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Learning from litigation. The role of claims analysis in patient safety

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Abstract

Claims for malpractice and medical negligence are a potentially important source of information on the causes of harm to patients and have provided valuable lessons in the past. However today, with many additional sources of information and methods of analysis, the role of claims analysis needs to be reappraised. We consider the role of claims analysis in relation to other methods of studying adverse outcomes, review previous studies of claims and summarize the findings of four recent British specialty claims reviews. Claims analysis has a number of inherent limitations. We suggest that there is now no case for *ad hoc* claims reviews which rely on data that have been assembled for legal purposes only. Claims review is still potentially useful for rare events or in cases where other sources of data are not available. However, future claims reviews need to meet basic criteria before being undertaken; these include prospective identification of the relevant questions and variables, adequacy and completeness of the data set, availability of expert reviewers and clear protocols for review.

Introduction

Claims for malpractice and medical negligence are a potentially important source of information on the causes of harm to patients. Even 10 years ago, claims were one of the few available sources of information on patient harm (Vincent 1993), and of clear value. Today, with many additional sources of information and methods of analysis, the role of claims data needs to be reappraised (Department of Health 2000).

In this paper, consider the role of claims analysis in relation to other methods of studying adverse outcome, review some of the major studies of claims and draw on four recent specialty reviews carried out by our own research team. This paper is part of a larger project commissioned by the UK Department of Health Patient Safety Research Programme on 'Learning from litigation'. The first phase focused on the analysis of computerized databases to examine the epidemiology of adverse events and litigation. The second phase addressed the potential of claims analysis and review for learning about the causes of adverse outcomes and for producing recommendations for change that would enhance patient safety. The full reports are available at http://www.csru.org.uk

Methods of studying errors and adverse events in health care

Thomas & Petersen (2003) classified and reviewed methods of studying errors and adverse events into eight broad groups, drawing some important conclusions relevant to the analysis of claims. First, there is

no perfect way of estimating the incidence of adverse events or of errors. For various reasons, all of them give a partial picture. Record review is comprehensive and systematic, but by definition is restricted to matters noted in the medical record. Claims are an unrepresentative subset of the totality of errors and adverse events, being biased by specialty, severity and influenced by the many other factors (Hickson *et al*. 1994; Vincent *et al*. 1994). Second, the methods are differently oriented towards detecting incidence of errors and adverse events, and examining their causes. Claims, they suggest, are particularly useful for understanding causes and background factors, though they have several limitations:

> Relative to other methods, the strength of claims file analysis lies in its ability to detect latent errors, as opposed to active errors and adverse events. This powerful example of the utility of malpractice claims is balanced by several limitations. Claims are a series of highly selected cases from which it is difficult to generalize. Also, malpractice claims analysis is subject to hindsight bias as well as a variety of other ascertainment and selection biases, and the data present in claims files is not standardized. Finally, although malpractice claims files analysis may identify potential causes of errors and adverse events that may be addressed and studied, the claims files themselves cannot be used to estimate the incidence or prevalence of errors or adverse events or the effect of an intervention to decrease errors and adverse events. (Thomas & Petersen 2003)

By latent factors Thomas and Petersen mean the background causes of error and harm such as poor design, faulty maintenance, inadequate staffing, that cannot necessarily be directly observed but can be inferred from close examination of specific errors or adverse events. We examined the assertion that claims review can reveal such factors in our own review.

Studies of closed claims

The anaesthesia closed claims project

The most important series of studies of claims is undoubtedly the ongoing closed claims project of the American Society of Anaesthetists (Cheney 1999). In this project a standard report form is completed by an anaesthetic reviewer for every claim where there is enough information to reconstruct the sequence of events and determine the nature and cause of the injury. Data entered are subject to further review by project investigators and staff for consistency and completeness before they are assessed as suitable for inclusion in the database. By 1999, there were more than 4000 claims in the database. We have summarized the principal studies arising from this database in Table 1.

Respiratory events accounted for a large share of claims, especially for brain damage and death (Cheney 1999). The most common events leading to injury were inadequate ventilation, oesophageal intubation and difficult tracheal intubation. However, Caplan *et al*. (1990) found that 'the distinguishing feature in this group of claims was the reviewer's inability to identify a specific mechanism of injury'. Only 9% of these (respiratory) claims involved obviously inadequate behaviour, although there was widespread agreement that better monitoring would have prevented the complication.

These findings contributed to the recommendation by the ASA Committee on Standards in the formulation of standards requiring pulse oximetry intraoperatively, the use of end-tidal CO_2 for the verification of endotracheal intubation and the use of pulse oximetry in the post-anaesthesia care unit. Since then further reports have appeared on ulnar nerve injury, spinal cord injury, airway trauma, office-based anaesthesia injuries and post-operative visual loss, published either in peer-reviewed journals or in the ASA newsletter.

Whereas all the reports from the database highlight important issues, the authors are assiduous in pointing out the limitations of the database as well as the potential for learning. The principal problems are shown in the right hand column of Table 1 and have been summarized by Lee & Domino (2002) (Box 1). Cheney's conclusion about the future of the claims database, in an era of heightened attention to patient safety, is nevertheless optimistic although hedged with some cautions:

> In summary, the ASA Closed Claims Project is a reporting mechanism that provides an indirect assessment of the safety of anaesthetic practice

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Table 1 Principal studies from the American Society of Anaesthetists (ASA) Database

Author and Paper	*Nature of claims and number of cases*	*Method of case selection*	*Case review by*	*Method of analysis*	*Lessons learned, Clinical conclusions*	*Reflections on claims reviews*
Cheney *et al.* (1994) (17) Burns from warming devices in anaesthesia	Claims for burns from 3000 claims in the ASA closed claims database 28 claims	Cases selected from ASA closed claims database for burns from warming devices	Reviewed by anaesthesiologists	Standardized format as employed in other ASA database analyses	Warm IV bags or plastic bottles are a hazard to the patient under anaesthetic, particularly when they are used for purposes other than they are designed for, i.e. maintaining body position instead of providing fluids by IV	As with other ASA database analyses limitations are recognized
Caplan *et al.* (1997) (18) Adverse Anaesthetics Outcomes Arising from Gas Delivery Equipment: A Closed Claims Analysis	3791 cases in database of the Closed Claims Project 72 claims	Claims associated with gas delivery equipment	Reviewed by practising anaesthetists	Standardized instructions to complete a standardized form detailing patient characteristics, surgical procedures, sequence and location of events, critical incidents, clinical manifestation of injury, standard of care and outcome, preventability of an AE with better monitoring	The frequency of equipment misuse was 75% compared to only 24% equipment failure suggests human factors are highly significant. Gas delivery equipment failure accounts for between 1 to 5% of anaesthesia-related death and brain damage claims. Claims involving gas delivery equipment account for 2% of the closed claim database.	Claims review limitations include lack of denominator data, no comparison groups, a bias towards adverse outcomes and a reliance on data from direct participants. Reviewer agreement has proved reliable.
Cheney *et al.* (1999) (19) Nerve injury associated with anaesthesia: A closed claims analysis	Claims for nerve injury since previous 1990 report, i.e. 1990–1995 670 claims	Cases selected from ASA closed claims database for anaesthetic related nerve injury	Reviewed by practising anaesthesiologists	Standardized information regarding patient characteristics, surgical procedures, sequence and location of events, critical incidents, clinical manifestations of injury, appropriateness of anaesthetic care and outcome	Ulnar neuropathy, the most common anaesthetic related nerve injury (28%). Spinal cord injured most prominent complaint in claims for nerve injury. 16% of claims from ASA project were for anaesthesia related nerve injury	Lack of data regarding total population of risk for injury and non-random retrospective data collection. No information regarding total number of anaesthetics provided or specialization vs. general anaesthetic split

Table 1 *Continued*

Author and Paper	*Nature of claims and number of cases*	*Method of case selection*	*Case review by*	*Method of analysis*	*Lessons learned, Clinical conclusions*	*Reflections on claims reviews*
Domino *et al.* (1999) (20) Awareness during Anaesthesia: A closed claims analysis	Drawn from a total of 4183 claims from the database of the American Society of Anaesthetists (ASA) Closed Claim Project collected between 1961 and 1995. 79 claims	Claims that involved awareness during anaesthesia	Reviewers not specified but given specific instructions about how to use a standardized review form.	Information on patient characteristics, surgical procedures, sequence and location of events, critical incidents, clinical manifestations of injury, standard of care and outcome. Severity of injury score was grouped into temporary/non disabling injury or disabling/permanent/ death	Claims for women involved a lower severity of injury than those for men suggesting that women may be more likely to file a claim for awareness during anaesthesia. Claims for recall during GA only accounted for 1.5% of the claims on the ASA database. 87% of claims are from elective surgery patients.	Closure of an awareness during anaesthesia claim may be quicker than in more severe claims thus making a greater proportion of these types of claims in the database.
Domino *et al.* (1999) (21) Airway injury during anaesthesia: a closed claim analysis	Airway injury claims taken from the American society of Anaesthesiologists closed claims project database 266 Claims	Airway injury cases from anaesthetic database	Reviewers not specified but given specific instructions about how to use a standardized review form.	Information on patient characteristics, surgical procedures, sequence and location of events, critical incidents, clinical manifestations of injury, standard of care and outcome. Severity of injury was grouped into temporary /non disabling injury or disabling/ permanent/death	A higher proportion of airway injury claims involved females, elective procedures and outpatient procedures. Difficult intubation was a factor in 39% of airway injury cases compared to 9% of general anaesthetic claims	Inability of closed claim analysis to provide estimate of risk because no denominator data. No comparison groups probably bias towards adverse outcomes reliance on direct participants rather than impartial observer

Lee & Domino (2002) (8) The Closed Claim Project: Has it influenced anaesthetic practice and outcome?	Closed claims for adverse outcomes in anaesthetics between 1961 and 1999. Data obtained from 35 liability insurance companies. Dental claims excluded 5480 claims	Data collected from cases where there was sufficient information to understand what had happened and to judge nature and causation of injury.	Trained reviewers who are practising anaesthetists	Trained anaesthetists used a standardized form to collate specified information particularly assessing the appropriateness of anaesthetic care. Each claim was also assigned a severity of injury score. The reviewer made a summary of the case and all data were sent to a Closed Claim Project Committee where at least two practising anaesthetists reviewed the claim. Claims were then classified into groupings for analysis.	Large numbers of claims make it statistically powerful. Results showed patterns of important anaesthetic complications	Closed claim analysis has a number of inherent biases. These claims are a subset of adverse outcomes in health care. Their bias is towards more serious injury. Overall figures for anaesthetic procedures for this group of anaesthetists were not available. Also, litigation rates vary geographically. Other sources of bias included: change in practice patterns, partial reliance on direct participants, retrospective description of the data, absence of comparison groups, judgement of appropriateness of care.
Ross (2003) (22) ASA closed claims in obstetrics: lessons learned (Reanalysis of an earlier paper by Chadwick H.S. 1996)	5300 cases from the Closed Claims database. 635 (12%) associated with obstetrical anaesthetic cases	Obstetric anaesthetic cases from the ASA Closed Claims database	As above	As above	Mostly supports commonly held views about the risks of obstetric anaesthesia but highlights the fact that minor injuries are more common in obstetric files than non-obstetric files. Suggestions for avoiding malpractice claims in obstetrics include: careful personal conduct, establishing good rapport, involvement in prenatal education, early pre anaesthetic evaluation, providing realistic expectations, regularly reviewing potential major and minor risks	Unfortunately, the claims data do not give general incidence figures for adverse events and anaesthetists may be named in a claim where there was no anaesthetic related adverse event. Also claims reflect out of date practice because of the time lapse between opening and closing a claim. But they do allow the identification of common injuries, the nature of precipitating events and differences between regional and general anaesthetics

Box 1 Limitations of anaesthesia closed claims analysis

1. Subset of adverse outcomes
a. Few adverse outcomes end in claims
b. Bias towards more severe injuries

2. Inability to calculate incidence
a. Lack of denominator data
b. Geographic imbalance

3. Other sources of bias
a. Changes in practice patterns
b. Partial reliance on direct participants
c. Retrospective transcription of data
d. Absence of rigorous comparison groups
e. Low reliability of judgements of appropriateness of care
f. Outcome bias (Lee & Domino 2002)

> in the United States. The project represents a national quality assurance system, albeit without a denominator. More than a decade of experience demonstrates that closed claims data can reveal important and previously unappreciated aspects of adverse anaesthetic outcomes. These insights can be used to formulate hypotheses aimed at improving the quality of anaesthetic care, thus providing a tool for advancing patient safety and reducing liability exposure for the anaesthesiologist. (Cheney 1999)

Other claims reviews

Although anaesthesia-related claims have dominated the research literature, reviews in several other specialties have been carried out (see full reports: http://www.csru.org.uk). For instance, Ennis & Vincent (1990) in a review of serious obstetric claims identified three major areas of concern: inadequate foetal monitoring, mismanagement of forceps, and lack of involvement of senior staff. Neale (1993, 1998a,b) carried out detailed reviews of cases in medical emergencies, in general medicine and in gastroenterology, extracting a number of key lessons to prevent similar outcomes in the future. In the practice of gastroenterology, Neale showed that insufficient attention was paid to the risk : benefit ratio of invasive procedures and to the after-care of patients who suffered an adverse event during a procedure (Neale 1998b).

A particularly sophisticated study of claims was carried out by Gawande *et al*. (2003) who employed a case control design to examine instances of retained instruments and sponges after an operative procedure. The main risk factors that predicted the occurrence of a retained foreign body were undergoing emergency surgery, an unplanned change in operation and body mass index. This design overcomes some of the limitations that occur in traditional methods of closed claims analysis, by setting the analysed claims within a representative cohort. However, not all instances of foreign bodies being left in cavities will result in a claim, and the factors involved in these cases may or may not differ from those that do result in claims.

Analyses of claims from British databases

In our own study, four specialty reviews were carried out spanning medicine and surgery, obstetrics, primary care and mental health. Four experienced clinicians, identified one or more themes (such as suicide in mental health patients) that were of both clinical and medico-legal importance. Reviewers were asked to focus on the clinical issues and potential for learning clinical lessons, but also to reflect on the value of the process of claims review and to note difficulties encountered with data quality, coding or the review process as they went. The development of the methodology and the methods of the studies are described in the report (http://www.csru.org.uk).

Only about 70% of the available cases were suitable for full review, as many had been abandoned at an early stage or had insufficient data to permit conclusions being drawn. An average of 10 years had elapsed between the occurrence of the original incident and our review, slightly less for medicine and surgery. Even in the restricted set of claims files that have sufficient data for review, reviewers judged that there was a number of cases in which the injury sustained was not caused by medical management. However, reviewers were generally able to make judgements about the nature of the principal clinical issue identified (Box 2) (such as a failure in diagnosis or monitor, problems with drugs or fluids) and to consider what clinical lessons might be learned (Box 3). Reviewers felt confident in drawing important clinical lessons from at least a proportion of

Box 2 Failure to diagnose tuberculosis

A very fit 25-year-old man (fitness instructor) presented with a lump in the groin. He was referred to a general surgeon who removed the enlarged lymph node. The histopathologist reported poorly formed granulomata, a finding that is consistent with but not diagnostic of tuberculosis. The differential diagnosis included toxoplasmosis and antibodies against this organism were found in a blood test (this is not an uncommon finding in the healthy general population). A chest radiograph showed infiltrative fluffy shadows at the right apex highly suggestive of TB. The findings were correctly reported and either the report was not seen or it was ignored.

Comment: failure to draw together all the evidence and consider its implications.

Over the next 12 months the patient's health deteriorated progressively and he lost 2 stones' weight and became unable to work. He was referred to a 'top' unit for infectious disease where he was told that he had 'chronic fatigue syndrome'.

Comment: failure to undertake a full physical re-assessment; making a diagnosis of a functional/psychological/psychiatric disorder without excluding organic disease.

A year later the patient became unable to walk. This was regarded as a back problem super-imposed on chronic fatigue and poor posture. A consultant rheumatologist diagnosed spondylitis. A further 6 months went by before it was recognized that the patient was actually very sick. A chest radiograph showed evidence of advanced pulmonary tuberculosis.

Comment: failure of specialist to look at the 'whole' patient as well as their area of special interest.

Box 3 Clinical lessons learned from claims reviews

- Surgery and general medicine
  - A full history and clinical examination remains vital to the art of diagnosis
  - There is a need for proper assessment of all the evidence at time of discharge and clear guidelines to GP's and to clinical staff in follow-up clinics
  - It is necessary to maintain awareness both of diseases that are less common than they used to be (e.g. perforated peptic ulcers) and common diseases of the past that are reappearing (e.g. tuberculosis)
  - SHO/Registrars should not be taking full responsibility for assessment of patients in outpatient clinics
- General practice
  - Computerized decision aids may assist diagnosis of rare diseases such as diabetes in children
  - Robust systems of care for the ongoing management of diabetes in adults are vital
  - Primary care trusts need to be able to access information about rare diseases easily
  - Lack of knowledge was a contributory factor in many of the cases analysed
- Obstetrics
  - Further training in CTG interpretation may be beneficial in avoiding adverse events, to ensure correct use of these monitors
  - Failure to adhere to guidelines may be an important cause of adverse events
  - Problems within the system of care, with doctor patient relationships and with teamwork/supervision were noted
  - Whereas many of the adverse events involved more junior staff, the judgements of the consultants/midwives were also questionable on occasion
- Mental health
  - Observation of patients on section needs to be defined in care plans
  - Psychiatric referral needs to be more easily accessed so that at risk patients can be seen quickly
  - Nursing notes need to be amalgamated into medical notes so that a full assessment can be made including a list of observations, past history, current stresses and symptoms
  - More and better training needs to be put in place for diagnosis
  - Emergency resuscitation equipment needs to be available, in working order and staff trained to use it

Box 4 Limitations of the process of claims review experience in Britain

- Evidence
  - Full case notes sometimes required for detailed assessment
  - Inadequate clinical notes impede the whole process
  - There is a very variable quality of evidence
- Organization of evidence
  - Expert witness reports and internal enquiry report may be missing from case files
  - Files are established for documenting a legal process, not for the purposes of study, therefore not all information that may have been required was available
  - Clear marking of where reports, statements and letters are to be found would help especially in multiple file cases
- Timescale
  - Delay between closing of case and claims analysis, so changes may have occurred in working practice
  - If investigated, documented and analysed at the time of incident, instead after a number years, many of the shortcomings of this method would be overcome
- Dropped/withdrawn claims
  - Notes on reasons why claim is not pursued would be useful
  - Death of patient inevitably means claim is dropped
  - Sometimes claim is withdrawn although care is clearly below standard
  - Where cases are barred because of statute (time) limitations, important lessons are lost
  - Sometimes causality may not be proved but nonetheless lessons could be learned from these cases

cases, and were often aided by the high quality of expert reports. However, they also noted a number of limitations of the claims review process which are summarized in Box 4.

Reviewers were also asked to comment on the presence or absence of a defined list of contributory factors (Vincent *et al*. 1998). In 40% of cases poor team factors to the injury/claim, the skills and behaviour of individual clinicians were judged to have contributed to the problem in 17% of cases and task factors accounted for 23% of cases. Overall, this suggests that problems in the wider organization can be identified, or at least inferred. However, we should caution that reviewers were very often 'unable to judge' whether a particular factor had any bearing on the case in question.

Conclusions

In spite of the inherent limitations of claims review, the authors of our own reviews, and of other studies of claims, were all able to draw conclusions about problems in the process of care in the cases they reviewed. Not all cases are suitable for review, and they vary considerably in the amount of detail and extent to which lessons can be learned. In general however, clinical themes are apparent, in terms of defined problems at particular phases of the care process and, to some extent, in the detection of background, contributory factors. Almost all the studies reviewed here have stressed that claims are an unrepresentative sample of adverse outcomes of health care and represent only a very small proportion of instances in which care has been substandard or patients have come to some harm.

The methodological limitations of claims review have been well summarized by the ASA reviewers (Box 1). They include the lack of denominator data, bias towards more severe injuries, problems in the reliability of judgements, outcome and hindsight bias, the unrepresentative nature of claims and so on. Some of these problems are potentially remediable, particularly those of data collection and standardization. Defining a minimum data set for the review of a set of claims would allow some standardization of the process as well as ensuring that, at least for those cases of interest, all relevant documents were assembled. If particular clinical issues had been identified in advance for claims review, experts could easily append answers to a standard set of questions at the time of compiling a report.

Claims data do have the ability, when data quality are good, to capture important facts about the process of care and factors contributing to adverse

events. But contributory factors can be much more effectively assessed by contemporaneous interviews and observation than by screening medical records and reports several years after the event (Vincent 2003; Vincent *et al*. 2004). Studies of any kind that prospectively set out to capture some aspect of errors and adverse events can define data collection methods and data quality in a way that opportunistic, retrospective review of claims data never can.

Claims review then is unlikely to be the method of choice for assessing either the incidence of, or understanding of, adverse outcomes. But are there any circumstances in which claims data could provide insights not available by other methods? Here again, the ASA closed claims project provides a model, in that the great strength of claims data are that it can provide information on rare events, not easily detectable by routine review or observation. Large scale reporting systems, such as that of the National Patient Safety Agency or the Australian Incident Monitoring System, also have this advantage but it is possible that claims could provide additional information or detect other types of incident.

The future use of claims review in improving patient safety

In summary then, we would propose that claims review can be useful as an approach to the understanding error and adverse outcomes. The strength of claims review lies in its potential in providing rich information and comment on particular cases, with the caution that these may not be representative of the wider class of adverse outcomes. However, a number of preconditions have to be met and certain standards of data quality and organization adhered to. We would suggest that the following are minimum requirements:

- That either the condition under investigation is sufficiently rare not to be easily detectable by other means or the claims data offer additional information not otherwise available.
- Other methods of investigating this class of problem have been assessed and claims review has been found to provide additional information of value.
- That cases are selected and analysed as soon as possible after the incident occurred by expert reviewers from the medical specialty in question.
- That more attempt is made to understand the patient's perspective and experience as this is, potentially, a strength of claims data in comparison with other methods.
- That due consideration is given, where possible, to defining an appropriate control group (Gawande *et al*. 2003).
- Claims data are assembled in a central database and are checked and subject to quality control at the time of entry to the database (as with the ASA closed claims analysis).
- The results of claims review are treated as working hypotheses and subject to further investigation in more formal studies.
- The claims review is used only as part of a more general quality and safety improvement strategy.
- Expert claims reviewers work to a defined data collection template and a defined set of questions.

We suggest that there is now no case for *ad hoc* claims review which relies on claims data that have been assembled for legal purposes only and with no thought to its use in improving the quality and safety of patient care. We believe that there may well be circumstances in which claims review can be justified as a valuable approach to a problem in health care. However, if resources are to be committed, we believe that a positive case has to be made for such a review, and that it must be clear that claims review can make a specific contribution in a broader attack on the problem in question.

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