

## Editorial

# Safe Medical Practice

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Over the last few years, there has been increasing interest worldwide in the issue of patient safety. At the heart of this debate has been the paradox that as other industries have become safer in recent years (*eg.*, travel, construction, oil, *etc.*), medicine has become less safe. Data from a number of developed countries indicate that around 10% of hospital patients experience some degree of medical error; these range from minor mishaps to fatal mistakes<sup>[1]</sup>. Serious critical incidents are uncommon in any one hospital or clinic. Nevertheless fatal errors are still unfortunately common; such events as giving penicillin to patients with known penicillin sensitivity, or administering intravenous anti-cancer therapy intrathecally continue to be reported on a regular basis and confusion with biopsy specimens still causes some patients to receive an inappropriate operation. These problems arise in the main, not from poor doctors carelessly delivering the wrong treatment to trusting patients, but from failures in the healthcare system that should have sufficient safeguards embedded to protect patients from such inadvertent mistakes. "To err is human" is a fact that all public safety systems must both accept and accommodate.

The numbers of patients harmed, however, are very large and ever increasing. As Sir Cyril Chantler, my predecessor as Dean of the Guy's, King's College and St. Thomas' Hospitals Medical and Dental School, put so succinctly "medicine used to be simple, ineffective and relatively safe, now it's complex, effective and potentially dangerous". So how do we best protect patients? Current opinion is that we should encourage doctors and other health professionals to reflect on their own clinical practice and openly audit mistakes that have been made and "near misses". Such an audit would be confidential and would not lead to disciplinary action even if the doctor or healthcare professional had manifestly been responsible for causing injury to the patient. Without such an open approach the argument is

that doctors will conceal such incidents, lessons will not be learned and unnecessary mistakes will be repeated, putting more patients at risk<sup>[2]</sup>.

This argument is supported by data from other safety-conscious industries such as the airline, nuclear and oil industries and by the deleterious effects experienced by some countries that invoked the criminal law to prosecute doctors involved in some medical accidents. The counter argument is that patients have both a right to know what happened and to appropriate compensation. Confession by the doctor may not in itself be sufficient; poor practice should cause the authorities to consider taking action against the doctor - and that action might be to place conditions on the doctor's practice or even withdraw the doctor's licence to practise altogether.

These issues are currently being debated in all countries with modern healthcare systems<sup>[3]</sup>. The specific problems stimulating this debate differ but the essence of the problem is the same. Within the UK the case of the general practitioner, Harold Shipman, who was convicted of murdering 15 patients but suspected of murdering more than 250 patients, has stimulated public, professional and political interest. A public enquiry lasting more than three years and costing in excess of £25M produced six reports and a series of recommendations. Around fifty recommendations were specifically directed at the General Medical Council (GMC). More than two years ago, the government invited the Chief Medical Officer (CMO) for England to explore the issues of patient safety, the recertification of doctors and the future composition and role of the GMC; that report was submitted in the summer of 2006 and the government's response is expected early in 2007.

The General Medical Council (GMC) is the regulatory authority for all doctors in the UK. Established in 1858 as the Council for Medical Education and Registration, its statutory remit is "to protect, promote and maintain the health and safety of the public" by promoting proper

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standards in the practice of medicine. We do that through four linked functions: setting standards of practice, determining the quality of medical education, assessing when necessary a doctor's fitness to practise and ensuring that all doctors working in the UK are registered.

Our recommendations *Good Medical Practice* indicate clearly the standards that we expect of all doctors. Revised in 2006, these recommendations have been accepted by patients, politicians, the profession itself and adopted by many countries around the world. They do not describe excellent or exceptional practice but the standards patients have the right to expect from all doctors on a daily basis. That guidance forms the basis for our educational recommendations and for our fitness to practise (disciplinary) procedures. In education, we have the statutory duty of "promoting high standards in, and coordinating all stages of, medical education". For undergraduates, we work with and regularly inspect the Universities and Medical Schools to ensure that they meet our standards as published in *Tomorrow's Doctors*. At the postgraduate level, we work closely with the Medical Royal Colleges and the Postgraduate Medical Education and Training Board (PMETB).

We also investigate concerns about the relatively small number of doctors whose quality of medical practice has been called into question. When appropriate we issue warnings, restrict what doctors can do, suspend them from practice or erase their names from the register which means that they cannot work as a doctor in the UK (and many other countries). Appeals to the High Court against our decisions are seldom upheld.

If we do all this so well, what is the problem? We, together with the medical profession and the government, recognised a decade ago that giving a doctor registration at the time of graduation to last for the rest of his or her professional life was no longer appropriate. It was generally accepted that all doctors should demonstrate on a regular basis that they are up to date and fit to practise. While that concept is no longer controversial, debate continues about the best mechanism for delivering the desired outcome. The CMO has suggested that our proposals for "revalidation" should be subdivided into "relicensing", a predominantly technical exercise which the GMC might pursue without delay, and "recertification" in which the Colleges would specify standards; they would also supply to the GMC the names of those Fellows and Members meeting these standards. Revalidation, leading to the issue of a time-limited (probably for five years) licence to practise, would now become a summation of relicensing and recertification.

But at its heart, the current debate is about how medical regulation should look in the 21st century. We have welcomed the Chief Medical Officer's contribution to this debate. We agree with many of the principles which underlie his report - protecting patients, raising confidence in the regulatory system, and setting and maintaining standards of good medical practice. But we have also questioned some of his proposed solutions - notably those which would fragment regulation and dilute its effectiveness.

Doctors in the UK are regularly described by the public as the most trusted professionals - as yet another opinion poll demonstrated recently. We are proud of the part that an effective system of regulation has played in helping to create the high public esteem in which the medical profession is held. But regulation is a dynamic process - it should not stand still. It must be scrutinised, challenged and improved to ensure it takes account of our changing society and the changing health care environment.

Clearly, whatever the outcome of the current consultation process in the UK, we shall work constructively to deliver solutions that will be fair to doctors, but which will not impose unreasonable burdens, drive doctors and patients apart or undermine the trust built up in the profession over many decades. And taken as a whole, we think that the outcome should provide some real potential benefits for doctors.

It is not in the interests of the public, politicians or the profession for the controversy which has surrounded medical regulation in the UK to continue. There is now an opportunity to create a partnership approach to regulation in which the GMC will have a balanced composition reflective of all those who provide or receive healthcare. It will ensure that doctors continue to own professional standards within a framework that is independent of Government; and it will mean the prospect of less adversarial and more locally-driven fitness to practise processes.

### **Governance and constitution**

Confidence in the GMC for the future will rest on several factors. First is independence - from Government as the dominant healthcare provider, and from any particular interest group. Second is membership reflective of all those who provide and receive healthcare. Third is appointment processes for membership that are independent, fair, transparent, and based on public interest and on competences. Fourth is a balanced composition of medical and lay members. As agreed by Council, we can no longer start from an inbuilt majority,

medical or lay: our aim therefore is an equal proportion of medical and lay members - 50% medical and 50% lay.

### Education

The English Department of Health's report on *Regulation of the non-medical healthcare professions* concluded that "Setting the necessary standards and verifying that education providers meet them is at the heart of professional regulation". We agree. We can be held accountable for the registers, and for the fitness to practise of those registered, only if we control entry and the standards required. We believe - along with many others - that the transfer of responsibility for undergraduate medical education from the GMC to the Postgraduate Medical Education and Training Board would compromise this. The "one roof" under which medical education is co-ordinated should be the GMC, and we have proposed a model under which three Boards (undergraduate; postgraduate; CPD) would report to a re-constituted GMC Education Committee.

### Standard of proof

We know that this issue has aroused strong feelings. The courts have, however, made clear that the civil standard of proof is flexible in its application. Flexibly applied, it enables proper account to be taken of the seriousness of the allegation and of the consequences. As such, the application of the civil standard with the required flexibility appropriate to the seriousness of the allegation and the consequences for the practitioner, should lead in practice to the same result as would application of the criminal standard. We do not believe it will result in more doctors being erased from the register.

### Adjudication

The Chief Medical Officer recommends that the GMC no longer carry out the adjudication of fitness to practise cases but that this function should be transferred to a separate tribunal. We do not think the case for this has been made. Current arrangements work well, with a very low rate of successful appeals. There is no evidence that an alternative model would deliver more robust or consistent outcomes or improve public perception. If, however, the Government were to conclude that the separation of adjudication was desirable we would be willing to use our expertise to help design a workable alternative subject to appropriate safeguards.

### Affiliates

We endorse the need for greater coherence and

co-ordination across medical regulation (personal, team, workplace and national), and in particular the need for a stronger local component. But we are not persuaded that the proposal to create a network of "GMC affiliates" at Trust level is the best solution. Assessing pilot schemes before any commitment to implementation would provide an opportunity to explore alternative approaches. In the meantime, we will continue to work with employers and their medical directors to improve the existing interface between the workplace and national professional regulation.

### Revalidation

We believe all regulated healthcare professionals should be required to demonstrate on a regular basis that they remain up to date and fit to practise. Implementing the new proposals will take time, however, both for the NHS and the Medical Royal Colleges. In the meantime, patients and the public have emphasised to us that they wish to see early progress. We agree with this, subject to the fact that final decisions will involve Government, the NHS and other healthcare providers who will need to support the delivery of re-licensing and re-certification.

This has been an enormously unsettling time - both for the profession and for the GMC as regulator. But there is an opportunity here to end the uncertainty and move forward to create a framework for regulation that can command widespread confidence and support. If that is the prize, then we will work tirelessly - without of course compromising our principles to achieve it.

In all countries with a modern healthcare system, medical regulation is a under scrutiny. The specific issues relating to the UK are less important than the general principles. Do we still believe in an independent body that "protects, promotes and maintains the health and safety of the public" by ensuring proper standards in the practice of medicine? If the answer is "yes" then some of the issues being addressed in the UK and other countries are worthy of further consideration - recognising that healthcare systems differ. There is not a single solution applicable to all.

### REFERENCES

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