Peer review of adverse events – a perspective on Macarthur

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Abstract

Recent investigations into the Macarthur Health Service have resulted in multiple reviews of a small number of cases. This article was prompted by a casual observation that these reviews have resulted in differing conclusions about what occurred in each case and what might have been done in response. The reliability of peer review is examined, together with the literature on the scale of adverse events and the issue of problem identification. Potential sources of bias and error during peer review are considered. Drawing on the lessons from the literature and the experience of Macarthur, suggestions are made to improve the identification and review of adverse events.

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What is known about the topic?

Recent events at the Campelltown and Camden Hospitals resulted in a number of different investigations of reported adverse events.

What does this paper add?

A review of the literature identified issues associated with peer review of adverse events, which raised issues regarding the effectiveness of the processes currently used in reporting and analysing adverse events in health care.

What are the implications for practitioners?

Further research and review of the evidence for best practice in incident reporting and analysis is recommended.

THIS ARTICLE EXAMINES the issues of adverse events and peer review by reflecting on recent investigations of the Macarthur Health Service (MHS), the available literature and my experience as a senior manager in the health service between 1998 and 2003. The investigations required reconstruction and interpretation of past events at both the individual and system levels and the catalyst for this article was a simple observation that the reviewers of the incidents seemed to arrive at different conclusions regarding what had occurred. One reviewer's conclusion of 'poor assessment' was another reviewer's conclusion of a 'communication problem'; one reviewer's 'adverse event' was another reviewer's 'inevitable consequence of a disease process'.

In November 2002, four nurses went to the NSW Health Minister with a broad range of allegations centred on poor clinical care and various human resource management issues. The allegations were investigated by the NSW Health Care Complaints Commission (HCCC) which reported its findings and recommendations in December 2003. Subsequently, the head of the HCCC was dismissed by the NSW Health Minister and a new investigation commenced — the Special Commission of Inquiry into Campbelltown and Camden Hospitals (SCI). Additional inquiries have also been undertaken by the Upper House of the NSW Parliament and the Independent Commission Against Corruption.

The HCCC investigated 47 incidents, many of which had already been reviewed by staff of the MHS, by establishing a series of clinical review panels. The SCI also reviewed the incidents, resulting in referral of doctors and nurses to their respective registration authorities.

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This article examines what is known about the process of reviewing clinical cases and the confidence that can be placed in the outcomes. The starting point was the available literature on peer review and the major studies in Australia and elsewhere that have examined the scale of adverse events.

Adverse events

The pioneering work on medical adverse events was the Harvard Medical Practice Study (HMPS), published in 1991, that identified adverse events in 3.7% of hospital admissions, with 27.6% of the adverse events assessed as being due to negligence, and close to 14% of the adverse events resulting in death (Brennan, Leape et al. 1991; Leape et al. 1991). The adverse events were not randomly distributed, with certain types of hospitals found to have higher rates (Brennan, Hebert et al. 1991). The HMPS was replicated in Utah and Colorado with similar results — adverse events occurred in 2.9% of hospital admissions (Thomas, Studdert et al. 2000a).

The best available evidence regarding adverse events in Australia comes from the Quality in Australian Health Care Study (QAHCS), published in 1995. A review of over 14 000 admissions to 28 hospitals in New South Wales and South Australia identified a much higher level of adverse events than the American studies, with 16.6% of admissions associated with an adverse event resulting in disability or longer hospital stay for the patient (Wilson et al. 1995).

An examination of the different adverse event rates in the American and Australian studies concluded that the higher Australian rate was at least due in part to methodological differences, with the American studies defining adverse events more stringently (Runciman et al. 2000; Thomas, Studdert et al. 2000b; Weingart et al. 2000). However, a real difference in the rates could not be excluded (Weingart et al. 2000). A similar 2% core of serious adverse events was found in both studies (Runciman et al. 2000).

Other studies have also identified high levels of adverse events among hospitalised patients. Ethnographers trained in qualitative observational techniques found that 17.7 % of patients admitted to three units of a large teaching hospital had at least one serious adverse event (Andrews et al. 1997). In this study, the adverse events were identified at the time or soon after clinical decisions were made, rather than by retrospective review of medical records as in the studies mentioned above. This facilitated identification of errors that did not result in harm, those due to interaction among health professionals, and those due to administrative factors such as defective equipment or inadequate staffing. The much higher adverse event rate compared with the HMPS is also attributable to differences in methodology, particularly the stringent criteria used in the HMPS (Andrews et al. 1997).

It has been suggested that the situation in Canada is similar to Australia and the USA (Baker & Norton 2001), with results from a recent small study showing an incidence of adverse events of 12.7% (Forster et al. 2004). Work in New Zealand identified adverse events in 12.9% of hospital admissions (Davis et al. 2002), and a study at two British hospitals found adverse events in 10.8% of patients admitted to hospital (Vincent, Neale & Woloshynowych 2001).

The result of all this work is best summarised by the authors who compared the Harvard and Australian studies:

> "… the precise prevalence and magnitude of medical error is unknown, but it is probably enormous. We are aware of no study showing that medical care can be provided without error. In fact, the more closely we examine patient care, the more error we find. No setting is free from hazards and no specialty is immune, and patients are at risk no matter what their age, sex, or health status." (Weingart et al. 2000, p. 776).

Problem identification

Identifying problems in patient care is not limited to detection of possible adverse events. Near misses and errors that result in no harm to patients are likely to be far greater in number

than those that harm patients. While there is no real argument about the premise that reporting systems are a good idea, there is debate about the relative merits of mandatory versus voluntary reporting, internal versus external reporting, and general versus specialty reporting systems (Leape 2002). Evidence indicates that incident reporting systems typically fail to identify a significant number of adverse events (Stanhope et al. 1999) and that the definition and classification of incidents can influence the level of reporting (Tamuz et al. 2004). Doctors and nurses tend to use different standards when deciding what to report (Lawton & Parker 2002). In addition to the active errors that tend to get reported, latent errors such as poor design, poor purchasing systems or inadequate staffing can lie dormant for considerable periods of time before contributing to an active error (Thomas & Petersen 2003).

The aim of reporting problems is to increase understanding of adverse events to prevent future clinical errors and improve patient safety. A systems approach to this issue assumes that organisational variables impacting on adverse events can be identified. Unfortunately, the results from a recent review of the literature on this subject indicate that much work still needs to be done to establish such links (Hoff et al. 2004). A good starting point for advancing knowledge in this area may be the development of a consistent and rigorous approach to reporting and analysis, such as that developed in the Department of Veterans Affairs in the USA, using a rating system to identify high priority incidents and root cause analysis of serious incidents (Bagian et al. 2001; Bagian et al. 2002). This program has recently been adopted in the New South Wales public hospital system, although without the basic infrastructure of a common reporting system. However, by focusing on adverse events with serious outcomes there is a risk with this approach of overlooking the far more numerous, largely mundane, problems that occur in everyday practice and consume significant resources (Runciman, Edmonds & Pradhan 2002). The effectiveness of using root cause analysis to identify and rectify factors contributing to adverse events remains unknown (Wald & Shojania 2001; Bagian et al. 2002). There is a need to evaluate this approach and compare it with other strategies to improve patient safety (Hofer & Hayward 2002).

Despite variations in methodology, the available evidence indicates that the proportion of adverse events that may be preventable usually lies in the range of 50%–60% (Leape et al. 1991; Wilson et al. 1995; Thomas & Brennan 2000; Vincent, Neale & Woloshynowych 2001). Work in this area has typically involved identification of causes (such as failure to follow a procedure) and an associated prevention strategy (such as new, better, or better implemented policies or protocols) (Wilson et al. 1999). However, the issue of prevention is itself problematic. It assumes that a causal link between process and outcome can be identified, as opposed to a mere association in time or place. The difficulty of assigning causation is well illustrated by the following hypothetical problem:

> "Suppose we identified a series of blood transfusion reactions and found that a set of process problems labelled as errors had occurred in 60% of patients who had reactions. Now, suppose that in transfusions in which no reaction occurred there was also an error rate of 60%. Can we argue that by engineering out the errors, transfusion reactions would be eliminated? It is clear that we cannot" (Hofer, Kerr & Hayward 2000, p. 263).

Trying to fix complex problems, either in 'one-off' cases or a series of cases, based on inadequate analysis can result in changes that may do the exact opposite of what they are intended to do by increasing rather than decreasing errors (Hayward & Hofer 2001).

The reliability and validity of peer review

When reviewing 'what went wrong' the temptation to see the obvious can be overwhelming, resulting in little understanding of why those present at the time could not be equally insightful:

> "Investigations that are anchored to outcome knowledge run the risk of not capturing the complexities and uncertainties facing sharp end personnel and why their actions made sense at the time ... Investigations have the luxury in hindsight of knowing how things will turn out; nurses, physicians, and technicians at the sharp end do not ... Such hindsight results in expectations by investigators that participants should have anticipated the mishap by foresight" (Henriksen & Kaplan 2003, p. 46).

Temptation also lies in the appeal of a good explanation, for something that 'feels right' in explaining the past (Trout 2002). According to seminal work by Fischhoff "we seem to have a remarkable ability to explain or provide causal interpretation for whatever we see." (Fischhoff 1982, p. 345).

Given the serious implications that can flow from investigations that may be flawed, it is worth considering this issue in more detail. There are in fact several sources of potential bias and error when reviewing clinical cases, including:

Outcome bias — the influence of knowledge about outcome when evaluating the quality of clinical decision making.

Hindsight bias — the tendency for those with knowledge of how events turned out to exaggerate the extent to which they would have been able to predict the outcome themselves, equivalent to picking the winner after the race has been run.

Attribution error — attributing a poor outcome to perceived flaws or defects of those involved, rather than considering the range of other factors, particularly systemic factors, that may have had a role to play (Henriksen & Kaplan 2003).

The influence that hindsight and outcome bias can play on judgements regarding quality of care has been demonstrated in a number of studies (Dawson et al. 1988; Caplan et al. 1991; Weingart et al. 2001). Retrospective analysis of management decision making is also likely to include systematic errors (Golden 1992). The evidence across different domains consistently shows that "event outcomes have been judged more likely when judgements are made from the perspective of hindsight rather than under the uncertainty of foresight" (Sanna, Schwartz & Small 2002, p. 1288). By making the outcome seem foreseeable, hindsight enhances a retrospective sense of control that would not have been apparent at the time (Thompson, Armstrong & Thomas 1998). The unreliability of identifying adverse events may result in high false positive rates, with more adverse events believed to occur than in fact is the case (Walshe 2000).

Studies have identified a poor level of agreement regarding whether an adverse event occurred (Localio et al. 1996; Thomas et al. 2002), what caused an adverse event (Localio et al. 1996) and whether an adverse event was preventable (Hayward & Hofer 2001). It can be difficult reaching a reasonable level of agreement on whether the process of care was optimal (Hayward, McMahon & Bernard 1993; Smith et al. 1997; Camacho & Rubin 1998; McQuillan et al. 1998; Margo 2002). Doctors and nurses reviewing the same medical records can arrive at very different conclusions, with one study finding that the level of agreement about quality was little better than would be expected by chance and with nurses more likely to identify process problems than doctors (Weingart et al. 2002).

Even in situations where expected adverse event rates are well known it is not a simple matter of reviewing a small amount of data to detect substandard practice. For example, a study examining mortality and morbidity data for two vascular surgery procedures with accepted adverse events rates concluded that data from large numbers of patients are required to determine high levels of adverse outcomes (Irvine, Grayson & Lusby 2000).

Peer review can be undertaken by individuals but typically involves a group of clinicians, justified on the basis that 'several heads are better than one'. While it has been argued that group discussion improves interrater reliability, the reasons for this are unclear (Levine et al. 1998). Other evidence suggested that discussion between reviewers does not appear to be a viable way to move reviewers closer toward the true rating, suggesting that the best way to improve the reliability of

peer review is by averaging multiple independent reviews (Hofer et al. 2000). While there are strong arguments for multiple reviewers (Goldman 1992) it has been suggested that this is unlikely to be practical (Walshe 2000).

In considering the question "what is an error?" Hofer and colleagues make the following observation:

> "With interrater reliabilities of 0.2 to 0.3, to support an investigation and response to the potential causes of error, several independent reviews of a single case must be done even to be sure that an error occurred. In most cases, reviewers cannot agree on whether a bad outcome occurred or whether it was caused by substandard care, much less what exactly caused it" (Hofer, Kerr & Hayward 2000, p. 266).

Discussion

Many of the cases investigated by the HCCC had already been reviewed by staff of Macarthur Health; the HCCC identified concerns about the adequacy of some of the case reviews undertaken by Macarthur Health (HCCC 2003). This position assumes, at least in part, that the reviews by the HCCC clinical review panels were correct and the reviews by staff of Macarthur were flawed.

The HCCC methodology has not been made public to the level of detail that would facilitate replication. Even the SCI was unable to work out "precisely what documents were given to the panels" (Walker 2004, p. 19). The literature identified significant problems with the reliability of peer review, suggesting that an unknown degree of error would be present in the HCCC reviews, just as error would be present in the reviews originally undertaken by Macarthur staff. This is not because those involved in any of these reviews were at fault, but because of the nature of the task. Many would have experienced the phenomenon of visiting two doctors with the same clinical condition and being given either two different diagnoses or the same diagnosis with different treatments. This is a reflection of the fact that medicine is not an exact science, with considerable variations in practice. The process of peer review is also subject to variation. This is well summarised by Weingart's comment that:

> "... poor inter-rater reliability is evidence of the difficulty of rendering judgements about quality. Attributing adverse outcomes to substandard care remains an exceedingly difficult task, particularly for patients with multiple co-morbid illnesses, subject to high-risk interventions, attended by numerous clinicians, and in a precarious and often deteriorating state of health" (Weingart 2000, p. 364).

The SCI also reviewed the cases, but with a specific purpose in mind: to identify those cases where an allegation of unsafe practice, if substantiated, would likely result in disciplinary action against a doctor or nurse (Walker 2004). Again, the methodology has not been made public but the same concerns regarding bias and error may have been present.

Rather than argue the merits or otherwise of the different overall adverse event rates reported in the literature a useful figure to place this issue in perspective is the common rate of 2% for serious adverse events identified in the major American and Australian studies (Runciman et al. 2000). This rate, applied to the activity level in the Macarthur Health Service during the period covered by the HCCC investigation, results in an expected number of serious adverse events of 2000 (about 10 per week). If one accepts the argument that Macarthur had a death rate and a complication rate no higher than similar hospitals (Walker 2004) this gives an indication of the scale of the problem faced by hospitals and compares with the total of 128 cases investigated by the HCCC and SCI.

There is clearly far more to improving the quality of care than identifying and responding to adverse events, but what happened in Macarthur has brought this issue into sharp focus. Incident reporting and peer review are two of the basic building blocks of a quality system and warrant careful consideration. In summary, the available literature indicates that:

- The number of adverse events among hospitalised patients is high.
- Incident reporting systems typically fail to pick up many of these adverse events.
- For those incidents that are reported there may be considerable disagreement about whether an adverse event occurred.
- Deciding what caused an adverse event is fraught with difficulty.
- Strategies to fix problems based on an inadequate understanding of causation may do more harm than good.

The major works quantifying the scale of adverse events are now ten years old, and yet progress has been slow in using this information to improve patient safety (Institute of Medicine 1999). It has been argued that tolerance of risk by the community and those working in the health system is too high (Smyth 2002). The events in Macarthur provide a powerful incentive to correct this situation.

The casual observation that prompted this article reflects the evidence from the literature. Drawing on the lessons from that literature and my own experience and involvement in the events in Macarthur it seems to me that the following issues merit attention as part of any thoughtful response:

- Implementation of an incident reporting system that is common to all hospitals (as is planned for NSW).
- Evaluation of the system of incident severity scoring and root cause analysis.
- Development of best practice guidelines for peer review, including recommendations for minimising outcome and hindsight bias.
- Development of standard tools for identification of adverse events.
- Reliability testing of any instruments used in the identification and review of adverse events.

These need to be underpinned by commitment of resources to research. If we cannot develop better tools for the identification and review of adverse events then the opportunity to learn from errors is severely compromised. Greater knowledge of the shortcomings of peer review and the influence of bias, such as hindsight, can only help to improve our processes. 'Why the adverse event happened' might appear obvious after the event but the obvious answer is quite likely to be wrong. Failure to recognise these inherent shortcomings and act accordingly potentially compounds the initial clinical errors.

Competing interests

Malcolm Masso was employed as the Director of Nursing and Acute Services with the Macarthur Health Service between August 1998 and the end of 2003. Malcolm was a member of the Critical Care Committee that was involved in reviewing many of the cases subsequently investigated by the HCCC. He was also involved in providing material regarding the cases to the HCCC on behalf of the Macarthur Health Service.

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