied also to various other sources of evidence traditionally used to assess the competence of doctors. It was agreed that for the majority of doctors, those who carried out clinical work, clinical audit represented an essential source of evidence for most doctors to use. The group proceeded to define exactly what would mark out effective audit practice which could be used to evidence the quality of a doctor's work in clinical medicine. In doing so a solution was found to the second and third issues identified.

There was a minority view that good results, in the form of good outcomes, should always be required as evidence. For surgeons, some ophthalmologists, some GPs and others, there is no doubt that individual results, especially where these showed health outcomes from patients and not simple process adherence, show effective practice in a very clear way. It was recognised that where these were available, and the outcomes could clearly be attributable to the work of an individual doctor, there was no reason why these could not be used in addition to evidence of participation, reflection and taking action, and they enhanced the use of audit activity. This was also true where results were very bad, and attributable, although in that case there was a strong view that revalidation was unlikely to be the primary place where such strong evidence of poor practice would be identified.

However the consensus was that audit results were not a prerequisite as evidence, not least of all because for no fault in a doctor's own practice, audit results at the first stage of measurement may not always be excellent, and did not always improve with re-audit, where this occurred. There was recognition that too much external 'noise' in the system – other factors, both local and national - affected audit findings; and that findings reflected the conduct of whole teams. Additionally, much clinical audit

practice reviews the work of teams in which an individual doctor is just one member, perhaps alongside other clinicians. The findings reflect failings (or successes) in clinical practice arising from the work of such whole teams, and affected by factors beyond the individual doctor, or their team, such as local demographic issues, large scale hospital and NHS changes at the national level.

Given these factors, the majority view was that the key point was the need for evidence of reflection and action, whatever the findings. A doctor needed to show that the cycle had been completed – that measurement was followed by action to address any compliance issues, and consideration of the issues raised – in a leadership or collective way. This was more relevant in most cases than showing outcomes.

Hence the solution in the final version was to exclude the requirement that results of audit should form part of the evidence of effective engagement in clinical audit. Instead good engagement in audit could be evidenced through demonstrating three factors: **participation, reflection on the findings and taking action on results.**

The individual markers of these three criteria were then defined, with these overall criteria:

- Doctors undertaking clinical activities must participate actively in high quality clinical audit related to the doctor's specialty. Doctors, including those whose work is not amenable to clinical audit, should also participate in other relevant systematic quality improvement activities.
- A doctor must reflect on the results of clinical audit that relate to their practice or to the care provided by the doctor's clinical team.
- Participation in clinical audit includes the taking of appropriate action in response to the results of audit that relate to the doctor's practice or to the care provided by the doctor's clinical team.

These were then fleshed out in more detail.

### Principle 1: Participation in High Quality Clinical Audit

- The doctor participates actively in local clinical audit.

- The doctor is involved in selecting the audit topic, designing the audit or assisting with data collection, analysis and presentation.
- The doctor attends meetings at which the design and/or results of clinical audit are discussed.

### Principle 2: Reflection on the Results of Clinical Audit

- The doctor reflects on the results of clinical audit.
- The doctor has made reflective notes in their appraisal folder about the implications for them of the results of clinical audit.
- The doctor has discussed the results of clinical audit at peer-supervision, professional development and/or multidisciplinary team meetings.

### Principle 3: Taking Action on the Results of Clinical Audit

- The doctor acts in response to the results of local and non-local clinical audit.
- The doctor has developed, or participated in the development of, an action plan, based on the results of clinical audit.
- The doctor has informed colleagues, including non-clinical managers, of findings of clinical audit and of any action required.

### General points:

- The doctor demonstrates at their appraisals that they have assured the quality of their practice through ongoing participation in local and non-local clinical audit.
- The doctor has presented evidence drawn from clinical audit and re-audit at appraisals that confirms improvement in practice has occurred or that good practice has been maintained.

These generalised criteria also allow for doctors at different levels to evidence greater or lesser degree of participation and taking action. For example the clinical lead for audit in a hospital for example, could demonstrate a degree of participation and leadership not being shown by a doctor three years post qualification having their first revalidation. A doctor who provided clinical leadership to a national audit could show an even higher level of leadership

and engagement in audit, and their reflection on the findings would include detailed analysis of large scale data and the presentation of findings to national or even international audiences of their peers.

As a whole, these general principles allow any doctor, at any stage in their career, to use examples from their audit work as evidence of their competence and professionalism. The process usefully agreed a consensus view within the medical profession that clinical audit is a cycle of quality improvement, and through being such a cycle, participation in all parts of which were needed to show its value and quality for an individual doctor, its value as a source of evidence for revalidation was clearly identified.

It is recognised that to use audit as part of revalidation, doctors require support to improve the way that audit is carried out, as well as good training in clinical audit in their pre and post qualification training and continuing professional development. HQIP operates a comprehensive programme of support for doctors at all levels, which includes the production of guidance in written and online form, either as online tutorials, downloadable resources or more traditional textbooks on clinical audit. We also support the practice of clinical audit through funding of small and large scale clinical audits. HQIP funds clinical networks, by specialty and through regions. HQIP provides specific guidance to junior doctors and supports their work on audit via work with the Foundation Year programme. Additional work includes an awards programme, an online networking tool, and motivational work delivered through a network of clinical champions. Much of this activity is delivered through Royal Colleges and specialist societies, with whom we work closely, to support their own audit work, and to encourage development of libraries of specialist tools and audit topics.

For more information, go to [www.hqip.org.uk](http://www.hqip.org.uk).

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# Robin Burgess



***Robin Burgess has been CEO of the Healthcare Quality Improvement Partnership (HQIP) since its formation in 2008.***

Robin delivered and managed health and social care services in the charitable sector, for addiction problems, between 1987 and 1999. From 1999-2004 he worked in regional and then central government policy and strategy. From 2004-8 he was a local commissioner of NHS and social care services and CEO of a national addiction charity. He has been a board member of several other national charities.

His career has centred on strategy, policy and programme management; promoting and developing best practice, performance management, and quality improvement work.

# Concluding remarks

The symposium was very valuable both in providing a forum for delegates to share what they have been doing but also to learn from each other and hear about the common issues that we have experienced and the challenges for the future. We are left with lots to think about in weeks and months to come.

One of the resounding messages from all delegates, no matter which country they were from, was that the public largely thinks that revalidation/relicensing is already happening. If this is the case, then it could be argued that it should not be a problem to implement. Over the course of the symposium, however, delegates heard that the implementation of revalidation/relicensing is complex and that professional acceptance is not universal. It has been noted that the group of doctors with the least opposition to revalidation/relicensing are doctors in training who are already used to a system of assessments, collecting evidence and meeting with supervisors about their current work. These doctors do not see revalidation/relicensing as a big change.

The words that we choose to convey the concept of revalidation/relicensing really matter and this is important regardless of where the process is being developed and implemented. The public hears one thing; doctors hear another thing. Many stakeholders are seeking to use revalidation/relicensing as a solution or catalyst to address a wide range of issues including better information sharing, performance management, income generation, wider regulatory issues, access to data and/or resources, strengthening training programmes or governance, and better patient engagement. We need to be clear what revalidation/relicensing is and what it is not. In doing so, we also need to be clear about what we mean by excellence, what we mean by competence, evidence and outcomes, and acknowledge that we may not all have the same definition.

Communication is critical as we share our plans, experience and good practice to ensure that we are all on the same page in relation to these issues. Communication of why and how we must introduce revalidation/relicensing is the other theme we must convey clearly to doctors, the public and legislators, making sure that everyone understands what we are trying to accomplish. This is essentially change management and cultural change on a massive scale, and it is much easier to lead the way when those affected can see the benefits at the end of the process.

Time was an issue that came up often in the speakers' presentations, in terms of both the time it has taken to develop and implement systems, and also what the appropriate length of any revalidation/relicensing cycle should be. What is the right number? Should it be 5 years, should it be 10, should it be 15 or 20? One could argue that there is no magic number and each nation will have to come up with what is suitable, fair and reasonable for its healthcare system. The key is not to rush into things as this is a radical change for any country to be implementing. It is essential to make sure you have input from the right stakeholders and, as you move forward, to be methodical whilst also remembering that at some point we must get it implemented as well.

Before the symposium, many of us thought perhaps we could come out of this with one unified global methodology for revalidation/relicensing, but really one of the things that has resonated the most is the notion that we all have a richness of culture that we bring from each of our nations, and it is therefore appropriate for us to have different approaches to revalidation/relicensing.

There are some basic principles which are very apparent in listening to all of the speakers. One is that medicine as a human art is indeed an art – it is not an exact science. The second is the notion of team support, an important factor that we must think about as we focus on the outcomes of an individual, whilst realising that health carers are increasingly part of a team. The other is the sense of medical professionalism and how we assess that.

We have explored a lot of theory but we do need to move into practice at some point and then allow best practices to emerge. Flexibility is important as we develop these programmes, even after we have implemented them to make sure that we are not rigid and that we continue to welcome, and are open to, modifications and necessary changes. We do not currently have a wealth of research regarding these programmes because we have never implemented revalidation/relicensing to the extent we are planning to, and certainly as we implement it we all need to commit to working together and sharing our experiences so that we can build the research to enable us to improve our programmes.

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