Practical experiences in auditing patient outcomes

M J Bardsley, J M Coles

Much of the recent effort in the development of clinical audit has focused on what Donabedian describes as the structure and process of care.1-3 There have been relatively few attempts at routinely monitoring outcome measures other than at the most basic level—for example, mortality statistics. Most current health service information systems describe the activities undertaken by the service yet, as the Griffith’s report4 pointed out, they tell us little about what actually happens to patients’ health. Such information, though, is important within the clinical audit process and to any complete assessment of the efficiency and effectiveness of health services.5-7

This deficiency in health service information has several causes, including uncertainties over how to measure outcome and the difficulties and the perceived costliness of collecting the necessary data. However, recent pressures for better information on the quality of care, together with improved technologies in data capture and outcome measurement, have made the assessment of patient outcomes more achievable.

The CASPE (Clinical Accountability, Service, Planning and Evaluation) study of monitoring patient outcomes started at Freeman Hospital in the autumn of 1988 as a feasibility study to examine ways in which practical outcome measures could be developed and included in clinical audit and decision making within the hospital.8 The study revolved around three key questions:

- Is it possible to agree acceptable indicators of patient outcome with clinicians?
- Is it possible to collect the information for routine monitoring of patient outcomes?
- Does information on outcome lead to changes in practice?

This paper describes the progress made in this difficult area and identifies issues of general interest concerning outcome monitoring.

Outcome measurement in the CASPE/Freeman study

The objectives of outcome measurement vary widely across studies and will necessarily affect decisions about the approach to be adopted and the scale of data collection. At one level outcome measurement may be part of the clinical process focusing on the individual patient and typically using clinical proxy measures of health rather than direct measures of patient wellbeing.9 10 Beyond the individual patient, outcome measurement has often centred on individual projects such as detailed clinical trials11 or retrospective epidemiological studies—for example, of avoidable mortality.12 13 Studies have also examined the effect of patient and process variables on outcomes,14 the clinical decision making process,15 and economic cost utility.16

In the past few years the emphasis has been on building outcome measurement into the routine clinical management of departments and hospitals. Initiatives have included, in the United States, interhospital comparisons of outcomes for selected conditions and specialties17 and, in the United Kingdom, identification of outcome measures based on existing data.18 19 Nationally, in the United Kingdom the confidential enquiries—for example, the confidential enquiry into perioperative deaths (CEPOD)20—come closest to an audit based approach to the continuous monitoring of outcomes. Such an approach accepts the total caseload, rather than specifying particular entry criteria, with the significance of particular presenting characteristics being examined a posteriori.

The CASPE/Freeman study followed this latter approach and aimed at providing a routine information system that would regularly make available to clinicians indications of the success or failure of care against agreed criteria. As Ellwood pointed out in his lecture on outcomes management it was to be expected that “… standards and outcome measures would be constantly subject to modification based on the results of analysis and feedback.”21

Developing local outcome criteria

Donabedian defined outcomes in terms of “a change in patients’ current and future health status that can be attributed to antecedent health care.”2 The first problem to face the research team was therefore to identify practicable ways of monitoring health status. The work was undertaken in parallel in several specialties covering both acute and chronic illness and across the inpatient and outpatient base. The case types studied included diabetes, cholecystectomy, knee replacements, care of the elderly (rehabilitation in the acute hospital), and percutaneous transluminal coronary angioplasty (PTCA). We adopted a similar approach in each specialty with seven discrete steps being identified, as described below.

CHOOSING SUITABLE REFERENCE GROUPS

In most of the areas examined a single condition was selected as an initial reference group around which to focus discussion. The choice of condition was guided by the
following criteria: (a) a sufficiently large volume of cases to enable reasonable statistical results to be obtained and to represent a sizable proportion of the specialty’s workload; (b) significance in terms of health status of the patient; (c) capability of reference to an agreed standard; (d) relevance to specific processes, areas of contention, or uncertainty in care; (e) practicability of data collection.

In many circumstances the study found that the potential outcome measure was relevant across different disease groups – for example, avoidance of death or improved “wellbeing.” However, even with these common measures variation was found between case types in, for example, the choice of relevant periods between measurements, the importance of different presenting characteristics, and the likely standards for comparison.

IDENTIFYING EXPECTED CHANGES IN HEALTH
After a reference group had been identified the next step was to agree with clinicians on the changes in health they would expect to see (the patient outcomes) over specified periods. For some conditions – typically those resulting in an acute inpatient episode – the outcomes were the changes noted from admission to hospital to three months and 12 months after discharge. In the case of chronic conditions it was necessary to consider longer timescales, with outcomes being considered as the marginal change in the patient’s health over time. These might be in terms of positive improvements in the patient or, alternatively, avoidance of a deterioration in health. The first time period typically started at the first contact with the service and continued until a follow up clinic or regular review appointment. When possible, the expected standards of outcome were agreed. However, given the novelty of some of the approaches, for example, patients’ own view of their health status, absolute standards were not always achieved and the study had to accept general directional terms such as “all patients should show improvement.”

IDENTIFYING POTENTIAL EFFECT MODIFIERS
In monitoring the benefits of particular interventions it was important to identify any presenting characteristics that might affect the eventual outcome. This was particularly important as the study focused on secondary care, where potential improvements might have been limited by a patient’s previous medical history. Such variables should then be used to define subsets of patients expected to achieve similar outcomes. For example the expected outcomes for young, otherwise healthy patients having cholecystectomy are likely to be different from those expected for elderly patients presenting with significant accompanying conditions. The practical importance of these variables in explaining observed differences in outcome can be evaluated once results become available.

In our experience there was a tendency to overspecify such characteristics. Variables such as obesity did not often seem to affect the eventual subdivision of the patients database, given that such subdivision would further dilute the sample size.

IDENTIFYING DATA REQUIRED TO MONITOR CHANGES
In most cases the relation between the outcome indicator and the type of data required to create it was clear and straightforward. For a clinical assessment of the patient important information will probably have already been collected in some form and the task will be to ensure the use of valid definitions, consistency of recording, and collection of data from various manual systems to a single analysable form. However, new data collection systems were required to examine outcomes from the patient’s perspective.

IDENTIFYING THE BEST METHODS OF DATA COLLECTION
The methods of data collection developed during the project showed strong similarities across specialties, although not all specialties required the full range of methods, which included (a) simple forms completed by clinicians or research staff, (b) questionnaires completed by patients, (c) extracts from existing computerised and manual systems, (d) information from carers outside the hospital, and (e) information from lists of notification of deaths.

Though existing data sources, when supplemented with information from patients, were able to provide much of the information required, some additional data collection by clinical staff was needed. This had to be justified on the grounds that it replaced or improved existing methods of data collection, it provided other significant benefits, as information, or it was considered essential for the review of outcomes.

PILOTING DATA COLLECTION
The pilot stages of any project raise questions over the feasibility of collecting certain items of information, particularly on a continuing basis. The different methods of data collection that emerged were tried and evaluated in terms of reliability and consistency. Issues over the definition of data items also arose at this stage – for example, how is unstable angina defined? The review of data collection systems and definitions formed part of the feedback process and the discussion of results. These systems underwent an iterative development which responded to demands for new items of data to be added without losing the necessary stability of key data items needed for longer term trend analysis.

FEEDBACK OF RESULTS
The purpose of collecting outcome information was to inform clinical practice and identify possible areas for change. This was undertaken within an audit framework with results being presented at regular meetings with the clinical staff concerned. Data were fed back to clinicians which summarised changes
in individual patients; provided specific reports on patients with "poor outcomes"; described the changes that had taken place, on aggregate and when subdivided into key groups. It was recognised that, increasingly, hospital management will need to become concerned at the aggregate level with the successful delivery of care through the contracting process and may well need outcome figures to support this process. Even here, careful interpretation of the data will be required.

**Results**
The findings are reported in relation to the three main questions of the study.

**OUTCOME MEASURES**
The indicators that emerged considered different dimensions of outcome as potential candidate measures and ranged from specific clinical and laboratory assessments to more general descriptions of health and patient wellbeing. It is becoming increasingly accepted that the patient’s perspective is critical in assessing the effectiveness of health care, and experience in polling patients on different aspects of their health, quality of life, or satisfaction with treatment is growing.

Table 1 summarises the sets of indicators used for cholecystectomy, knee replacement, and angioplasty and table 2 those for diabetes and care of the elderly. The range of outcome measures identified and used in this study are described below.

**Deaths and survival** – Though the observed rate at which patients die varies widely across conditions, in most settings survival is a critical outcome measure.

**Major adverse events** – After treatment there may occur possible serious health related events, typically indicators of worsening patient health, which might be considered as proxies of outcome. These include readmissions, attendance at accident and emergency, and repeat angioplasty in stable angina patients.

**Treatment complications** occurring over a short period – for example, infections, urine retention, deep vein thrombosis, and other specific complications related to particular body systems – might be considered important in assessing outcomes.

**Technical success of treatment** – In some circumstances the successful administration of the treatment itself may be considered an outcome – though it is also a process measure; the best example from this study is dilation of vessels during angioplasty.

**Relief of specific symptoms or problems** was

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**Table 1 Examples of outcome indicators for cholecystectomy, PTCA, and knee replacement**

<table>
<thead>
<tr>
<th>Cholecystectomy</th>
<th>Angioplasty or PTCA</th>
<th>Knee replacement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Successful treatment or care</td>
<td>Successful removal of gallstones and no immediate complications</td>
<td>Vessel dilated during PTCA</td>
</tr>
<tr>
<td>Treatment complication</td>
<td>Minimal postoperative problems</td>
<td>Minimal problems after PTCA</td>
</tr>
<tr>
<td>Specific symptom or problem</td>
<td>Relief of pain, vomiting, distension, bowel function, flatulence, fatty foods</td>
<td>Decreased anginal pain, increased walking distance</td>
</tr>
<tr>
<td>General health</td>
<td>Improved NHP score</td>
<td>Improved NHP score</td>
</tr>
<tr>
<td>Major adverse events</td>
<td>No related readmissions</td>
<td>No related readmissions, especially CABG, repeat PTCA</td>
</tr>
<tr>
<td>Death</td>
<td>None</td>
<td>None for stable angina</td>
</tr>
<tr>
<td>Other indicators</td>
<td>No related visits to accident and emergency</td>
<td>Reduced potency of medication</td>
</tr>
<tr>
<td>Important discriminatory variables</td>
<td>Age, acuity, comorbidity</td>
<td>Age, angina type, degree of stenosis, previous history</td>
</tr>
</tbody>
</table>

PTCA = percutaneous transluminal coronary angioplasty. NHP = Nottingham health profile. CABG = Coronary artery bypass grafting.

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**Table 2 Examples of outcome indicators for diabetes and care of the elderly**

<table>
<thead>
<tr>
<th>Diabetes</th>
<th>Care of the elderly (rehabilitation)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Successful treatment or care</td>
<td>Improved metabolic control HbA1c, body mass index</td>
</tr>
<tr>
<td>Treatment complication:</td>
<td>Control of risk factors (for example, hypertension, cholesterol)</td>
</tr>
<tr>
<td>Specific symptom or problem</td>
<td>Improvement in Barthel score (basic function)</td>
</tr>
<tr>
<td>General health</td>
<td>No worsening mental test score</td>
</tr>
<tr>
<td>Major adverse events</td>
<td>Minimal episodes hypo- or hyperglycaemia</td>
</tr>
<tr>
<td>Death</td>
<td>Minimal readmissions</td>
</tr>
<tr>
<td>Other indicators</td>
<td>Minimal (with caveats)</td>
</tr>
<tr>
<td>Important discriminatory variables</td>
<td>Minimise burden on carers</td>
</tr>
<tr>
<td></td>
<td>Maintain independence of home environment</td>
</tr>
<tr>
<td></td>
<td>Medical condition, route of admission</td>
</tr>
</tbody>
</table>
MEASURING OUTCOMES FROM THE PATIENTS’ PERSPECTIVE

In discussions with the clinicians involved it became clear that patients’ views of perceived changes in their health over the period of a particular intervention would be an important contribution. With the large number of tried and validated instruments already described, some developed over many years, it seemed inappropriate to embark on devising further measures before ensuring that none of the existing measures would suffice. However, ambiguities in the use of the terms health status, functional status, wellbeing, and quality of life and considerable variation in what are considered the relevant dimensions of health exist across such measures. Ware suggested five generic concepts: physical health, mental health, social functioning, role functioning, and general health perceptions which are reflected in many measures. These categories overlap slightly, but they are a useful framework for considering the variety of outcome measures in the different specialties.

In selecting the instrument for any particular condition the following criteria were used.

- The instrument was an established and validated tool which had been used in the United Kingdom
- It had been used in a similar patient group or if not the questions or items in the scale were deemed relevant to that patient group
- It was expected to be sufficiently responsive to show longitudinal change after intervention
- It was as quick and easy as possible to administer, which effectively meant a patient completed instrument
- It was a generic rather than a disease specific measure.

One of the measures selected for this study was the Nottingham health profile (NHP), which has been used for various types of patients in cross sectional studies and for determining longitudinal change. Compared with some other instruments it is fairly short and easy to administer when completed by the patient. The results in this project found the instrument to be sufficiently responsive in detecting changes in a patient’s health after cholecystectomy, knee replacements and PTCA.

One of the disadvantages of the NHP is that a patient’s problems need to be fairly severe to score, and the modal response for a normal population will be zero. In chronic conditions, for example, the questions were not sufficiently sensitive, and a different scale, based on the sickness impact profile, was tested. In this case the advantages of using a familiar instrument (and one common to different conditions) was outweighed by the need to use a measure that was thought to be better suited to the particular case type. A similar consideration lay behind the choice of the Barthel scale for the elderly. This simple scale is based on activities of daily living can be assessed by clinical staff, and was found to reflect some of the key goals of care in this specialty.

Patient assessed measures were used in conjunction with other indicators and the inevitable overlaps between measures were used to test their validity and sensitivity, both of which were found to be satisfactory.

PRACTICALITIES OF DATA COLLECTION

The choice of conditions (two chronic and three acute) in this project was reflected in the data collection methods that developed in the early part of the study. Two general models (figures 1 and 2) were developed, reflecting the different types of care and, specifically, the need for continued monitoring over longer timescales in the case of chronic conditions.

In the acute model (fig 1) the benefits of the intervention were expected to emerge within a fairly well defined period. Data collection required a pretreatment baseline assessment of the patient supplemented by detail at discharge and, most importantly, at follow up after an agreed period, say three months and 12 months. Success was measured by the changes from baseline to follow up. Patients
whose initial treatment failed, for example, repeat PTCAs, caused some logistical difficulties for the analysis, but these difficulties were overcome by considering the first intervention as an important presenting characteristic for the second episode.

In the chronic model (figure 2) there are no clear end points at which to measure outcomes, which are in any case typically concerned with maintaining health and preventing deterioration. The clearest example in the study was the annual review process in diabetes with all clinic patients being seen at this hospital at least once a year. The details of the patient’s health were captured at each visit, and outcomes were expressed as longitudinal change between visits. The exploitation of databases on local clinical microcomputers can fulfil a useful role in this respect by maintaining a register of patients, recording some of the basic information (which may be integral to most consultations), and enabling longitudinal comparisons across groups of patients and over different periods to determine the process-outcome relation. In many cases patients with chronic disease will from time to time experience a stay in hospital. These were regarded as events within the longer term course of treatment, although the specific goals of the inpatient episode are studied separately – as, for example, in diabetes inpatient studies when the acute treatment model is more appropriate to examine short term changes.

Among other lessons learnt from the data collection systems in the study were that

- Patient completed postal questionnaires were easy to administer and achieved very high (90%) response rates
- Retrospective data collection from notes was feasible, although locating notes and ensuring consistency of definitions were among the problems identified
- Collecting data in specific time slots, for example, at a particular outpatient appointment, may prove expensive
- When possible, routine systems and existing databases should be exploited, if necessary by adding one or two more data items
- Death notifications systems were often inadequate and caused unnecessary distress when attempts were made to approach patients who had died after an inpatient stay.

BRINGING ABOUT CHANGE

The raison d’être for the interest in monitoring outcomes of care and indeed for the audit process in general must be to enhance knowledge about how to achieve improved benefits for the patient and, having obtained that knowledge, to bring about change to effect such improvements. The short timescale of the study (just over two years to establish the research, collect, and report back on data to 12 month follow up) meant that substantial changes in practice were unlikely. However, some changes in practice were noted, together with attitudinal changes of clinicians and changes in the collection and use of information on the quality of care. Some instances are given in the following paragraphs.

Changes in attitudes – The commitment of the clinical staff to outcome measurement has been considerable and has grown throughout the study. As well as committing time to discussing the results some clinical staff have also made their own research staff available to collect and collate data. They have also been willing to share data, discuss new and fairly advanced instruments, and develop new areas of study. The hospital trust has shown its commitment to the project by funding the maintenance of these systems since research funds ended.

Perhaps as important has been the acceptance during the course of the project of the value of the patient’s perceptions in assessing care. These variables are now considered alongside clinical indicators when outcomes are reviewed. In care of the elderly the main carer has also been providing information which is being used by the nurses to highlight potential problem areas. The pooling of outcome information from different perspectives is accepted as being highly desirable.

Changes in gathering data – In most specialties concerned the study benefited the way information was being collected for audit. Generally, a greater degree of consistency in recording was required, and some additional data items were sought by particular clinicians; standardised knee scores in orthopaedics and the care giver strain scale are two examples. Examining data in different ways, for example, longitudinally, was found to be valuable, although comparisons with “bench marks” in published reports and elsewhere proved...
Many patients in the guidelines may have an awareness of their condition, but might be reluctant to take necessary actions, such as medication adherence or lifestyle changes. This is because the changes in their health status are not always immediately apparent, and they may not have a clear understanding of the reasons behind the changes. For example, a patient with diabetes may not always notice the effects of poor glycemic control on their health outcomes, such as an increased risk of heart disease or kidney damage. However, it is crucial to establish these awareness gaps and develop strategies to overcome them, such as education and counseling programs. This will enable clinicians to improve patient outcomes and reduce readmission rates, as well as the associated healthcare costs. In conclusion, there is a need for better tools and approaches to measure and improve patient outcomes in diabetes care.
beneficial. Indeed, the work is continuing through various funding agencies, including the hospital trust. The study has shown that a non-threatening environment can be established in which critical analysis of the success of clinical practice becomes an accepted part of the culture. In common with process-based audit systems, however, outcome information requires that an appropriate organisational framework is present to maximise its value. Taken in isolation, a more explicit knowledge of either the process of care or patient outcomes may be of interest to the professional staff involved yet produce little in effecting changes in practice or use of resources. The goal should be to bring together clinicians and managers, both of whom are empowered by the necessary information on process, outcome, and resource use, to develop approaches and agree decisions on how to improve health care. The pieces of this jigsaw are now all present within the NHS but development is fragmented geographically and across specialties. It may not, however, be too long before it is possible to put them all together.

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