Patient safety: lessons from litigation

Learning from litigation: an analysis of claims for clinical negligence

Charles Vincent
Caroline Davy
Aneez Esmail
Graham Neale
Max Elstein
Jenny Firth Cozens
Kieran Walshe

School of Primary Care, University of Manchester
Manchester Centre for Healthcare Management, University of Manchester
Clinical Safety Research Unit, Imperial College, London
Nottingham University Business School
Health Economics Research Centre, University of Oxford

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EXECUTIVE SUMMARY

This report presents the methods and findings of a study commissioned by the Department of Health's Patient Safety Research Programme to examine what could be learned from claims for clinical negligence and how such learning could be used to improve patient safety in the NHS.

The study described in this report was the second phase of a larger project. The first phase was concerned with the epidemiology of adverse events resulting in litigation and was focused on the analysis of existing available computer databases of litigation cases held by the NHS Litigation Authority and the medical defence organisations. The second phase of the project focused on the causation and avoidability/prevention of certain types of adverse event resulting in litigation in four key specialties, and used a structured review of case series by expert reviewers.

This report is one from a series of three reports which present the findings from the research project:

- The epidemiology of error: an analysis of databases of clinical negligence litigation
- Learning from litigation: an analysis of claims for clinical negligence
- Case studies in litigation: claims reviews in four specialties

The project was cleared by the North West Multicentre Research Ethics Committee, and we negotiated access to data with the four medical defence/litigation organisations concerned – the NHS Litigation Authority, the Medical Defence Union, the Medical Protection Society, and Capsticks solicitors.

This report examines the role of claims analysis in the understanding of the causes of error and harm. We have approached this question in three ways. First, we briefly review some of the major current methods of analysing errors and adverse outcomes, of which claims analysis is only one possible approach. Second, to give a broader context to our own studies, we describe some of the findings of other claims reviews reported in the last ten years. Third, we report on our own reviews of claims in four specialties from the major UK databases previously described.

It is worth restating the obvious but important point that claims data have not been collected for the purpose of improving clinical care or contributing to patient safety. The analysis of claims data does of course shed light on patterns of litigation and the specific characteristics of cases that have come to litigation. However, claims are an unrepresentative sample of adverse outcomes of healthcare and represent only a very small proportion of instances in which care has been sub-standard or patient have come to some harm.

The methodological limitations of claims review are significant. 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. The practical limitations of the available records are also considerable. In our study, only about 70% of claims proved capable of full review. Clinical notes, where available, were of varying quality as were expert reports and other documents. Key information was sometimes missing and on occasion

the reviewer felt unable to make an assessment from the expert reports alone, and would ideally have needed to see the full medical record. Organisation and retrieval of data was sometimes difficult.

Claims review is only one of a number of approaches to the study of adverse events. Other methods of enquiry (all of which have limitations) do not suffer from some of the major disadvantages of claims review. Systematic record review captures incidence much more effectively. Claims data does have the ability, when data quality are good, to capture important facts about the quality 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. Studies of any kind which 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. In general, we would suggest, claims review has no unique place in the armament of methods of understanding adverse outcomes and that many other methods have obvious advantages. Claims review may not be the method of choice for assessing either the incidence of or understanding of adverse outcomes. Certainly claims data can never give reliable data about the underlying incidence of events, only about procedures and specialties at high risk of litigation.

Surely a better understanding of incidents can be achieved if investigations begin soon after the incident has occurred. No other high-risk industry waits years to begin investigations into serious incidents or relies on claims data from the resulting litigation. What possible reason can healthcare have to continue to use claims data to advance patient safety?

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 organisation adhered to. We would suggest that the following are minimum requirements:

- That either the condition under investigation is a sufficiently rare not to be easily detectable by other means or claims data offers 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

- 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 is assembled in a central database and is 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

We do not suggest that this is necessarily a complete set of requirements for a claims review to be of value. However, these requirements do indicate that, given the availability of other methods, there is now no case for ad hoc claims review which relies on claims data that has been assembled for legal purposes only and with no thought to its use in improving the quality and safety of patient care. It is also clear that this list of requirements, particularly that claims review is most useful for rare events, narrows the potential use of claims review considerably. We believe that there may well be circumstances in which claims review can be justified as a valuable approach to a problem in healthcare. 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.

1 INTRODUCTION AND BACKGROUND

Improving patient safety, and reducing error and adverse events, have emerged as a national priority in many countries. It is now clear that many people are harmed in every healthcare system so far studied. Tackling these problems requires a systematic programme of research and action which can, broadly speaking, be divided into five stages. First, there must be an awareness of the problem. Then, the nature and scale of the problem must be assessed, the causes of harm must be investigated and understood, appropriate methods of prevention developed and finally, safety initiatives must be implemented and sustained.

We consider that any use of claims data must be considered in the broader context of attempts to improve patient safety. This report examines the role of claims analysis in the understanding of the causes of error and harm. What role can the analysis of individual claims play in improving patient safety?

We have approached this question in three ways. First, we briefly review some of the major current methods of analysing errors and adverse outcomes. Claims analysis is only one possible approach and its utility must therefore be assessed in relation to other available methods. Secondly, to give a broader context to our own studies, we describe some of the findings of other claims reviews reported in the last ten years. In our original submission for this work we proposed only assessing claims from UK databases, but we believe that the broader context must be understood if we are to assess the current, as opposed to the historical, value of claims analysis. The third, and most substantial part of our investigation, concerns our own reviews of claims from the major UK databases previously described. Four specialty reviews were conducted in obstetrics, medicine and surgery, mental health and primary care and conclusions drawn about both the particular specialties and the value of the review process itself. In summary therefore, the specific objectives of the second part of this study are:

- To assess the potential of reviewing claims documentation for learning meaningful lessons about the causes of adverse events
- To assess the value and feasibility of reviewing claims documentation on an ongoing basis
- To draw lessons for clinical practice for the specific classes of cases reviewed

This report presents a summary analysis across those four specialty reviews, but a more detailed account of each study can be found in the accompanying report titled *Case studies in error: claims reviews in four specialties*.

1.1 Methods of Studying Errors and Adverse Events in Healthcare

In the late 1980s there was comparatively little awareness, and even less research, on the nature and causes of harm to patients. So few systematic studies had been carried out that a paper published in 1989 went so far as to describe the lack of research on medical negligence and patient harm as in itself negligent (Vincent 1989). At that time claims and complaints were one of the most important sources of information on patient harm and drivers of risk management in healthcare and, latterly, patient safety. In fact, reports of the 'hazards of hospitalisation' go back to the 1960s (Schimmel 1964) and before, but these pioneering studies, did not develop into a sustained body of research and seldom addressed the more contentious topics of error and substandard care.

There are now several different methodologies available for studying adverse events, and each has its respective strengths and limitations. Discussions of appropriate methodology in this area are frequently marred by a simplistic attempt to identify the 'best' method, as if only one type of study was needed. This is most frequently seen in arguments about the value of the major retrospective reviews, sometimes criticised for not providing data on human factors and other key issues not identified in medical records. In fact such studies are not intended to provide such information. Their primary purpose is to assess the nature and scale of harm, although recent review techniques also suggest that valuable information on cause and prevention can be extracted (Woloshynowych, Neale, & Vincent 2003). The key point is that the appropriate methodology will depend, as it usually does, on the questions being addressed, the resources available and the context of the study. Claims data, in particular the assessments of expert reviewers, are one route to understanding the causes of adverse outcomes and of suggesting potential methods of prevention.

Thomas and Petersen (2003) classified methods of studying errors and adverse events into eight broad groups and reviewed the respective advantages and disadvantages of each method. In their paper they use the term error to include terms such as mistakes, close calls, near misses, active errors and latent conditions. Adverse events imply harm or, at the very least, additional days in hospital. Active errors, broadly speaking are specific acts or omissions by people 'at the sharp end' (doctors, nurses etc), whereas latent errors are contributory factors that may give rise to active errors. Latent conditions include such factors 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.

Table 1: Error Measurement Methods

Error Measurement Method	Advantages	Disadvantages
Morbidity and mortality conferences and autopsy	Can suggest latent errors Familiar to health care providers and required by accrediting groups	Hindsight bias Reporting bias Focused on diagnostic errors Infrequently and nonrandomly utilized
Case analysis/ Root cause analysis	Can suggest latent errors Structured systems approach Includes recent data from interviews	Hindsight bias Tends to focus on severe events Insufficiently standardized in practice
Malpractice claims analysis	Provides multiple perspectives (patients, providers, lawyers) Can detect latent errors	Hindsight bias Reporting bias Nonstandardized source of data
Error reporting systems	Can detect latent errors Provide multiple perspectives over time Can be a part of routine operations	Reporting bias Hindsight bias
Administrative data analysis	Utilizes readily available data Inexpensive	May rely upon incomplete and inaccurate data The data are divorced from clinical context
Chart review	Utilizes readily available data Commonly used	Judgements about adverse events not reliable Expensive Medical records are incomplete Hindsight bias
Electronic medical record	Inexpensive after initial investment Monitors in real time Integrates multiple data sources	Susceptible to programming and/or data entry errors Expensive to implement Not good for detecting latent errors
Observation of patient care	Potentially accurate and precise Provides data otherwise unavailable Detects more active errors than other methods	Expensive Difficult to train reliable observers Potential Hawthorne effect Potential concerns about confidentiality Possible to be overwhelmed with information Potential hindsight bias Not good for detecting latent errors
Clinical surveillance	Potentially accurate and precise for adverse events	Expensive Not good for detecting latent errors

(adapted from Thomas and Petersen 2003)

The strengths and limitations of the different methods are shown in Table 1. While we do not need to review all the methods in detail, some general points can be made. 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, Young, & Phillips 1994). Other studies, as the table shows, are subject to various limitations. Second, the methods are differently oriented towards detecting incidence of errors and adverse events, active errors and the latent, contributory factors. Thomas and Petersen suggest that the methods can be placed along a continuum with active clinical surveillance of specific types of adverse event (e.g. surgical complications) being the ideal method for assessing incidence, and methods such as claims analysis and morbidity and mortality meetings being more oriented towards latent conditions. We have added one additional category to their list: the systematic analysis of individual cases, usually referred to as root cause analysis or systems analysis. These analyses share some of the features of morbidity and mortality meetings, but are generally more focussed, following a particular method of analysis (Vincent 2003). They are particularly relevant here as the aims are, broadly speaking, the same as in claims analysis. The difference is that they are conducted shortly after the incident occurred so that staff can be interviewed while memories are still fresh.

Thomas and Petersen's conclusions about the relative merits and limitations of claims analysis are worth quoting in full:

> *'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 generalise. 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 standardised. 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)

Claims analysis, according to Thomas and Petersen, gives little indication of the incidence of errors and adverse events, cannot be used to assess prevention, but potentially gives important information on the latent factors – the background causes of error and harm. They consider that whereas the broad nature of the substandard care might be identified, it is seldom possible to infer specific errors but more general conclusions may be drawn. This particular assertion is considered in more detail in our own study.

Claims data, as they point out, are not collected in a standardised form and the documents available may be of variable quality. Cases are highly selected and it may be difficult to generalise, though a claims review can produce hypotheses about the causes of problems that may be followed up in more systematic studies

Thomas and Petersen also cite hindsight bias as a problem for claims review and several other methods. The term derives from the psychological literature and in particular from experimental studies showing that people exaggerate in retrospect what they knew before an incident occurred – the 'knew it all along' effect. Looking back after the event, the situation faced in actuality by the clinician is inevitably grossly simplified. We cannot capture the dynamic, unfolding story of a clinical encounter, still less the clinician's anxiety, the fact that he needs a break, and that he is

simultaneously being harassed by a nurse about another patient and paged to resolve a discrepancy in a medication order.

Hindsight bias has another facet, perhaps better described as outcome bias, particularly relevant in healthcare. When an outcome is bad those looking back are much more likely to be critical of care that has been given and more likely to detect errors. For instance, Caplan et al (1991) asked two groups of physicians to review sets of notes. The sets of notes were identical except that for one group the outcomes were satisfactory, and for the other group the outcome was poor for the patient. Much stronger criticisms were made of the care of the group who believed outcomes were poor, even though the care described was exactly the same. Cases that have led to claims have, by definition, poor outcomes of some kind and so are particularly subject to this bias, although notably where outcomes were fatal, claims tended to be discontinued.

There are therefore a number of different methods of studying errors and adverse events, each with their own strengths and limitations. The analysis of claims, if it is to be useful and effective, needs to be considered in this broader context and ideally show that this approach has some distinctive advantages. With this in mind we now turn to studies of claims data.

1.2 The Analysis of Closed Claims

Claims data, as Thomas and Petersen have commented, has a number of limitations. However, some important insights have been derived from this approach to studying adverse outcomes. We have supplemented our own reviews of British claims databases with an examination of some of the principal studies of the last twenty years. We did not intend, in this project, to carry out a full systematic review of the results of closed claims studies. Rather, our aim was to illustrate the potential and limitations of this method by reviewing some of the major studies. Vincent (1993) has already considered reports appearing in the later 1980s and early 1990s, and so we have restricted our formal review to studies published in the last ten years. We searched Medline and Pubmed from 1993 to 2003 using the search terms: claims analysis, closed claim review, closed claim analysis, medical negligence litigation claims review, insurance claims review and clinical negligence. A comprehensive literature search was not attempted as that was not the purpose of our study.

The primary purpose of an expert review of the various statements, depositions and medical records assembled is to decide whether care fell below an acceptable standard and, if so, whether it led to harm. Potentially therefore the expert reports, in turn derived from the other documents, contain information that is relevant to patient safety and the quality of care. However we should note at this point that, just as claims databases were not developed to enhance patient safety but to manage claims, the same is true of expert reports. Their purpose is to assist the adjudication of a case. In the course of this analysis the expert reviewer, whether plaintiff or defendant, will comment on the nature of the substandard care and may, by chance if not design, comment on background factors that contributed to the sub-standard care. Those analysing claims data may or may not have access to the full medical records. At the very least we should remember that the quality and extent of data available to researcher in this area is extremely variable.

The most important early studies on closed claims were derived from the database assembled by the American Society of Anesthesiologists, with the first reports appearing in 1988. The findings of this series of studies, being of particular relevance to this project, are discussed in more detail below**.** Two analyses of British closed claims were also carried out in the late 1980s (Ennis &

Vincent 1990;Vincent, Martin, & Ennis 1991). Cases were drawn from the files of the Medical Protection Society and, for the second study, from the charity Action for Victims of Medical Accidents. The cases considered were those in which the outcome was either (a) stillbirth (b) peri-natal or neonatal death (c) CNS damage leading to handicap or (d) maternal death. Human error was frequently implicated in such incidents. Junior and middle grade staff were most frequently involved and three major areas of concern were identified: inadequate fetal monitoring, mismanagement of forceps (undue traction, too many attempts), and lack of involvement of senior staff. Problems included an inability to recognise abnormal or equivocal fetal heart traces and a failure to take appropriate action when an abnormal trace was recognised. Inexperienced doctors were frequently left alone for long periods in labour wards, even in cases where consultants had previously expressed doubts about their competence. Moreover, junior doctors frequently had difficulty in obtaining prompt assistance when problems were recognized. Although these incidents represented a tiny fraction of the millions of safely delivered babies born in the period of the studies, the authors suggested that the findings might reflect more general problems. Further studies on training and fetal heart monitoring by Ennis (1991) provided some support for this viewpoint.

Vincent (1993) reviewed these and other closed claims studies, and also considered emerging findings from other sources of information about adverse events: occurrence screening (record review), confidential enquiries, critical incident reporting, studies of specific errors and some early observational studies. Many of the studies discussed offered, at that time, only tangential information on patient harm. Claims were one of the most important avenues of enquiry in that they were squarely focused on the issue of harm. Vincent concluded that, whereas claims were not a good reflection of overall risk, valuable information had nevertheless been obtained about underlying clinical problems which at the very least provided hypotheses and direction for more focused studies. A more pertinent question however, was whether one needed to wait so long before investigating such incidents. Caplan et al (1990) had already pointed out, when reviewing anaesthesia claims, that 'the objectivity of an eyewitness is degraded by the passage of time, interactions with other observers and premature efforts to reach conclusions'. A better understanding of these cases might be achieved if investigations began sooner after the incidents occurred, a recognition that underlies the drive to develop incident reporting systems to inform both the management of claims and risk management systems.

1.2.1 The Anesthesia Closed Claims Project

The most important initiative in collecting claims data is undoubtedly the ongoing closed claims project of the American Society of Anesthetists (ASA), started in 1984 as part of a number of safety improvement projects, at a time when there was little comprehensive information about the scope and cause of anaesthetic injury (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. Typically, a closed claim file consists of the hospital record, the anaesthetic record, narrative statements of staff involved, statements from the patient, expert and peer reviews and reports of both clinical and legal outcomes. The project has collected claims information from 35 insurance companies covering more than half of all United States anaesthetists and, by 1999, there were more than 4000 claims in the database. The project has been well reviewed by Cheney (1999) who, looking back over the project's history, considered what had been learned, how the project had affected practice and its potential future role. This careful construction of a customised database is clearly a model for other claims projects and we should note at once that the 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. We have summarised the principal studies in Table 2.

Author & 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 Burns from warming devices in anesthesia	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	Standardised 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 recognised
Caplan et al. 1997 Adverse Anesthetics Outcomes Arising from Gas Delivery Equipment: A Closed Claims Analysis	3,791 cases in database of the Closed Claims Project 72 claims	Claims associated with gas delivery equipment	Reviewed by practising anaesthetists	Standardised instructions to complete a standardised 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 1-5% 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 Nerve injury associated with anesthesia: 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 practicing 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 versus general anaesthetic split
Domino et al. 1999b Awareness during Anesthesia: A closed claims analysis	Drawn from a total of 4,183 claims from the database of the American Society of Anesthetists (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 standardised 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.

Author & 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. 1999a Airway injury during anesthesia: a closed claim analysis	Airway injury claims taken from the American society of Anesthesiologists closed claims project database 266 Claims	Airway injury cases from anaesthetic database	Reviewers not specified but given specific instructions about how to use a standardised 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 The Closed Claim Project: Has it influenced anesthetic 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 standardised 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 was 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 healthcare. 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 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 does 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

Cheney summarises a number of studies that appeared between 1988 and1999, making the important point that claims are a particular useful source of information on rare events that might not otherwise appear in routine reviews. One of the first studies (Caplan et al. 1988) examined 14 cases of sudden cardiac arrest during spinal anaesthesia. From patterns analysed the authors hypothesized that poor outcome may have been a result of poor cerebral perfusion pressures engendered by closed cardiac chest massage in the presence of sympathetic blockade. They suggested the administration of epinephrine when this crisis occurs, and subsequent reports have confirmed the efficacy of this approach (Cheney 1999). Further investigation of major trends showed that respiratory events accounted for a large share of claims, especially for brain damage and death. The most common events leading to injury were inadequate ventilation, oesophageal intubation and difficult tracheal intubation. However, we should note that 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 postanaesthesia care unit. Cheney comments that this is not to imply that the standards would not have been written without this data but that 'at the time closed claims data were the only substantive supporting evidence that was national in scope'. 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 identified in each study are shown in the right hand column of Table 2 and have been summarised by Lee and Domino (2002) (Box 1).

Box 1. Limitations of 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)

The incidence of adverse outcomes is vastly greater than the number of claims filed, and conclusions are in turn limited by the fact that the database does not cover all relevant insurers. A host of factors affect whether or not a patient sues, with communication and doctor-patient relationship a major predictor of litigation (Hickson et al. 1992; Vincent, Young, & Phillips 1994). In addition there can be a long lag time between the occurrence of an injury and subsequent claim, and a further delay while a study is carried out. In the ten years or so that may then have elapsed practice patterns may change. Data is derived from those directly involved which is in some respects a great strength but, given the medical negligence context, reports may be incomplete or biased in a number of respects. Reliability of judgements of care and difficulties in judging appropriateness have also been discussed (Cheney et al. 1989). These limitations should make us cautious about claims data, but it is important to recognise that any approach to the study of adverse outcomes has limitations. Discussion of strengths and limitations tells us what claims data can and cannot tell us and how such data might best be employed in the overarching aim of improving patient safety.

Gratifying trends are apparent in this claims database. The first is that the severity of malpractice claims is decreasing, as indicated by the reduction in claims for death and brain damage. While claims generally may not reflect levels of adverse events, they are more likely to reflect underlying rates here when anaesthetic death or brain damage, being very serious, very rare and often preventable, are highly likely to lead to claims. Patterns of other injuries are also changing, with nerve injury emerging as a leading cause of claims, but it is not clear how far this reflects underlying rates at the clinical level. Cheney's conclusion about the future of the claims database, in an era of heightened attention to patient safety, is 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 anesthetic practice 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 anesthetic outcomes. These insights can be used to formulate hypotheses aimed at improving the quality of anesthetic care, thus providing a tool for advancing patient safety and reducing liability exposure for the anesthesiologist'* (Cheney 1999)

1.2.2 Other claims analyses (1993-2003)

Table 3 shows claims analyses from 1993-2003, covering only formal analysis of cases rather than general commentary on malpractice, litigation, risk management and so forth. Most reviews have been conducted for the purpose of learning about the causes of adverse outcomes and putting forward possible methods of prevention, though some have additional aims. For instance Greenwood et al (2003) reviewed claims relating to cerebral palsy to define essential criteria for acute intrapartum hypoxia, which in turn predicted the outcome of the claim.

Anaesthesia claims are again highlighted, with further reviews of respiratory incidents and (Larson & Jordan 2001) and problems with regional anaesthesia (Peng & Smedstad 2000) supporting the previous ASA closed claims analysis. Reviews have also been carried out on medication errors, paediatric cardiology

Some analyses have a particularly strong clinical focus. For instance, Neale (1993; 1998a; 1998b) 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 1998a).

Neale also identified general aspects of medical care that, if strengthened, could significantly reduce serious AE's. For example, he recommended for the optimal assessment of medical emergencies experienced physicians should have no other duties on the 'take'-day other than to teach trainees how to assess and manage acutely ill patients (Neale 1998b). Neale (1993) pointed out, that increasing specialisation was likely to lead to a cadre of hospital physicians insufficiently experienced in general medicine to be able to cope with a wide range of emergency admissions. This has been recognised recently by the College of Physicians which is supporting the concept of training specialists in emergency assessment and care.

Many of the authors offer reflections on the claims review process. There is general agreement, where comments are offered, that claims reviews can be used to highlight potential problems and at least suggest the causes of those problems. There are however seldom any explicit attempts to compare claims review with other available methods. A number of limitations of the process are discussed, such as the uncertain relationship of claims to the underlying rate of adverse outcomes. However, the ASA claims reviewers have provided a complete summary of these various limitations and no new problems were highlighted in this series.

A more sophisticated study of claims was carried out by Gawande and colleagues (2003) who employed a case control design to examine instances of retained instruments and sponges after an operative procedure. Cases were selected from an insurance database of closed claims. For every case that was identified through the insurance company files an average of 4.4 cases were retrieved for comparative record review. These cases were matched, where possible, from the same hospitals and with the same procedures. By employing this methodology it was possible for Gawande et al to examine the possible factors that may have led to the error occurring. 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 (each unit increase of BMI increased risk of retained foreign body). Further, as the data included the hospital in which the error had occurred, it was also possible to consider the relative rate of the type of error given the total number of operations in the hospital per year. 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, as is pointed out in the article, there are still limitations to these studies. 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.

Author & 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
Neale 1993 Clinical analysis of 100 medicolegal cases	General medicine, especial gastroenterology surgery for period 1984-1993 100 cases	100 successive requests for a medical opinion on legal claims against hospital doctors	Reviewed by author	Detailed assessment by author of case from clinical perspective	Need for improved understanding and improved explanations of medical mishaps, avoidance of clinical error, recognition of poor standards of care, Adverse effects of litigation include: inappropriate risk avoidance and reduction.	No particular reflection except the need for prompt investigation
Neale 1998a Reducing risk in Gastroenterological practice	Gastroenterological cases where medical opinion was sought between 1987 and 1996 85 cases	Solicitors requests to author for medicolegal report	Reviewed by author	Clinical assessment	Endoscopic procedures have increased risks of claim by approximately 50%. Several clinical key points made to help gastroenterologists avoid errors/adverse events e.g. endoscopic examination should not be undertaken lightly. Mentions side effects of medication and the delicate balance between benefit and risk	Claims should be used to more to improve standards of practice. Evidence from the US suggests that "prospects of liability to litigation was considered a more potent factor in influencing standards of care than peer review (audit)".
Neale 1998b Risk Management in the care of medical emergencies after referral to hospital	Emergency admissions to general medicine wards 40 cases	40 successive requests for a medical opinion made by solicitors during period 1987 - 1996	Reviewed by author	Hospital records, relevant radiographs, GP's notes and associated correspondence and statements of patients and relatives were used for clinical assessment	Lack of consultant staff early in management led to 75% of these adverse events. Use of clear protocols for management of defined problems.	"This pilot stud underlines the need for a central office for the collection and analysis of similar data in order to improve medical practice and to minimise the incidence of adverse events"
Peng & Smedstad 2000 Litigation in Canada against anesthesiologists practicing regional anesthesia. A review of closed claims	Anaesthetic malpractice closed claims from a medical defence association 7909 cases	Claims that closed between 1990 and 1997	Research and education department of the Canadian Medical Protective Association	Case summaries prepared including demographic and other data, e.g. surgical procedure, location, type of anaesthesia, consent etc. Then subdivided according to anaesthetic technique and practice. Disabilities and other patient outcomes, and legal outcomes given	Recommendation that anaesthetists write detailed notes re assessments, consent, details of procedure etc Approx 20% of anaesthesia related claims associated with regional anaesthesia.	Limitations re closed claim review were that there is no denominator re total number of anaesthetics given during same time period.

Author & 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
Bruner & de Jong 2001 Lipoplasty claims experience of US insurance companies	Claims of adverse events related to lipoplasty or liposuction from January 1985 to June 1998 292 claims	Cases selected from a data sharing project database of Physicians Insurance Association of America claims	Reviewed by authors	Raw data output forms processed and analysed. Results sorted physician specialists, severity of complication, board certification, practice location, indemnity payment, medical school, age, years of experience.	67% of lipoplasty claims arose from informed consent or breach of contract issues compared with 26.5% of the aggregate of national claims in the same period. Claims related to mainly hospital based lipoplasty (65.4%).	No comments about the usefulness of claims data.
Larson & Jordan 2001 Preventable adverse patient outcomes: A closed claims analysis of respiratory incidents.	Claims involving Certified Registered Nurse Anesthetists (CRNAs) from the AANA foundation database 223 claims	Certified Registered Nurse Anesthetists (CRNA) claims	CRNA investigators	An instrument of more than 150 variables including events associated with the surgical procedure and intraoperative anaesthetic technique and management.	Claims were more likely to have involved inappropriate anaesthesia management, a lack of vigilance and to be judged as preventable. A higher number of respiratory incidents occurred in emergency and general anaesthetic cases. Adverse respiratory incidents are largely preventable and frequently result in serous patient morbidity and mortality.	Closed claims review very useful in terms of influencing practise standards and future education. Limitations include reviewer bias, the fact that it is retrospective, non-random selection and does not reflect the actual prevalence of malpractice.
Troxel 2001 Diagnostic pitfalls in surgical pathology – discovered by a review of malpractice claims.	Review of surgical pathology and fine needle aspiration biopsy claims between 1995 and 1997. The author focuses on the diagnostic problematic areas in lymphoma, prostate and frozen sections. 218 claims	Pathology malpractice claims from The Doctors Company- a physician owned professional liability insurer covering 10% of pathologists in the US.	Author is a practising pathologist and consultant to The Doctors Company.	46% of surgical pathology claims represent "random errors" i.e. no pattern relating to diagnostic category, whilst 54% were categorised as "systemic errors" i.e. falling into a distinct diagnostic category. Total number of claims for each specimen/diagnostic category was noted plus the number of false negative and false positive results. This is used as a basis for improved clinical practice.	Failure to diagnose accounted for 75% of lymphoma related claims (7% of total). Immunohistochemical stains are imperative as part of diagnostic testing. Prostate biopsy claims (4%) were characterised by false positive diagnoses (78%). Recommendations include a consideration of cytohistologic features, repeat biopsy for atypical small acinar proliferation, and adequate sampling of prostate needle biopsies. Frozen section	This is the fifth of a series of articles written as a result of a review of malpractice claims. No particular comment on claims review is offered.

Author & 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
					claims (10 in all) were evenly divided between false positives and false negatives	
Gould et al. 2003 An analysis of Orthopaedic Liability in the Acute Care Setting	Literature review of orthopaedic claims N/A	N/A	N/A	Search of Medline, Lexis (law database) and database of Physician Insurers Association of America to identify literature specific to orthopaedic medical malpractice, litigation and risk management. The latter provided useable data.	Orthopaedic claims fall into 2 categories: technical errors or communication errors. The former could be addressed by methodological evaluation, good communication, accurate documentation and reliable follow up. The latter by good rapport between doctor and patient plus full explanation of the injury and treatment plan.	By extrapolating data from risk management comments, the current authors were able to reasonably ascertain several scenarios frequently resulting in litigation and thus provide lessons.
Rothschild et al. 2002 Analysis of medication-related malpractice claims; causes, preventability and costs	Medication related malpractice claims from January 1 1990 to December 31 1999 2040 cases	Database searched cases involving certain allegation descriptions: improper treatment, medication mismanagement, medication monitoring, medication errors, ADE's, and adverse drug reactions	Pharmacist then physician review	Cases electronically screened for possible Adverse Drug Event (ADE) and followed up by independent review of case abstracts. In depth claim file review (on site) identified potential human factors failures associated with ADE, claims not associated with patient injury or unrelated to medication excluded	ADE's represent 6% of malpractice claims and were preventable in 2/3 of cases with computerized physician order entry (CPOE). 46% of the ADE's identified were life threatening or fatal. System deficiencies and performance errors were the most frequent cause of preventable ADE's. Interventions suggested include error proofing and process standardisation.	Closed claim review does not predict risks. They provide a snapshot of liability not a comprehensive picture of injury. Malpractice claim records are an additional resource, including information not available in medical records. New knowledge after the event can be reviewed. Expert opinion provides alternative perspectives and explanations surrounding an event and patient injuries.
Gawande et al 2003	61 cases of retained foreign bodies from a	Cases only involving retained foreign	Senor surgical residents	Developed a form for record review, employing both hospital	Risk factors for a retained foreign body were found to be having an	By using a case control design was able to overcome some of

Author & 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
Risk factors for retained instruments and sponges after surgery	single insurer covering multiple hospitals, and 235 matched control cases	bodies during the period 1985 to 2001, matched cases were, where possible selected from the same hospital and having undergone the same procedure		and legal records	emergency surgical procedure, an unplanned change in operation and increases in body mass index increased risk also.	the traditional limitations of closed claim review process, however, do point out that not all cases of foreign body retention will necessarily lead to litigation, so the sample may still not be representative
Greenwood et al 2003 Cerebral palsy & clinical negligence litigation: a cohort study	Retrospective review of medical records to find criteria for intrapartum hypoxia and whether this influenced cerebral palsy (CP) claims. 138 subjects	All born with CP between 1984 and 1993 in Oxfordshire HA. Excluded cases of CP due to post natal causes.	Blinded observer	Reviewed medical records to find criteria for intrapartum hypoxia in children with CP who have and have not been the subjects of clinical negligence legal claims.	3 essential criteria for acute intrapartum hypoxia. If these are present, the case is more likely to lead to a legal claim but did not influence outcome of claim.	Not about claims per se but indirectly comments on the clinical validity of claims
Waldman & Spector 2003 Malpractice claims analysis yields widely applicable principles.	Consecutive claims in paediatric cardiology from 1984 to 2000 50 claims	Lawsuits referred to the first author for assessment – 25 by Plaintiff's counsel and 25 by defence counsel	Authors who presumably are physicians/paediatric cardiologists.	Same questions asked of each case: What happened, in chronological order, both medical and legal? Was there an adverse outcome, with what long term effect on the patient? What caused the outcome? Could the outcome have been prevented and, if so, by whom or what? Was the quality of care within or below the acceptable standard	Findings: 38% of claims were due to clinical error. 20% showed cognitive negligence (delayed or wrong diagnosis resulting in pt injury). In 20% of claims bad outcomes could not have been avoided. Erroneous attributed causes of death –45%. 68% of claims were settled but on the decision of the defendant's insurance company	Claims data from large databases: are inaccurate and non specific and affected by other factors e.g. severity of injury, age of patient, communication issues, social factors or legal, medical, systemic & insurance issues..

1.3 Learning from past claims reviews

In summary then, it is clear that most authors of claims review have found that they were able to draw useful clinical lessons from claims data. However, the more thoughtful reviewers have drawn attention to a considerable number of limitations of claims data, some of which are inherent (for instance long time lag) and some of which are potentially remediable (uneven data quality). The most successful project overall has undoubtedly been the American Society of Anaesthetists closed claims project and it is noteworthy that this project has benefited from a strong research team, careful attention to data quality, sustained analyses over a long period of time and a good understanding of both the strengths and weaknesses in their process. Most studies have been more ad hoc in nature, relying on claims data collected by the authors who have little control over the information submitted to them. Only one study, to our knowledge, (Gawande et al 2003) has attempted a formal case control comparison in an effort to determine the features of a case which are specifically associated with a claim. Finally, we should note that there are no formal comparison of claims review with any other method of investigating adverse events, though several authors have noted that investigating an incident several years after it happened is bound to lead to a restricted, and possibly biased, view of the events that preceded it. These points are considered further later in the report in the light of our own reviews of claims from British databases.

2 EXPLORING THE POTENTIAL OF CLAIMS REVIEWS

Having reviewed the existing literature and commentary on claims review, we now turn to the examination of four samples of United Kingdom claims data. The aims of this part of the project are essentially the same as those of the preceding two sections. We wished to examine the potential of reviewing claims documentation for learning meaningful lessons about the causes of adverse events, to draw clinical lessons where possible and to assess the value and feasibility of reviewing claims documentation on an ongoing basis. The potential value of claims data is strongly dependent on the local context, in particular the extent and quality of documentation, which in turn is influenced by the legal framework and the extent to which the organisations involved look beyond legal resolution towards patient safety. It is therefore crucial to examine current British claims data as well as reviewing claims reviews internationally.

2.1 Overview of approach

Four specialty reviews were carried out spanning medicine and surgery, obstetrics, primary care and mental health. Cases were selected from a number of different databases, depending on the availability of the relevant data in each of the various sources. Four experienced clinicians, each with both medico-legal and research experience, reviewed samples of cases from each of the four specialty areas. Each reviewer identified one or more themes (such as suicide in mental health patients) which was of both clinical and medico-legal importance. Cases were then selected according to the themes chosen. Each case was first assessed to determine whether there was sufficient data to carry out a full review, as a key question for our study is what proportion of claims is potentially informative. Those judged to contain sufficient data were reviewed in detail and data recorded on a standard template, which recorded both generic (common to all four specialties) and specialty specific information. In addition the reviewers noted any other issues that they deemed relevant. 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 four specialty reports, which can be found in the accompanying report *Case studies in error: claims reviews in four specialties* give full details of the cases, the data quality and the individual conclusions of the reviewers. Readers should consult that report for detail on the clinical lessons of claims review in each specialty. In this report we draw together the principal conclusions of the individual studies to examine the more general question of the value of claims review. Data which pertains primarily to the specialty in question has been placed in the specialty reports, although some aspects are also summarised here in the interest of clarity. Data which is directed at answering more general questions, such as the detection of organisational influences on adverse outcomes, is discussed below.

2.2 Development of methodology

Medicine and surgery, obstetrics, primary care and mental health deal with very disparate clinical conditions and each has their own clinical processes and procedures. Clearly they needed to be examined separately by reviewers' expert in the relevant discipline. However, we considered that it was desirable to outline a set of common questions which would be applicable across specialties and to use, as far as possible, a common data collection format. If we had only been concerned to learn specific clinical lessons within each specialty, this generic approach would not have been necessary. However, one of the broader aims of the project was to consider how claims data might best be used in the future which would probably require defining a minimum data set and a common approach to analysis. We therefore developed a generic assessment form with a core set of questions, which could be expanded and adapted by speciality reviewers. This approach provided standardisation across a core set of questions, while allowing flexibility to address speciality specific clinical issues.

The template for the initial assessment instrument was derived from three sources:

(i) Retrospective record review studies
The retrospective record review draws on the methods employed by the major epidemiological adverse event studies carried out in the United States, Australia and the British pilot study. The original review forms were recently revised by two of us (GN & CV) and our colleague Dr Maria Woloshynowych. The revised forms and review process place a much stronger emphasis on the analysis of the causes of adverse events and on possible methods of prevention. An important feature of the revised retrospective review forms has been the analysis of the sequence of events and the identification of the phase of care in which problems occurred (Woloshynowych, Neale, & Vincent 2003). This basic approach, originally devised for medicine and surgery, has proved adaptable to other specialities and influenced the development of the claims assessment instrument.

(ii) Review instruments provided by specialty reviewers
Additional information was derived from review forms previously used in study of high-risk practices on obstetrics wards (Ashcroft et al. 2003) and a framework developed for analysis of obstetric incidents provided by Capsticks solicitors. Questions and themes applicable across the range of specialties were extracted from these forms and incorporated in the generic assessment form.

(iii) Protocol for Investigation and Analysis of Clinical Incidents
This protocol was developed by Vincent and colleagues (2000) in a series of studies over the last few years, is widely used in the UK and has been translated into a number of other languages. The clinician or researcher examines the chain of events that led to an accident or adverse outcome and considering the actions of those involved. The investigator then examines the conditions in which the staff were working and the organisational context in which the incident occurred. These contributory factors are similar to the latent factors discussed earlier in the report (Thomas & Petersen 2003). In a healthcare setting this will involve identifying care management problems, the clinical context and patient factors and the contributory factors. This forms the final section of the assessment instrument approach has been adapted for use in record review and claims analysis .

Box 2. Contents of the analysis of claim form

Instructions for reviewers

Case information: reviewer, specialty, source of data, number and type of documents available, decision whether sufficient evidence to review

Section A: demographic data, diagnosis, co morbidities, judgement of cause of injury

Section B: description of nature of injury; its short term and long term effects

Section C: stage of care when adverse event occurred, staff involved

Section D: nature of clinical failures, description of other clinical problems

Section E: contributory factors including patient characteristics, task factors, individual factors, team factors, work environmental factors, organisational/management factors

Space for a case summary including reviewer's own judgement of events plus any additional comments on claims review

A first draft of assessment instrument was sent to all members of the project team, with comments being received from all four specialty reviewers. Questions were added or amended in response to feedback. This process was repeated several times until a consensus was achieved.

After the generic assessment form had been finalised, reviewers then added to their own questions as appropriate. For instance, in primary care the clinical process is usually more complex, owing to a longer timescale and multiple attendances. Some additional data was required to capture this complexity. In obstetrics there are really two patients rather than one. The assessment form had to be adapted to chart stages of care and both mother and baby experience. Piloting on actual cases showed that the assessment form was effective in defining the key questions and data items, but also revealed a number of minor flaws. Further amendments to various sections of the form were made to clarify and allow appropriate judgements about the data. The final generic assessment form is shown in Appendix 1 and a summary of the contents in Box 2

2.3 Study methods and procedures

2.3.1 Case selection

In collaboration with the relevant organisation providing cases, each expert identified the category of cases that they felt might yield useful information (with regard to medical care) while at the same time allowed them to judge the value of assessing litigation claims. The decision about which type of case to review included practical considerations such as the numbers of cases available in each database and the conditions required by each organisation. Each organisation contributed cases from their database according to the appropriateness to individual specialties. Primary care cases came from the Medical Protection Society database. These were cases that had been part of an in house review (Silk 2001) of a cohort of 1000 claims from July 1996 onwards. The data was provided electronically. Secondary care (obstetric and general medicine/surgery) cases came from Capsticks solicitors. Mental health involved both primary and secondary care cases and these were supplied by Capsticks and the Medical Defence Union. The NHS Litigation Authority assisted us but as they do not necessarily hold computer case files, we relied primarily on the other three organisations.

We aimed to review 50 cases in each specialty. However, many cases did not contain sufficient information for review. This was generally because they had not proceeded to litigation, and so the file did not contain a full complement of reports and statements. In addition there proved to be some duplication of files and missing information. As our primary aim was to assess the potential value of claims data, reviewers therefore made an initial assessment of whether the case contained sufficient information to permit a clinical review and completion of the assessment form. If so, they proceeded to full review. If not, they recorded the fact that the claim file did not contain sufficient information. Reviewers have therefore generally carried out a full review of less than 50 claims. The number of cases that were suitable for analysis varied considerably between specialties and organisations.

The only exception to this rule was in medicine and surgery where the expert reviewer (GN) had asked Capsticks to select cases that proceeded to some outcome rather than claims that did not proceed. He was able to deduce what the issues were even on little documentation as the problems he chose to look at were fairly clear cut with clear diagnoses. Only one case was deemed to be unsuitable for review, but we must acknowledge that cases had been pre-selected to some extent.

The clinical topics and specialty reviewers selected are set out below in box 3.

Box 3. clinical topics and specialty reviewers

Obstetrics	Professor Max Elstein	• Shoulder dystocia (7 cases) • Cerebral palsy (34 cases)
Medicine and surgery	Professor Graham Neale	• General medical and surgical cases – missed diagnoses (52 cases)
Primary care	Dr Aneez Esmail	• Diabetes (8 cases) • Meningitis (1 case) • delayed diagnosis – cancer of the cervix and ovarian cancer (5 cases) • delayed diagnosis of ischaemic heart disease (8 cases)
Mental Health	Professor Jenny Firth Cozens & Caroline Davy	• Parasuicide/suicide (22 cases) • Medication errors (15 cases)

2.3.2 Review procedure

Caroline Davy, project coordinator, visited all four claims organisations and discussed access to data, confidentiality and anonymisation issues and informed them of arrangements for the review. Arrangements for access to data and extent of data available differed in the four organisations. Each reviewer selected the organisation best able to offer the most complete data for the review of that particular specialty cases so as to make the best argument for the review of claims data. Not all the organisations were able to offer good quality data across all specialities, either by virtue of the work undertaken or in virtue of confidentiality arrangements or data organisation. One organisation insisted on the anonymisation of all reports and information which limited the usefulness of the data, because of the time and expense involved.

Claims data were accessed in different ways, depending on the format of the data and the access allowed by individual organisations. Some data were available in electronic format and sent direct to the reviewer. Most commonly reviewers visited the relevant organisation and reviewed cases on the premises. Time taken to review each case depended on the number of files involved and the complexity of the case. Informal comments regarding the legal process or case notes or clinical events were written on the back page of the form.

Review of actual clinical records was not attempted as previous experience suggested that review of expert reports and related documents provides all relevant and available information and is more efficient. We reviewed witness statements, all plaintiff and defendant expert reports, legal summaries, statements of claim and any internal inquiries or coroner's reports. All documents in the case file, used for the review were noted on the form.

2.3.3 Specialty reports

A basic common format for specialty reports was agreed, with some common data presented in each report. Individual reports naturally varied considerably in final form owing to the particular clinical topics under discussion and the approach of that particular reviewer. Common elements to the reports are as follows:

- Description and justification of selection of cases reviewed
- Assessment of strengths and limitations of documentation reviewed
- Summary of findings from case review
- Clinical themes emerging from review
- Commentary on value of review of claims documentation in that specialty as compared with other methods of examining the causes of adverse events

2.3.4 Data entry and statistical analysis

After completion of the assessment forms they were sent to the project coordinator (CD) for entry onto the database. Analysis of data applicable to all specialties was carried out by the project leads (CV & CD), although reviewers also supplemented these with their own specialty specific analysis.

Coding was entered according to specialties. Standardised codes, where they existed already (e.g. NHSLA codes and coding for the original review form for adverse events), were adhered to in order to allow comparison statistics where appropriate. Medical terminology, ambiguities, confused or missing data were checked with the specialty reviewer where necessary. Data were analysed using Statistical Package for the Social Sciences (SPSS).

2.4 Results of the specialist reviews

The specialty reports provide considerable detail about the relevant clinical issues and the reviewer's individual reflections on the claims review process. Data which specifically pertains to clinical issues, such as phase of care and the nature of the clinical issues identified are contained in the individual reports which follow this report. In this section of the main report we provide an overview of the clinical data, bringing together the perspectives of all four specialty reviews and addressing general questions such as the potential of claims review to identify background contributory factors as well as specific lapses in care. We also include illustrative clinical lessons learned and a summary of comments on the strengths and limitations of claims review from the four specialty reports.

2.4.1 Documents reviewed

The cases were taken from three different sources. Table 4 shows how many cases each source supplied to the different specialty reviewers. It also indicates the number of cases proceeding to full review i.e. those which had sufficient documentation in order to make a full analysis of the case, for each specialty.

Table 4: Source and Number of Cases

	Specialty				
Source of Data	**Primary Care**	**Medicine and Surgery**	**Obstetrics**	**Mental Health**	**Total**
Medical Defence Union	0	1	0	26	27
Medical Protection Society	39	0	0	2	41
Capsticks	0	52	49	29	130
Total	39	53	49	57	198
Cases Proceeding to Full Review	23	52	41	39	155

As Table 4 shows, only a proportion of cases are suitable for full review. Those for Medicine and Surgery were pre-selected to some extent, but only about 70% of the remainder had sufficient data for full review.

All the data and tables set out below show figures for cases proceeding to full review. In some cases, for instance documentation, we have also shown data for the whole sample if we regarded it to be useful. Unless otherwise stated however, we are considering cases that proceeded to full review as only these contained sufficient data to permit a full analysis.

2.4.2 Document Availability and Workload

The amount of paperwork to be reviewed for each case varied greatly. Documents included expert reports for each case, witness statements, legal summaries, and other documentation, such as coroners' reports and statements of claim. Table 5 shows the mean number of documents for each speciality as an indication of the amount of work that was required of reviewers. Table 6 shows the professions of expert acting for plaintiffs and defendants.

Table 5: Documentation

Specialty	**Mean number of docs**	**Mean docs for cases reviewed**	**Mean docs for cases not reviewed**	**Range**
Primary Care	1.8	2.1	1.3	0 -5
Medicine and Surgery	4.8	4.8	0	1 - 19
Obstetrics	5.7	6.4	1.4	0 - 19
Mental Health	3.7	4.3	2.4	0 - 13
Overall	4.1	4.7	1.6	0 - 19

Table 6: Profession of Experts

	Specialty									
	Primary Care		**Medicine & Surgery**		**Obstetrics**		**Mental Health**		**Overall**	
Profession	Pl	Def	Pl	Def	Pl	Def	Pl	Def	Pl	Def
Cardiologist	0	1	3	8	0	0	0	0	3	9

GP	2	7	1	0	0	0	7	5	10	12
General Surgeon	0	0	4	15	1	0	0	0	5	15
Midwife	0	0	0	0	2	6	0	0	2	6
Neurologist	0	0	1	3	3	6	0	0	4	9
Obstetrician	0	0	1	0	12	29	0	0	13	29
Oncologist	0	0	4	2	0	0	0	0	4	2
Orthopaedic Surgeon	0	0	0	0	0	2	4	2	4	4
Other	3	6	4	13	2	2	4	8	13	29
Pathologist	0	0	1	0	1	1	0	0	2	1
Paediatrician	0	0	0	0	1	8	0	0	1	8
Physician	1	1	8	2	0	0	2	2	11	5
Psychiatrist	0	0	0	1	2	1	14	9	16	11
Radiologist	0	0	0	1	1	2	0	0	1	3
Total	6	15	27	45	25	57	31	26	89	143

Unsurprisingly the cases proceeding to full review contained more reports than those which could not proceed to review. The principal reason for a case being excluded was usually lack of documentation, usually because the case had not proceeded to any resolution. A wide range of experts are involved in these cases and it is interesting to note that defendants' solicitors generally commissioned more reports than plaintiffs solicitors in this sample of cases, however cases may settle before all exchange of all reports. Some cases involve experts from several specialties, as when psychiatrist considers the impact of a child with cerebal palsy on the mother or an orthopaedic surgeon assesses the severity of injury following a suicide attempt.

2.4.3 Time Elapsed Between Incident and Review

Table 7 shows the mean length of time (in years) since the incident occurred for cases which then proceeded to full review. Clearly a claim may have been initiated some years before our review, but claims review only become feasible some time after the initiation of a claim once full documentation is assembled. This is particularly in relation to learning clinical lessons from the data as often working practices will have changed during the interval between incident, claim and analysis.

Table 7: Time from Incident to Review

Specialty	**Mean (years since incident)**	**Range**
Primary Care	9.5	7 - 14
Medicine and Surgery	8.8	3 - 23
Obstetrics	12	6 - 31
Mental Health	11	4 – 28
Overall	10.3	3 -31

2.4.4 Demographic information

Table 8 shows the mean age and sex of the patients involved in the claims reviewed in by specialty in this report for cases that proceeded to full review. The nature of the patient's disease, as well as

the specialty obviously influence the age and sex of patient under review (e.g. in primary care one of the disease categories selected was ischaemic heart disease which mainly affects older men).

Table 8: Demographic Information

Specialty	Mean Age (range)	Male - Female
Primary Care	41 (11 – 71)	16 (68%) – 7 (32%)
Medicine and Surgery	40 (3 – 73)	26 (50%) – 26 (50%)
Obstetrics	28 (19 – 41)	0 – 41(100%)
Mental Health	36 (21 – 75)	19 (49%) – 20 (51%)

2.4.5 Cause of injury to patient

The questions below in table 9 mirror those posed in the classic retrospective reviews of adverse events in healthcare, which are aimed at delineating the cause of adverse events in in-patient care. By injury here, we mean injury that may be due to medical management, either through a direct effect or through omission or sub-standard care. Given that we are concerned with the potential of claims review for quality of care and patient safety, these questions are more appropriate than the generally narrower focus of questions framed in terms of negligence, Bolam test and so on.

Table 9: Cause of Injury

What was the cause of the injury?	**Primary Care** (n=23)	**Medicine/ Surgery** (n=52)	**Obstetrics** (n=41)	**Mental Health** (n=39)	**Overall** (n=155)
Healthcare management	6 (26%)	4 (8%)	5 (12%)	1 (3%)	16 (11%)
Healthcare and disease process	14 (61%)	25 (48%)	16 (39%)	28 (72%)	83 (54%)
Disease Process	3 (13%)	11 (21%)	13 (32%)	3(7%)	30 (19%)
Unable to judge/don't know	0	12 (23%)	7 (17%)	6 (15%)	25 (16%)

Table 9 shows that 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. Injury was judged to be due to the disease process in 20% of cases overall, and in an additional 16% of cases reviewers were unable to make any firm assessment of causation of injury.

2.4.6 Impact of Injury

Table 10 shows the consequences of the adverse event for the patient. In primary care events such myocardial infarctions led to death, whereas in medicine and surgery perforated duodenal ulcers led to death. In the mental health review both suicides and parasuicides led to death. However the only death in the obstetrics review was a result of further complications.

Table 10: Impact of Injury

Impact of Injury	**Primary Care**	**Medicine/ Surgery**	**Obstetrics**	**Mental Health**	**Overall**
Disability	2 (9%)	11 (21%)	13 (32%)	10 (26%)	36 (23%)
Death	11 (48%)	17 (33%)	1 (2)	10 (26%)	39 (25%)
Cognitive impairment	0	1 (2%)	4 (10%)	6 (15%)	11 (7%)
Pain	1 (4%)	5 (10%)	0	1 (2%)	7 (5%)
Other Complication	6 (26%)	11 (21%)	4 (10%)	10 (26%)	31 (20%)
Cognitive Impairment & Disability	0	1 (2%)	12 (29%)	0	13 (8%)
Other	3 (13%)	6 (11%)	7 (17)	2 (5%)	18 (12%)
Total	23	52	41	39	155

2.4.7 Nature of clinical problems identified

Table 11 shows the nature of the clinical problems identified, which obviously varies considerably from specialty to specialty.

Reviewers were given four options (definite, probable, possible, and unable to judge) and they were allowed to select up to three type of clinical problem. The summary data below gives the numbers of cases that were considered to have the clinical problem as a definite factor in the adverse event. As both primary care and medicine and surgery specialty reviewers selected cases with delays in diagnosis as a feature, diagnostic processes are naturally prominent. However, it is noteworthy that reviewers were able to make definite judgements regarding these factors from the review process and also though they frequently identified more than one problem per case.

Table 11: Clinical Problems Identified

	Primary Care (n=23)	Medicine/ Surgery (n=52)	Obstetrics (n=41)	Mental Health (n=39)	Overall (n=155)	Overall %
Failure/delay to diagnose or assess correctly	16	23	12	10	61	39%
Failure/delay to appreciate the patient's overall condition	15	4	4	15	38	25%
Failure/delay in clinical monitoring/management	13	7	11	17	48	31%
Related to a problem with an operation or procedure	0	3	10	1	14	9%
Related to prescribing/administration of drugs/fluids	1	0	0	9	10	6%
Related to monitoring of drugs/fluids	0	0	1	7	8	5%
Related to resuscitation procedure	0	0	1	0	1	0.6%

2.4.8 Clinical lessons learned

Clinical issues are fully discussed within the specialty reports. In Box 4 we have summarised some of the main themes in order to address the general question of whether clinical lessons of importance can be identified from claims review. These comments were drawn both from the reports themselves and from reviewers' case summaries and additional comments. While reviewers, drawing on their own experience, are clearly inferring more general clinical problems from a small set of cases, they nevertheless consider that these cases do draw attention to important clinical issues.

Box 4. 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
  - Computerised 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

2.4.9 Detection of contributory factors

Thomas and Petersen argued that, although claims data could never reliably reflect incidence or prevalence of adverse events, it was useful for detecting `latent failures' in healthcare process. By this they implied that in addition to identifying particular instances of sub-standard care, it should also be possible for reviewers to identify the background contributory factors contributing to the incident, which reflect more general, systemic issues which are of particular importance in preventing future incidents. In our review, we specifically asked reviewers to comment on a defined list of contributory factors (Vincent, Taylor-Adams, & Stanhope 1998) to assess the validity of this claim. For each contributory factor they judged whether it was of definite relevance, not relevant or that they were unable to judge. In practice it was almost impossible to

say that a factor was definitely not relevant, as opposed to simply being unable to judge, so those categories were combined. Table 12 shows the proportion of times each contributory factor was identified as being of definite importance.

Table 12: Factors Contributory to Outcome

Contributory factors	Primary Care (23)	Medicine/ Surgery (52)	Obstetrics (41)	Mental Health (39)	Overall (155)	Overall %
1. Patient characteristics						
1.1 Patient not able to understand/communicate with clinical team	0	2	1	3	5	3.2
1.2 Personality or social factors	3	8	2	20	33	21.3
1.3 Previous treatment history	6	11	6	27	50	32.3
1.4 Previous relevant personal history	2	3	0	23	28	18
2. Task Factors						
2.1 Evidence of lack of guidelines	6	3	1	3	13	8.4
2.2 Failure to use guidelines	6	0	10	11	27	17.4
2.3 Evidence of lack of protocol	4	0	1	1	6	3.9
2.4 Failure to use protocol	1	0	3	6	10	6.5
3. Individual Staff Factors						
3.1 Staff working outside of their expertise/experience	0	8	3	5	16	10.3
3.2 Lack of staff skills and knowledge	3	14	7	2	26	16.7
3.3 Use of locum or bank staff	3	2	6	0	11	7.1
4. Team Factors						
4.1 Poor teamwork or team relationships	1	5	3	3	12	7.7
4.2 Inadequate supervision	1	12	2	6	21	13.5
4.3 Poor verbal communications	2	4	2	4	12	7.7
4.4 Poor written communication	4	3	2	8	17	11
4.6Problems with referral to another service/specialty /team	5	13	1	12	31	20
5. Work environment						
5.1 Lack of equipment/ equipment failure	1	9	2	2	14	9
5.2 Inadequate staffing/too high workload	0	6	0	3	9	5.8
5.3 Other work environment factors	1	0	1	1	3	1.9
6. Organisational/ Management Factors						
6.1 Lack of essential resources	0	2	1	3	6	3.9
6.2 Poor co-ordination of overall service	3	8	0	4	15	9.7
6.3 Inadequate senior leadership	2	12	2	1	17	11
6.4 Organisation of system for record keeping care/follow up	6	4	2	2	14	9
6.5 Systems for liaison with other agencies	3	3	0	3	9	5.8

In addition to examining the contribution of specific factors we also assessed the proportion of cases in which a particular class of factors was held to contribute to the outcome. Patient characteristics were particularly significant as 50% of cases demonstrated evidence of one or more examples of various personal factors being relevant to the claim. With 40% of cases being reported as having contributory team factors to the injury/claim, clearly there is also a problem with team working. The skills and behaviour of individual clinicians were judged to have contributed to the problem in 16.7% of cases and task factors accounted for 23% of cases. At 25%, organisational/management issues were less in evidence and work environment factors were

judged the least frequent contributory factor at 6%, but these may be harder to discern or infer from medical records and claims data. Some factors were particularly relevant to specific specialties, e.g. patient characteristics was judged to be contributory in 92% of Mental Health cases and less dramatically but still significantly at 49% of Primary Care cases. General Medicine/Surgery cases had strongest evidence of most contributory factors in the team factors section (44% of cases), whilst Obstetrics had the highest number of cases in the Individual staff factors category (29%).

We cannot, of course, provide any evidence that these factors were of definite importance in the occurrences of any particular adverse outcome. Nevertheless Thomas and Petersen's (2003) view that claims data could provide useful information on contributory factors is supported to the extent that reviewers felt able to infer some of the background causes of these events as well as identifying particular clinical problems. However, we should caution that reviewers were very often "unable to judge" whether a particular factor had any bearing on the case in question.

2.4.10 Reviewers' reflections on the claims review process

Reviewers felt confident in drawing important clinical lessons from at least a proportion of 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 summarised in Box 5.

Box 5. Limitations of the process of claims review

- Evidence
  - Full case notes sometimes required for detailed assessment
  - Inadequate clinical notes impede the whole process
  - There is a very variable quality of evidence
- Organisation 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

3 Conclusions

We have now reviewed methods of understanding errors and adverse events, reviewed closed claims analyses carried out since 1993 by other clinicians and researchers and summarised the results of our own four specialty reviews using British claims data. In this section we draw together the conclusions and themes from all these sources in an effort to define a consensus position. We will not attempt to summarise all the preceding material, but rather to draw out the major themes and conclusions, particularly those relevant to claims data in the United Kingdom. Recommendations for the collection, coding and use of British claims data will be considered separately in our overall conclusions from the entire project. Here we focus on defining the scope and limitations of the clinical review of claims data.

3.1 The scope and value of claims review

It is worth restating the obvious but important point that claims data have not been collected for the purpose of improving clinical care or contributing to patient safety. The analysis of claims data does of course shed light on patterns of litigation and the specific characteristics of cases that have come to litigation. However, almost all the studies reviewed here, have stressed that claims are an unrepresentative sample of adverse outcomes of healthcare and represent only a very small proportion of instances in which care has been sub-standard or patient have come to some harm. The crucial question is whether claims data sheds light on more general problems in healthcare and whether claims data can be used to improve patient safety.

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.

We should not, however, forget that these cases are being reviewed long after the event. The data has been filtered through the eyes of previous expert reviewers and, to some extent, by the lawyers engaged in producing statements and other documents. Most importantly, it is clear that our own specialty reviewers, and no doubt those in other studies, are drawing extensively on their own clinical experience in reviewing these cases. Their reviews, and it is no disrespect to say this, are more a matter of interpretation than data collection. Reviewers, and the experts who reviewed the original notes, are often reading beyond the information available to surmise what must have happened to produce this outcome. This is not in itself fatal to the enterprise, but it does underline that the results of such reviews are best considered, in Cheney's (1999) words as 'working hypotheses'. The results of the ASA closed claims project are clearly seen in this light, as one source of information about anaesthetic misadventure to be used as part of a more general effort at data collection and quality and safety improvement.

3.2 Limitations of claims review

The methodological limitations of claims review have been well summarised 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. The most important point to make here is that these conclusions have been echoed by many other reviewers of claims and by our own specialty reviewers (Box 7).

In addition to problems inherent in the claims review process, our reviewers were also very concerned about the completeness of the record and the quality of the data available. Only about 70% of claims proved capable of full review, though this figure should be treated with caution as it varied between specialties and is based on quite small sample sizes. Suffice to say that any review of claims is likely to encounter this problem. Clinical notes, where available, were of varying quality as were expert reports and other documents. Key information was sometimes missing and on occasion the reviewer felt unable to make an assessment from the expert reports alone, and would ideally have needed to see the full medical record. Organisation and retrieval of data was sometimes difficult. Some of these problems are potentially remediable. It is noteworthy that the ASA closed claims project invests considerable time and resources to ensuring that full clinical records are retrieved whenever possible, documents and facts are checked and all possible material retrieved before a case is entered in a database. With sufficient resource, this could also be done in Britain. However, inevitably, claims that do not proceed or are withdrawn will often have insufficient data for review and it may not always be possible to assemble a defined set of documents that might be considered a 'minimum data set' for claims review.

Defining a minimum data set for the review of a set of claims would allow some standardisation of the process as well as ensuring that, at least for those cases of interest, all relevant documents were assembled. While this might not always be necessary from the legal point of view, it would be enormously helpful from the point of view of learning from claims. Assembling a standard set of documents would also be a first step to standardisation of the process and some basic quality control in at least ensuring that all necessary papers had been collated. Standardisation of coding across different data sets has already been discussed in the first report, in respect of the various different coding systems in use and the inconsistencies within the coding schemes. Standardising the approach to the collection of basic data is an important step to making better use of claims and, once established, need not require any additional resources. In relation to case review of claims, as opposed to epidemiological analysis, some standardisation of approach would also be beneficial. A consistent coding system for the basic data set would, to begin with, make the task of identifying a set of claims with similar themes a great deal easier. Our reviewers had to spend a considerable amount of time hand searching sets of claims as those identified by searching databases by coding categories produced many spurious and irrelevant cases. Case review of individual claims, by its very nature, cannot be a completely standardised process. Nevertheless it would certainly be possible to enhance the quality of the information available by, for instance, devising a standard set of questions that expert reports should address. While lawyers do attempt, in many case, to do this their instructions are probably too generic in a research context. If particular clinical issues had been identified for claims review, experts could easily append answers to a standard set of questions at the time of compiling a report. As they would be reviewing the records anyway, this would not be costly. Alternatively, clinical reviewers could simply use the basic medical records and answer the questions themselves, as we have done. Whatever system is adopted, the main point is that a defined set of questions aimed at specific clinical and organisational issues will produce more robust and persuasive analyses than unstructured post hoc review.

3.3 Comparing claims review with other methods for studying adverse events

Patient safety has become a major priority in British healthcare in the last five years and in many other countries. It easy to forget that the subject of harm to patients was, even ten years ago, barely researched, seldom discussed openly and largely unacknowledged. In the 1980s and early 1990s, claims reviews were one of the few direct examinations of the problem of harm to patients, though other studies such as the confidential enquiries also addressed these issues. At that time, claims reviews and the lessons learned from them were of undoubted importance. Now however, with the formation of the National Patient Safety Agency, the recent launch of their National Reporting and Learning System (NRLS), their educational programme in root cause analysis and a rapidly expanding programme of research on patient safety world-wide, claims review is only one of a number of approaches to the study of adverse events. At the time of writing it is difficult to know how rich the data from the NRLS will be. Certainly the system should have the power to detect rare events but, in regard to learning, much depends on the detail and quality of the actual report made. Most reports in the NRLS pilot study were relatively brief and would not seem, by themselves, to offer the same richness as claims data.

Other methods of enquiry (all of which have limitations) do not suffer from some of the major disadvantages of claims review. Systematic record review captures incidence much more effectively. Claims data does have the ability, when data quality are good, to capture important facts about the quality of care and factors contributing to adverse events. But contributory factors can be much more effectively assessed by contemporaneous interviews and observation (Vincent et al, 2000; Vincent et al, 2004) than by screening medical records and reports several years after the event. Studies of any kind which 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. In general, we would suggest, claims review has no unique place in the armament of methods of understanding adverse outcomes and that many other methods have obvious advantages. In particular, we should return to the comments of Caplan et al (1990) who noted that the objectivity of eye witnesses and others recalling the incident is degraded by the passage of time and premature efforts to reach conclusions. Surely a better understanding of incidents can be achieved if investigations begin soon after the incident has occurred. No other high-risk industry waits years to begin investigations into serious incidents or relies on claims data from the resulting litigation. What possible reason can healthcare have to continue to use claims data to advance patient safety?

The above summary of limitations and comparison with other methods suggests that, if other methods are available, claims review may not be the method of choice for assessing either the incidence of or understanding of adverse outcomes. Certainly claims data can never give reliable data about the underlying incidence of events, only about procedures and specialties at high risk of litigation. 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 is 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.

One further facet of these various methods of learning should be considered: their motivational potential. The potential of different methods of analysis for engaging clinicians and others will be the subject of a separate project commissioned by the Patient Safety Research Programme. We

will simply note here that, as the experience of being sued can be very unpleasant, even traumatic, for clinicians that it is possible that reviews of claims may attract more attention than reviews of other sources of information. We do not present this as a cynical argument, that clinicians will only take notice if they are personally affected by an event. We take it for granted that the vast majority of clinicians wish to improve the quality and safety of care. However, the additional personal involvement, albeit vicariously, of reading about claims may add to their power to engage clinicians and promote reflection on the lessons they offer.

3.4 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 organisation adhered to. We would suggest that the following are minimum requirements:

- That either the condition under investigation is a sufficiently rare not to be easily detectable by other means or claims data offers 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
- 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 is assembled in a central database and is 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 do not suggest that this is necessarily a complete set of requirements for a claims review to be of value. However, these requirements do indicate that, given the availability of other methods, there is now no case for ad hoc claims review which relies on claims data that has been assembled for legal purposes only and with no thought to its use in improving the quality and safety of patient care. It is also clear that this list of requirements, particularly that claims review is most useful for

rare events, narrows the potential use of claims review considerably. We believe that there may well be circumstances in which claims review can be justified as a valuable approach to a problem in healthcare. 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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Appendix 1 - analysis of claims form

Reviewer……
Case No……..
Date of Review……...
Type of case (e.g. Para suicide, delayed cancer diagnosis etc.)
……
Nature of Review:

Inspection of electronic document ☐
Visit to organisation ☐

Source of Information:

M.D.U. ☐
M.P.S. ☐
Capsticks ☐
NHSLA ☐

Documents used (please tick):

How many plaintiff expert reports? ……

Professions of experts
(Please specify)

…..…….
……..
…….…….

How many defendant expert reports? ……..

Professions of experts (please specify)
……
……..
……

How many witness statements? (please specify)
……..
…….
……..

How many legal summaries? …….

What other documents did you use in this review? (please specify*)*

……
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……

DECISION POINT:
Is there enough information for a review of this case?
If no, please explain briefly. More detailed comments can be added to case summary section on last page.
……
……
……
……

Section A – patient information and background to incident

Patient name/identifier……

Date of incident……
Date of claim…….
Date of birth…….
Sex…….
Primary diagnosis……
Co morbidities /risk or pre existing factors (please specify).
……
……
……

Principal Specialty involved in care……

Please answer yes/no/unable to judge to the following questions:

	Yes	No	Unable to judge
Was there a patient injury/complication?			
Was the injury/complication caused by: i)healthcare management			
ii) healthcare management interacting with a disease process/condition			
iii) solely by disease			

process/condition			

Section B – the injury and its effects.
(Please complete all sections. State if unable to judge or insufficient information.)

Nature of Injury…….
…….
…….

Describe the impact of the adverse event on the patient…….
……..
……..
……..

What additional procedures were performed as a result of the incident?
…….
……
……

What additional medications were administered as a result of the incident?
…….
……
…….

What additional treatment was given as a result of the incident?
……..
……..
……..

Section C – period of care during which the incident occurred
(Please adapt this section for your particular speciality)

During which stage/phase of care did the incident occur?
Pre admission ☐
A & E ☐
Admission Ward/pre procedural ☐
Procedure related
(please specify nature of procedure) ☐
…….
Immediate post procedural/high dependency/ITU care ☐
Ward care ☐
Discharge
Post discharge ☐
Re admission ☐
☐

What members of staff were involved?
…….
…….

……
……
……
……

Section D – nature of problem in this phase of care
(please adapt for your specific specialty)

What was the nature of the principal problem?
(Select up to 3 boxes as appropriate indicating degree of certainty e.g. definite delay in diagnosis, possible problem in prescribing of drugs*)*

	Definite	Probable	Possible
Failure/delay to diagnose or assess correctly			
Failure/delay to appreciate the patient's overall condition			
Failure/delay in clinical monitoring/management			
Failure/delay to prevent/control/manage infection			
Directly related to a problem with an operation or procedure?			
Related to prescribing of drugs/fluids (including blood)			
Related administration of drugs/fluids (including blood)			
Related monitoring of drugs/fluids (including blood)			
Related to a resuscitation procedure			
Other			

Were there any additional problems during this period of care? (please specify)
……..
……..
…….

Section E

Causative/contributory factors to incident	Yes	No	Unable to judge
1. Patient characteristics			
1.1 Patient was not able to understand/communicate with clinical team *e.g. language/hearing/speech probs*			
1.2 Personality or social factors *e.g. recent life stresses, addiction problems, difficulties in relationship*			
1.3 Previous treatment history *e.g. non compliance, high risk, complications etc*			
1.4 Previous relevant personal history *e.g. history of violence, suicidal attempts, bereavement /trauma*			
1.5 Other relevant factors (*please specify)*			
2. Task Factors			
2.1 Evidence of lack of guidelines			
2.2 Failure to use guidelines			
2.3 Evidence of lack of protocol			
2.4 Failure to use protocol			
3. Individual Factors			
3.1 Staff working outside of their expertise/experience			
3.2 Lack of staff skills and knowledge			
3.3 Permanent/locum/bank staff			
4. Team Factors			
4.1 Poor teamwork/relationships			
4.2 Inadequate supervision			
4.3 Poor verbal communications (with teams/other agencies) *e.g. inadequate handover*			
4.4 Poor written communication (within teams/ other agencies)			
4.5 Other team factors			
4.6 Referral to another service/specialty/consultant/team member			
5. Work environment			
5.1 Lack of equipment/ equipment failure			
5.2 Inadequate staffing/too high workload			
5.3 Other work environment factors			
6. Organisational/ Management Factors			
6.1 Lack of essential resources			
6.2 Poor co-ordination of overall service			
6.3 Inadequate senior leadership			
6.4 Organisation of system for record keeping/appointments/emergency care/follow up			
6.5 systems for liaison/referral with other agencies/specialties			
7. **Treatment as a contributory factor**.			

Case summary including reviewer's own judgement of events.

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Any additional comments on claims review process stemming from this case?

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Notes for Reviewers

Please complete this form for every case selected whether or not it is suitable for a full review.
It is important to record every section and every question.
If you are not able to judge from the documentation please indicate. If the question is not applicable please indicate.
A brief case summary should be made on the last page with your own view of events.
Any additional specialty specific sections should be added as
Section F.
Please add any comments at any point on the form and particularly on the last page under case summary section.
Please send all forms back to Caroline by April 20th 2003.