The quality of care in hospitals

Brian Jarman

The 1518 Royal College of Physicians charter stated that one of the functions of the College and its members was to 'uphold standards ... both for their own honour and for public benefit.' The current Royal College of Physicians (RCP) website states: 'since the College's creation by Royal charter of King Henry VIII in 1518, it has engaged in a wide range of activities dedicated to its overall aim of upholding and improving standards of medical practice.' The motto of the College which appears at the bottom of its notepaper is 'RCP – Setting standards in medical practice.' Hence the College is now, as it was 480 years ago, very concerned with setting and upholding standards of medical practice – this could be described as the nearest thing to its raison d'être.

One definition of healthcare quality is that it 'is the degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge.' One suggestion of what patients want, which is similar to that used by Maxwell (who also added equity), is that health care should be:

- available – within a time period consistent with clinical need
- appropriate – the best choice of treatment, with the patient sharing in the decision
- effective – provided correctly and safely, consistent with current research evidence
- acceptable – as judged by the patient or patient advocate
- efficacious – can be shown to benefit the patient.

How does medicine perform?

Comparisons can be made between modern air travel and medical treatment: they are both highly complex activities in which potentially fatal accidents can occur. As with aviation, medical knowledge and technology are rapidly changing. But what are the comparative safety records of aviation and medicine?

Berwick, who is the chief executive officer of the Institute for Healthcare Improvement, in Boston, USA quotes an estimate that it would be necessary to fly continuously for 20,000 years to have a 50% chance of an accident causing injury in an aeroplane. In medicine, by contrast, injuries from adverse events (from medical care itself) were found in 3.7% of hospital admissions in the Harvard Medical Practice Study of 30,000 hospital records examined in New York State hospitals: over half were preventable and about 14% fatal. If these results are scaled up and applied to the 11 million hospital admissions in England in 1996 it would imply that there may be about 28,000 deaths from medical accidents every year (33,000 in the UK). About half of all deaths in this country occur in hospital (a total of about 240,000 hospital deaths in England annually) and, if the figures from this US study could be applied to England, it would mean that about 12% of the deaths in English hospitals are as a result of preventable fatal adverse events resulting from the medical care received. 'Any honest review of the literature in clinical science and health services research' Berwick writes, 'must conclude that there is a large gap between how health care could perform and how it does perform.'

Sikora, in a recent paper on cancer survival in Britain, points out that, in comparisons with Europe, survival rates for common cancers are below the European average and that if the European average survival rates were to apply in Britain about 10,000 lives would be 'saved' every year – 25,000 if the survival rates of the best country in Europe were achieved in Britain. He concludes that the problem in the UK is unlikely to be due to delay in diagnosis and that 'the finger has to point at the quality of cancer care and its integration.'

Human beings are more complex than aeroplanes and ensuring quality is even more difficult in medicine than in aviation. However, studies such as these have drawn attention to the quality of care in hospitals. In the UK the Secretary of State for Health recently announced that he had asked the Chief Medical Officer, Professor Liam Donaldson, to establish an expert group with the task of making recommendations about how to avoid service failures in the NHS. The group will include the Health Service Ombudsman and a director from the Audit Commission.

Ensuring quality of care in hospitals

There is a long history of attempts at improving the standards of medical care. Hurwitz has drawn attention to the fact that in the 4th century BC, Plato investigated
setting up panels of doctors and lay people to look at 'the ways in which the treatment of the sick is practised.' Florence Nightingale, in the nineteenth century, was one of the first to study death rates in hospital. Within the NHS the Griffiths Report on management, published in 1983, draws attention to the need to concentrate on measures of the quality of health care; it stated that 'real output measurement, against clearly stated management objectives and budgets, should be a major concern of management at all levels.' We should note that the Griffiths Report gives management a clear responsibility for involvement in quality measures. Performance indicators were introduced into the NHS in 1983 as proxy measures for efficiency. More recently audit, the clinical guidelines movement and the quest for evidence-based medicine have evolved into the current situation with the introduction last year of the NHS White Paper, A first class service: quality in the new NHS, which announced that the National Institute for Clinical Excellence was to be the standard setter and the Commission for Health Improvement the monitoring and enforcing agency for quality standards and clinical governance. The quality of care in hospitals can be looked at from the point of view of the standards of individual hospital staff and the overall performance of the hospital.

Standards of hospital staff

I will consider doctors first. Doctors are members of a powerful profession; as Moran and Wood put it: 'Medicine is so central to modern society that doctors have emerged as perhaps the key profession.' To quote a recent document on public policy and public service, the NHS is so heavily influenced by its lead professionals that both policy and service have to be seen as a product of a power-sharing agreement between professionals and ministers.

This document also notes that although there have been considerable changes over recent years in the audit and inspection processes in medicine, the Government is aware that 'care must be taken not to overload the policy system with inspection processes that fragment rather than integrate.'

Doctors

Students entering medical school in the UK need high grades in their A level examinations, and the medical education which they receive is very thorough and has a high reputation. Some doubts have, however, been expressed regarding the continuing maintenance of standards after qualification. For instance, in 1994 Donaldson reported on the results of a survey carried out in hospitals in the Northern Region of England. He found that, over a five-year period, concerns serious enough to warrant the consideration of disciplinary action were raised in 49 of 850 (6%) of the senior medical staff, of whom about half had retired or left their employment. The 96 problems he noted were categorised as:

| Problem | Number |
|---------|--------|
| poor attitude and disruptive or irresponsible behaviour | 32 |
| lack of commitment to duties | 21 |
| poor skills and inadequate knowledge | 19 |
| dishonesty | 11 |
| sexual matters | 7 |
| disorganised practice and poor communication with colleagues | 5 |
| other problems | 1 |

His conclusion was that existing procedures for hospital doctors within the NHS are inadequate to deal with serious problems. The point has been made however that senior doctors carry enormous clinical workloads and often have additional educational and managerial roles, and that there should perhaps be some form of structured mentorship or supervision to support them as occurs in other professions.

The General Medical Council

The GMC, which covers doctors in the NHS and in private practice, was established by the Medical Act of 1858 to maintain a register of professionally qualified doctors and to protect the public from quacks. The Merrison Committee, set up in 1974 to examine the workings of the GMC concluded that its main functions were to maintain the register and to remove practitioners unfit to practise. In the last decade or two the GMC has also concerned itself more than previously with promoting high standards of medical education and fostering good medical practice. Since the 1858 Medical Act the GMC has disciplined doctors for serious professional misconduct (until 1969 this was termed 'infamous conduct in a professional respect'). From 1980 it has also been able to take action regarding doctors' serious health problems and, since 1995, for seriously deficient performance. It has set standards for medical school undergraduate education and, since 1992, for the preregistration year. It has the power to inspect medical schools' final qualifying examinations. It keeps the register of doctors whose registrations are classified as: full (which applies to doctors after the pre-registration year, of whom there were 189,567 on the register on 1st January 1999); provisional (after qualifying, 5,912 doctors); limited (from overseas medical schools) and specialist (after completion of specialist training, 34,279 doctors). Doctors can apply for full or provisional registration if they qualify at a UK medical school or elsewhere in the European Economic Area (EEA) and are EEA nationals, or graduates of one of 22 recognised medical schools outside the EEA. It tests the competence of other doctors who have trained abroad. Hence the GMC is the body responsible for ensuring that the public are cared for by professional, competent doctors.
Details of the GMC activities are given on its website.29

The cost of the GMC is borne by its members by means of a relatively small annual subscription (roughly the equivalent of one hour's work for a doctor). Currently there are 54 elected medical members of the GMC (these are GMC registered doctors elected by doctors on the register), 25 appointed medical members (appointed by universities with medical schools, and by medical Royal Colleges and Faculties) and 25 lay members. Lay members of the GMC are not elected but nominated on the advice of the Privy Council. The recent Health Act, which received Royal Assent on 30 June this year, has confirmed (after negotiations between the BMA and the government) that the GMC will continue to have a professional majority and will report to the Privy Council (and not the Secretary of State for Health).

There have long been controls on qualified doctors' professional conduct but only relatively recently on serious deficiencies of health (such as alcoholism, drug misuse or mental illness) or on professional performance.30 The Medical (Professional Performance) Act became law in November 1995 and came into effect in September 1997.31 So far it has been used to discipline one doctor. Hence, although the GMC can now discipline doctors for seriously deficient conduct, health or performance, its range of action is limited to the extreme, seriously dysfunctional end of the spectrum. When the professional performance procedures were introduced in 1995 proposals were defeated that would have resulted in a lower threshold of performance below that of 'serious' or, alternatively, a two-tier system, the lower tier of which would have been defined as unacceptable performance.32 Such proposals, had they been adopted, would have widened the range of poor performance which could have been dealt with by the GMC.

The standards expected of doctors are set out in Duties of a doctor: Good Medical Practice33-35 first published in 1995, with a second edition in 1998. Until the last few years, most complaints about doctors came to the GMC from the public and were about professional conduct. Only a small proportion of these (about 5%) reached the Professional Conduct Committee and many patients were referred to other NHS complaints procedures. By 1997 more than 50% of hearings were considered 'essentially clinical’.36 There is little public knowledge about what goes on at the GMC and the disciplinary procedures may not fit with others within the NHS.37 It is clear that there have been considerable changes at the GMC within the last decade but Stacey suggested, in 1992, before the more recent changes, that the GMC was reluctant to take a harder line with doctors because it was afraid of losing the legitimacy of the profession.38

Sir Donald Irvine, Chairman of the GMC Standards and Medical Ethics Committee from 1984 to 1995, and President since 1995, stated in September 1999 that during the period 1984-1995.39

Doctors were (and still are) having to make clinical decisions, and judgements, on evidence which is likely to be imperfect, often in circumstances where agreed evidence for what constituted good practice was not available. Consequently, quite wide variations in practice were tolerated under the umbrella of 'clinical freedom'. The combination of individualism, clinical uncertainty, an elitist ethos at the top of medicine intolerant of failure, and the growing fear of litigation, resulted in closed and defensive attitudes around questions of individual performance.30

Although the GMC has introduced the health and performance procedures and has increased the proportion of lay members, it is important that the GMC is seen to be relevant to the maintenance of standards of clinical care throughout medicine, not just at the extremes of seriously deficient professional performance. The GMC was set up in the 19th century mainly to keep a register of qualified doctors. In future it will need to fulfil the 21st century requirement of ensuring high standards of care throughout the profession, in the context of increasingly complex health care organisation and the greatly enhanced powers of modern medical technologies.

Self-regulation and revalidation

The role of the GMC is closely allied to questions about self-regulation. The medical profession is typical of other professions in that it restricts access and protects its own body of knowledge.39,40 Thus, as an independent profession, has it retained the privilege of self-regulation.41 The Merrison Committee was firmly of the opinion that 'only those in the profession are in a position to judge many of the matters of professional conduct.' However, in recent years, there have been increasing concerns as to whether self-regulation is working well.22,32,38,41-54

The GMC agreed in February this year (by 62 votes to 5, with 14 abstentions)55 the principle, to be implemented within the next two years, of a system of regular mandatory revalidation for all doctors – specialists and GPs, junior doctors and locums.56,57 The mechanism of self-regulation will involve local profiling of a doctor's performance (which would take into account the views of patients, colleagues, and employers), external peer review of the profiling process and submission of evidence of doctors' fitness to practise.58 A doctor who refuses revalidation may be removed from the register; one who fails revalidation would, after attempts at remediation, be referred to the Committee on Professional Performance for an assessment of his or her knowledge, skills, attitudes, and performance and could ultimately be removed from the register.

In the US most doctors have to renew their specialist licences every 7-10 years and if they fail to do so they may lose admission rights to hospitals. In 1998, 22 of the 24 boards of the American Board of Medical Specialists used multiple choice question (MCQ) examinations for revalidation. The 'high administrative costs and the demand for evidence of reliability and validity that will withstand threats of litigation have prevented the US boards from introducing methods of assessing clinical reasoning and communication skills'.59 Although there are doubts about the value of doctors
learning more and more facts, it has to be admitted that, as a test of knowledge, and in terms of their relative simplicity, objectivity and legal defensibility, MCQ tests possess many advantages. In Europe, continuing medical education is based on participation in a certain number of hours of approved educational activities. In Canada and Australia maintenance of certification has a similar basis.

The implementation of revalidation by the GMC leaves regulation of doctors firmly in the hands of the profession. Papers supporting the concept of self-regulation have recently been published by the BMA, the RCP, the chairman of the Central Consultants and Specialists Committee (CCSC), and jointly by the BMA, the Academy of Medical Royal Colleges and committees of postgraduate deans and undergraduate medical deans. Johnson, chairman of the CCSC, stated in 1998: 'Appraisal must ... be rooted in peer review, and with increasing subspecialisation genuine peer review will increasingly need to come from outside the hospital in any event the assessor must be independent and therefore external.' On the question of the GMC and self-regulation, Smith, editor of the BMJ, has stated:

My judgment is that the government will decide against wholesale reform of the GMC. Firstly, although previous presidents may have been slow to read the signs that self-regulation was under threat, the current president, Sir Donald Irvine, has committed himself to substantial reform.

Secondly, the government won't want to waste its time fighting with doctors while trying to modernise the NHS: the rhetoric is all about partnership. Thirdly, the Treasury will not want to pick up the cost of trying errant doctors. Fourthly, a system run by non-doctors would inevitably depend on doctors for judgments on what was acceptable, and doctors (clever people still) would probably prove adept at subverting a system that they didn't own. Fifthly, the government will want to try out the many systems it has proposed in its white paper for raising performance.

It seems therefore that the leaders of the profession generally support compulsory revalidation provided it remains in the hands of the profession. It might be interesting to ask the public their opinion.

Contracts with employers

In the UK most doctors, as opposed to other professionals such as lawyers, accountants and architects, work in the NHS and are therefore paid ultimately by the state from funds derived almost entirely from taxation. In spite of this the profession has maintained its self-regulating status and doctors are answerable professionally to the GMC and not to an independent NHS body. Whether or not a doctor is fit to be a doctor, from a professional point of view, is guaranteed to the public by the GMC. It can be argued that the question as to whether that doctor is competent to do the job is another matter. It was noted in the 1987/88 Joint BMA/DHSS working party report on Disciplinary Procedures for Hospital and Community Doctors and Dentists that from 1981 to the time of the report 37 doctors had been dismissed by their employers, 17 for redundancy where a post is made redundant, 13 for personal misconduct, two for professional misconduct, three for professional incompetence and two for other reasons. For professional incompetence this amounts to less than one per year. It was recognised that if an employer had doubts about a doctor's competence there was little that could be done until the doctor's behaviour, or level of competence, had reached the extreme position of being so poor as to lead to dismissal. There is the 'three wise men' procedure designed 'to receive, and take action on, any report of incapacity due to physical or mental disability, including addiction' but this is confidential and appears to have led to virtually no dismissals for incompetence. The Joint BMA/DHSS working party recommended the need for a continuum of formal and informal disciplinary procedures for doctors.

In 1994 a conference was held on core values for the medical profession in the 21st century. Representatives of the BMA, GMC, Joint Consultants Committee, medical Royal Colleges and undergraduate and postgraduate deans all took part. The conference was needed, it was held, because changes in society, demography, health care organisation, patients' expectations and techniques of medical care are challenging doctors' traditional role and core values; indeed many doctors have been confused, if not demoralised, by the pace and magnitude of these changes which call into question their traditional responsibilities.

One of the core values agreed was that of competence - meeting appropriate standards. The details of what constitutes 'appropriate standards' were not spelled out at the conference. When Good Medical Practice was published by the GMC in 1995 it made clear in a positive way what could be expected of a doctor. It has been discussed whether doctors' contracts need to contain the full details given in Good Medical Practice, or whether the fact that a contract specifies that a doctor is being employed implies that, as a doctor, the employee would be expected to comply with its requirements (which define what is expected of a doctor). The publication of Good Medical Practice marked a significant change from the previous situation when the GMC's Blue Book published in 1984 set out mainly what a doctor should not do (prior to the Blue Book the GMC had, since 1858, only issued 'warning notices' about unacceptable behaviour).

One of the strictures in the Blue Book was that doctors should not disparage colleagues but should be under a duty only to report serious professional misconduct. In the 1987 Blue Book this was changed to a duty 'to inform an appropriate body about a professional colleague whose behaviour may have raised a question of serious professional misconduct or whose fitness to practise may be seriously impaired by reason of a physical or mental condition.' Good Medical Practice now makes it clear that the GMC requires doctors to put the interests of patients first and to report a colleague's adverse behaviour, health, or performance if this
puts patients at risk; it states: ‘You must protect patients when you believe that a doctor’s or other colleague’s health, conduct or performance is a threat to them.’ The 1997 edition of the CCSC’s Guidance for Medical Directors (but not the 1993 edition) made it explicit that ‘for ordinary consultants, merely discussing a concern with a colleague or referring it to an informal procedure does not in itself discharge the responsibility defined by the GMC. Only if the doctor is fully satisfied after any informal action that the problem no longer exists has that responsibility been discharged.’

If revalidation works, in future a doctor, who must be registered with the GMC to be employed in the NHS, will have had his or her competence certified by revalidation. There will need to be a link between registration with the GMC, revalidation and employment.

The medical Royal Colleges and continuing medical education

If both the GMC and employers have problems in ensuring high standards of care on a day to day basis, not just policing the extremes, is this a responsibility of the medical Royal Colleges? The RCP is involved in achieving standards by:

1. approving posts for training (accreditation of an individual for a particular post, and accreditation of a hospital);
2. approving job descriptions for consultants and now non-consultant career grade doctors;
3. providing representatives on advisory appointment committees (a statutory power);
4. the work of the Clinical Effectiveness and Evaluation Unit (formerly the Research Unit) producing studies and reports;
5. collecting and using data, in particular associated with junior staff in medical training and continuing medical education;
6. exercising the duty to approve the quality of training that doctors receive in posts in support of the appointment.

Although the Royal Colleges are involved in continuing medical education (CME) (which has evolved into continuous professional development (CPD)) there is no compulsory requirement for doctors to indulge in CME. Professor George Alberti, President of the RCP, stated when questioned about this in March this year: ‘Of course, there is major peer pressure so to do, but that is one of my aims within the next two to three years, when we have a good CME system operating, that it will be compulsory.’ The CME to which he was referring was ‘50 to 100 hours per year of particular forms of attendance at educational sessions.’

The RCP is also now more likely to be actively involved in questions of clinical freedom than has been the case in the past as the President of the RCP also indicated when questioned.

A. [Professor Alberti]. I think now we would be much more interventionist on the grounds of safety, particularly, and quality.
Q. What you are telling me is that in those particular years [1984 to 1995], at any rate, the Royal College of Physicians would hesitate to interfere or influence the exercise of clinical freedom upon the grounds that it perceived generally that the public interest lay in an opposite direction?
A. I think that, first of all, if we were not informed that there were problems, we would not have any ability to interfere, other than informally.
Q. So it would be reactive rather than proactive?
A. Correct.

In their role of approving training posts at hospitals and accreditation of hospitals the Royal Colleges do not coordinate their activities so that the assessments made by the different Colleges are collated and an overall impression formed. Banerjee has suggested that: ‘close audit of both the trainees’ and the trainers’ case-mix and outcomes is essential. This might best be supervised by the appropriate specialist society under the aegis of the Royal Colleges and postgraduate deans.’

It is clear that the medical Royal Colleges are important in maintaining and improving standards but their role has been questioned in that, for instance, they provide little management of members’ performance. The chairman of the Academy of Medical Royal Colleges, has stated: ‘when the lines cross between the interests of the patient and the Colleges’ membership, the patient must always take precedence.’ For professional bodies such as the Royal Colleges, which depend to a considerable extent on the support of their members, it is likely to be easier to introduce new quality assurance methods (which might not be popular with some of its members) if they are given statutory powers to do so.

The Royal Colleges do now have statutory responsibility for Specialist Registrar training, devolved from the Specialist Training Authority, as a result of the reforms of specialist training published in 1993 (the Calman Report). These reforms were intended to bring the UK in line with other EU countries. They aimed to reduce the minimum length of postgraduate specialist training to seven years, merge registrar and senior registrar grades, and introduce more specific training criteria. They introduced the Specialist Training Authority and the Certificate of Completion of Specialist Training (CCST) for entry to a specialty thus leading to specialist registration with the GMC.

In discussion of the role of the Royal Colleges I have concentrated on the RCP but the other medical Royal Colleges and Faculties have also been very active in quality assurance in hospitals. For instance, the Royal College of Surgeons, with the Anaesthetists, have developed the National Confidential Enquiry into Perioperative Deaths (NCEPOD). Also, in October last year, the four Royal Colleges of Surgeons and the nine subspecialty surgical associations proposed guidelines for a rolling programme of external peer review, at least every five years, to monitor
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proficiency and to help keep surgeons up to date. For cardiac surgery the Royal College of Surgeons of England and the Society of Cardiothoracic Surgeons discussed the formation of a 'rapid response group' so that, if there are problems in a hospital a member of council and a senior cardiac surgeon can visit the hospital within 48 hours and advise on action.83

In the context of continuing medical education it is worth mentioning the role of the pharmaceutical companies. With their large resources they can pay for travel, and other facilities and may have a considerable influence, albeit from a potentially biased viewpoint, on how medicine is practised.84

Audit

Doctors have, for many years, used clinico-pathological conferences to audit performance. Pathologists have a duty to carry out postmortem examinations, acting as an agent for the Coroner, if, for instance, there has been a death within 24 hours of surgery. It is usually the pathologist of the local hospital who does the examination and he or she may be dependent on the surgeon who did the operation to draw attention to possible problems during the surgery. The Coroner will rely to a considerable extent on the pathologist to alert him if the death was unnatural, for instance due to an error in the surgery, and therefore one for which the Coroner is required to hold an inquest. There could be a conflict of loyalties for a pathologist who has the responsibility of alerting the Coroner to the need for an inquest which might possibly criticise a surgeon colleague.

In 1989 the Conservative Government published the White Paper on the reforms of the NHS which formally set in train medical audit.85,86 In 1991 medical audit became clinical audit when nurses and therapists were also involved and in 1993 all three were combined into one multidisciplinary clinical audit programme. Medical audit was meant to be primarily a professionally led educational activity run by Local Medical Audit Committees with regular meetings and reports. The Department of Health allocated £50.1m revenue for clinical audit in 1994–95 (£42.9m for medical audit and £8.9m for audit of nursing and therapy professions) plus £3.2m for multi-professional clinical audit. The hope was expressed that, within five years 'audit will increasingly focus on outcomes and their relationship to the process of care.'87

The audit process was time consuming and at times it was uncertain who was responsible for monitoring its results and taking any remedial action needed. Audit standards and activities undertaken varied considerably from district to district. It has been suggested that audit was more of a research activity owned by the doctors involved86,88 — 'a cosy club of clinicians [with] ... limited mechanisms ... for providing solutions where deficiencies are highlighted':77 Macara, when President of the BMA in 1998, stated that 'clinical and medical audit has ... largely failed.'89 Scally and Donaldson90 commented:

although the concept of peer review is well established in the United Kingdom, the implementation of clinical audit in the NHS is not a complete success. Concerns have focused on the failure of audit processes to detect and moderate significant clinical failures; on incomplete participation ..., on the lack of connection and flow of information to those responsible for managing services; on substantial declines in the amount of regional audit; and on the value for money for what amounts to a significant annual investment.90

In the USA doctors are not enthusiastic about medical audit.91

A report in 199691 from the Clinical Audit Committee of the BMA entitled Guidance notes for the commissioning of clinical audit stated: 'specific results of audits carried out by providers should remain confidential, but it may be appropriate for anonymised data and the conclusions to be shared.' This was to enable 'open and frank discussion during peer review audit meetings'.92 This could at times conflict with the ethical requirement for doctors to be open and frank with patients and to report to a responsible body if a colleague's conduct, performance, or health is a threat to patients.33,34,66,93 Beresford and Evans have recently stated that:

clinical governance should promote high quality care by making individuals accountable for setting, maintaining, and monitoring standards, to produce a hitherto elusive culture of clinical excellence.21 Systems of clinical risk management and audit should contribute to this process by facilitating greater self evaluation, open debate about clinical practice, and the routine investigation of adverse events. For clinicians to learn and improve, conclusions reached during these processes need to be documented. Clinicians also need to feel safe with the process and that it will not be used against them.

They go on to point out that 'in Britain audit activities are protected neither by statute nor by case law' and quality assurance initiatives would be inhibited (a) because of concerns regarding confidentiality since clinical audit is multidisciplinary, and (b) because of the problem of disclosure, since all documentation must be disclosed, if requested, to patients considering litigation. They suggest a solution which is used in Australia and the US, namely that of providing legal protection for audit, but they recommend that this should not be introduced until, as they put it, 'the medical profession can deliver greater openness when things go wrong'.

Clinical guidelines

The development of audit has been part of the progression towards the development of clinical guidelines and evidence-based medicine. Clinical guidelines have been defined as 'systematically developed statements to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances.'95 Clinical guidelines have both potential benefits and harms,96 and few have been rigorously evaluated for example by randomised controlled trials.97 Clinicians fear that they might be forced
to use guidelines for which there is little evidence rather than using their clinical judgement in a particular clinical situation. Hurwitz has summarised his views, particularly on the legal aspects, of clinical guidelines:

- Clinical guidelines cannot offer doctors thought-proof mechanisms for improving medical care
- However well linked to evidence, clinical guidelines need to be interpreted sensibly and applied with discretion
- Under UK common law, minimum acceptable standards of clinical care derive from responsible customary practice, not from guidelines. (Some guidelines may well be good evidence of customary care — others may not be. It all depends upon the guidelines in question and that is determined in court by expert testimony. It is usually a good defence to negligence that one has complied with guidelines. However, deviation from guidelines is not in itself (yet) prima facie evidence of negligence or even a case to answer.)
- If clinicians implement faulty guidelines it is they, rather than the authors of such guidelines, who are likely to increase their liability in negligence
- The NHS Executive has stated that clinical guidelines cannot be used to mandate, authorise, or outlaw treatment options.

Publications from the Cochrane Centre and the NHS Centre for Reviews and Dissemination, which publishes Effective Health Care, both help in the development of clinical guidelines. Doctors are able to use these and other sources of information, such as the internet, in conjunction with their clinical experience, but most doctors who have been in practice for any length of time are conscious of how fallible clinical experience can be: it was defined by Michael O'Donnell as 'making the same mistakes with increasing confidence over an impressive number of years'.

Clinical governance and The New NHS

Doubts about the value of clinical audit have been partly responsible for the introduction of the quality agenda in the government's White Paper The New NHS which came into effect on 1st April 1999. It is too soon to see how it will work but it includes (in England):

- evidence-based National Service Frameworks to help ensure consistent access to services and quality of care across the country
- a National Institute for Clinical Excellence (NICE) — national standards and guidelines for services and treatments
- clinical governance: hospital trusts have a statutory duty for quality and hospital doctors have to participate in external clinical audit and compare their results with national averages
- a Commission for Health Improvement to address shortcomings.

The Chairman and Chief Executives of NICE and the Commission for Health Improvement have been appointed and we now know more about what NICE will do. Also, the 1999 Health Act makes it clear that the Commission for Health Improvement will have qualified rather than absolute privilege, and patients' records should not be disclosed to it without proper justification. Since the publication of Good Medical Practice by the GMC, registered doctors have been required to 'take part in regular and systematic medical and clinical audit' and, where necessary, they 'must respond to the results of audit' to improve their practice, for example by undertaking further training.

The Health Service Commissioner

The Health Service Commissioner or ombudsman investigates complaints about administration of NHS services. The post, which is wholly independent, was created in 1973 and has the power to require access to records and to examine witnesses. From 1996 complaints about clinical judgement were included within the remit of the Health Service Commissioner as were general practitioner and family practitioner services which had previously been excluded. If there is an alternative way of pursuing a complaint through an independent tribunal or court the complainant is expected to take that route if it is reasonable to do so.

The number of complaints received by the Health Service Commissioner is increasing. In 1998–99 there were 2,869 complaints, an 8% rise on the previous year. Many of the complaints were excluded because they had not gone through the NHS complaints procedure and only 248 complaints were investigated of which 153 (62%) were upheld. Of the 119 investigations completed in 1998–99, 62 were clinical (36 involved hospital and community services) and 57 non-clinical.

If the Health Service Commissioner finds a complaint to be justified he recommends changes which should be made to deal with the problems uncovered, but his recommendations are not enforceable. He has no statutory powers to impose sanctions. The investigations are very thorough, take about a year and are published in anonymised form.

Unlike other ombudsmen, the Health Service Commissioner cannot initiate investigations even if he receives information about possible problems. This could change and the number of clinical complaints could increase significantly. It is possible that the role could develop into something like an independent NHS inspectorate.

NHS complaints procedures

The NHS complaints procedures are complex and the number of complaints is increasing. From 1985 to 1995–6 the total number of written complaints in England about Hospital and Community Health Services increased from 28,990 to 105,664 (264% increase): those which were wholly or mainly clinical increased from 10,624 to 40,083 (277% increase). From 1996, when the complaints procedure...
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changed, to 1998 the number has decreased. The people involved in investigation of the complaints are themselves part of the organisation against which the complaints are being made and they may have split loyalties – if the managers defend the doctors inappropriately, for instance by not being helpful to the complainant, then they are not doing their job properly; if they take the opposite line, then this will probably not help to foster good doctor/manager relations. It is difficult for patients to complain – they know little about the procedures, they may not know or remember the names of the people involved, and they are usually ignorant of medical matters. However, complaints have the advantage of coming from the users of the service who are the people most concerned with what happens to them during medical care and they could, in a non-punitive atmosphere, potentially be helpful in improving the service. The new complaints procedures which were introduced in 1996 are intended to be more user friendly and to enable learning to take place from the complaint.

The courts and medical negligence claims

Ultimately, patients may seek legal redress in the courts if they consider that they have suffered as a result of poor treatment. Although the detailed analysis of the circumstances of the events leading to medical negligence claims may be instructive to the people involved, it has been questioned as to how much the medical fraternity at large learn by any mistakes uncovered. The American study of adverse events in hospitalised patients showed that medical negligence litigation rarely identifies substandard care.

Total quality management

In the managerial language of the quality movement in industry, the language of total quality management (TQM) and continuous quality improvement (CQI), complaints should be ‘treasured’ because they can help towards quality improvements. If, however, complaints are linked to disciplinary procedures, which are inevitably stressful and lead to defensiveness, this will conflict with the need for the organisation to learn from the complaint. There will inevitably be a conflict between the disciplinary elements of quality control which are associated with inspections, litigation and complaints against individuals on the one hand and, on the other hand, the improvement and learning aspects of quality control associated with a systems approach, one which involves everyone in an organisation. This is seen clearly with medical audit.

The characteristics of TQM have been summarised as:

- Making customers’ needs a priority for everyone
- Defining quality in terms of customers’ needs
- Recognising the existence of internal customers and suppliers
- Examining the process of production rather than individual performance for explanations of flaws or poor quality

- Using sound measurement to understand how to improve quality
- Removing barriers between staff and promoting effective team work
- Promoting training for everyone
- Involving the whole work force in the task of improving quality
- Understanding that quality improvement is a continuous process.

Should we concentrate less on blaming individuals and more on improving the systems?

In Sweden a ‘no-fault’ system of compensation for medical negligence has been used and doctors learn from the regular feedback about the types of cases that lead to medical accidents. One key point is the separation of the question of ‘fault’ from that of compensation. This possibility of a ‘no-fault’ system has been discussed for the UK. Berwick states:

So far as I know, all modern, effective systems to assure and improve safety involve a culture in which the reporting of error or apparent error is a valued and positive act, which leads, not to blame, but to curiosity and study.

And again:

When medical errors do surface, often with heart rending accounts of the suffering of the primary victims, the patients harmed, the reaction in medical settings is most commonly an attempt to fix blame and to punish someone. This will not work. If we can take any lessons from the stunning progress in safety in aviation and other high risk industries it is that fear, reprisal, and punishment produce not safety, but rather defensiveness, secrecy, and enormous human anguish. Scientific studies in human factors, engineering, organisational psychology, operations research, and many other disciplines make it clear that, in complex systems, safety depends not on exhortation, but rather on the proper design of equipment, jobs, support systems, and organisations. If we truly want safer care we will have to design safer care systems.

Evans has pointed out that one important difference between aviation and medical practice is that ‘unlike the airline pilot, medical professionals do not share the fate of those in their care.’ Evans, who is from the Automotive Safety and Health Research Department of the General Motors Corporation, goes on to question the use of the term ‘accident’ which implies that adverse events occur due to Fate and are therefore not preventable, whereas our aim should be to discover preventable factors which affect risk and use them to reduce that risk.

Reason, Vincent and Taylor-Adams and Leape have emphasised the need for an understanding of the underlying factors that lead to medical accidents with less focus on individuals who make errors but more on the organisational factors that provide the conditions in which errors occur. They describe ‘active failures’ and ‘latent
failures. Active failures are unsafe acts or omissions such as slips, memory lapses or violations of operating procedures. Vincent and Taylor-Adams list examples of latent failures—conditions in which unsafe acts occur—as:

1. Heavy workloads
2. Inadequate knowledge or experience
3. Inadequate supervision
4. A stressful environment
5. Rapid change within an organisation
6. Incompatible goals (for example, conflict between finance and clinical need)
7. Inadequate systems of communication
8. Inadequate maintenance of equipment and buildings.

Apart from number 2 and possibly numbers 3 and 7 in the list above, the other latent failures would probably feature in any catalogue of potential hazards associated with hospital work in the NHS.

The subject of system and individual errors has recently been discussed by de Leval, a cardiac surgeon.

The traditional teaching is that medical doctors are expected to function without error. This need to perform faultlessly has created a strong pressure to intellectual dishonesty to cover up mistakes, rather than admit them, and to overlook opportunities for improvement. In addition, the realities of the malpractice threat provide strong incentives against disclosure, or investigation of mistakes... Whatever you do, if you see a doctor that doctor is fallible; he can make mistakes. So we have to have a system which is built with human beings who make errors. What we have to do is to build systems which are error tolerant.

He went on to say:

One of the problems is that the medical profession has behaved as a very independent body and, furthermore, the English system is such that through the consultant system, which is a parallel system, each consultant more or less has his or her own freedom and independence on judgment. I believe that there has been, in the past, a lack of coordination and organisation within units, partly because of that independence between surgeons or cardiologists or physicians, and there has been a lack of co-operation between the professional body and the Department of Health. I think there has been a lack of auditing to find out what was going on and I think that the recent reforms of the Health Service, the Trust system, has been such that, health care [has] become a commodity and patients a source of income...

Medicine may be able to learn from industry where all the steps in risky processes are subjected to analysis to identify faults in the system. This may be more productive than concentrating upon the faults of individuals. This makes it particularly important to identify what are the most important underlying faults in the system.

Is it all too much?

It is clear that doctors in hospital are going to be highly regulated. Richard Smith has questioned whether revalidation, clinical governance, compulsory audit, CME and other quality initiatives may all be too much and too confusing. Doctors may spend time on these activities which could be spent on patient care. With all this activity we should bear in mind that, as Berwick reminds us,'...inspection alone cannot improve quality... Inspection is important for safety, but unless it is linked to strategies for improvement it produces tremendous waste and timid aspirations.'

The important factors for doctors in the maintenance of standards

Allsop and Mulcahy and Smith have divided regulatory systems for doctors into internal and external, each of which may be formal or informal. Smith suggests that it is the internal, informal forces which have the most influence—colleagues (particularly bosses), professional education, medical culture and clinical experience. I would add one's own inner influences from parents and upbringing as probably being the most influential. Doctors work in clinical situations of considerable uncertainty which are therefore difficult to regulate. Clinical guidelines, evidence-based medicine, audit and fear of the GMC or the courts can all have an influence on doctors' behaviour but ultimately it is mainly internal, informal influences which actually lead to the decisions which doctors take in clinical situations.

Other, non-medical, health care professions

The nursing professions and some of the professions allied to medicine (PAMS) have strong regulatory mechanisms. For managers there is no national regulatory body but as part of their employment they are subject to continuing professional development programmes and annual individual performance reviews which are linked to the setting of objectives.

For the nursing professions the training and registration functions are both clearly invested in one authority—the UK Central Council for Nursing, Midwifery and Health Visiting (the UKCC which was formed in 1979). The functions of the UKCC are to establish and improve standards of training and professional conduct for nurses, midwives and health visitors (its principal functions); to determine the requirements for entry to training and the kind, content and standard of courses leading to registration; to maintain a register of qualified nurses, midwives and health visitors; to make rules regulating the practice of midwifery; and to make rules regulating removal and suspension from, and restoration to, the register, as well as cautions. The main function of the National Boards (such as the English National Board) is to approve institutions to provide courses of training and to hold or arrange for others to hold such examinations as are necessary to satisfy requirements for registration or additional qualifications. The government intends to introduce a single, UK-wide body, a Nursing and Midwifery Council, to replace the UKCC and the four National Boards with ultimate responsibility for regulating the nursing professions. This will
be equivalent to the functions, in medicine, of the Royal Colleges in respect of training and accreditation, being merged with those of the GMC in respect of registration and discipline, to form a single body, thus enabling registration, discipline, training and maintaining the standards of day-to-day practice to be closely linked.

Nurses registered with the UKCC (and registration has to be renewed on a three-yearly basis) are required to report any matters of concern (including for example concern about clinical care provided by doctors) to an appropriate person of authority such as the Director of Nursing.

A nurse cannot be a member of the Royal College of Nursing (RCN) unless she/he is registered with the UKCC.

In addition to its role as a trade union, analogous to the BMA, the RCN also aims to set and raise standards of best practice in nursing. In the 1980s, for example, the RCN developed their Dynamic Standard Setting System to enable health care practitioners to define quality of care locally. Hence, in the nursing professions, the organisation responsible for registration and discipline (the UKCC) is also responsible for training and it is not possible to belong to the trade union (the RCN, which also aims to raise standards) without being registered with this regulatory organisation.

The UKCC is funded entirely by the subscriptions of the people who are on its register and is a registered charity (which the GMC is not). The national boards are funded by and accountable to the various departments of health such as the Department of Health in England.

Quality of hospitals as institutions

We have seen that some doubts have been expressed about the effectiveness of the GMC, contracts of employment, the Royal Colleges and clinical audit in maintaining and improving everyday standards of medical care in hospitals. We do not yet know how effective revalidation and the new government quality initiative will be. Attempts have been made to develop external, objective measurement of the performance of hospitals, and units within hospitals, in order to provide a mechanism for detecting problems at an early stage and also to evaluate which hospitals are doing well. Taylor has listed some of the quality initiatives which are used. These are too numerous to consider in detail. Some of the important ones are: the Audit Commission which has as one of its functions the promotion of economy, efficiency and effectiveness in the NHS and has produced reports on, for instance, the management of hospital doctors and hospital services for children; the National Audit Office which has a statutory duty to carry out Value For Money reviews within the NHS; the King’s Fund Health Quality Service (the successor to the Organisational Audit) which is involved in accreditation and management aspects of hospital care; and the Health Advisory Service (now HAS 2000) which undertakes service reviews on topics such as the quality of care for older people in acute hospitals.

Donabedian has classified the elements of healthcare into structure, process and outcome.

Structure

The structure of health care includes characteristics of the building (including factors such as overcrowding), equipment, and human and financial resources. Although structural characteristics are relatively easily measured, and make a strong contribution to the environment of care, they are not given a high profile in studies of the quality of care in hospitals. The general impression one has of the buildings and works facilities of some NHS hospitals, particularly in comparison with hospitals in other Western countries, is that they are at times poor. The Government’s Expenditure Plans for 1998–99 for the Department of Health show a reduction in capital expenditure from 1992–93 to 1997–98. In discussing the Private Finance Initiative this document states: ‘...the PFI offers an opportunity for providing many new health care facilities now urgently needed’ (para 4.29). We need routinely collected meaningful measures of the fabric and function of the hospital buildings in the NHS.

Process

The process of health care is what happens to patients and in particular the quality of the care process. I would like to say more about one process study with which I have been involved – this is a survey of the opinions of patients, who are the best witnesses, regarding what happened to them when they were in hospital.

The patient survey

The Patient’s Charter introduced in 1992, states that the NHS should: ‘always put the patient first, providing services that meet the clearly defined national and local standards, in ways responsive to people’s needs.’ Responding to this, surveys were carried out to determine patients’ needs and their satisfaction with local services. There are however doubts as to how valuable patients’ satisfaction ratings are because, although they may report an overall high satisfaction rating, when asked more specific questions about their experiences they often report poor services. Questions about particular aspects of the patients’ care and what actually happened to them are more useful than general satisfaction questions. Our questionnaire, which was developed in conjunction with Professor Tom Delbanco and his colleagues from Harvard and Social and Community Planning Research (SCPR), was based on one which was used to survey 90 hospitals in the USA and 60 in Canada, and is also now being used in Europe. At least 35 questions were common to the surveys in all three countries. A similar survey is planned for Scotland. We are the junior partners in work with the same colleagues on the National Survey of NHS Patients in England which is a self-
completion questionnaire which was sent by post to 100,000 people selected at random from the electoral registers (1,000 people in each of the 100 health authority areas) between October and December 1998, with a 61% response rate.

Our hospital survey identified key dimensions of care from the patient’s perspective. These dimensions were: communication, patient preferences, emotional support, physical comfort, pain management, education, family participation, discharge planning and financial information. It asks detailed questions such as: ‘Did a doctor explain your condition or treatment to you?’ and ‘Was the purpose of the tests explained to you by a doctor or other member of staff?’

We surveyed 36 randomly selected acute NHS hospitals in England with 200 or more beds and covered medical and surgical specialties. Twenty-two other hospitals which had been chosen by regional health authorities were included in the survey but these were not included in the final analysis because they had not been randomly selected. Ward sisters were asked to identify patients being discharged over a period of a week or so until about 160 patients had been contacted and asked to take part in the survey. They were then interviewed by trained interviewers in their homes or at their place of discharge two to four weeks after discharge. The interviews were carried out between April and October 1993.

A total of 8,303 patients were interviewed of whom 5,150 were from the 36 randomly selected hospitals. The questionnaire took an average of 47 minutes to complete and on average 143 patients per hospital were interviewed. The response rate of patients asked to take part was 86%. The results were sent to each hospital in the survey giving the figures for their hospital together with the aggregated results from all the hospitals in the random sample. In the USA the results of similar surveys are made available to the public.

Although the stated level of satisfaction with the overall care was consistently high, there was a large variation in results between hospitals in the replies to the specific questions. Particular problems were found in communication between staff and patients, pain management and discharge planning.

Outcome

Outcomes are, ultimately, the most important measures for patients, but concentrating on outcome measures can be difficult for doctors. Professionals are trained to work in a “single silo” (a single department which “stores” a policy and resourcing for that policy) way, and can be trained to work for outcomes in partnership with others outside their professional group.

There have for many years in the UK been useful outcome measurements such as the confidential inquiries — those into maternal and perioperative deaths, stillbirths and deaths in infancy, and into suicide and homicide by people with mental illness. These have analysed the causes of deaths in particular circumstances. The Society of Cardiothoracic Surgeons has collected activity and mortality data on cardiac surgical procedures performed in NHS cardiac surgical units since 1977 (currently about 35,000 procedures per year). The Department of Health has recently published hospital league tables which include death rates. The need to adjust for co-morbidities or case-mix (risk stratification), the fact that deaths outside the hospital are not allowed for, and a range of other factors has made it difficult to interpret the meaning of such data.

The challenge, and the importance, of measuring hospital death rates which are adjusted in a way in which hospitals can be compared is something which would not only make it possible to detect hospitals with particularly high or low mortalities but may also enable important underlying system failures to be identified. How can this be done in a satisfactory way?

Johnson has stated:

For cardiothoracic surgery Keogh et al have described some of the problems of risk stratification, including the necessity for good data collection. It is an even more daunting prospect to extend such systems to specialties like general surgery, where surgeons undertake a wide variety of procedures and where outcomes other than mortality need to be investigated. An alternative would be to compare unadjusted results with the range of outcomes obtained by most doctors performing that procedure. This would allow individual doctors and their hospital’s audit process to determine when results fell short of what could be expected throughout the NHS. When the adverse result was an excess mortality, the doctor, together with the medical or clinical director, might decide to stop performing the procedure until corrective action could be taken. This approach would allow doctors and the public to know that a particular hospital performed an operation satisfactorily compared with similar institutions, but would avoid the disadvantages of league tables, which might lead to high risk patients being denied treatment if doctors felt that their position in the league table might be jeopardised.

Keogh has stated:

However, our specialty [cardiac surgery] represents the tip of the iceberg in medical quality assurance, and the major challenge will be determining realistic, measurable, and auditable outcomes for other medical and surgical specialties, where poor outcomes also occur but the process is less transparent.

My colleagues and I from Imperial College School of Medicine, together with Lisa Iezzoni, Professor of Medicine at Harvard, tackled the subject by studying individual diagnoses. There are clearly different death rates within different age and sex groups so the first adjustment which we made was aimed to make allowance for these age and sex differences. We obtained the Hospital Episode Statistics (HES) data which records details of all hospital admissions in England: we used the four years 1991–92 to 1994–95 — the years for which the data were of good quality. There are approximately 11 million admissions
annually in England and we used the data for the 183 largest hospitals which had not changed over the four years. We analysed the 85 diagnoses responsible for 80% of all deaths. The 183 hospitals covered 85% of all admissions in England for the 85 diagnoses. For each diagnosis we calculated the number of deaths that would be expected for each hospital in each 10 year age-group, for males and females, if the hospital had the national death rate for that age, sex group. These were summed over all the age, sex groups and all 85 diagnoses to produce the total deaths over the four years which would be expected in each hospital if it had the English national death rates in each age, sex group, for each of the 85 diagnoses. The ratio (multiplied by 100) of the observed number of deaths to the expected number of deaths calculated was defined as the hospital (indirectly) standardised mortality ratio (HSMR). We found that the crude, unstandardised, death rates varied from 3.4% of all admissions to a maximum of 13.6%, with an average of 8.5%. After standardisation the variation of HSMRs was from 53 to 137, the average for England over the four years being 100 by definition. There was a reduction in the overall standardised mortality ratio for England of 2.6% per year.

The next step was to carry out multiple regression analyses, using the HSMRs as the dependent variables and using a range of independent variables to determine the power of each variable to explain the variation of HSMRs in the 183 hospitals. Before the multiple regression analysis we carried out a univariable analysis for each of the independent variables and entered into the multiple regression analysis those variables with the greatest explanatory power.

We consulted widely and studied the literature in order to choose the explanatory variables — the appendix lists the variables used. Length of stay was obviously important because hospitals discharging patients early could potentially have lower death rates if a higher than average proportion of their patients die outside hospital after discharge. Also different co-morbidities can lead to different case-mixes, some hospitals having more seriously ill patients. The proportion of patients who were admitted as emergencies was likely to be important because 93% of all deaths occur in the 60% of patients admitted as emergencies. Social factors related to the patients admitted and the health and social care services available in each area were noted. Data on staffing levels of hospital doctors and nurses were also collected for each hospital, as well as GPs per 1,000 population. Altogether more than 100 possible explanatory variables were examined. We conducted weighted multiple linear regression analyses — the weights took account of the number of cases per hospital.

The results of the regression analyses confirmed, as expected, that the percentage of cases which were emergencies was the most powerful predictor of HSMRs — higher death rates being associated with higher percentages of emergency admissions. We were surprised that, at the 0.1% significance level the only other significant explanatory variables were the numbers of hospital doctors per bed and general practitioners per head of population — in both cases the more doctors the lower the death rates. The adjusted $R^2$ was 0.59 meaning that these three variables explained 59% of the variation of HSMRs at the 0.1% significance level (see Table 1). Length of stay, co-morbidities and social factors proved not to be significant at the 0.1% significance level. Figure 1 shows the HSMRs for low doctored hospitals (HSMR 112), intermediate doctored hospitals (HSMR 99), and high doctored hospitals (HSMR 88), with their 99% confidence limits. Figure 2 shows the hospitals with the highest and lowest HSMRs with their 95% confidence limits.

If the observed number of deaths in each hospital is used as the dependent variable and the age, sex, diagnosis standardisation factor used to calculate the expected number of deaths is used as an explanatory variable together with the number of admissions to hospital and the normal explanatory variables, then 90% of the variation of the observed number of deaths per hospital can be explained (see Table 2).

Since publication of these results I have been asked whether the numbers of managers or administrative and

| Steps in model | Variables Entered | Adjusted $R^2$ (x100) |
|----------------|-------------------|------------------------|
| 1              | Percentage of cases admitted as emergency | 49 |
| 2              | Hospital doctors per 100 hospital beds | 54 |
| 3              | GPs per 100,000 ONS population | 59 |

Dependent variable: hospital standardised mortality ratios, HSMRs (0.1% significance level). ONS = Office of National Statistics

Figure 1. Hospital standardised mortality ratios (HSMRs) in low, medium and high doctored hospitals and their areas.
Table 2. Multiple regression analysis.

| Steps in model | Variables Entered | Percentage of variance explained |
|----------------|-------------------|---------------------------------|
| 1              | Number of admissions to hospital | 64                              |
| 2              | Age/sex/diagnosis standardisation factor | 85                              |
| 3              | Percentage of cases admitted as emergency | 89                              |
| 4              | GPs per 100,000 ONS population | 90                              |

Dependent variable: observed number of deaths per hospital (0.1% significance level).
ONS = Office of National Statistics

clerical staff are significant in explaining HSMRs. There are significant correlation coefficients between senior managers plus managers plus clerical & administrative staff per doctor and HSMRs ($R = 0.18$, $p = 0.013$, managers per doctor positively correlated hospital death rates) and between clerical & administrative staff per bed and HSMRs ($R = -0.31$, $p<0.001$, clerical & administrative staff per bed negatively correlated with hospital death rates) but these were not significant in the regression analyses because the other explanatory variables are much more powerful.

One of the unexpected findings of this study was the very strong association between hospital death rates and the numbers of hospital doctors per bed or GPs per head of population – the higher these doctor ratios, the lower the death rates in both cases. High medical workload may be one of the latent factors which should be considered in hospitals with above average mortality rates. Compared with other countries in the Organisation for Economic Cooperation and Development (OECD), the UK had only 1.7 physicians per 1,000 population compared with the mean of 2.7 for the 27 countries recorded by the OECD in 1996.173 There are plans to increase the numbers of doctors in the UK (Department of Health press release 98/337, 14 August 1998) but the planned increase may be too small.174

Patients

Berwick has stated:

the ultimate measure by which to judge the quality of a medical effort is whether it helps patients (and their families) as they see it. Anything done in health care that does not help a patient or family is, by definition, waste, whether or not the professions and their associations traditionally hallow it.

I presume that he includes public health measures in the definition of health care. Alberti and Alberti have stated:175

the primary factor, and the deciding factor, must be the patient. Has the time come for the patient led NHS and the primacy of the patient?

Primary Care Groups (PCGs) and Trusts (PCTs) provide a possible vehicle for greater patient involvement. If supplied with useful information about their local hospitals PCGs and PCTs could work with their patients and hospital colleagues to maintain high quality standards.

Summary

In recent years there has been an increase in the regulation of the medical profession. In the past there have been problems. The GMC can act only when things go seriously wrong. It has, however, introduced the health and performance procedures, increased the proportion of lay members, is working on revalidation and has introduced Good Medical Practice which makes very clear what is expected of a doctor and will be relevant to doctors' contracts. The medical Royal Colleges can be influential in raising general standards but the activities of the different colleges are not well co-ordinated and they cannot compel doctors to take part in continuing medical education, although this is an aim. Without statutory powers to introduce changes they have to carry their members with them. Audit has its problems and these are understandable because of the natural defensiveness which can occur if there is a threat of possible litigation. The Department of Health has had no proper system for measuring the quality of the care for which it is responsible and largely sees this as the responsibility of individual doctors.176 Responsibility for the quality of care is shared in a confusing way between different groups. But there is change in the air. There are moves for a 'patient led NHS.' The Government has a new
emphasis on quality of care, there is greater sophistication in the methods used for surveying patients' experiences. Measurement of hard outcome data such as adjusted death rates can reveal underlying system failures. Finally, there is a growing realisation that within medicine, as within other complex organisations, doctors are not perfect and will always make errors. Blaming individuals will not in itself make much contribution to the improvement of the overall system: we have to work towards ways of reducing system failures.

Appendix: Independent (explanatory) variables

Aggregate discharge data

- Percentages of: emergency cases, live discharges who went home, cases and deaths with a range of co-morbidity measures
- Average number of diseased bodily systems
- Standardised admissions ratio for health authority where hospital located
- Average length of stay
- Number of cases

Hospital data

- Hospital doctors per bed and per case
- Percentage of nurses at grades A to I, nurses per doctor and per bed
- Number of hospital beds
- Percentage of geriatric beds
- Bed occupancy
- Location inner London, outer London, or outside London
- University teaching, non-university teaching, other general hospital
- Provision of a range of specialist units
- Hospital income per bed and per case
- Total and first accident and emergency attendances
- Hospital charter standards (including waiting times)
- Results of survey of patient centred care (51 hospitals only)

Community attributed data

- General practitioners per 100,000 population (based on health authority of patient residence, individual data averaged at health authority of residence level)
- General practice nurses per 1,000 population in hospital local health authority area
- NHS facilities per 100,000 population in hospital local health authority area
- Underprivileged area (UPA) score (individual data averaged at electoral ward of residence level)
- Percentage of patients with individual UPA social factors with limiting longstanding illness (individual data averaged at electoral ward of residence level)

- Provision of nursing homes, residential care homes in hospital local health authority area

References

1. Ellis R, Whittington D. Quality assurance in health care: a handbook. London: Edward Arnold, 1993.
2. Royal College of Physicians website 1999: http://www.rcplondon.ac.uk
3. Lohr KN, Harris-Wehling J. Medicare: a strategy for quality assurance. Quarterly Review Bulletin 1991;17(1):6-9.
4. BMA, Association of Quality in Healthcare, NAHA. Improving the quality of healthcare – a partnership agenda. London: Association of Quality in Healthcare, BMA, NAHA, 1995.
5. Maxwell RJ. Quality assessment in health. BMJ 1984;288:1470-7.
6. Smith R. Renegotiating medicine's contract with patients. BMJ 1998;316:1622-3.
7. Berwick DM. Reducing errors in medicine BMJ 1999;319:136-7.
8. Brennan TA, Leape LL, Laird NM, Hebert L, Localio AR, Lawthers AG et al. Incidence of adverse events and negligence in hospitalized patients: results of the Harvard Medical Practice Study I. N Engl J Med 1991;324:370-6.
9. Berwick D. Medical associations: guilds or leaders? BMJ 1997;314:1564.
10. Sikora K. Cancer survival in Britain. BMJ 1999;319:461-2.
11. Coebergh J, Sant M, Bertino F, Verdecchia A. Survival of adult cancer patients in Europe diagnosed from 1978-1989: the Eurocare II study. Eur J Cancer 1998;34:2137-78.
12. Department of Health. Minister holds year of delivery for quality in the NHS. Press Release, 3rd February 1999.
13. Hurwitz B. Legal and political considerations of clinical practice guidelines. BMJ 1999;318:661-4.
14. Plato. Statesman (Anna's, Waterfield R, eds). Cambridge: Cambridge University Press, 1995 xvi-xvii, 60-1.
15. Nightingale F. Notes on hospitals. 3rd edn. London: Longman Green, 1863.
16. Department of Health and Social Security. NHS management inquiry (Leader: Roy Griffiths). London: DHSS, 1983.
17. NHS Executive. Clinical guidelines. Leeds: NHSE, 1996:10.
18. Secretary of State for Health. The new NHS. London: Stationery Office, 1997 (Cmd 3807).
19. Grimley Evans J. Evidence-based and evidence-biased medicine. Age Ageing 1995;24:461-3.
20. Scally G, Donaldson LJ. Clinical governance and the drive for quality improvement in the new NHS in England. BMJ 1998;317:61-5.
21. Department of Health. A first class service: quality in the new NHS. London: DoH, 1998.
22. Moran M, Wood B. States, regulation and the medical profession. Buckingham: Open University Press, 1993.
23. Department of the Environment, Transport and the Regions. Cross-cutting issues in public policy and public service. London: HMSO, 1999.
24. General Medical Council. Tomorrow's doctors. London: GMC, 1993.
25. General Medical Council. Implementing Tomorrow's doctors. London: GMC, 1999.
26. Donaldson LJ. Doctors with problems in an NHS workforce. BMJ 1994;308:1277-82.
27. Gainsborough N. Formal mentoring might have helped. BMJ 1998;317:811.
28. Merrison Committee. Report of the Committee of Inquiry into the Regulation of the Medical Profession. London: HMSO, 1975. Cmd 6018.
29. GMC website: http://www.gmc-uk.org
30. Brearley S. Seriously deficient professional performance. BMJ 1996;312:1180-1.
31. General Medical Council. The new performance procedures: consultative document. London: GMC, 1997.
32. Allsop J, Mulcahy L. Regulating medical work: formal and informal controls. Buckingham: Open University Press, 1996.
33. General Medical Council. Duties of a doctor: Good medical practice. 1st edn. London: GMC, 1995.
Irvine General 2nd

Stacey E. Regulation: the political economy of the Health Service. BMJ 1989;309:1114-5.

Armstrong M. Medicine as a profession: dilemmas of change. BMJ 1989;309:927.

Klein R. The state and the profession: the politics of the double bed. BMJ 1990;301:700-2.

Smith KG. Medical discipline: The Professional Conduct Committee of the GMC. BMJ 1989;308:1753-4.

Rosenthal MM. The incompetent doctor: behind closed doors. Buckingham: Open University Press, 1995.

Select Committee on the Parliamentary Commission for Administration. Report of the Health Service Ombudsman for 1995-96. London: Stationery Office, 1997.

Ashley-Miller M. Doctors have surely forfeited privilege of self-regulation. BMJ 1999;317:811.

Rosenthal MM. Multidisciplinary. Lloyd-Bostock S (eds). Medical mishaps: pieces of the puzzle. Buckingham: Open University Press, 1999.

Warden J. Minister to look at safety at NHS hospital's threat to GMC. BMJ 1999;318:482.

Belsey S. Regular check-ups on doctors agreed. The Guardian, 1999 February 11.

General Medical Council. Revalidation. Report of the Steering Group. London: GMC, 1998.

Parboosingh J. Revalidation for doctors. BMJ 1999;317:1094-5.

Irving D. National Health Service: the performance of doctors – the new professionalism. Lancet 1999;353:1174-77.

Weed LL. New connections between medical knowledge and patient care. BMJ 1997;315:231-5.

Browse N, Irving D, Johnson J, Macara A, MacSween R, Turnberg L. Self-regulation and clinical governance at local and national levels. London: BMA, 1998.

Macara A. Making self-regulation work at a local level. BMA Paper. The Royal College of Physicians. Functions and structures of the Royal College of Physicians. Report of a working party. London: RCP, 1998.

Johnson J N. Making self-regulation credible. BMJ 1998;316:1847-8.

BMAC Academy of Medical Royal Colleges, COfMED, Committee of Undergraduate Deans. Making self-regulation work at a local level. London: BMA, 1998.

Smith R. All changed, changed utterly. BMJ 1998;316:1917-8.

Irving D. The performance of doctors. I: Maintaining good practice, protecting patients from poor performance. BMJ 1997;314:1613-4.

Department of Health and Social Security. Discipline: disciplinary procedures for hospital and community doctors and dentists. Report of a joint working party. London: DHSS, 1988.

Department of Health and Social Security. Prevention of harm to patients resulting from physical or mental disability of hospital or community medical or dental staff. Health Circular HC(82)13. London: DHSS, 1982.

Report of Conference. Core values for the medical profession in the 21st Century. London: BMA, 1994.

BMA. The handbook of medical ethics. London: BMA, 1984.

Central Consultants and Specialists Committee. Guidance for medical directors. London: BMA, 1993.

Central Consultants and Specialists Committee. Guidance for developing the role of medical directors. London: BMA, 1997.

Alberti G. Bristol Royal Infirmary Inquiry. Day 9 (30 March 1999). http://www.Bristol-inquiry.org.uk/brisqa.htm.

Banerjee AK. Bristol case highlights potential weaknesses of Calman system BMJ 1998;317:811.

Klein R. Competence, professional self-regulation, and the public interest. BMJ 1998;316:1740-2.

Kerrison S. Roles of GMC, Royal Colleges, and Department of Health remain unclear. BMJ 1998;317:811.

Bloor K, Maynard A. Clinical governance: Clinician heal thyself? London: Institute of Health Services Management, 1998.

MacSween R. The monitoring of clinical standards. Hospital Doctor 1998 June 11:15.

Department of Health. Hospital doctor-training for the future. The report of the Working Group on Specialist Medical Training. London: DoH, 1993 (Calman report).

Buck N, Devlin H, Lunn JN. Confidential inquiry into perioperative deaths. London: Nuffield Provincial Hospitals Trust, 1987.

Gallimore SC, Hulie RW, Ingram GS, Sherry KM. The report of the national confidential inquiry into perioperative deaths 1994/1995. London: NCEPOD, 1997.

Murray I. Closer scrutiny is the response to Bristol deaths. The Times 1998 October 23.

Treasure J. Lessons from the Bristol case. BMJ 1998;316:1685-6.

Smith R. Regulating doctors: what makes them practise as they do? In: Klein R, ed. The quest for excellence: what is good health care. London: King's Fund, 1998.

Secretaries of State for Health, Wales, Northern Ireland and Scotland. Working for patients: HMSO: London, 1989. Cmdn 555. (The White Paper on the review of the NHS.) Working Paper 6: Medical Audit.

Department of Health. Medical audit in the hospital and community services. Circular HC(91)2. London: DoH, 1991.

NHS Management Executive. Clinical audit in HCHS: allocation of funds 1993-94. L(93)334, 23 April 1993. Leeds: NHS, 1993.

Thomson RG, Barton AG. Is audit running out of steam? Quality in Health Care 1994;3:225-9.

National Audit Office. Clinical audit in England. HC 27 Session 1995-96. London: National Audit Office, 1995.

Casanova J. Status of quality assurance programmes in American hospitals. Medical Care 1993;31:1104-9.

BMA. Guidance notes for the commissioning of clinical audit. London: BMA, 1996.

BMA. Ethical issues in clinical audit. London: BMA, 1996.

Berwick DM. You cannot expect people to be heroes. BMJ 1998;316:1925.

Beresford NW, Evans TW. Legal safeguards for the audit process. BMJ 1999;318:654.

Field MJ, Lofah RN. eds. Clinical practice guidelines: directions for a new program. Washington, DC: National Academy Press, 1990.

Wood SH, Grol R, Hutchinson A, Eccles M, Grimshaw J. Potential benefits, limitations, and harms of clinical guidelines. BMJ 1999;318:527-30.

Grimshaw JM, Russell IT. Effect of clinical guidelines on medical practice: a systematic review of rigorous evaluations. Lancet 1999;354:1317-22.

Kirwan JR. Use of guidelines should be evaluated in randomised controlled trials. BMJ 1999;319:543 (letter).

Black D. The limitations of evidence. J R Coll Physicians Lond 1998;32:23-5.

Hurwitz B. Personal communication. 1999.

O'Donnell M. A sceptic's medical dictionary. London: BMA, 1997.

Barton AG, Thomson RG, Bhopal RS. Clinical audit: more research is required. J Epidemiol Community Health 1995;49:445-7.

Walsh K, ed. Evaluating clinical audit: past lessons, future directions. London: Royal Society of Medicine Press, 1995.

Committee of Public Accounts. National Health Service Executive Clinical Audit in England. 3rd report. London: HMSO,1996.

Journal of the Royal College of Physicians of London Vol. 34 No. 1 January/February 2000
Clinical pharmacology and therapeutics in a changing world

A report of a working party of the Royal College of Physicians

The role and influence of specialists in clinical pharmacology and therapeutics in the health service, medical education, government policy and the pharmaceutical industry needs to be more clearly understood and recruitment to the specialty strengthened. Changes in the NHS structure, less flexible training programmes and lack of a clear career structure have led to uncertainty about the role of the specialty — both among employers and those who wish to follow a career in clinical pharmacology — and also to a deficit in training opportunities.

This new report describes in detail the work of clinical pharmacologists in the NHS, in academia and the pharmaceutical industry. Wide ranging activities include the clinical care of patients; clinical toxicology; the use of medicines in the community (pharmacoepidemiology); drug safety (pharmacovigilance); the economics of prescribing (pharmacoconomics); advice to government agencies on the licensing and use of medicines; the teaching of undergraduates and postgraduates; research; and new drug evaluation within the pharmaceutical industry. Many of these activities have particular relevance and importance at a time when the cost and efficacy of new drugs is high on the health care agenda. Extensive appendices include the core content of an undergraduate course, the curriculum for higher specialist training, job plans, and job descriptions for clinical pharmacologists working in industry as project or unit physicians, or in hospitals where they can combine clinical pharmacology with general internal medicine. A full explanation of their role in pharmacoconomics is also given.

Strong recommendations are made for the specialty to be strengthened by training more clinical pharmacologists and by employing them to optimum advantage, for example in training both medical students and doctors as part of their continuing professional development, by involving them in cost-effective prescribing and by creating joint appointments and training opportunities between industry, universities and the NHS.