Setting national standards

Quality: a view from the centre

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"Where is the life we have lost in living?
Where is the wisdom we have lost in
knowledge?
Where is the knowledge we have lost in
information?"

T S ELIOT

There is no doubt that quality is a central issue in health care at present. Indeed it could be said that quality is at the heart of medical practice. The concept, however, is not new and can be viewed as a part of the long tradition of professional practice. Recently, targets and quantitative aspects have been introduced into the measurement of quality – for example, in relation to immunisation – formalising what has been until now a fairly subjective approach. From the centre it is a concept seen as basic to the continuing improvement of health care. It is also an issue which is part of professional development and education and is related to clinical audit, accreditation, standards, guidelines, and protocols. This paper will set the scene as viewed from the centre and place quality and standards in perspective. There are two broad themes. The first is to discuss the role of the doctor and other health professions in the delivery of high quality health care, and the second is to emphasise the role of the patient and the public in determining quality. This paper will, firstly, tackle the definition of quality and its implications. It will then set quality in the context both of health and health care. Finally, it will discuss some of the issues surrounding clinical standards. Though this paper will be relevant to all health care professionals, most of the specific issues will relate to doctors.

Definition of quality

"I know there is such a thing as quality, but
as soon as you try to define it, it goes
haywire and you can't do it."

R PIRSIG

Zen and the Art of Motorcycle Maintenance

The topic of quality raises a series of difficult questions including what does quality mean, how can it be measured, and who should measure it? The literature is full of definitions, and the following, though not entirely original, tries to encapsulate some important components.

"Quality is a concept which describes in both quantitative and qualitative terms the level of care or services provided. Quality as a concept therefore has two components. The first is quantitative and measurable, the second is qualitative, though assessable, and associated with value judgements. Quality is a relative not an absolute concept."

Quality is not therefore an analysis of activity. In describing the quality of a service it must always be compared with something else – either a similar activity or the same activity measured at another time. It also implies measurable consistency over time. Thus quality, as a relative concept, can always be improved, and that is at the heart of all quality initiatives, the process of continual improvement.

Quality can be related to the achievement of specific aims, objectives standards, and targets. These standards should not be seen as fixed, as they will inevitably change as medical advances arise and improve the outcome of care.

As quality of care is a multidimensional issue, how can the quality of care provided by doctors or other health care professionals be measured? The following suggestions are made to stimulate discussion and to raise a further question as to who should measure quality. Thus quality of medical care, as an example, could be seen to comprise:

- Knowledge, technical skill, and competence
- Professional standards, including ethical issues
- Attitudes and behaviour, including communication skills
- Managerial functions, including the ability to work within resources
- Teaching, audit, and research.

There is considerable overlap between these headings, but for each it is possible to determine how, and who, should measure performance. For example, it might be reasonable that the first of these – knowledge, clinical skills, and competence – would be assessed by doctors, but that most of the others could be assessed by other professionals, managers, and the public, as well as by doctors. Objective as well as subjective assessments are required.

Thus the interest in raising quality is a long standing one. What is more recent is the proliferation of specific initiatives and systematic methodologies to achieve it. The background and description of some of these do not readily identify them as tools for improving quality. It is suspected that many participants in medical audit programmes or accreditation schemes would not immediately recognise the close relation between their activities and a quality assurance programme. Therefore there is the risk that several disparate activities can be simultaneously under way, based on quite different concepts of quality, with the potential for conflict and duplication of effort. The Department of Health has recently created an identified focus for quality in health services with the intention of integrating work on all those activities related to quality. Health authorities are recognising a similar need.

This raises the general issue of total quality management and continuous quality improvement. Both of these initiatives are being developed within the NHS. They build on two crucial principles which are well established elsewhere and should be equally familiar to those in the health service.

- (1) Do things right first time,
- (2) Work for continual improvement.

It is important that the challenge of improving quality is taken up by the professions and that attempts are made to quantify the issues and to improve the care provided. This improvement should be based not only on the processes involved but on the outcomes. This is difficult. In working towards achieving improvements, however, the management tasks, so derived, need to be addressed, and professional staff need to ensure that managers are fully involved at the earliest possible opportunity and that initiatives to improve care are seen as examples of joint working.

Outcome of health care

An outcome of health care might be said to be the effect on the patient, family, and community as the end result of one or more episodes of care provided over a period for an individual. Episodes of care may be judged objectively and subjectively by that individual, the community, and the professional staff involved. The outcome must be related to the objectives of care set by the patient and staff at the start of the episode. Outcomes are important as they form the basis of decision making, and hence resource allocation, and identify areas requiring more work.

This definition emphasises the importance of time in determining outcome and, in addition to objective measures, the need for subjective evaluation and value judgements. It also places some onus on the community to be involved in assessing outcome, as its measurement will be one factor in determining the need for resources. Finally, it makes the point that patients should be involved in setting the objectives of their care at the start of the process.

Some factors influencing outcomes of care

- (1) The health of the individual at the start of the process of care. This is a complex issue and will include broader social dimensions such as support at home
- (2) The illness, its natural history, and the prognosis. This is often forgotten, yet it may be the most important determinant of outcome
- (3) The treatment available and its effectiveness. This assumes that the treatment has been properly evaluated
- (4) The clinical skills available and the skill mix of staff. The educational and manpower dimension
- (5) The facilities and resources

Several factors influence the outcome of care (box), and, though it is usual to consider mortality or morbidity data when dealing with outcome, quality of life is equally important. This emphasises again the importance of involving patients in decision making.

In considering how best to improve quality of care for an individual patient, the first two items – previous health and the natural history of the disease – are clearly important, though to change them will require more research and effective public health intervention. The third and fourth items relate very specifically to the quality of clinical care provided. In particular, they refer to the need to use effective treatment and to keep up to date with new developments. They also emphasise the need to improve skills continually and to ensure that the individual doctor is competent to carry out the tasks required. These requirements will be discussed in more detail later. The final point on facilities and resources will be influenced by the ability to determine effective outcomes and to achieve value for money, hence the need for involving management. Outcomes are known to vary by geographical location and by the individual professional providing care. For this reason there is, once again, a real professional challenge to measure outcomes and improve quality.

OUTCOMES IN A WIDER CONTEXT

Outcomes are generally considered in relation to the effect on the individual patient. But three other matters need to be considered (box). The first relates to the role of professional staff in measurement. They have a crucial role in assessment of outcome, and, indeed, this process should be part of routine practice. However, there may be differences between what a patient or relative and a doctor thinks of as a “good” outcome. These

Issues associated with improving quality and outcomes

- Effect on patients
- Reconciling differing views of good quality care of staff, relatives, and patients
- Public involvement
- Resource implications

differences should be recognised and analysed. They can be the beginning of greater insight into "outcomes" for staff, relatives, and patients. Thus what patients and families think as of "quality" and their response to existing services need to be carefully considered.

The second issue relates to quality, outcomes, and the community. Ultimately it is the public, through a series of processes, who determine the resources for health care. It is important therefore that the public, as citizens as well as potential patients, are informed and involved in what outcomes and quality mean and that this dialogue is seen to be part of the ongoing process of continually improving the service. This represents a further challenge to doctors in communicating to the public the nature of the issues concerned and the standards of care which can be expected.

Assessment of outcomes is very complicated. It requires an ability to measure baseline and end point states, whether in relation to health, reassurance, satisfaction, or other effects. Measurement of health, which, as mentioned, includes not only disease states but also function and patients' perceptions of wellbeing, is in itself complicated. But outcomes go beyond just measurement of change from baseline to end point. For such change to reflect quality of care we have to be able to show that it was actually a result of that particular care. Demonstrating a change in health status, for example, requires teasing out the effect of that care from all other possible influences on health.

In order to coordinate the development of ability to undertake such assessment, at both professional and organisational levels throughout the NHS, the Department of Health has created a Central Health Outcomes Unit. The unit will provide a central focus for understanding the issues, challenges, and omissions; it will formulate objectives and strategies, provide a lead in technical development and implementation of the methods, and critically appraise the results. In addition, the department has commissioned the University of Leeds to establish a UK Clearing House for Information on the Assessment of Health Services Outcomes. The clearing house will collect, collate, and disseminate the most up to date international information on assessment of outcomes, both from published reports and from people working on outcomes assessment, and it will be a source of expert advice.

The third issue relates to implications for managers. Managers, including those doctors who manage resources, need to be aware of the consequences of searching for quality and continually improving the service. All concerned are on the same side and should be working as a team towards better patient care.

Several tools are available to help in trying to improve quality, and some of them will now be discussed further. They include the information and databases available; medical

(or clinical) audit; guidelines, protocols, and standards; and the assessment of competence.

Information requirements

It is extremely difficult to assess quality or competence or to set standards for outcomes without the ability to monitor and measure progress. The basic building block of all health care is the medical consultation and the consequent diagnosis, and there is no excuse for this not to be well documented and recorded. The medical record is the basis of much subsequent information, and without elaborate computer systems the recording of data by doctors could be considerably enhanced. The sophistication which can then be provided by computers and information systems would be much more effective. Doctors and managers need to think about the types of information they require and to develop systems to collect and analyse the data obtained.

Role of medical audit

Medical audit is not a new concept but one which has been rediscovered. Various definitions have been used but the most common is that medical audit is "the systematic critical analysis of the quality of medical care, including the procedures used for diagnosis and treatment, the use of resources and the quality of life of the patient." Thus this definition emphasises the role of medical audit in improving quality. The process has been called "medical audit," implying that it is an activity carried out by doctors. But this is clearly not always the case. All health professionals are involved, and for this reason the process is perhaps more accurately referred to as clinical audit. The term "clinical audit" has been used to embrace "the activities of all health care professionals who work directly with patients, such as nurses, doctors, and paramedical staff." Clinical audit can thus be equated with "multidisciplinary audit."

The definition of medical audit used above makes several important points. Firstly, that the process is systematic, in which the doctor (or other health care professional) regularly reviews his or her work. Secondly, it is a process in which the outcome is critically analysed. Medical audit is not therefore simply a collection of data for its own sake, rather it must ask questions both of the outcome of care and the ways in which the care is provided. Thirdly, the process is generally one of peer review, and this relates particularly to the confidentiality of data. The longstanding grand rounds, clinicopathological conferences, and ward meetings show how effective this can be. However, the results of audit need to be shared with others and to be used to inform decision making about the resources required for care. For this reason it is essential that doctors and all other professionals, including managers, become more used to working together as the norm and that they recognise within the process the importance of con-

tributions from the patient and the public. Clinical audit is a multidisciplinary process and should be encouraged.

But what of the process itself? In outline, the process of "medical" audit is like many similar cyclical schemes which involve reviewing data, changing behaviour, and monitoring progress. The educational cycle or the quality cycle would be an example of this. In essence, it begins with an assessment of the issue to be audited. This might entail data collection or an analysis of existing information. This process in itself may be sufficient to modify practice. The second step is to plan the intervention or change required. It might be introduction of a new procedure, the modification of an existing one, or the clearer definition of the standards required. The third step is to implement the plan, over a period of time, and the final step is to monitor the outcome and revise the objectives. At any stage there may be a return to the assessment or planning stage. The cycle is then repeated, the standards being regularly updated and improved. It should be emphasised that the topics chosen can represent a very wide range of issues and that the audit can be of outcome or process. The cycle described above is intimately linked with educational development, which assesses knowledge, skills, and attitudes; determines the changes required to improve patient care; and implements them with due regard to resources.

Guidelines, protocols, and standards

Consideration of the audit process leads to a discussion of the use of guidelines, protocols, and standards in improving patient care. It is important that these three terms are not confused. Protocols relate to specific illnesses and are generally tightly written; deviation from them is unusual. Guidelines are more flexible and more general. Standards indicate the overall objective of management and may be achieved by using guidelines and protocols.

In general, it seems to be a good idea to ensure that methods of patient management are written down and agreed. The educational value of doing this is, in fact, considerable. There are, however, some problems. The first is the obvious problem of the patient whose management does not quite fit into a particular protocol, or who, for perfectly good reasons, does not wish to agree to the proposed management – that is, the patient choice factor. The second is the issue of clinical freedom and the need to be able to improve current best practice and to carry out research and development. The third is in some ways more serious and refers to possible legal constraints if protocols or guidelines are not adhered to. Each of these issues can be overcome, and the whole process could be kept within the professional sphere with one important proviso – namely, the ability to deal with doctors or other professionals who do not perform to an adequate standard. Professional competence will be discussed in more detail later. Finally, there is the issue of resources, an

important element in the development of standards.

Where do protocols, guidelines, or standards come from? They arise from the systematic analysis and evaluation of clinical practice and the audit of the results of outcome. They are modified by new developments and there will always be the need to retain flexibility and encourage ways of improving care. Based on the concept of continuous improvement, this is, in fact, an essential component of any quality programme. Thus standards or guidelines represent a view of the best practice in clinical care at a particular moment and should not be seen as the definitive statement on how best to manage a specific clinical problem. For any given illness several guidelines may be available because of differing views on the best treatment. Such differences then highlight the need for comparative trials. This does, however, emphasise that with some illnesses there may be no "right" way to achieve the most effective outcome.

A further function of writing down standards is that they can then be communicated to others, including patients and the public at large, who have a right to know what to expect of treatment and its outcome and to assume that their clinical team is using up to date methods of treatment. Finally, there is a real educational value in communicating with other staff about the standards to be adopted and delivered. The audit process and the development of guidelines are thus powerful aspects of continuing education.

Structured approach to clinical decision making

By taking this process further it is possible to develop what might be called a structured approach to clinical decision making, which essentially formalises current good clinical practice. The process begins with listening to the patients, explaining the issues, giving information, and involving and communicating with them. The importance of choice needs to be emphasised. The second part is the diagnosis, assessing the relevant prognostic factors, and ensuring that investigations required are then identified. When necessary, specialist advice is sought. At this stage the objectives of treatment become clearer and can be developed with the patient so that the final assessment of outcome can take these into account. The importance of choice again needs to be emphasised. The third part is the development of a structured treatment plan, based on guidelines or protocols or related to defined standards which have been devised by specialist groups. This allows the individual doctor, in consultation with the patient, to use the treatment best tailored to fit individual needs. This is a crucial step as it allows for flexibility but at the same time offers a structured approach. However, it carries with it an obligation to evaluate the outcome and to ensure that the results of a clinical management programme, developed by an indi-

vidual doctor, compare with those of others. This must include a value for money exercise and an assessment of the management and resource implications. Without this there is little justification for deviating from "best practice" guidelines developed by others. The final part is the identification of outcome measures and the assessment of the timing and need for follow up. This is then the start of the audit process, which is then fed back into the cycle.

The action therefore required by the doctor might be summarised as follows:

- For each disease or illness each clinician or clinical group should develop structured plans which cover the issues raised above, based on guidelines prepared by specialist groups locally, regionally, or nationally
- Regular audit and monitoring of the plan is essential
- Involvement of patients within the process and in determining the objectives of care is crucial
- The management and resource implications of using protocols need to be carefully considered in conjunction with general and financial managers.

Much of this and previous discussions have centred, and indeed have been based on, the notion of clinical competence.

Competence and performance review

Competence is an issue central to quality. It concerns standards of care and the knowledge, skills, and attitudes which doctors and other health professionals should possess at different periods in their career. Thus it should be possible to distinguish between a house officer and consultant in terms of performance and competence. The assessment of competence is an important activity and relates the performance of an individual doctor to a given set of criteria. In general, it is carried out by other doctors and based on comparisons with others in similar specialties and grades. As discussed earlier, there is of course no reason why the assessment should be the responsibility of doctors. Others, including nursing staff, managers, and patients have a role in the process. Indeed, it might be claimed that they could be more objective than doctors.

The criteria by which an assessment of competence is based can be derived in various ways. The simplest is to compare the activity and the outcome of care provided by an individual doctor with those provided by a range of other doctors. This can be done by observation and by objective measurement of evidence of activity and outcome, such as results of treatment, scrutiny of case sheets, participation in clinical trials, and the results of audit. The results may be compared with others working in the same geographical area, or in other parts of the country, or abroad. From such experiences it becomes possible to identify the criteria required of the competent doctor.

Another way of developing such criteria is to use the process of critical incident analysis. Such a process analyses the results of asking

large numbers of doctors in a particular specialty what are the areas of particular difficulty or importance and which are easier to deliver. From this an assessment can be made of those areas, or "competencies," which are required to deliver a proper level of service. These can then be evaluated in individual doctors.

Once a doctor has been designated as "competent," perhaps at the end of the period of postgraduate training, the next question which arises is whether or not he or she should at regular intervals undergo periodic "accreditation." In an ideal world continuing medical education would be the way in which doctors kept up to date. For various reasons this may not be sufficient in itself, without some incentive to continue to learn. It is for this reason that several medical organisations in different parts of the world have used some form of re-accreditation process. In general, this involves a formal assessment of workload, outcome and audit of clinical work, and educational experience, on a regular basis – for example, every five or ten years. This is not the norm, but several specialist societies and colleges are discussing its implementation. There is an ethical obligation for doctors to ensure that the management of an individual patient is both competent and up to date. This is the least that patients can expect.

This process, however, has an important implication. There is no problem if the doctor is found to be competent and is able to be re-accredited. But what if the doctor is found wanting? This is a key issue, and it has been discussed for many years. If the medical profession, and other professional groups, are to be self regulating and are to retain the confidence of the public then they must be able to tackle these difficult problems. The General Medical Council is in the process of discussing the issues of performance review.

Role of doctors

In issues of quality, what then is the role of the doctor? There are three possible roles:

- (1) To provide the best possible care for individual patients. This is the traditional clinical view of quality. It is related to skills, experience, and knowledge. It involves the patient in determining the objectives of care and in the assessment of outcome.
- (2) To recognise the needs of the wider community in which doctors practice. This emphasises the role of the doctor in improving the public health as well as that of the individual citizen. Doctors have a responsibility for the health of the community in which they work.
- (3) To ensure that resources are used effectively. This combines the first two points and highlights the need to provide a service which manages resources most effectively and delivers to the patient and to the wider community value for money. This implies that doctors will have a greater responsibility for setting priorities and for resource management and that cooperation and collaboration with managers is crucial.

Conclusions

Creating a climate and culture of quality and excellence should be part of professional education. This emphasises the need to create an atmosphere, an ethos, a social context, in which certain standards of behaviour and professionalism are seen to be built into the education and training in medical schools, and through postgraduate training and continuing medical education.

The challenges, repeatedly emphasised, are there to be seized. In the interests of continually improving the quality of the

service it is essential that doctors and other professional groups pick up the challenge and take part in leading the process of change and improvement. Perhaps the rallying cry should be "Carpe diem," "seize the day," and make use of the great opportunities which are now presented but which require leadership to succeed.

"We shall not cease from exploring
And the end of all our exploring
Will be to arrive where we started
And know the place for the first time."

T S ELIOT.