Stroke services: the good, the bad and the . . .

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ABSTRACT – The introduction of clinical governance has increased the emphasis placed on measuring the quality of health services. This article addresses the problems associated with assessing the structure, process and outcomes of care of stroke services. The main problem in assessing the structure of stroke services is the difficulty in defining each component and applying criteria which ensure that each component, eg stroke unit, stroke physician, is actually in place and meets minimum standards. The structures of stroke services inevitably also vary to meet local needs and conditions. Audits of process and outcome are usually based on aggregated patient data and often include a review of case notes. They are therefore prone to case selection bias, variation in case-mix, measurement error, and random variation. These factors limit the conclusions which can be drawn from most audits. The adverse effects of audit must also be taken into account. It may lead to distortion of health service priorities, divert resources from patient care and encourage individuals responsible for particular services to cheat. Any quality assurance framework should be designed to minimise these effects and to encourage real improvement in the organisation of services and patient care.

In recent years patients have become increasingly aware of the fallibility of the medical profession. Fuelled by almost daily reports in the media of our apparent failings, our patients, their families, our chief executives, the health authorities and government now demand proof that the quality of the health services we provide. This concern has led to the introduction of clinical governance and revalidation amongst other so-called ‘quality initiatives’. In this article I will address some of the practical difficulties that arise in trying to establish the quality of health services in general, and of stroke services in particular.

What is quality?

When people talk about the quality of health services it is not always clear to which aspects they refer. Which are regarded as most important depend on one’s perspective.

Table 1. Aspects of the quality of health services – different aspects are given different emphasis by different groups.

| Aspect          | Of particular interest to                      |
|-----------------|------------------------------------------------|
| Effectiveness   | Health professions                             |
| Appropriateness | Health professions                             |
| Efficiency      | Funding bodies                                 |
| Acceptability   | Patients and families                          |
| Accessibility   | Patients and families                          |
| Equitability    | Government                                     |
| Relevance       | Government                                     |

(Table 1). A widely known model of a quality assurance programme is the Donabedian1 one, which refers to the structure, process and outcome of health services. However, in adopting this model we must keep in mind the limitations of any method employed to measure the quality of health services. Failure to do so in the future may lead to inappropriate reorganisation of services and even inappropriate revalidation, or failure of revalidation, of those responsible for them.

Structure of stroke services

A comprehensive stroke service should probably have access to all of the facilities or personnel listed in Table 2. It would seem a simple matter to decide whether these

Table 2. Facilities and personnel required to provide a comprehensive stroke service.

| Facility/Personnel |                                      |
|--------------------|--------------------------------------|
| Acute stroke unit/assessment area |
| Stroke rehabilitation unit |
| Neurovascular clinic |
| Stroke physician |
| Supporting medical staff |
| Imaging with support staff |
| CT/MRI scanner |
| Carotid duplex |
| Vascular surgery unit |
| Neurology/neurosurgery (usually off site) |
| Multidisciplinary team including as a minimum: |
| • nurses |
| • physiotherapists |
| • speech and language therapists |
| • occupational therapists |
| • social worker |
| Each with their infrastructure |
| Community based (or early supported discharge) rehabilitation team |

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components were in place. However, taking three examples makes the difficulties clear.

CT scanner

A hospital may have a CT scanner but one also needs to know, for example, how much access stroke patients have to it, especially outside normal working hours, and also the accuracy, speed and appropriateness of reporting.

Stroke physician

In line with guidelines, hospitals may have identified a consultant with responsibility for stroke services but it is clearly vital to know whether that individual has had any relevant training, experience or even any interest in stroke.

Stroke unit

Care within a stroke unit is associated with lower mortality and disability than in a general ward. However, one can set up a ‘stroke unit’ in just a few minutes with a screwdriver and a sign. Such a unit is unlikely to bring the benefits seen in randomised trials.

If we are to measure the quality of stroke services on the basis of their structure, we must have clear definitions and criteria on which to judge whether these services are acceptable. To establish whether services comply with these criteria we will probably need to introduce a system of external peer review.

Measuring process and outcome

This introduces even more difficult methodological issues since it relies on aggregated patient data (Table 3).

Table 3. Methodological issues introduced when using aggregated patient data.

- Are the patients included in the audit representative of all patients managed by the service or are they systematically different in some way, ie was there selection bias, eg were their notes destroyed?
- Are judgements made about the quality of service valid? Are the data accurate? Did the auditor systematically under- or over-rate the performance of the service, ie was there observer bias, was there any conflict of interest?
- How much of the difference in performance (based on outcome or process) between services, or in the same service over time, is attributable to different types of patients cared for, ie was case-mix similar or was there adequate adjustment for differences?
- How precise is the estimate of performance? Could differences between services, or changes within a service over time, be attributable to random variation or chance? Put simply, was good or bad performance simply due to good or bad luck?

Key Points

The methodological difficulties in providing reliable indicators of the quality of health services should not be overlooked in our rush to introduce clinical governance

The quality of stroke services can be defined simply in terms of their structure, process and patient outcomes but we should not ignore aspects of quality (eg acceptability, accessibility) which are of particular interest to the user.

When interpreting measures of process and outcome, one must take full account of variations in case-mix and the play of chance. These are likely to contribute more to any observed variation in ‘performance’ than any differences in the quality of care.

Over-reliance on a small number of ‘quality indicators’ is likely to produce misleading results, may cause distortion of health service priorities and may ultimately damage patients.

As more emphasis is placed on measuring quality there will be greater temptation for those responsible for services to manipulate data.

A quality framework should include measures of structure, process and outcome and should be designed to drive improvements in the organisation of stroke services.

Identifying patients to include in audit

One obvious method of identifying patients on which to base an audit is to obtain a listing from the hospital patient administration system (PAS). However, many patients given stroke codes have not had a stroke at all, and many patients with stroke were not identified in this way. Such problems may be due to: clinician’s diagnostic inaccuracy, the use of vague terms in records and discharge summaries, eg acute hemiparesis; coding inaccuracy due to poor training etc; coding of stroke in a secondary position.

To overcome selection bias, audits should be based on large consecutive series of admissions or random samples. Failure to retrieve the records of a very high proportion of patients identified may also introduce bias. For instance, the notes of patients who die are often more difficult to retrieve from medical records because they are filed less carefully or have been destroyed. Patients who are badly looked after often have chaotic notes, possibly without even a folder, so that they are less likely to be retrieved for audit. A low rate of case retrieval may well lead to an audit giving an overly optimistic measure of performance.

Problems of measuring process

It is possible directly to observe the process of care but in doing so, one is likely to alter that process. For practical reasons, audits of the process of care are usually based on case note review but this may not reflect the actual care the patient received.
The recently published National Sentinel Audit of Stroke, an audit of the process of care, incorporated several methodological features to improve its reliability. These included auditing consecutive series of 40 admissions and using an audit form which had been extensively piloted and tested for inter-rater reliability. Incidentally, this audit gave useful insights into the low level of adherence to well-accepted guidelines relating to many aspects of the process of care.

Measuring outcome

Most audits of stroke based on outcomes have so far relied on case fatality since this is obviously important and may be routinely available through data linkage. However, this does not tell us anything about the care of the majority of patients who survive. Other measures used include the length of hospital stay but this reflects the efficiency and adequacy of social services in the area, as well as the local coding practices, more than the quality of hospital care provided. Complication rates, for example pressure sores or fractures, might be used, but these are generally low even where care is poor. Also, good services may paradoxically appear to have higher complication rates because patients are monitored more closely, so that complications are diagnosed more frequently; and also standards of recording may be better. Although stroke services aim to minimise mortality, complication rates and length of stay, other objectives (Table 4) should be reflected in the outcomes chosen to monitor performance.

It is important that outcomes are measured at a set point after the stroke, or at least after admission. The easy option of measuring outcomes at the time of discharge from hospital can produce misleading figures. For instance, the in-hospital case fatality for stroke in Medicare hospitals in New York was 26% whilst that in California was only 16%. At first sight this might have suggested a major difference in the quality of care. However, the mean length of stay in Californian hospitals after stroke was only nine days whilst in New York it was 25 days. The Californian hospitals simply discharged their patients before they could die. The 30-day case fatality was almost identical.

Interpreting outcomes

The outcome for patients is likely to be dominated by their age, pre-stroke status and the severity of the stroke. Variations in outcomes between provider units will therefore reflect the types of patients admitted to the units, and luck, as well as the quality of care. Given the limited impact of most of our interventions, variation in case-mix and luck is likely to account for most of any observed variation in outcomes.

In Scotland, routinely collected discharge data have been linked to death certificate data to provide 30-day case fatality for those admitted as an emergency with a stroke to any hospital. Based on three-year cohorts, these reports have demonstrated significant variation in case fatality: from as low as 18% up to 35%. Unfortunately, the data were not available to adjust for much more than variations in the age, sex and social deprivation of patients. Not surprisingly, these have led to considerable media interest, with publication of ‘league tables’ and some sensational headlines, eg Stroke Deaths Shock in City Hospitals! No doubt these boost circulation figures and maintain advertising revenue but they probably did little for the psyche of present and future patients who have little choice as to which hospital they will be taken to when struck down by a stroke. The media largely ignored the published ‘health warnings’ which suggested that the data could not be used to imply variations in quality of care.

We have recently completed a three-year prospective study to investigate whether such stroke outcomes might be used to indicate the quality of care in different hospitals. We were able to adjust outcomes for key prognostic indicators: age, pre-stroke dependence, whether patients lived alone before the stroke, Glasgow Coma Scale on admission, their ability to lift both arms against gravity and walk without help. Our data suggest that most, but not all of the variation in outcome is explained by differences in the prevalence of these factors between the hospitals. Small, unexplained and statistically significant differences in case fatality remain between hospitals. Interestingly, the hospital with the highest case fatality was unique among the five hospitals in having no stroke unit or physician responsible for stroke services; very few patients had access to a multi-disciplinary team and only 53% of patients had a CT scan. Thus there appeared to be some correlation between process and outcomes. However, the adjusted outcomes were insensitive to moderate, but potentially important variations in the process of care in the remaining four hospitals, eg two-fold variations in proportion of patients going to a stroke unit. Also, the ranking of hospitals based on perhaps a clinically more relevant outcome of death or dependency at six months after the stroke was different from that based on death alone. Unfortunately, these data

Table 4. Some objectives of stroke services.

| Reduction of:  | Maximising of: | Facilitation of: |
|---------------|----------------|------------------|
| case fatality | quality of life | research         |
| complications | psychological state | training |
| residual disability | satisfaction with services | education |
| length of stay | patients' and carers' knowledge |         |
| recurrent vascular events | |         |
relating to functional outcome were even more difficult to interpret due to incomplete follow-up (despite best efforts) of a significant and variable proportion of patients at each hospital.

**Luck**

If audits of process or outcome are based on only small numbers of patients, then any estimate of performance is bound to be imprecise, and any differences between services or changes in the same service over time may well result from the play of chance. The National Sentinel Audit of Stroke required Trusts to audit only 40 cases. Thus a trust with an average performance for swallowing assessments would have recorded appropriate assessments in 22 of 40 cases – 55% but with 95% confidence intervals of 38 to 71%. The point estimates of more than half the trusts in England and Wales fell within these intervals. The results of the European Carotid Surgery Trial (ECST) and the North American Symptomatic Carotid Endarterectomy Trial (NASCET) suggested that carotid endarterectomy prevented strokes if it could be performed, with a combined operative mortality and morbidity of less than 10%. If one’s local surgeon performed 50 operations in the last year, with only two deaths or perioperative strokes, this is an acceptable 4% complication rate. However, the 95% confidence intervals extend up to a very unacceptable 14%. In fact, in a recent audit of carotid surgery in Scotland only three vascular units (each including several vascular surgeons) performed as many as 50 operations in a year, so that the confidence intervals would be even wider for individual surgeons. None of us can therefore be confident that the surgeon to whom we refer cases has an acceptably low rate of complications based on only one year’s data.

If 75 of 300 stroke patients admitted to a service died, this indicates an average case fatality of 25% but with 95% confidence intervals of 20 to 30%. This is extremely wide if one considers that the randomised controlled trials (RCTs) demonstrated an absolute difference in case fatality of only 4% in trials comparing stroke unit care with that in general wards. An audit of only one year’s performance will therefore depend more on luck than on the quality of care.

To improve the precision of our measures of performance we have to increase the number of patients included in audits. We might: collect data over prolonged periods but this will delay identification of problems and services and personnel change; pool data from several centres but then the audit tells one little about individual providers; centralise services but this reduces accessibility for patients.

**Raising the stakes**

As greater emphasis is placed on the results of audits, for example as a basis for revalidation of an individual’s practice, greater efforts will be made to improve performance. There will be pressure on clinicians to manipulate the systems to measure their performance. This is called cheating, but is the logical response to an audit which might ultimately threaten one’s income or which is perceived as providing a falsely poor measure of performance.

To improve your performance in any audit of the process or outcome you could:

1. Lose the notes of patients whom you mistreat or who do badly. This is traditionally achieved by keeping their notes in your office or, more subtly, by putting a non-stroke code in the primary diagnosis on the discharge summary. If a patient suffers a pulmonary embolus due to your failure to provide prophylaxis, then code this as the primary diagnosis. This patient will not appear in any audit.
2. Improve your performance with respect to process by simply re-labelling what you do. The end-bay of your ward becomes the stroke unit, your ward round becomes a multidisciplinary team meeting. Instantly, compliance with guidelines rockets.
3. Admit transient ischaemic attacks (TIAs) and code them as strokes. In fact, if you do so, you will find that many have subtle signs on the day after admission which justify that code. Avoid admitting patients with severe strokes and deflect such patients to another hospital (eg by stating that your beds are full). If the audit of outcomes takes into account the case-mix of your patients by adjusting for prognostic variables on admission, simply record that adverse factors, such as pre-stroke dependency, were present.

This final tactic is known as upstaging or gaming and was successfully employed by cardiac surgeons in New YorkState. In New York the adjusted operative mortality fell dramatically. However, the frequency of reporting of adverse preoperative prognostic factors, used to adjust mortality data, eg cardiac failure, increased as much as seven-fold over two years. The crude case fatality had hardly changed. The increased co-morbidity was hardly likely to be due to a shift in case-mix but reflected surgeons’ concerns that their personal operative complication rates were being published in the newspapers.

Many systems to monitor the process or outcomes of care are run by those responsible for providing the care. However, as the stakes rise this will become increasingly unsatisfactory. Where the measurement of performance relies on anything less than a totally objective assessment of process or outcome (eg death), it is liable to observer bias. Ideally, those measuring our performance should be independent of us and have no vested interest in the results of the audit.

**Advantages of measuring process rather than outcome**

As illustrated in the National Sentinel Audit of Stroke, it is fairly easy to arrive at evidence and consensus based standards for the process of care but less easy to set standards for outcomes.

It is easier to demonstrate differences between services and changes over time in process, since adverse outcomes,
such as deaths and complication rates, are usually relatively uncommon. Variations in case-mix generally have less impact in audits of process than outcome so that comparisons are easier.

Audits of process indicate where performance is poor and the remediable actions are usually obvious. Poor outcomes may indicate the presence of bad care but will not indicate the causes of bad results.

Perhaps the greatest strength of introducing routine monitoring of the process of care is that to do so will require considerable organisation of the care itself. For instance, it would be greatly facilitated by: an individual with responsibility for stroke; integrated care pathways; and concentration of patients in a stroke unit. All of these changes are likely to have direct benefits for patients. An appropriately designed system of monitoring performance could be used to drive forward the development of better stroke services.

The way forward

Given the limitations of relying solely on measures of structure, process or outcomes, any framework for assuring quality should incorporate all three. Although it may be possible to manipulate one or two indicators it would be almost impossible to do so for a whole range. By using several methods and targets for improvement, one avoids measurement fixation where attempts to improve one particular performance indicator can inappropriately distort priorities and ultimately damage patient care. An example has been the inappropriate fixation by government on waiting times. Finally, if measurement of the structure, process and outcome all suggest there is a problem, then based on the principle of triangulation, one can be more confident about that conclusion.

Clinical governance ensures more emphasis on quality. However, simply monitoring performance, however accurately, will not improve quality. We must ensure that improved training and adequate resources are available and appropriately organised. We should build on what has already been achieved. The Scottish Stroke Services Audit provides a basis on which the structure of services could be assessed, ideally by external peer review. The National Sentinel Audit of Stroke provides us with a tool to audit the process of care, and realistic standards to which we can aspire. We can also refine our methods of identifying stroke patients admitted to hospital, using routine data, and collect simple variables which allow fuller adjustment for case-mix to enable us better to interpret outcome data. These might also be supplemented by local audits of other aspects of the service (Tables 1 and 4) which better reflect the user's perspective. A national framework, with uniform systems throughout, would avoid duplication, help develop realistic standards, allow us to compare services and ultimately help to improve services.

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