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. No other high-risk industry waits years to begin investigations into serious incidents or relies on claims data from the resulting litigation. 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.

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
- That 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
- That claims data is assembled in a central database and is checked and subject to quality control at the time of entry to the database
- That the results of claims review are treated as working hypotheses and subject to further investigation in more formal studies
- That the claims review is used only as part of a more general quality and safety improvement strategy
- That 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 little call 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.

CONCLUSIONS AND POLICY IMPLICATIONS

The development of new systems for measuring the quality of care and sources of data – particularly the National Patient Safety Agency's National Reporting and Learning System (NRLS) for sharing information on adverse events – probably goes some way to make the existing information about claims for clinical negligence less attractive as a way to learn lessons and bring about improvements in patient safety in the NHS. As has been noted, the quality, completeness and timeliness of both the litigation databases and the paper records of claims for clinical negligence are far from perfect.

Where other sources of data – like NRLS, or local incident reporting systems, or other methods for studying adverse events including more prospective and observational approaches – are available, it seems likely that they will be preferred. But there will be areas in which those other sources of data are not available, are too costly, or cannot address the issue at hand, and in these circumstances the analysis of claims databases and claims reviews will still have their place. However – and this is a crucial caveat – for claims data to be genuinely useful, steps need to be taken to improve its quality, completeness, consistency and accuracy. If claims data continues to be collected primarily or even solely to serve the operational needs of the litigation process and the medical defence organisations, it will not be of much use in improving patient safety. Better data management and auditing, standardised coding of diagnoses, procedures and errors, and the collection of an expanded and clinically more detailed set of data are needed.

PROJECT TEAM

This project was undertaken by a team of researchers from the University of Manchester, University of Oxford, Imperial College London, and the University of Nottingham. The contributors were: Caroline Davy, Aneez Esmail, Max Elstein, Paul Fenn, Jenny Firth Cozens, Alastair Gray, Graham Neale, Oliver Rivero-Arias, Gemma Trevethick, Kim Trevethick, Charles Vincent and Kieran Walshe.

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LESSONS FROM LITIGATION: USING CLAIMS DATA TO IMPROVE PATIENT SAFETY

PROJECT SUMMARY AND OVERVIEW

In 2002, the Department of Health commissioned a consortium led by the University of Manchester to research whether and how information about claims for clinical negligence against the NHS could be used to learn lessons and bring about improvements in patient safety. This is a short summary and overview of the findings of the research. The project findings are published a series of three reports all of which can be found on the Manchester Centre for Healthcare Management's website at www.mbs.ac.uk/mchm

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The University of Nottingham

INTRODUCTION

In 2002, the Department of Health commissioned a consortium led by the University of Manchester to undertake a research project aimed at examining whether and how information about claims for clinical negligence against the NHS could be used to learn lessons and bring about improvements in patient safety. Within that straightforward aim, the project set out with two main objectives:

- To audit the quality of data held in the litigation databases of the NHS Litigation Authority and the medical defence organisations – examining their completeness, accuracy, and potential utility in examining and improving patient safety; to use data from those databases to explore the epidemiology of errors and litigation; and to develop guidance or recommendations for future data collection and management.

- To identify a sample of cases of clinical negligence litigation in four specialties, and to subject the paper records of those cases to a structured process of claims review; to identify key management problems and contributory systems factors using a formal method of root cause analysis; and to report on the utility of such claims review in examining and improving patient safety.

The epidemiology of error: an analysis of databases of clinical negligence litigation reports on the first phase of the project, in which the data from litigation databases was collated and used to examine the epidemiology of error and the quality and utility of that data in improving patient safety.

Learning from litigation: an analysis of claims for clinical negligence reports on the second phase of the project, in which a series of cases in four specialties were analysed using a structured process of claims review aimed at examining causation and contributory factors. It discusses the potential value of such claims reviews, and some of the problems and limitations involved in using them to examine patient safety issues.

Case studies in litigation: claims reviews in four specialties contains the detailed reports from the claims reviews in four specialties – primary care, general medicine and surgery; psychiatry; and obstetrics. In each case the reviewers report on the common characteristics and lessons learned from the case reviews, and on the process of review itself.

This brief paper first summarises the background to the research, then presents a concise account of its key findings and recommendations. It then concludes by discussing the implications of the research for future policy and practice on patient safety in the NHS.

PATIENT SAFETY, ERRORS AND CLAIMS FOR CLINICAL NEGLIGENCE

It is now widely recognised that errors in healthcare organisations are a major cause of unnecessary and avoidable morbidity and mortality, and have a high financial cost to patients, the healthcare system and society at large. More positively, it has been increasingly seen that errors represent opportunities for improvement, and that by discovering and understanding errors and their causes, we can bring about changes in clinical and organisational practices which will improve patient safety, prevent future harm, and improve the quality of healthcare. In the UK, the newly established National Patient Safety Agency (NPSA) has a lead role in developing national reporting systems for adverse events and using that data to bring about improvements in healthcare.

One obvious source of information on adverse events is the extensive set of data which is collected by NHS organisations and other agencies on cases of clinical negligence litigation, where patients and their families sue NHS organisations because they believe they have received negligent care. However, cases of clinical negligence litigation constitute a small and unrepresentative subgroup of adverse events in healthcare organisations. Past research has shown that the great majority of patients who suffer an adverse event do not litigate, and some patients who do litigate have not experienced an adverse event. Moreover, while NHS organisations and the medical defence organisations (the Medical Defence Union, Medical Protection Society and NHS Litigation Authority) collect a large volume of data about cases of clinical negligence, much of that information is difficult or impossible to access – held in unstructured paper records, distributed across a number of organisations, fragmented across multiple sets of records for the same cases, and not collected consistently using common data definitions and standards. Perhaps most importantly, this data has not been collected for the purpose of improvement. It has been gathered primarily by litigation managers, lawyers, risk managers, assessors and others for the purpose of determining legal liability and establishing the quantum of damages. An obvious – and increasingly important – question is to what extent this readily available data set might hold important lessons for patient safety, and could be analysed and used to bring about improvements in the quality of healthcare? Looking forwards, it is equally important to consider whether the way this data is collected and managed in the future might be improved, so as to make data on clinical negligence litigation more directly useful in improving patient safety.

USING LITIGATION DATABASES TO STUDY ERRORS AND PATIENT SAFETY

We extracted samples of around 500 cases each, from the litigation databases held by the NHS Litigation Authority, the Medical Defence Union, the Medical Protection Society, Capsticks, and the John Radcliffe Hospital in Oxford. The cases were randomly or quasirandomly selected. Our key findings were:

By far the commonest error in primary care (representing 50% of cases) was a failure or delay in diagnosis. Other common errors included medication prescription errors, failure or delay in referral and failure to warn of or recognise side effects of medication (each around 5%).

The commonest recorded outcome of these errors in primary care was the death of the patient (in 21% of cases). Other commonly cited outcomes included deterioration in clinical condition (6%) and unnecessary pain (4%).

The commonest errors in secondary care were failure or delay in diagnosis (21%) and the unsatisfactory performance of a procedure (18%). Other common errors included unintended injury during a procedure (5%) and various problems around vaginal delivery (5%).

The commonest recorded outcome of these errors in secondary care was unnecessary pain (11%), death (10%), cerebral palsy (7%), brain damage (6%) and a need for further surgery or treatment (5%).

We calculated standardised incidence ratios of errors in relation to total consultations (primary care) and total hospital episodes (secondary care). In primary care, the standardised incidence ratio of error was highest for patients in groups with neoplasms, congenital problems, and complications of pregnancy. More detailed analysis revealed a number of conditions – such as septicaemia, meningococcal infection, appendicitis and various neoplasms – with high standardised incidence ratio of error/claim.

In secondary care, the standardised incidence ratio of error was highest in the specialties which traditionally produce the most claims – accident and emergency, obstetrics and trauma and orthopaedics. Similarly, the standardised incidence ratio was highest for cases with diagnostic codes concerning pregnancy and injury/trauma. Interestingly, the standardised incidence ratio was highest for cases undergoing procedures on the female genital tract, whether pregnancy related or not. Detailed analysis largely confirmed these areas of highest standardised incidence ratio.

The quality of data in the available databases of clinical negligence litigation cases varied widely, and between 2% and 41% of our original samples had to be excluded due largely to a lack of essential information needed to code or categorise the case. It must be remembered that these databases were not necessarily designed or intended to provide data for the kind of analyses we wished to undertake.

We conclude that it is possible to use the data from clinical negligence litigation databases to provide important insights into the epidemiology of error. Given the sample sizes on which this study has been based, it might best be seen as providing proof of principle, and offering a demonstration of what could be achieved. However, in order to make full use of the potential of these databases, it would be necessary to introduce a number of changes in the way in which they are currently structured and managed. Most importantly, the coding of diagnoses, procedures, errors and outcomes would need to be performed in a much more comprehensive and consistent way. This would allow much more detailed analyses to be performed at a more disaggregated level, and would also permit more accurate identification of areas with error rates significantly above or below average. We believe the benefits, to understanding adverse events and improving patient safety, could be substantial. We would suggest three key areas for action:

Data on cases of clinical negligence could and should be used much more fully to learn lessons for patient safety, if it were more consistently gathered, reported on and applied.

All medical defence organisations should collect a common data set of information on cases of clinical negligence, using the same approaches to coding diagnoses, procedures, errors, causes of errors and the outcomes of errors.

Mechanisms should be put in place to make more use of these data sources, a function in which both the medical defence organisations and other agencies such as the National Patient Safety Agency could play an important role. NHS organisations should have more ready access to these data and analyses as they evolve.

USING CLAIMS REVIEWS TO STUDY ERRORS AND PATIENT SAFETY

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.

We can separate our learning from these claims reviews into two main areas – that concerning the content of the reviews themselves, and that concerning the process of claims review and its value orlimitations in relation to improving patient safety. In each of the four specialties, reviewers identified a number of important recommendations for improving patient safety, including::

Careful clinical assessment, history taking, use of routine monitoring equipment and documentation of the patient's problems are the foundation of subsequent diagnostic and therapeutic action – many errors begin here.

Systems are needed for dealing with rare diseases or conditions which clinicians do not often encounter, keeping their skills and knowledge up to date and supporting their decision making on unfamiliar terrain.

Clinicians who are less experienced or in training should not be asked to work beyond their skills and abilities, and should be enabled to decline responsibilities they do not feel able to shoulder. Simple lack of knowledge can result serious errors.

Where clinical guidelines or defined systems/pathways of care exist, the failure to follow those guidelines may signal problems and so arrangements to highlight or flag such variances are needed.

Integrated clinical records and strong systems for communication between different healthcare professionals help to prevent errors which arise as a result of knowledge not being shared or communicated properly.

Systems for identifying patients who are particularly at risk, for whatever reason, and prioritising their treatment and focusing on their care in more detail help to prevent errors.

Turning to the process of claims review itself, it should be recognised 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 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, the time lapsed between the event and the review, and so on.

Other methods of enquiry into adverse events (all of which have limitations) do not suffer from some of the major disadvantages of claims review. Systematic record review