UK government white paper puts patient safety at the heart of medical practice

On 21 February 2007, the government published its white paper *Trust, assurance and safety—the regulation of health professionals in the 21st century*\(^\text{(1)}\) which sets a framework to assure the safety of patients and quality of care. The paper considers the English chief medical officer Sir Liam Donaldson’s review of medical regulation, *Good Doctors, Safer Patients*\(^\text{(2)}\); the Department of Health’s report, *Regulation of the Non-medical Healthcare Professions*\(^\text{(3)}\); and subsequent consultations with professionals and lay people.

The main areas covered by the white paper are how to assure the safety of patients in situations where a doctor’s performance or conduct pose a risk, the introduction of an effective system of revalidation, and modifications to the role and function of the General Medical Council (GMC).

Patient safety is central to the proposals. At local level the value of attempts to ensure quality in the current National Health Service is recognised. In the current system poor medical performance is dealt with separately by the employer (NHS) and the regulator (GMC). This may result in a “regulatory gap,” whereby a doctor may be providing care that does not inspire the confidence of his or her colleagues and employer but his or her performance is not so poor that referral to the GMC is indicated. Under the new proposals, “GMC affiliates” (senior clinicians) are supposed to bridge this gap by providing guidance to employers on local investigations, and to enter “recorded concerns” against a doctor’s GMC registration. This novel idea, probably too expensive as a local solution, will be piloted in England at regional level.

At national level two key changes are proposed. The first is a standard of proof for adjudicating on concerns about a doctor’s fitness to practise. The previous criminal standard of proof—beyond reasonable doubt—now changes to the civil standard—the balance of probability. This change was proposed by Dame Janet Smith in the fifth Shipman report.\(^\text{(4)}\) The civil standard will be flexibly applied using a sliding scale, with serious cases needing evidence at the level of the criminal standard. Sliding scales, used by other healthcare regulators and the Financial Services Authority, have a credible track record.\(^\text{(5)}\) However, where a doctor’s reputation is at stake some doctors may feel their human rights are being violated. Also, it is the role of those adjudicating to judge the facts against a standard, and there is a theoretical risk that in setting the standard the process of judgment has already started before the facts are heard. The second change is the introduction of an independent panel that will adjudicate cases instead of the GMC and separate the role of investigation from judgment.

Against these local and national changes is a firm commitment that doctors with performance and health problems will be supported, and that options for rehabilitation and retraining will be made available. This is to be welcomed but will require a change in culture from both the profession and the public to avoid defensive practice and a climate of fear.

Doctors accept that revalidation is needed, and half of patients think that it already happens. The chief medical officer’s previously proposed two tier approach of relicensure (to enable doctors to remain registered to practise) and specialist recertification (to maintain the specialist and general practice registers) is endorsed.\(^\text{(6)}\)
The new system of relicensure will be based on the generic standards in *Good Medical Practice*,(7) will involve an annual appraisal, which will now contain a summative element, and any concerns raised by the medical director or GMC affiliate will need to be resolved. A 360° feedback tool (to give feedback on performance from several sources) will be piloted to support the process. Care will be needed to ensure that the valued developmental aspect of appraisal is not lost and that new 360° feedback tools have a positive effect on clinicians’ practices.(8)

Specialist recertification, the responsibility of the medical royal colleges, will be a comprehensive assessment against the standards that apply to the particular medical college. Information required may include clinical audit, simulator tests, knowledge tests, patient feedback, observation of practice, and continuing professional development activities. Standards will need to be set, agreed with stakeholders, and tested by each specialty.

Clarity is essential for individual practitioners as to what information is required for both relicensure and recertification. In terms of how the process might work in practice, doctors have been shown to prefer simple systems that have a clear structure, with support for individuals.(9)

The changes to the GMC are fewer than were initially proposed. Members will now be chosen by an appointment commission, with equal numbers of lay and medical members being appointed. The GMC will be accountable to parliament, but independent from government. Crucially, the GMC’s international reputation and expertise in undergraduate education is recognised and their proposed model of undergraduate, postgraduate, and continuing professional development boards is accepted.

This white paper sets patient safety at the heart of medical practice. Medical regulation has evolved. The professionally led regulation of the 1990s now gives way to partnership regulation with our patients and the NHS. Operational details need to be determined, particularly in Scotland, Wales and Northern Ireland, and many will require legislation. The challenge now is to work with our colleagues, professional groups, and patients to deliver a fair regulatory system that can inspire the confidence of all.

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