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STUDIES IN HEALTH SERVICES

John Fry Fellowship Lecture

Revalidation of Doctors:
The Credibility Challenge

Professor Mike Pringle

The John Fry Fellowship and Lecture

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This paper accompanies the lecture given by Professor Mike Pringle on 8th June 2005, at Cavendish Centre, London.

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John Fry Fellowship Lecture

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On the morning of the 15th December 2004 two vital meetings were held in different parts of London. In its new premises on the Euston Road the General Medical Council met in closed session to discuss its response to the Fifth Report of the Shipman Inquiry¹ led by Dame Janet Smith. Simultaneously, in the Department of Health in Whitehall a summit was convened to discuss the department's initial response to the same report.

That morning the General Medical Council decided that the right policy was to stick by its guns, including reiterating its support for its model of revalidation for doctors, only three months away from being introduced. Simultaneously, the Department of Health decided that revalidation could not be allowed to proceed. Its formal announcement of the Chief Medical Officer for England's review was made two days later².

The effects of these concurrent meetings cannot be under-estimated. Revalidation, that started with noble idealism in 1998, that had been dramatically re-designed in 2001 – a re-design found in Chapter 26 of the Fifth Shipman Report to be not fit for purpose – had been re-affirmed by the body that owned it, and had been terminated, or at least deferred by political power just before it was to be

launched. This was a profound event in British medical history.

In the debate on the future of revalidation the stakes are high. There are two powerful ideologies currently fighting for the soul of British medicine. At issue is whether the new culture of healthcare will be to refine but essentially maintain our long tradition of medical paternalism; or whether it will be to maximise patient care and choice, to protect patients from harm and to promote a patient-centred, patient-led health care system³.

In this paper I will look at the background to the decisions on the 15th December 2004 and will try to offer an analysis of the way forward for revalidation. I will be arguing from the perspective of protecting and supporting patients. I will be talking about all doctors, for an effective system of quality assurance has to apply across the profession, but particularly referring to those doctors in independent practice – consultants and general practitioners.

Before I start, however, I do need to tell you a little about myself, and to offer a working definitions of the term “revalidation” and “licence” that I will use in this paper.

My background

Before I can ask you to accept my analysis, you do need to know something about my credentials. I am, first and foremost, a general practitioner. For over 25 years I have delivered care to my patients in Collingham, a medium size rural practice in Nottinghamshire. I have also been an academic for over two decades and one of my themes has been the promotion, the quality assurance and the recognition of excellence of clinical care, in order to enhance patient outcomes. I was the first ever Fellow by Assessment of the Royal College of General Practitioners, I coined the term “significant event auditing” and introduced it to primary care: it is now embedded in the new General Medical Services contract’s quality and outcomes framework. I was co-chair of the Diabetes National Service Framework, which set out a patient centric vision for diabetes care⁴.

In 1998, the year that revalidation was first proposed by the General Medical Council, I was elected to be chair of the Council of the Royal College of General Practitioners, a post that was, over the next three years, to give me increasing insight into policy development around revalidation⁵. Soon after completion of my term as chairman of the Royal

College of General Practitioners I became that College’s representative on the General Medical Council and then, in 2003, I was elected to the reformed General Medical Council, continuing my involvement in revalidation.

What are revalidation and a licence to practise?

Before I get too embroiled in this narrative I need a working definition of “revalidation” and “licence to practise” since it has become obvious to me that semantics underlie some apparent disagreements surrounding this debate.

Since the General Medical Council coined the term “revalidation” it can claim, as it does, that it means exactly what the General Medical Council wants it to mean. It says that “the purpose of revalidation is to ensure that patients have the confidence that licensed doctors are up to date and fit to practise”⁶, a positive endorsement of their performance. It goes on to say that revalidation identified for further review those whose fitness to practice may be in doubt.

It is not, they say, about identifying poor performance. Yet that is exactly what the legislation introducing revalidation (which refers to revalidation as an “evaluation of a medical practitioner’s fitness to

practise”⁷⁷), Dame Janet Smith and the Shipman Inquiry, and the public at large⁸ think it is about.

My view is as follows. We are embarking on a process that has two components – continuous monitoring and episodic re-certification. Either of those processes can lead to concerns and these will result in either assessment or, if thought sufficiently severe, referral to the Fitness to Practise Procedures of the GMC.

The vast majority of doctors are up to date and fit to practice. The continuous processes will raise no concerns; they will satisfy revalidation’s first stage (the episodic submission of evidence) and their licensure will be continued (the left hand side in Figure 1).

However, let us imagine a doctor who is slipping into under-performance. Perhaps the doctor has developed a tremor that interferes with surgery, an alcohol problem or a depressive illness. Or the doctor hasn’t kept his clinical knowledge base up to date. Or poor communication skills are being compounded by increasing lack of insight.

In a perfect world such doctors would always be detected and dealt with by the continuous process; in the real world many will not be. The episodic submission of evidence will be identified some for further assessment which may even lead to

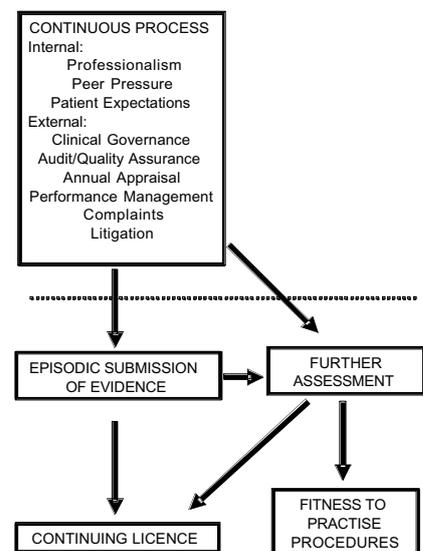


Figure 1: The full system of continuous and episodic quality assurance

the Fitness to Practise Procedures of the GMC. Since the processes are an integrated system of proactive scrutiny I refer to everything beneath the dotted line in Figure 1 as “revalidation”. Thus for me revalidation both identifies those who are up to date and fit to practise, **and** those who are not – and deals with them appropriately.

The outcome of revalidation is a continuing licence to practise. Most would regard that as a licence to undertake the work that they purport to undertake. So a licence to do renal transplants for a renal surgeon; a licence to undertake general practice for a general practitioner; a licence to do dermatology for a consultant

dermatologist; and a licence to offer supervised care for a junior doctor. The essential outcome of revalidation, however defined, is that the public and the profession can have confidence in the licensure of doctors.

This is the credibility challenge referred to in the title – the public will expect revalidation to protect them from poor and under-performing doctors. If it will do so, then let us say so. If it will not, then I would argue that we are wasting our time.

The background to revalidation

In 1975, the Merrison Committee⁹ recommended periodic tests of competency for doctors. The Alment Committee then examined the concept in more detail and in 1976 declared it impractical. The idea was never fully discarded, but it had few friends or supporters for the next two decades.

1998 was to be the pivotal year for revalidation. The General Medical Council's hearing into paediatric cardio-thoracic surgery at Bristol Royal Infirmary was concluded^{10,11}; the second edition of *Good Medical Practice*¹² and the first edition of *Maintaining Good Medical Practice*¹³ were published by the General Medical Council; The Department of Health followed up its overarching

policy document of the year before (*The New NHS: Modern and Dependable*¹⁴) with *A First-Class Service: Quality in the NHS*¹⁵ in which it set out a new commitment to ensuring all patients had better and safer care; and the concept of regular re-certification of a doctor's competency – now called revalidation – was seriously resurrected¹⁶.

The 1998 revolution did not arise out of a void. While I regret that there is insufficient time to explore the foundations of revalidation in full here, I believe that a summary will help to develop my argument.

The promotion and assessment of quality in individual doctors

First I will look at the attempts to promote and assess quality in individuals. The very formation of the General Medical Council in 1858 was the first codification of entry into the profession and the General Medical Council through first its conduct procedures, then its health procedures and finally its performance procedures (now all wrapped together as the Fitness to Practise procedures) has taken a lead in examining evidence concerning individual doctors and acting to protect the public when action was justified. By regulating medical education, the General Medical Council has a major

role in ensuring young doctors are fit to enter the medical register and by setting standards of both ethics and practice it sets the philosophical framework in which competency and fitness to practise can be assessed.

Individual doctors have always been subject to the laws of the land and complaints and litigation have been used by aggrieved patients. They have been exposed to the opprobrium or applause of their colleagues in ward rounds, post-mortems, perinatal mortality meetings and more recently in the “confidential inquiries”. In general practice I have been a protagonist, as I said earlier, of significant event auditing – a system of peer review in which events leading to good and adverse outcomes can be discussed in an atmosphere of quality improvement.

The Royal Colleges have set entry examinations, usually taken well after registration, and these have acted as filters for doctors wishing to progress to independent practice as a consultant or general practitioner. They have traditionally concentrated on knowledge and skills in preference to attitudes and behaviour although this is evolving. The Royal College of General Practitioners has, additionally, defined what it means by excellence in clinical practice – starting with *What Sort of Doctor?*²⁷ and *Fellowship by Assessment*¹⁸, and

then *Membership by Assessment of Performance*⁹.

In the post-1998 world, the NHS has become much more involved in the quality assurance of individual doctors. The one that has most impact has been annual appraisal to which I shall return. Individual doctors now have much greater direction in what care they should deliver through the National Institute of Clinical Excellence’s²⁰ guidelines and technology assessments, and National Service Frameworks. The other major change for individuals – and it applies to only a few – is the National Clinical Assessment Service²¹ (now part of the National Patient Safety Authority) and its system for assessment.

The promotion and assessment of quality in healthcare teams

In more recent times there has been considerable activity to promote and assess the quality of healthcare teams. As hospitals came to deliver care in firms and directorates and as care became more complex – surgical outcomes may depend as much on the quality of nursing in intensive care or of the anaesthetists as to the quality of the surgeons – so measuring outcomes of teams, units or whole hospitals became important. Indeed, developing health informatics has

made it easier to monitor the clinical outcomes of whole hospitals or general practices than to monitor individuals within those institutions. Medical audit²² (promoted heavily in the 1990s) has been renamed clinical audit and then often as quality improvement. It primarily looks at the outcomes of team care.

General practice contracts have rewarded some “quality” activities since the 1965 General Practice Charter²³ and especially since immunisation and cervical cytology uptake rates – quintessentially team activities – were rewarded with target payments in the 1990 contract²⁴. The New General Medical Services Contract²⁵ is the first to be explicitly a “team contract” but this was merely an acknowledgement of the prevailing reality.

Most of the changes of the last few years, since the watershed year of 1998, have been targeted at quality assuring teams. The most dramatic of these is clinical governance²⁶ which combines some aspects of individual doctors’ care, such as complaints or satisfaction surveys, with a predominant emphasis on data from clinical teams such as practices, clinical directorates or whole hospitals.

There are now many assessments and comparisons between teams and whole institutions. Some, such as Dr

Foster²⁷, are in the private sector and use NHS data to inform the NHS and the public. Mainly though such scrutiny comes from the NHS itself, with monitoring of performance targets, Star Ratings, the NHS Litigation Authority, Healthcare Commission²⁸ reviews, and the like.

The new concept of “patient safety” has been promulgated by the National Patient Safety Agency²⁹. The recognition of the importance of system failures was led by the Chief Medical Officer for England with *An Organisation with a Memory*³⁰ and will hopefully, in time, change the culture of the health service. The responsibility of individuals will then be appropriately placed alongside the responsibility for systems that those individuals use in order to effectively protect patients from harm.

However the most significant change from 1998 has been the erosion of the old assumption that leaving individuals and teams to “get on with it” was sufficient. The real catalyst was the Bristol hearings at the General Medical Council and then the Kennedy Inquiry. The chain-reaction was reinforced by a roll-call of shame: Shipman, Ayling, Neale, and Ledwood. The system was clearly not working to protect patients.

International perspectives

Developments in the UK need to be seen in an international context. Our concerns about protecting patients have their echoes elsewhere in the world as other examples of long-term unacceptable performance have come to light³¹. Further, as doctors migrate throughout the world there needs to be international coherence in how we train, register and continually quality assure doctors.

Most other countries, including those in the European Union, do not see the need for re-certification of doctors. Perhaps I should add the word “yet”. The move to re-certification is, so far, mainly a feature of Anglophone countries – the United States, Canada, New Zealand, Australia and Ireland – with Singapore also leading the way.

In some of these countries re-certification is undertaken or is proposed to be undertaken by the registration body, the equivalent of our General Medical Council.

From 1995, New Zealand doctors in independent practice have had to obtain an Annual Practising Certificate from the Medical Council of New Zealand and for this they must demonstrate that they were taking part in continuing medical education and clinical audit. This has

been considerably strengthened since 2001 with each doctor expected to spend at least 50 hours per year on re-certification activities including external audit, peer review of cases, analysis of outcomes and reflective practice³². Doctors can supply their evidence through their College (see below).

The Federation of Medical Licensing Authorities in Canada is proposing a system of re-certification based on demonstrable performance using a three stage process: screening of all doctors; assessment of doctors at risk or in need; and then a detailed needs assessment. Finally registration would be at risk. However there is, as yet, no date for its launch³³.

Also in the design stage are proposals from the Irish Medical Council in which a doctor will need to demonstrate 250 hours in each five years cycle of approved continuing medical education, a peer review of competence and a performance review³⁴.

In some other countries professional bodies – Boards or Colleges – require continuing or episodic evidence in order to retain membership in good standing, which in itself holds rights to practise. In some countries, such as New Zealand where failure to meet the standards of the College results in removal from the Medical Council of New Zealand’s

register, the College is in fact re-certificating the licence to practice; while in others failure of re-certification by a College results in withdrawal of membership of that College with no direct effect on registration.

Let me start with the United States of America where the situation is, perhaps inevitably, complex. The American Board of Medical Specialities, through its member boards, must certify a doctor if that doctor is to be a specialist or sub-specialist. So failure of re-certification does not remove registration *per se*, but can remove the doctor's main source of livelihood. The American Board of Medical Specialities started with re-certification solely by examination. However It is moving to a system called Maintenance of Certification involving evidence of professional standing (peer assessment), self-assessment, lifelong learning (typically 300 hours of approved continuing education over 7 years), an examination of knowledge and attitudes (including ethics and professionalism), and auditing of performance including of communication and professionalism^{35,36}. This is clearly the most comprehensive approach and stands in a category of its own.

Some Colleges – the Royal Australian and New Zealand College

of Obstetricians and Gynaecologists³⁷, the Royal New Zealand College of General Practitioners³⁸, the Royal Australian College of General Practitioners³⁹, The Royal College of Physicians and Surgeons of Canada⁴⁰, The College of Family Physicians of Canada⁴¹ – have a long track record of 3 to 5 year cycles of re-certification based on points for taking part in audit, continuing education and other professional activities such as teaching and research. The College of Family Physicians of Canada's evolving programme requires evidence of reflective practice – audit and education linked in a quality improvement cycle and the Royal College of Physicians and Surgeons of Canada additionally requires accredited self-assessment, and structured learning with outcomes achieved; these latter two appear particularly innovative and credible.

Another approach is that of the College of Physicians and Surgeons of Ontario which introduced in 1980 a system for peer assessment of both a random sample of their members, anyone thought to be at risk, any doctor requesting an assessment and all doctors reaching 70 years of age. The assessment includes the physical environment, the medical records and, through case review, the quality of patient care⁴².

My conclusions from this summary of the international position will be included in my discussions of ways forward. Suffice it to say here that the UK is at or near the leading edge in re-certification but that we do not appear to have taken the lessons from abroad fully to heart in our discussions of policy options.

A partial history of revalidation in the UK

I will not attempt to provide a blow by blow account of the development of revalidation. For that I can recommend Chapter 26 of the Fifth Report of the Shipman Inquiry. I can however give a personal perspective.

In 1998 the Royal College of General Practitioners was asked by the General Medical Council, as were the other Royal Colleges, to lead on filling in the gaps in revalidation for general practice. We worked on this with the General Practitioners' Committee of the British Medical Association, the General Medical Council itself, and lay people. We first took *Good Medical Practice* and in a team led by Professor Martin Roland we wrote and consulted on *Good Medical Practice for General Practitioners*⁴³. This expanded on *Good Medical Practice* and crucially defined a range of characteristics that we felt described

an unacceptable doctor as well as an excellent doctor. This was a vital first stage in defining the standard expected for revalidation.

Then, again with a broadly representative group including two senior officers of the General Medical Council, we wrote a document describing a system for revalidation in general practice⁴⁴ – well received on consultation – and a core document called *Criteria, Standards and Evidence for Revalidation of General Practitioners*⁴⁵. Although first written in 2000, we have kept this document up to date. The Royal College of General Practitioners consulted on it in the autumn of 2004 with wide support from the profession and interested parties.

By 2000 we had achieved, I believe, a high level of consensus on both the general methodology and the standards for revalidation in half the profession. The process is outlined in Figure 2:

In essence every doctor, in hospital or primary care, would submit a folder of evidence, much of the evidence gathered for appraisals and through clinical governance, to be assessed against the *Criteria, Standards and Evidence* (based on *Good Medical Practice*) for their discipline. The folder would be assessed by at least three people including a clinical peer and a lay

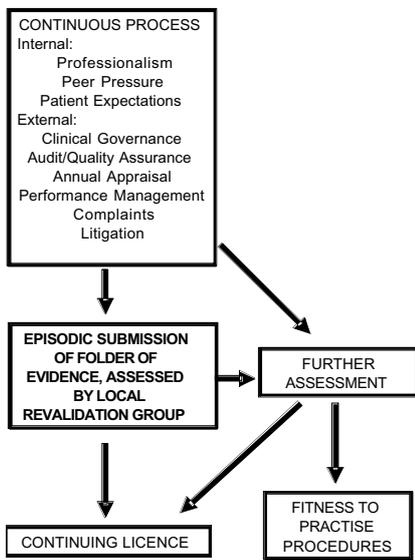


Figure 2: The original model of revalidation pre-1998

person. If they recommended revalidation the General Medical Council would normally continue that doctor’s licence for a further five years.

Everything started to change, however, in April 2001 when the Royal College of General Practitioners’ group was stood down on the recommendation of the representatives from the General Medical Council. It was at this time that the “five appraisals” route was first adopted⁴⁶ for doctors working in General Medical Council approved managed organisations (code for the NHS and large private providers). This became the “appraisal and clinical governance” methodology

which became General Medical Council policy in May 2003 and is still the General Medical Council’s preferred option for most doctors. In essence it is as shown in Figure 3.

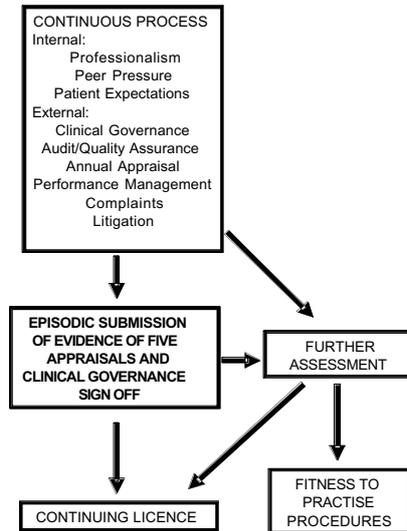


Figure 3: The appraisal and clinical governance system of revalidation for doctors in GMC approved organisations

What changed? Well, the routine submission of folders was jettisoned, with only a small sample being examined. The lay input to assessing evidence went too. *Criteria, Standards and Evidence* disappeared for most doctors, only to be used in the “further assessment”. The essence of revalidation became the ability to satisfactorily manage five appraisals and to avoid coming to the attention of the clinical governance team.

There is no doubt that there was a shift in policy in the spring of 2001.

Why it occurred is for others to say; but I believe that this was when principles gave way to pragmatism and the seeds of the current debacle were sown⁴⁷. Right from my first opportunities, I have argued that this was an error of judgement, and I will continue to do so in this monograph. My reasons for doing so will become more apparent in my discussion of the ways forward.

Options for the future of revalidation

In this section I will look at each of the tension points, as I see them, phrased as a series of ten questions and, based on the account given so far in this monograph, offer ways forward.

Question 1: What is the purpose of revalidation?

It might seem bizarre that this question would need asking. If there is no clear consensus answer by now, then what have we been doing for the past seven years?

The sad reality is that there are two clear cut answers to this seminal question. The prevailing answer is that it is to affirm that the vast majority of doctors are up to date and fit to practice.

The credibility of this position lies on the specificity and sensitivity of

the episodic submission of evidence (Figure 1). If it can identify with reasonable accuracy and precision those doctors who are under-performing then the affirmation of a doctor as fit to practise will have some meaning to doctors, employers and, most importantly, patients and the public. This was, of course, one of the foundation principles of revalidation as set out by the General Medical Council in 2000 – it must be effective in sorting out those who are fit to practise from those who are not⁴⁸.

I have heard the argument, as you will have, that the continuous process will be so efficient that no under-performing doctors should need to be identified at the five-yearly revalidation. That, by inference, means that revalidation need not be an effective detector of under-performing doctors since none will get there. In that case I would argue that there is no function for revalidation and we should scrap it. It will add nothing to the identification of fitness to practise.

So the credibility of revalidation depends on whether it can detect, with reasonable accuracy (no system will be 100%) under-performing doctors who have slipped through the continuous system net. As I will argue, the current “clinical governance and appraisal” method of revalidation

will definitely not achieve that role with any degree of credibility.

Before I make that case, I wish to return to this question: what is the purpose of revalidation? I believe it is primarily to protect the public from under-performing doctors. In doing so, revalidation will reassure the public, employers and the profession that those with a licence to practise are fit to practise. To achieve this all the aspects of the overall system (Figure 1) must work effectively; and in particular revalidation must be fit for purpose.

Question 2: Is annual appraisal a good foundation for revalidation?

In the current proposals from the General Medical Council a key element of revalidation is evidence that appraisal has been undertaken effectively; in other words, that the doctor has had annual appraisals and has taken part in the process positively. These appraisals are usually a one-to-one discussion between a doctor and a peer, in hospitals this peer is often the head of the clinical directorate. There is usually no third party present and certainly not lay input.

My experience of appraisal is as follows. I have been trained as an appraiser and I have trained doctors in how to be appraisers and how to be appraised. I have experienced

appraisal by a GP colleague and, in my capacity as an academic, I have been appraised by more senior academics. As Head of School I am also asked to be an appraiser, with an NHS colleague, of clinical academics, including consultants, on behalf of the university.

For my appraisals, I have found the preparation for appraisal and the reflection involved useful. I have, however, not found the appraisal itself rigorous or searching and was I a poorly performing doctor I would not find it a difficult hurdle. The formative nature of general practitioner appraisal – a principle I whole-heartedly support – may account for this.

However when attending appraisals of consultants on behalf of the university I have seen no evidence there that performance was being assessed. No clinical audit information was disclosed, no outcomes measured. Almost all the discussion concerned the content of “programmed activities”. The NHS manager wants to ensure productivity and flexibility and I am concerned that the academic activities of the consultant are maximised.

The most concerning characteristic of appraisal in this debate is that it is completely free of any explicit standards. There is no attempt to define minimum standards

other than the taking part in the process. Even the idea that if an appraiser finds unacceptable practise he or she should stop the appraisal has never been associated with any definitions.

The only report on the working of annual appraisals in the UK that I have been able to find was published in Wales and covers General Practitioner appraisals in 2003/4⁴⁹. There were no reported cases of an appraisal revealing under-performance. This might, of course, be because there are no under-performing general practitioners in Wales. Or it might be that appraisal is the wrong tool to use to detect under-performance unless volunteered by the doctor in a moment of catharsis.

While I believe that appraisal can be a useful formative process that can be used to generate evidence for revalidation, it could not be and probably never will be a robust foundation for a system of revalidation that commands the respect of the profession and the public. The idea that five appraisals alone, as conceived in 2001, would offer a reasonable method for revalidation is patently absurd, yet it still permeates the thinking of those who support the current General Medical Council proposals.

Question 3: Is clinical governance, alone or with appraisal, an appropriate tool for revalidation?

I was pleased when the “appraisal route” to revalidation became the “appraisal and clinical governance route”, mainly on the grounds that anything was an improvement. I believe that clinical governance will, in time, become a very useful keystone in revalidation. But either alone or with annual appraisal, clinical governance is not, and will never be, a revalidation methodology that is fit for purpose.

My reasons are as follows. The application of clinical governance in the NHS is still variable and its presence outside the NHS is even more erratic. To rely on a system that is in early development and has not bedded-in would be, in my view, unreasonable. This is compounded by the variation between Trusts – primary care and acute – in how clinical governance is managed.

As I explained earlier, the focus of clinical governance is partly on individual doctors through complaints, patient surveys and significant events. But its main focus is on teams, often large teams or whole organisations.

Since revalidation is about quality assuring individual doctors, we need to be certain of the robustness of those parts of clinical governance as

they pertain to individuals before we trust it as a main element for revalidation. And again there are no explicit standards for the clinical governance sign off: the implicit understanding is that clinical governance leads can recognise the threshold of under-performance without guidance or training.

The most powerful argument against relying on clinical governance and appraisal is that there is a logical inconsistency in doing so. Since these two systems are the cornerstone of the continuous processes of the NHS, any under-performing doctor not detected by these continuous processes will not be detected through revalidation. In this model, revalidation is no more rigorous or effective than local processes and the outcome will be, naturally, that no doctor will be found to be under-performing by revalidation.

In the early years of revalidation this will be a vindication of the use of the continuous processes; in later years the illogicality would be exposed and the whole charade of this method of revalidation exposed. Again I ask: why put in place a methodology for revalidation that offers no more assurance to the public than current continuous processes. Not only would it be a waste of time and effort, but it would further erode the public's confidence in medical regulation.

So clinical governance offers promise, as yet unfulfilled, but cannot alone or in combination with appraisal be relied on for revalidation. However it can, as with appraisal, be used as a way of gathering information that can be used in the revalidation assessment.

Question 4: Is more than appraisal and clinical governance required for revalidation?

My answer is, of course, unequivocally "yes".

But what? I am very struck by the approach of the College of Physicians and Surgeons of Ontario which uses peer assessment of the performance of a sample of their members. However I would only support such a system here if it applied to every doctor and it included lay input; that would be impractical.

I return therefore to the requirement for clinical audits of the care delivered by that doctor; adequate standards of care shown by those audits; and continuing education, linked where appropriate to the evidence from the audits. This is both similar to the approach of the College of Family Physicians of Canada and to our own *Criteria, Standards and Evidence*.

I use the term "clinical audit" to include both case-based audits – significant event auditing in primary

care – and audits of cohorts of patients looked after by that doctor. These data can be used to demonstrate a range of skills and standards of care, and the doctor’s reflection on them.

It is my expectation that each doctor would develop a folder of evidence through their appraisals and involvement in clinical governance. But the folder itself would be assessed – all folders would be assessed – against clearly defined standards, criteria and evidence. For the avoidance of doubt I will illustrate this last point.

There is a statement in *Good Medical Practice* that says: “you must keep your knowledge and skills up to date throughout your working life”.

Good Medical Practice for General Practitioners elaborates on this, offering a number of definitions of an unacceptable general practitioner including that such a doctor has little knowledge of developments in clinical practice; has limited insight into the current state of his or her knowledge or performance; rarely attends educational events or chooses ones which do not reflect his or her learning needs; reads little and is heavily reliant on trade press for information; and does not audit care in his or her practice, or does not feed the results back into practice.

Then, *Criteria, Standards and Evidence* contains:

Criterion 9: The doctor in clinical practice maintains skills in cardio-pulmonary resuscitation.

Standard 9: The doctor can demonstrate continuing proficiency in cardio-pulmonary resuscitation.

Evidence 9: Evidence of proficiency in cardiopulmonary resuscitation, for example a certification of competence issued at an appropriate course annually over the last five years.

This approach allows for objectivity and transparency in assessment and it allows lay input. In my view a revalidation folder should include:

- A statement of what the doctors does
- Evidence that the doctor is fit to practise those activities, including:
 - Certification of having effectively taken part in appraisal,
 - Certification of meeting local standards for clinical governance and that there are no local concerns,
 - The results from case-based and conventional audits,
 - The doctor’s reflective continuing professional

development within an annual personal development plan,

- The views of patients and colleagues (360 degree assessment) including complaints and their outcome,
- Certification of technical skills required for the doctor's role (such as communication skills, medical record keeping and cardio-pulmonary resuscitation),
- Self-certification of health and probity,
- Other speciality specific evidence as required

If there are concerns that this sounds onerous, I can reassure you. This material is available for doctors whenever required in most general practices with the exception of the views of colleagues – and that is because the General Medical Council still has not published its questionnaire. I cannot speak for hospital doctors, but I see no reason why they cannot meet these requirements as well.

Question 5: What is the role of a knowledge test?

Competency is the potential ability to apply appropriately – through the use of judgement and communication – knowledge, skills, and attitudes. This is what a doctor can do in a perfect world. Performance is what the doctor

actually does in this imperfect world. “Performance could be thought of as being competence minus distraction”⁵⁰. Knowledge is, therefore, one dimension to competency and competency is a requirement for performance.

If we assess performance we are assessing knowledge, which is an essential pre-requisite, but we are also assessing the doctor's application of that knowledge. However, there is another argument. Since many under-performing doctors have poor knowledge and it is relatively cheap and simple to measure, inclusion of a knowledge test within a multi-dimensional assessment would strengthen revalidation. A knowledge test is a key element of the GMC's Fitness to Practise procedures where performance is in doubt.

My view is that over-reliance on knowledge tests would be a serious error; using them as one element of revalidation might be reasonable. However, I would need evidence on its effectiveness, and I know of no such evidence at present. And any case for direct assessment of knowledge might equally apply to technical skills, such as surgical or communication skills, and attitudes.

Question 6: What should the role of lay people be in revalidation?

I regard this as crucial. If revalidation is to have credibility with the public, and even in time to earn the trust and support of the public, there must be effective lay input at all levels. The first part of revalidation, which I argue here should include the examination of a folder from every doctor, should include lay people, suitably trained. It is important that they retain a non-medical perspective, and therefore we may need to use each of them for limited periods – say five years at a time.

The further assessment of those who do not satisfy the revalidation group's assessment of their folder should include lay input. The Fitness to Practise procedures already include lay people. The changes in April 2001 effectively excluded lay involvement in the process of revalidation for the vast majority of doctors. This must be corrected.

Question 7: At what level should revalidation be set?

There are several possible answers. Currently revalidation is “set”, in the final outcome, at the level of the Fitness to Practise processes. If revalidation is set higher than the Fitness to Practise level many doctors who initially appear to be under-performing will not be found to be so

in the end, especially since the Fitness to Practise test is regarded by the President of the General Medical Council himself to be “remarkably low”⁵¹.

An alternative is for revalidation to be set at the level of a newly registered doctor. This would, in my view, be very similar to the notional level of the Fitness to Practise procedures.

The third option is to expect a doctor to be performing at the level of entry into their current post. For a consultant or general practitioner this would be the level of their College's examination; for a second-year foundation-scheme doctor it would be at the level required for registration.

This would be what most members of the public would expect. If they consult a dermatologist in out patients they would expect revalidation to have assessed that doctor's fitness to practise as a dermatologist. It is entirely appropriate, therefore, that the level of revalidation should be at the level of the specialist qualification.

The prime objection to this is that setting such standards would be too complex for a single national organisation such as the General Medical Council. It is therefore easier to re-license all doctors who do not

fall foul of the very low levels of the fitness to practise procedures.

However, I will shortly offer a way to achieve this through the Colleges. Meantime, let me reiterate the principle: the need to protect the public and have a credible system for revalidation requires that we revalidate doctors for what they do at the level required for that role.

The logic would then be that revalidation maintains a licence for the role and the Fitness to Practise procedures maintain or remove the basic medical licence required for supervised practice.

Question 8: Should the General Medical Council be the body to oversee revalidation?

My preference has always been for the General Medical Council to be, as the guardian of the register, the body to administer revalidation. It has never intended to do so alone. The Colleges, by writing their versions of *Good Medical Practice* and *Criteria, Standards and Evidence* for their disciplines have a key role in deciding standards for revalidation; the local employers and peers have key roles in the continuous processes locally. But I have always seen the General Medical Council as the conductor of the revalidation orchestra.

My confidence in the General Medical Council's ability to deliver a

credible form of revalidation was shaken when its revalidation steering group and its programme of pilot studies was abandoned three years ago. It has been further eroded by the continuing support for a system of revalidation that would not protect the public and the lack of clarity around the content of the assessments that follow on from the initial stage of revalidation.

Recently a number of folders of evidence from senior doctors were examined by the General Medical Council. There have been no recent pilots on folders from "real" doctors. We have been promised a report on 360 degree peer assessment but by 1st April 2005 – the date when revalidation would have come in – no report has been presented to the Council.

Now the General Medical Council, after the date on which they intended to introduce revalidation, is proposing a larger pilot study⁵². This conversion back to basing revalidation on pilots and evidence is, in my view, too little too late.

We are now seven years after the 1998 watershed and there are numerous un-resolved questions of principle, substance and detail on revalidation. In an atmosphere in which expectations have been raised, regulation is under the microscope, patients are at risk and medical

careers are at stake, it seems to me unacceptable that revalidation is being pursued so unsatisfactorily.

If the General Medical Council continues to promulgate a system of revalidation that is not fit for purpose and which lacks credibility, and if it continues to fail to manage the process effectively, then other bodies should conduct revalidation.

Question 9: What should be the role of the Colleges in revalidation?

What other bodies could credibly conduct revalidation? Building on the New Zealand and USA experience, the only other obvious route would be through the Royal Colleges. In this model the Colleges would set the criteria, standards and evidence required for revalidation (as most already have); the Colleges would organise the local examination of folders including lay input; the Colleges would undertake further assessment if required; and each College would decide if a doctor continued in membership of that College.

If membership in good standing of a College were a requirement for practising as an unsupervised doctor – a consultant or a general practitioner – then a College’s failure to certify a doctor as a member in good standing would mean withdrawal of the right to practise in

that discipline. At every stage there would need to be real and effective lay input. A College-based system would, of course, require legislation, but I cannot see any other practical impediment.

Could we trust the Colleges? My response is, and I am of course heavily biased, that I would prefer to trust the Colleges, with their long tradition of standards setting and examinations, rather than the General Medical Council. But trust would not be enough. I would propose that the General Medical Council would hold the key function of quality assuring the Colleges’ processes. The management of the re-accreditation of membership in good standing and, through sampling of folders, the quality of decision making would be signed off by the General Medical Council.

Clearly this solution would not deal with doctors in training or long term supervised practice. There are also a few doctors, health informaticians for example, who do not fit within the conventional College system.

Finding a suitable solution for these doctors seems to me to be well within our capacity. I would not want to pre-judge what solution might be best, but the General Medical Council might revalidate these doctors, or the College’s might run schemes for

associate membership in good standing.

Question 10: So what does my final model look like?

The best way that I can draw this together is to describe one theoretical doctor's journey through a future career in British medicine.

At 19 years of age, this doctor enters medical school where the curriculum and assessment processes are periodically reviewed and approved by the General Medical Council. The university tests him and the General Medical Council gives provisional registration. After the first foundation year the university certifies the young doctor as competent for that stage in their career, and the General Medical Council grants a full licence to practise.

Five years later the first revalidation point arrives. The young doctor – he is now aged 30 – is in training to be a gastroenterologist. He is an associate member of the Royal College of Physicians. His folder is assessed by a panel from the Royal College of Physicians that includes one or more lay people. He passes with flying colours and continues to be an associate member of the Royal College of Physicians.

By the age of 35, he has passed the MRCP examination, been registered

as a specialist, and is looking for an appointment as a Consultant Gastroenterologist. He submits his folder to a panel at the Royal College of Physicians who confirm he is fit to continue to be a member in good standing.

The next two revalidation assessments are satisfactory. But the time he is aged 50, this doctor is a consultant in a major district hospital, attends a community hospital and has a moderate private practice in a local private hospital. There have been some complaints about his attitude and communication skills in the district hospital but then complaints are common anyway. One episode of not attending his clinic has been explained as an administrative mix-up. Colleagues see him as “coasting” but no red flags have been raised by clinical governance.

In the community hospital they are much less sanguine. He is unpleasant to team members and doesn't inform them of his clinical decisions. There have been a number of informal patient complaints about his attitude but only two full complaints. Even when clearly in the wrong, he was unwilling to apologise. The Community Hospital fears that if he leaves he might not be replaced and the service will disappear.

The private hospital has had only one significant problem with this

doctor's performance. He recently missed a cancer when doing a gastroscopy – the cancer was picked up a few days later when a colleague had to repeat the procedure. Nobody was surprised. Our doctor was known to be a bit slap-dash.

However, the doctor's revalidation folder which included all informal and formal complaints, patient surveys, the views of colleagues and reports from the clinical governance leaders in all three settings, demonstrated a likely pattern of increasing poor performance. Further assessment by the Royal College of Physicians confirmed this and he was offered a period of support and re-training.

However, at the end of this period The Royal College of Physicians finds it cannot issue a certificate of membership in good standing. This has three consequences. The first is that the doctor can no longer practise unsupervised. The second is that a full assessment maps out what needs to occur for him to return to membership in good standing. And third the General Medical Council reviews him with a view to deciding whether fitness to practise procedures is required. Any return to unsupervised practice would require the approval of the General Medical Council and might require revalidation in a reduced interval.

In this case it can be seen that I visualise revalidation as a partnership between the General Medical Council, the Royal Colleges, the NHS, employing organisations and lay interests, with the key objective of protecting the public and ensuring that a revalidated doctor is fit to practise the work they undertake.

Conclusions

In this paper I have agreed with Dame Janet Smith, as she set out in her findings in the Fifth Report from the Shipman Inquiry, that the current system for revalidation, as proposed by the General Medical Council, is not credible because it is not fit for purpose. I have described what I believe needs to be put in place in order to develop a methodology for revalidation that is credible and would adequately protect the public. To continue with a system that was not credible with the public would merely reinforce the commonly held view that the General Medical Council exists to protect doctors at the expense of patient interests⁵³.

The system for revalidation that I have described here is based on each doctor in whatever branch of medicine submitting folders that are assessed against clear criteria, standards and evidence. That assessment must include lay people

and it must be externally quality assured. Continuous local processes must be used to identify and deal with under- and poor performance; but revalidation cannot rely on those alone to achieve a credible outcome.

I have concluded that if the General Medical Council is not prepared to instigate a credible system for revalidation, then the Colleges should be given the task. I have described how such a system might work. It relies on independent practice requiring “membership in good standing” with the medical licence as a lower test of fitness to practise as a supervised doctor.

I must return to the challenge I set at the beginning. I said that there are two powerful ideologies currently fighting for the soul of British medicine. This may have sounded over-dramatic. But I hope I have illustrated the nature and importance of that fight.

The expedient outcome is to agree a system of revalidation which will not threaten the livelihood of doctors, will not therefore identify poor-performance and will pass the buck to local clinical governance systems to “sort the problem out”. The public’s confidence in such a system would be gained through a united face, with the General Medical Council, the British Medical Association and the Department of Health all saying that

the emperor’s clothes were the finest they had seen. This façade would collapse when the first under-performing, but revalidated, doctor was identified. The public’s reaction is easy to imagine.

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

We have a once in a generation chance to do something that will transform the quality of patient care, protecting them from unacceptable doctors. It is in our gift to create a new culture of healthcare that will maximise patient care and choice, protect patients from harm and promote a patient-centred, patient-led health care system. If we fail this challenge, public trust in doctors will be significantly eroded and we will lose the right to professional involvement in medical regulation.

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Published by
The Nuffield Trust
59 New Cavendish Street
London W1G 7LP

Telephone: 020 7631 8450
Fax: 020 7631 8451

Email: mail@nuffieldtrust.org.uk
Website: www.nuffield.org.uk

ISBN: 1 905030 08 8

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