GMC and the future of revalidation
Failure to act on good intentions

Aneez Esmail

The GMC's response to rapidly changing attitudes towards the medical profession seems to have been to bury its head in the sand

Editorial by Baxter, and p 1139

This is the first in a series of articles examining the regulation of doctors

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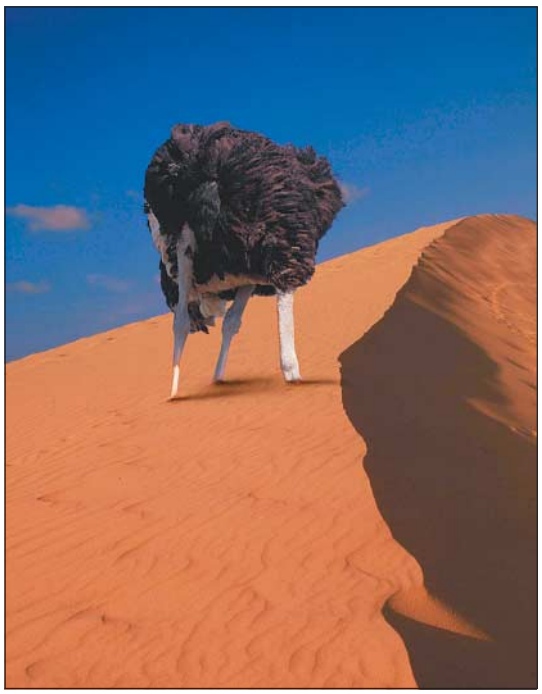
As a result of the Shipman inquiry, the chief medical officer of England has been instructed to carry out a review of the General Medical Council's proposed system of revalidation and reassess its role, structure, and functions. If the inquiry's recommendations are implemented it will result in the most far reaching reforms ever envisaged of the GMC. Much of the commentary in the medical press about the recommendations has been fairly negative, and because of the nature of the inquiry and the fact that it has now completed its work, it is difficult for the chairman to respond publicly to criticisms. Although I cannot speak on behalf of the chairman, I was her medical adviser and am therefore able to explain the thinking behind its recommendations. In contrast to many doctors, I believe that the reforms will strengthen the GMC, preserving self regulation but crucially offering the public and doctors better safeguards.

Findings of the inquiry

The GMC had never been subjected to such an in-depth scrutiny by a public inquiry. Thousands of pages of evidence, mainly provided by the GMC, were considered, and the processes relating to their new fitness to practise procedures and revalidation were put under intense scrutiny. Surprisingly, the GMC admitted that it had serious deficiencies. In his opening statement to the inquiry, the GMC's counsel gave an overview of these deficiencies, which covered the operation of procedures, the consistency and quality of decision making, and the way that procedures were developed and operated. Admission of such fundamental inadequacy will give little solace to any doctor who has been brought before its fitness to practise procedures and felt that they had been wrongly disciplined or any patient who has had complaints against doctors dismissed.



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Like the ostrich, the GMC needs to get its head out of the sand

What has the GMC, the main regulatory body, been doing all these years? It is not as if these criticisms are new. In many instances the GMC's internal reports going back nearly 10 years exposed these deficiencies and made recommendations for change. A cynic would argue that it decided to admit its faults at the beginning of the inquiry because it recognised the depth of the criticism that would ensue from the detailed examination of its procedures and operation.

The GMC seems to have adopted a similar approach in relation to revalidation—admitting that the review imposed by the Department of Health was welcome while trying to justify its own position. Does this suggest a real desire for change within the organisation? In my view, the GMC has nowhere to go but down. This decline has two phases. The GMC realises that the modern world is running away from it, and it hopes that by reasserting its views it can re-create the time when its orthodoxy was accepted by all. Even its critics admire its refusal to compromise with reality. However, the pretence can't last forever, and the gulf between what it says and what everyone else thinks will becomes so preposterous that it will be forced into the second stage of decline when it must reform or die.

Many doctors, encouraged by the views of organisations such as the BMA and some of the royal colleges, are also fearful, believing wrongly that the inquiry wants all doctors to undergo some form of examination as a prelude to being revalidated. In her proposals Dame Janet Smith was clear that the main platform for revalidation should be the preparation by each doctor of a folder of evidence that shows what a doctor has been doing in the past five years. This would include information on prescribing, audits that they may have carried out, record reviews, and some form of 360° appraisal including feedback from patients. She pointed out that evidence presented to the inquiry suggested that no doctor can function well unless his or her knowledge base is adequate and kept up to date. The fact that a knowledge base is satisfactory is not in itself a guarantee that the doctor is practising well. She suggested that the revalidation folder should include a certificate of a satisfactory completion of a knowledge test taken at some time within the past five years; the test would be taken in private and doctors would be

Revalidation in the UK

Zosia Kmietowicz

Revalidation was first proposed by the General Medical Council in 1998 as a way to win back the trust of the British public after a series of medical scandals. The GMC, which regulates UK doctors, said it would ensure that all of the UK's 200 000 doctors were up to date and fit to practise. For the first time every competent doctor in the UK would be issued with a licence to practise. And every five years they would be required to prove that they had kept up to date and continued to perform to required standards or lose their licence.[1]

Why revalidation was needed

In the past the GMC has taken a reactive rather then proactive approach to doctors' performance. It followed up complaints made against doctors but did not routinely check competence. Deficiencies in the way the GMC regulated doctors came to light in 1995 after concerns emerged about three doctors running the paediatric cardiac service at Bristol Royal Infirmary.[2] The GMC began discussing ways of modernising its methods, although revalidation was not universally accepted at first.

Two high profile cases of professional incompetence probably helped to accelerate a move towards licensing doctors. In September 1998, Rodney Ledward, who had worked as a gynaecologist in Kent for many years, was struck off the medical register.[3] He had been known to be delivering care that was below acceptable standards for some years but had been allowed to continue practising. In the same month Harold Shipman was arrested, and his catalogue of killings that stretched back at least 23 years began to unfold.

Initial plans

By February 1999 the GMC voted to introduce revalidation. In June 2000 it published a consultation paper in which it set out the objectives of revalidation and explained how the scheme would run. Doctors would be required to maintain a folder which contained information about how they practised. This could include certificates of postgraduate training, results of significant event analysis, audits, patient satisfaction surveys, complaints, lessons learnt, and results from clinical governance visits.

The folders would be reviewed every year at a doctor's annual appraisal, which has been recently introduced into the NHS for both hospital doctors and general practitioners. In addition, every five years doctors would go before a revalidation panel made up of doctors and lay people. This panel would decide whether a doctor was fit to practise based on the contents of the folder and standards of practice set out by the GMC and the royal colleges. Doctors who could not be revalidated would be referred to the GMC, which would decide whether to invoke fitness to practise procedures, to suspend the doctor, or to issue a licence with conditions attached.

The proposals on revalidation were launched at a time when clinical governance was taking hold in the NHS, and the paper acknowledged that this would provide added protection for patients against poor performing doctors. But it also stressed that neither revalidation nor clinical governance alone was able to identify incompetent doctors at the earliest opportunity. In December 2002, the Medical Act 1983 was amended and revalidation (as defined in the GMC's consultation paper) was enshrined in law.

Modification

However, by April 2003 the GMC had changed its plans. The proposal to evaluate doctors by revalidation panels was dropped. Instead, revalidation would be based on doctors' annual appraisal forms. Provided that they could show they had had five consecutive appraisals doctors would be given a licence to practise before the end of 2004. Then from April 2005 doctors would be required to prove they were fit to renew their licence through revalidation every five years.

The terms of revalidation had also altered. Doctors who worked in a quality assured environment where clinical governance operated and who had annual appraisals could base their application for revalidation on the results of their appraisals. Those doctors who worked outside the NHS would have to collect documents that reflected their practice similar to those described in the consultation paper. The GMC told doctors that they would be revalidated provided there was no evidence that they were not fit to practise.

During the Shipman inquiry, Dame Janet Smith raised concerns that the GMC was equating appraisal with fitness to practise.[4] However, appraisals were not set up to make judgments about doctors' competence but as an opportunity for a doctor to discuss issues of practice and plan improvements and career developments. Her concerns led the GMC to alter its plans for revalidation again. As well as providing evidence of appraisal, doctors would be required to produce a clinical governance certificate signed by a senior officer from the organisation that employed them.

In effect, said Dame Janet in her report, the onus of checking a doctor's fitness had passed from the GMC to the appraiser and clinical governance systems within the NHS. Neither of these systems was fully established. They varied in quality across the NHS, and Dame Janet was doubtful that in its current form revalidation would offer any more protection to patients than that already available.[5] She was also concerned that the public was being duped by the GMC's insistence that revalidation tested doctors' fitness to practise. "The public has been told that revalidation is rather like an MOT test for doctors … It is nothing of the sort," she said.

Revalidation was due to be launched this April, but the publication of the fifth report of the Shipman inquiry[5] forced the GMC to shelve its plans. There were suggestions that new measures may need to be introduced to protect both patients and doctors.[4] A high level review of the GMC's proposals is now being conducted by the chief medical officer for England, Sir Liam Donaldson.

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1 Esmail A. Failure to act on good intentions. *BMJ* 2005;330:1144-7.
2 Dyer O. Hospital banned from doing neonatal operations. *BMJ* 1995;310:960.
3 Dyer C. Gynaecologist showed "lack of care and judgment." *BMJ* 1998;317:965.
4 Shipman Inquiry. *Safeguarding patients: lessons from the past—proposals for the future.* www.the-shipman-inquiry.org.uk/fifthreport.asp (accessed 19 Apr 2005).
5 Department of Health. *Revalidation to be reviewed.* Press release 17 April, 2004 (Series No 2004/0453).

allowed to remedy the situation if they found that their knowledge base was inadequate. This is different from a simple pass or fail examination.

Revalidation and appraisal

It is worth recounting the original purpose of revalidation—namely, to ensure that within the context of medical regulation, measures existed to assure patients that doctors continue to perform effectively throughout their working lives. Central to its purpose was the notion in the GMC's consultation documents that revalidation would "Protect patients from poorly performing doctors who would be identified as early as possible." This was enshrined in legislation through the amendment of the Medical Act 1983 in December 2002.

The GMC's initial proposals for revalidation, first promulgated in June 2000, indicated that it intended to be directly responsible for the revalidation of all doctors. The process would involve an evaluation of a doctor's fitness to practise by a local revalidation group, of which one member would be a lay person. The twin purposes of the initial proposals were to protect patients and the public from underperforming doctors and to improve the quality of health care generally. However, in April 2003, it became clear that the GMC had abandoned the idea of evaluation by a local revalidation group and now intended to revalidate, without further scrutiny, all doctors who had successfully completed five appraisals.

The NHS appraisal system has been designed for purely formative purposes, to provide doctors with an opportunity to think and talk about their work. Appraisers were not trained to, nor was it intended that they would, form any judgment about the appraisee. The appraisers' role was to stimulate self examination in circumstances of complete confidentiality and to help doctors plan their future professional development. The process of appraisal cannot be a basis for revalidation as intended either in the amended Medical Act or by the earlier plans developed by the GMC.

GMC's changing position

All the GMC's problems relate to this fateful decision in April 2003. It was at this point that they lost sight of their aspirational proposals to evaluate doctors' fitness to practise. The current view of the Department of Health and the GMC is that appraisal is an adequate foundation on which to base revalidation.

The Shipman inquiry investigated the implications of these changes. GMC witnesses kept insisting that this was not a substantial change but a refinement of its original plans. In my view, the GMC was trying desperately to present a gloss on how appraisals were going to be enhanced so that they fulfilled the original intention of revalidation. The inquiry attempted to trace the history of the change and discovered that many relevant meetings of the GMC were held in private. This is in contrast to its usual procedure of consulting publicly on important policy issues. It was difficult not to form the view that the GMC was embarrassed about its change and had not wished the public to be aware of the nature of the changes or of the dissent within its ranks.

Despite these fundamental changes to the nature and purpose of revalidation, the public is being given the impression that doctors being revalidated will have to pass some sort of objective test. The GMC drew a comparison between revalidation and the periodic assessments that airline pilots have to undergo. Some senior members of the GMC have informally but publicly given the impression that revalidation is a sort of MOT test for doctors. The MOT is a test of the roadworthiness of an individual vehicle. Various features of the vehicle are examined against specific standards. The vehicle must reach all those standards. If it fails any part of the test, it fails the whole test. Revalidation does not, as currently proposed, incorporate any detailed standards with thresholds by which it is possible to pass or fail. The only threshold by which the doctor can fail is that of being unfit to practise, yet the mechanism by which this is to be determined is totally inadequate. There are no clear standards by which a doctor's fitness to practise can be determined, no objective test, and no independent scrutiny of that test. It is therefore unsurprising that Dame Janet was so scathing about the proposals.

Why the GMC changed its view

In my view three reasons explain why the GMC changed its stance on revalidation. Firstly, it was daunted by the prospect of having to administer a rolling programme of scrutiny of revalidation material for about 30 000 doctors a year. The proposals would undoubtedly have been expensive and onerous. Secondly, the GMC was subject to pressures from doctors' organisations, principally the BMA and some royal colleges. The pressure was exerted from within the GMC as well as from without. The GMC knew that many people were convinced that the direct linkage between revalidation and appraisal was unsatisfactory on grounds of principle. The GMC had been warned that the public would not have confidence in the efficacy of the new proposals and that there would be objection at the lack of lay involvement. Finally, cost was a factor. The GMC's own estimates were that the cost of revalidation would be about £10m ($19m, €15m) a year and that this money would have to be raised from its members.

Inquiry's suggestions for revalidation

Revalidation is supposed to weed out doctors that are not fit to practise. They might be irredeemably bad, in which case they could be struck off, or they may need remediation. No one knows how many such doctors there are, but let us assume that around 3% of doctors are seriously deficient. There will be no perfect test that can correctly identify that 3%, and a good test that attempts to do so will have to identify more than 3% because the consequences of missing a failing doctor are so severe. Appraisal is a blunt instrument and as yet (despite being in operation for nearly three years) has probably not identified a single doctor whose performance is seriously deficient. Appraisal for all doctors is conducted by a peer. Is it right that a single doctor

should have the responsibility to make that judgment about one of his or her peers?

The GMC needs to ensure that the correct standards are set as a tool for assessing doctors for revalidation. Those standards should include detailed guidance on the sort of evidence that should be assessed over five to seven years. The assessment of individuals should take place locally by independent panels, drawing on the knowledge and information available locally to assess if a doctor is practising satisfactorily. For general practitioners, this might include a review of notes, an assessment of a video of a sample of consultations, information on prescribing, and audits of aspects of their practice.

The aim should be to develop a system that correctly identifies the doctors with problems and then refers them to the GMC for further scrutiny. The standards by which the GMC should assess these doctors should be robust and broadly speaking set at the standard at which they gained admission to their specialty. In its current fitness to practise procedures, the GMC already assesses doctors' knowledge and their performance against their peers. However, by its own admission to the inquiry, these standards are currently set too low. Use of these standards for revalidation cannot be right.

The GMC should periodically and randomly assess how well the system is operating through inspection of the local revalidation groups and random checks on individual doctors. Such a process would concentrate on identifying the doctors about whom there was cause for concern and passing the majority of doctors who are practising at the required standards. We know the epidemiology of the doctors at risk from data available to local performance panels and from the GMC's data on fitness to practise. Typically it is doctors who are over 50, are professionally isolated, have a lot of complaints against them, may have clinical negligence claims against them, and may have been referred for health related problems. It's not rocket science.

Revalidation also has immense value for individual doctors. As a practising doctor I would like to be able to show my patients that I am practising at a standard which is safe and up to date. I do not fear revalidation and, like the majority of doctors, would welcome it. We need to view it from the lens of a patient rather than narrow professional interests, and it saddens me that some of the leaders of the profession are using obfuscation and fear to prevent the implementation of a robust system that can have the confidence of the public. Revalidation is not about catching another Shipman or about judges dictating to doctors how they should regulate themselves. It is about safeguarding patients—nothing more and nothing less.

Contributors and sources: AE was medical advisor to the Shipman inquiry, and the article is based on the material discussed in the fifth report of the inquiry together with transcripts of evidence given during the public hearings.
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Summary points

- The GMC's revised plans for revalidation will not detect poorly performing doctors
- The Shipman inquiry's recommendations have been greatly criticised
- Doctors have nothing to fear from the recommendations
- Implementation will ensure a robust system that the public can trust

One hundred years ago

Japanese students

M. Revon, a Frenchman who was for seven years a Professor in the University of Tokio, says that the most characteristic feature of the Japanese student is that he studies. So keen is he about his work that he will read by the light of a cage full of glow-worms if he can get no better source of illumination. He hangs on his master's lips, taking notes with feverish eagerness, and asking innumerable questions after the lecture. So far from having to be urged to work, he rather needs, as Johnson might have said, to be "sufflaminated." One of M. Revon's pupils went mad, and several died as the result of excessive study. Abundant provision is made by the University authorities for gymnastics and other physical exercises; nevertheless, overwork is making Japanese students a race of bespectacled prematurely aged men, foredoomed to consumption. Overpressure begins early and lasts throughout the whole period of studentship. Before entering the University a young man has to go through the secondary and afterwards the higher schools, where in the space of three or four years he learns three or four European languages, besides the general principles of the science to which he may wish later to devote himself. Owing to the length of the curriculum, Japanese are for the most part older than European students; many of them, indeed, are married, and fathers of families. Academic discipline is easily maintained, as the students have the greatest veneration for their teachers, who on their part are always courteous and accessible. Exchanges of hospitality between masters and pupils are frequent, and social intercourse is constant and intimate. The Japanese student has from childhood been familiar with the ancient maxim: "Thy father and mother are as the sky and earth; thy lord as the moon; thy teacher as the sun." These sentiments have been crystallized into a proverb of three words—*Oudji yori sodatchi*, which means education is more than birth. (*BMJ* 1905;i:205)