Editorial: medical audit and the wider quality debate

Richard G. Thomson and Liam J. Donaldson

The publication of the White Paper, Working for patients, heralded a major revolution in the provision of medical care within the National Health Service. Throughout the heated debate which preceded the enactment of the proposals in the NHS and Community Care Bill, the issue of medical audit remained relatively free of the contention which attended other aspects of the reforms.

Yet the decision to implement a comprehensive programme of medical audit raises fundamental questions: Is there a clear understanding by the medical profession as to how medical audit should be practised? What is the relationship between medical audit and other processes for improving the quality of care? What should be the relationship between medical audit and health service management? Are there any lessons in the industrial sector for improving quality in health care?

Working for patients defined medical audit as 'the systematic, critical analysis of the quality of medical care, including the procedures used for diagnosis and treatment, the use of resources, and the resulting outcome and quality of life for the patient'. The achievement of this wide-ranging concept, in practice, requires the establishment of criteria of care so that standards can be set and current practice assessed against them. Opportunities for improvement identified in this way must prompt action, the effects of which are then evaluated to demonstrate that audit has achieved its desired aim. Standards can then be reviewed and, if necessary, redefined. This cyclical process is crucial to effective medical audit. Without the complete cycle, audit will be performed as an act of faith, and those involved will not receive feedback to encourage continuance.

The full implications of this for the practice of medical audit may not yet have been grasped by clinicians. Effective entry into this medical audit cycle necessitates the collection, analysis and interpretation of data on populations of patients, for comparison against standards so that an objective analysis is possible and a baseline can be set to assess subsequent change. Thus, although discussion of individual cases is an integral feature of good medical practice and may itself suggest topics for subsequent audit, it cannot drive the cyclical process, nor can it reveal the overall quality of service.

Therefore, medical audit is not equivalent to specialty-based meetings to discuss esoteric or interesting cases, albeit that such meetings have important professional and educational value. Moreover, although the discussion of individual deaths or disasters may point towards areas for improvement, without data on a population of such cases over time, improvement will be impossible to demonstrate and there will be a tendency for subjective analysis to predominate. This importance of aggregated data to feed the audit cycle needs to be more clearly recognized.

Another practical issue arises from similarities between projects undertaken under the auspices of medical audit and those styled as health services, or clinical, research studies. Already, it is commonplace to see committees sifting proposals for medical audit schemes and rejecting some on the grounds that they are 'research'. Yet there is often no clarity of thinking underlying such judgements.

Medical audit will undoubtedly depend upon an already validated body of knowledge, informed by research studies, to set standards, for instance. It is also clear that much medical audit will require the application of research methodologies and that such methods will need to be well understood and correctly applied to ensure appropriate conclusions. In the broadest sense, as a means of advancing knowledge through critical or scientific enquiry, medical audit might be considered as research, but there is a legitimate question as to whether original research can be placed within the bounds of...
medical audit. On the other hand, medical audit may well reveal areas where further original research is required.

Thus, although there is no precise demarcation between medical audit and research, the debate is clearly more than a semantic one and warrants further consideration. In the mean time, those planning and practising medical audit would do well to bear in mind both the ethical framework which protects patients in the research context and the rigour associated with thinking through a research proposal which helps to justify the investment of resources in it.

The relationship of audit to medical education is clearer. It is, in itself, an educative process, and there is a clear role for undergraduate and postgraduate medical education, both in terms of the methods appropriate to audit and, in the latter case, in the response to areas where deficiencies of skill or knowledge are identified. Links between medical education and audit will also serve to emphasize the role of audit as a tool for improvement.

Improvement in the quality of care provided to patients is the ultimate aim of medical audit. Donabedian views quality of health care as having three major components: technical, interpersonal and amenity. The technical elements constitute investigations, treatment and interventions, which most clearly fit into that which much clinical opinion would see as the remit of medical audit. Interpersonal elements include such features as communication and consideration of patient dignity, and amenity elements include, for instance, catering, laundry and environmental conditions. The public health perspective would add to this the care provided to the community, involving dimensions such as access and equity.

It is obvious that medical audit alone is insufficient to ensure improvement in all these areas. Moreover, few doctors would argue that the quality of care they provide is not influenced by nursing and paramedical staff, by radiography and catering services, by portering and patient transport. To take account of such features, the assessment of quality must go beyond medical audit, which is an important part of wider quality improvement programmes, but only a part. Yet there is a danger that medical audit may become an isolated, purely professional activity, focusing on physician performance and hence discouraging synthesis into this wider, corporate view of quality. There is a risk that doctors will perform medical audit and others, including managers, will be responsible for 'quality assurance'.

But any suggestion that medical audit should be subsumed into wider quality management programmes causes concern in some clinical quarters, with the fear that professional interests will be open to wider scrutiny. This is bound up with misgivings about managerial interference in medical practice, a theme developed by Black in the previous issue of this Journal. These concerns are partly explained by experience elsewhere, particularly in the United States, where peer review has become somewhat discredited in the eyes of the medical profession, not least because of its mandatory imposition by Federal Government for Medicare and Medicaid patients. Carried out by external Peer Review Organizations (PROs), this review process has, as a final sanction, the withholding of payment for care from physicians and health care organizations, following a process of consideration of individual cases against defined standards.

Despite this, in the United States models of integration of peer review into wider quality assurance programmes have been developed. However, although many health care organizations have developed systems and structures for quality management that include peer review as one element of the quality management approach, there is still a tendency for the peer review element to be largely concerned with identification of the outlier.

Recently, commentators have discussed quality improvement in health care employing Total Quality Management (TQM), which has been widely lauded as the reason for the dominance of Japanese over U.S. manufacturing industry. TQM is grounded in relatively simple theories with obvious face validity. Ironically, the theorists who have driven this process in Japan are American, particularly Deming and Juran. The basic postulates of their theories provide an interesting contrast to the approach that appears to be developing under the label 'medical audit'.

The TQM approach concentrates much more on processes and systems than on outcomes (outputs) and individuals. As such, it is less concerned with identification and sanction of outliers and more with the improvement of the whole. Its influence is aimed at the whole population rather than the tail, a concept that should be comfortable for practitioners in public health. Consequently, TQM recognizes the multidisciplinary nature of quality improvement.

In industry, TQM is largely built upon well-defined linear processes amenable to intervention, with a knowledge that such intervention will produce higher-quality output. It depends upon statistical analysis of the processes of production and subsequent process improvement, leading to reduced waste and decreased need for output inspection.

TQM has a number of essential elements: a commitment to quality from the highest level of the service; a participative environment, where all members of an organization are valued; a good quality system, concen-
trating on processes rather than individuals; a personnel approach based upon training, education and staff development; a focus on and a relationship with the customer that takes account of their views and wishes; a recognition of the importance of continuous quality improvement; and an investment in quality, recognizing that quality improvement can increase returns through reduced wastage.

The most compelling critic of the present approach to quality improvement in health care in the United States, based as it is upon sanctions, discipline and concentration on the individual, is Berwick. He has described this as the 'bad apple' approach, and points out that it leads to defensive responses and a desire to be acceptable, to conform to minimum standards. It risks alienation, fear and unease, in contrast to the TQM approach.

Berwick favours the term 'continuous quality improvement' to TQM. He argues that this can be realized through constant effort to reduce waste, rework and complexity. By concentrating on the mean rather than the outlier, the entire curve of variation can be shifted. By concentrating on the processes of care, using well-founded analytical tools, opportunities for general improvement can be identified. By developing protocols and guidelines for the complex processes of patient care, improvement of all, rather than the outlier, can be realized. Dialogue with the consumers of health care is necessary to underpin this, and the approach is based upon respect for health care workers, assuming that, in general, they act in good faith and very rarely with malintent.

There is a question as to how applicable such an approach is, given the inherent variation of patients and the greater complexity of health care. Some light is thrown on this through a practical example. Doctors take blood samples for investigational purposes. Before further investigation or treatment, there is a complex process, which involves a multitude of actions and decision points, including taking the right sample, correct labelling, transport, laboratory handling and quality control, transmission of results, receipt in the doctor's office, interpretation, and finally decisions on the response. Each element of health care will include a multitude of such complex processes. Poor quality outcome for the patient will arise from poorly designed, run and executed processes. Thus, without a co-ordinated approach that recognizes the organizational as well as the more restricted medical issues, quality improvement will be constrained and potentially fragmented.

The creation of a shared view of health care quality, incorporating consumer, managerial and professional perceptions, and the development of effective organization-wide processes for continuously improving quality, poses a major challenge for the NHS. There is a nettle to be grasped in addressing the sensitive and, for some, threatening issues which underpin this debate. However, the changes in the service, currently under way, offer an opportunity for all staff groups to recognize their common purpose in ensuring high-quality health care, and to begin to work together to stimulate continuous quality improvement. Medical audit has an important role to play, not least in monitoring and displaying quality improvement, but it must not be allowed to develop in an indefensible isolation from other quality improvement programmes.

References