Patient safety: lessons from litigation

The epidemiology of error: an analysis of databases of clinical negligence litigation

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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 first phase of a larger project. It 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. It examined the available databases of cases of clinical negligence and explored the utility of those databases in learning lessons for patient safety and improving patient care. 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, using 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. We also obtained permission to access information from the Oxford database of clinical negligence litigation. Obtaining these agreements was of necessity a complex and somewhat time-consuming process, as we needed to make an agreement on confidentiality and data access with each one.

In this study, we have analysed samples of around 500 cases drawn from each of the four organisations listed above. A substantial amount of data processing and manipulation has been needed, to assign diagnostic and operation/procedure codes to each case and to assign or agree error or outcome codes for the adverse events or errors. There are understandable inconsistencies and substantial divergence in data collection practices and data definitions between the organisations, which make comparisons difficult. We have audited the data quality in each database and examined and reported on the arrangements for data collection and data entry.

The main findings from the study are:

- 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.

In conclusion, this study has demonstrated 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.

1. Background

1.1 Adverse events and litigation: an overview

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.

There is a large and fast-growing literature on patient safety and error in healthcare organisations (see Shojania, Duncan, McDonald et al 2001; Cooper, Sorenson, Anderson et al 2001) but a rather more limited literature which focuses on the analysis of instances of clinical negligence litigation. For example, Ennis et al (1990) carried out a review of 64 serious obstetric accidents referred over a five-year period to the MPS. This research highlighted a number of underlying problems in obstetric units, such as problems in supervision and fetal heart monitoring, going beyond the identification of immediate errors and anticipating a systems approach to understanding adverse events. Fenn et al (1994) carried out several analyses of the negligence database held by the Oxford region of the NHS, and Dineen and Walshe (2000) studied the management of the clinical negligence litigation process. These various studies suggest that the information that can be obtained from medico-legal cases is limited partly by the large

differences in the quality of information held by the different organisations and the differences in completeness of information. The organisations vary in terms of how they classify cases and the level and amount of information that they hold electronically. Even the categorisation or coding of these cases by any recognised system (such as ICD-10) is variable making it difficult to identify common cohorts or sets of cases for further study. However, they also show that there is some value to be gained from analysing data on adverse events from clinical negligence claims, and suggest that they could have a significant potential for learning about patient safety issues.

1.2 Aims of the project: lessons from litigation

It is clear that the quality, comprehensiveness and utility of the data on cases of clinical negligence which is held by the various medical defence organisations has not been widely examined or tested, and that we do not know whether and to what extent that data could be used to improve patient safety by analysing and then acting to prevent the causes of adverse events. It can be reasonably hypothesised that the data may be of limited value because these data were collected for primarily administrative purposes and not with a view to analysis in order to learn lessons to improve patient safety. The idea that they may be used to improve patient safety has not been tested except in small and limited pilot studies. In this project, we have set out to examine systematically the computerised databases and paper records of the major medical defence organisations and to test their utility in assessing and improving patient safety.

The project has seven main aims, which are listed below:

1. To carry out a data quality audit of the litigation databases held by the MDU, MPS, NHSLA, Capsticks and Oxford Radcliffe Hospitals Trust, to describe their structure, coding frames, strengths and weaknesses and their potential for informing threats to patient safety.

2. To describe, using representative and appropriate sampling techniques, the epidemiology of errors held in the litigation databases.

3. To develop guidance for future collection of information in the litigation databases so that this information can feed into broader system (e.g. being developed by the NPSA) for reducing harm.

4. To identify a representative sample of cases covering primary care, obstetric care, mental health and non-obstetric hospital care from which more detailed root cause analysis could be carried out.

5. To identify key management problems and contributory systems factors using a formal method of root cause analysis for specific conditions in primary care, obstetric care, mental health, and hospital based general surgery and general medicine.

6. To carry out a comparison with current recommendations obtained from confidential enquiries (CEPOD, CESDI, the national audit of suicides and the confidential enquiry on maternal mortality) in order to identify common and divergent action points.

7. Based on the finding from this work to make a series of recommendations to the NPSA and DoH on areas of concern where patient safety is compromised.

The project falls into two main phases. The first phase has focused on the analysis of computerised databases held by the medical defence organisations to examine the epidemiology of adverse events and litigation (addressing the first three aims set out above), and is the subject of this report. The second phase has focused on developing a methodology for undertaking structured clinical reviews of selected groups of cases of litigation, aimed at understanding the causes and contributory factors and producing recommendations for change which would produce improvements in patient safety. The findings from this second phase will be presented towards the end of 2003, in a separate report.

1.3 Data access and confidentiality

Before commencing work on this project, we consulted with the North West Research Ethics Committee (MREC) to seek their advice on whether the project would require formal ethical approval and whether they could identify any potential ethical problems or dilemmas in our proposals. MREC advised us that because the project involved work with anonymised data sources which could not be traced back to individual patients and because three of the four medical defence organisations with which we planned to work were independent organisations outside the NHS, ethical approval would not be required. They did not identify any particular ethical problems or dilemmas which they thought could arise.

We have negotiated access to data with each of the four medical defence organisations who were named in our original proposal – the NHS Litigation Authority, Capsticks Solicitors, the Medical Defence Union and the Medical Protection Society – and with Oxford Radcliffe Hospitals Trust. None was under any obligation to participate in the study, and we regard it as a testament to their commitment to improving patient safety that all have been willing to collaborate with and provide data for this study, in both phase 1 and phase 2.

Members of the project team met with representatives of each organisation in turn to explain the purposes of the project and the access to data which it would require, and to seek their agreement in principle to take part. We then negotiated access arrangements, drawing up for each organisation a short memorandum of understanding setting out our agreed approach. Each organisation then produced a confidentiality agreement or statement for the project team to sign. These confidentiality agreements varied somewhat in style and presentation, but they essentially provided a legal and ethical safeguard for both the organisations and the research team, confirming that we would adhere to the requirements of data protection legislation and to the need to ensure confidentiality and anonymity in all data which was provided to us. The process of securing data access and drawing up confidentiality agreements was undertaken carefully, and some of the medical defence organisations needed to seek formal approval at board level for their participation.

2. Data analysis and audit methods

2.1 Introduction

Medico-legal cases are by definition generated from alleged medical errors, and as such the analysis of the allegations behind claims is a potential source of information on sources of risk to patients. Because of the variety of reasons for making legal claims, it is recognised that medico-legal cases represent an unrepresentative cross section of NHS care and are not representative of the wider epidemiology of errors that occur in the NHS. Nevertheless, an understanding of the kinds of errors that lead to litigation is potentially of value to improvements in patient safety, and this is the assumption driving this study.

Of course, information that can be obtained from medico-legal cases is limited partly by the large differences in the quality of information held by the different organisations and the differences in completeness of information. The organisations vary in terms of how they classify cases and the level and amount of information that they hold electronically. They were set up for primarily administrative purposes and not with a view to analysis in order to learn lessons to improve patient safety. In this part of the study, the databases of all the medico-legal organisations have been systematically examined in order to assess whether the information held can be used to improve patient safety through a statistical analysis of patterns of error. We will also be able to develop guidance on how information to improve patient safety can be collected and organised in the litigation databases so that it can complement information that will in future be collected through the national reporting system of the National Patient Safety Agency (NPSA).

This section of the report describes how we have approached drawing samples of cases from each of the four organisations involved in the project, and how we have then coded, categorised, managed and analysed the data they provided. It also describes the approach we have taken to auditing the quality of data in these samples, and provides some information about how the organisations collect, manage and use their databases.

2.2 Approach to sampling and coding

Preliminary meetings were held with the agencies responsible for each of the litigation databases of interest, and conditions of access and confidentiality were agreed, as described in section 1. From each database, a sample of cases was drawn from all cases dealt with by that organisation which had been opened since April 1st 1995 or nearest practicable date. As the study was not primarily interested in litigation outcomes no condition was imposed that the sampled cases had been completed[1]. The following initial samples were drawn from each of the databases examined:

Primary care databases:
The Medical Defence Union (MDU) provided a random sample of 501 cases that had commenced since April 1996.

[1] Litigation outcomes are dependent on proof of fault; we are concerned rather to use the medico-legal databases as a source of information about adverse events, irrespective of whether the legal standard of care had been breached.

The Medical Protection Society (MPS) provided a database containing a random sample of approximately 1000 claims, from which a random sub-sample of 650 cases were drawn for detailed coding in order to assure consistency across databases.

Secondary care databases:
The National Health Service Litigation Authority (NHSLA) provided two samples for Existing Liabilities Scheme (ELS) and Clinical Negligence Scheme For Trusts (CNST) cases respectively. The total sample size was 435, of which 125 were ELS cases and 310 were CNST cases. The ELS cases are an inherited "tail" of cases and all relate to events which took place prior to the commencement of the CNST scheme in April1995.

Capsticks provided a sample of 839 randomly selected cases that had commenced since April 1996, sampled by letter of the alphabet in relation to claimant surnames[2].

The senior claims manager at Oxford Radcliffe Hospitals Trust provided information on 574 claims that had been opened since April 1996, sampled again by letter of the alphabet in relation to claimant surnames.

The information on each case was then coded where possible by the type of error alleged, the outcome of the alleged error, the specialty in which the alleged error occurred, the primary diagnosis, and any procedure undertaken.

Each litigation database had evolved different coding procedures and conventions for different characteristics of cases, and to facilitate comparison and integration of data it was necessary to find some common way of coding information. In addition, to allow comparison between error rates and national activity rates and thereby assess the relative risk of errors occurring in particular areas of medical practice, it was desirable where possible to use codes for which national activity information was also available. This was possible in relation to the coding of specialties, presenting conditions, and procedures, but not for the coding of errors and outcomes.

Specialty coding was performed according to the standard list of specialties used in the Hospital Episodes Statistics (HES), as reproduced in Appendix 1. In most cases the organisations had entered their own specialty codes which were not always consistent with the standard list, and assumptions had to be made in order to assign a code in these cases. A second issue relates to the interpretation of specialty codes in medico-legal databases: they may relate to the specialty of the clinician who is alleged to have made the error, rather than the specialty of admission (which is the case with the HES). We discuss this issue further below when analysing the results.

Presenting conditions were coded according to the full set of ICD-10 codes for all hospital based litigation databases, and the full set of ICD-9 codes for the primary care databases. This difference arose because information on national activity rates in hospitals was available using ICD-10, but for primary care the main source of information on national activity rates was coded using ICD-9.

Procedure coding was based on the full set of OPCS-4 procedure codes. These were relevant only for the secondary care databases.

[2] These of course remained anonymous to ourselves.

There are unfortunately no recognised national or international coding systems readily available for errors and outcomes during episodes of care. For errors it was decided to use an adapted version of the list of codes devised by the National Health Service Litigation Authority (NHSLA). It was necessary to adapt these lists in a number of ways to meet the purposes of this study. Some codes (e.g. Code 0570, Failure to monitor dose/rate of syntocinon, referring to an error associated with a particular drug primarily used in labour to help induce birth) were too specific and were aggregated into higher level codes (in this instance, code 14 - negligence during delivery.) Excessively specific codes were unhelpful given that phase 1 of this study did not have access to full records for each incident.

By contrast, in some cases it was necessary to adapt the error codes devised by the NHSLA because they were too general for the purposes of this study. For example, one NHSLA error code is G170-'medication errors': within the context of this study such a descriptor would not have provided sufficient detail, because in order to highlight high risk procedures we needed to know how the medication error occurred, to aid another part of this project concerned with root cause analysis. In consequence, 2 error codes and descriptors were devised, based around the original NHSLA code: Code 47 'Incorrect dosage of medication prescribed/administered, and Code 48 'Medication inappropriately prescribed/administered', the former referring to the dosage of medication (either in the form of an over- or underdose) and the latter to how the drug was administered (correct injection site etc) and whether it was an appropriate drug to use. Two final lists of 54 error codes for primary care and 58 error codes for secondary care to which errors in all databases could be coded was adopted for the study, and are given in Appendix 2 and 3.

A similar approach was adopted for outcome codes. The NHSLA outcome codes were used as a starting point, but adapted for the purposes of the study, resulting in two lists of 126 codes for primary care and 112 codes for secondary care to which outcomes in all databases could be coded. Appendix 4 and 5 list these.

2.3 Data audit, data collection and data entry

There is now a wide recognition in the NHS of the importance of good quality coded clinical data and the fundamental role it plays in the management of healthcare organisations. The analysis of information held by the NHS and medico-legal organisations on complaints and litigation helps provide useful insights into the nature and cause of error, which could lead to organisational changes. It is therefore becoming an increasing priority to ensure that the provision of data and information relating to patient care is accurate, comprehensive and available to all those who need it. For this reason we undertook a number of semi-structured interviews with officials responsible for coding and data entry in order to ascertain how the data were obtained and processed within their organisations, and the results are reported below for two of the four organisations.

2.3.1 Nature and scope of data collection and data entry

The data available to the MDU includes the patient's medical records from the GP, including any relevant previous history, case notes surrounding the episode of care and all solicitors' notes and documentation that is relevant, including expert reports. A variety of data may be available to Capsticks, including a letter stating allegations, a formal letter of claim or direct instructions

from the NHSLA. Other sources may include formal complaint documentation and or a risk manager's summary/opinion.

The medical records received by the MDU do not include any form of initial coding of the patients primary diagnosis or treatment by the GP. Information is provided in the form of a written summary surrounding the episode of care relating specifically to the alleged negligent act. The MDU rely entirely upon an internal classification system. They have a set of prearranged key terms that build up a large computerised thesaurus when inputting information surrounding a negligence case. Therefore external coding systems such as ICD 9/10 and OCPS-4 are not used within this organisation. Capsticks similarly complete a short text description as well as categorising the claim according to an internal classification system.

2.3.2 Auditing and quality assurance

Advisors and claim handlers enter data into the MDU databases. Claim handlers are clinically trained, but some also have legal qualifications. In Capsticks the basic data are entered by the accounts department. One of two of the legal partners put in the specialist category and description of the case.

As soon as a claim is registered with the MDU a database record surrounding that case is set up. This database record is a standard template used for all cases. It has a number of specified fields for data entry, including legal information, patient information and a summary. Each category has a pre-specified answer choice disallowing the use of free text apart from within the summary. The summary is filled in initially by the claim handlers with the information supplied at that time. As more information comes in relating to the episode of care then that information is added. However, information is never deleted from the initial summary unless it is found to be incorrect.

The MDU data are audited by the in-house advisor Madeline Try. She is trained as an IT advisor though has no medical or legal qualification. In Capsticks data are audited externally twice each year, and internally once a year.

2.3.3 Analysis and interpretation

The primary objective behind the MDU's current database system is for risk management and finance purposes. Because the database system has fields which have pre-arranged specific input choices, data from large numbers of cases can be pooled in order to highlight high areas of risk within primary care. Interpretation of the claim description in the MDU is done by the claim handling department and each individual is either medically or legally trained. They have training provided, although this mainly relates to the use of the databases themselves, for example how to input correct keywords etc. Capsticks' main objectives were data collation for financial projection, improved accuracy of case management information (e.g. date of claim), identification of potential risk factors (e.g. how many claims per Trust), teaching and training.

The emphasis in medico-legal organisations is understandably on the legal aspects of each case and their long-term goal is risk management and financial management. Whilst GPs and others with medical knowledge deal with each claim they do not have a system whereby they identify and code each patient's presenting disease and the treatment received. Any information related to this is noted only in accordance with the specifics of the negligent act believed to have

occurred. In the following section we therefore present the results of our own audit of data quality in each of the databases provided to us, where it should be noted that data quality is judged in relation to its usefulness for identifying accurate and reliable information on medical conditions, procedures and errors. Of course we acknowledge that the data in each case may well be fit for purpose (claims handling and management), and that the exercise reported below should be interpreted as a means of identifying opportunities rather than problems.

2.3.4 Audit of data quality

In addition, to make an assessment of the quality of the information recorded in each database, an audit was performed as part of this study, with the underlying objectives of assessing how well the error, outcome, diagnosis and procedure information described in the medico-legal case notes could be extracted for coding purposes; and promoting the potential for interchange between medico-legal organisation and coders in order to improve the future quality of coded data for the purposes of monitoring and analysis.

Information was extracted on the frequency of specified coding errors using a template specifically designed to record such errors, and on the proportion of cases in each sample that could not be coded to the standard code lists adopted in this study. The main error types were:

1. Inconsistency within source documentation. Examples of this included differing diagnostic statements in clinical case notes and discharge summary.
2. Document inadequate/incomplete. Examples included insufficient information within source document to be able to determine the primary condition, primary procedure, alleged error, or outcome of error.
3. Illegible document. Examples included poor spelling, incomprehensible writing, and use of technical jargon rendering case illegible without further information.
4. Repeats. In a number of instances the sampled cases included more than one case dealing with the same error.
5. “Irrelevant” indication. Examples of this included cases that could not be attributed to specific medical errors but had arisen due to mishaps such as slipping on a wet floor. It should be noted that this is only a coding “error” in the sense that the case was erroneously sampled for the present study, which is primarily concerned with medical errors.

Due to the way cases were sampled these errors were identified as each case note was reviewed. If a case note did show any of the above error types then it was automatically withdrawn from further analysis to reduce coding errors. The results of this data quality audit are reported in section 3 below.

3. Results of database analyses

3.1 Introduction

Here we present the results of our analyses of the NHSLA, MDU, MPS, Capsticks and Oxford databases. First, in section 3.2 we report results from the audit of data coding quality/reliability in each database. Next, in section 3.3 we report frequency counts of the types of errors recorded by each database, using the coding system described above to classify errors to facilitate comparison between databases, and similar frequency counts of the outcomes of errors recorded by each database, using the coding system described above to classify outcomes. In section 3.4 we report for each database the incidence of error categorised by national specialty codes, and compare error rates within each database with national activity rates (local activity rates in the case of the Oxford database) in corresponding specialties to estimate the standardised incidence ratio (Armitage and Berry, 1987) and its associated confidence limits (Daly, 1998) of an error in relation to activity; we measure activity in terms of consultations for primary care, and in terms of inpatient episodes for secondary care. Thus, if the proportion of all errors in our sample occurring in, for example, the cardiothoracic surgery specialty is the same as the proportion of all hospital episodes occurring in that specialty, the standardised incidence ratio will be 1; if the proportion of errors in that specialty is double the proportion of episodes in that specialty the standardised incidence ratio will be 2, and so on. Standardised incidence ratios greater than 1 therefore indicate a larger than expected error rate, while standardised incidence rations of less than 1 indicate a smaller than expected error rate. Because of the large number of standardised incidence ratio calculations involved in this study and the consequent risk of statistically significant findings that are due to the play of chance, we use 99% confidence intervals.

In sections 3.5, 3.6 and 3.7, we estimate similar standardised incidence ratios and their associated confidence limits by broad ICD chapter, by procedure using OPCS-4 groups, and then by diagnostic code and procedure at a level of disaggregation below ICD chapters and OPCS-4 groups.

It should be noted that these estimations of standardised incidence ratio are highly sensitive to a number of characteristics of the data including the way data have been collected, coded and aggregated or disaggregated. Consequently it is quite possible that standardised incidence ratios that are statistically significantly above or below 1 reflect some artefact of the data rather than a real deviation from average error rates. Identifying such artefacts is of course part of the objective of this study. Meanwhile, the results should be interpreted with caution.

3.2 Audit of coding quality

Table 1 summarises the initial sample sizes, cases excluded by reason, and final sampling numbers available for analysis from each database.

Table 1: Initial sample sizes, cases excluded, and final sample sizes, by database

	MDU		MPS		NHSLA		Capsticks		Oxfordshire	
	No.	**%**	**No.**	**%**	**No.**	**%**	**No.**	**%**	**No.**	**%**
Initial sample size	501	100%	650	100%	435	100%	839	100%	574	100%
Case excluded due to (one or more of):										
Irrelevant information	6	1%	19	3%	13	3%	34	4%	79	14%
Document inadequate or incomplete	5	1%	130	20%	65	15%	178	21%	102	18%
Illegible document	1	0%	0	0%	1	0%	4	0%	2	0%
Repeated case notes	0	0%	0	0%	0	0%	131	16%	0	0%
Total database errors	12	2%	149	23%	79	18%	347	41%	183	32%
Final sample size for analysis	**489**	**98%**	**501**	**77%**	**356**	**82%**	**492**	**59%**	**391**	**68%**

Only 2% of the initial sample had to be excluded from the MDU database, which in general provided an easily navigated set of case notes. They provided a description of the episode of care (from which information was extracted for coding purposes). In addition to this they provided what they felt to be the patient's primary disease state, which consistently matched with their narrative description. The patient's outcome was also clearly stated which was also consistent with their previous description, therefore making error type, inconsistency within document, a scarce one. The case notes also contained a set of standardised allegations devised by the MDU, e.g.: Medication issue, consent issue etc, which helped highlight the alleged negligent act and was good for cross reference purposes when dissecting the information given in the descriptive. The speciality within which each episode of care occurred was not however reported. The layout format was a spreadsheet, which was clear and easy to dissect for coding purposes. The style throughout the notes was also consistent, thus suggesting that a form of standardisation had been implemented for the purposes of formulating the data set.

23% of the initial sample had to be excluded from the MPS database. The MPS provided case notes that were difficult to dissect, mainly due to inconsistencies between the narrative and their proposed presenting disease and treatment with each case. Drug and medication cases will also be underrepresented within the final database of cases drawn from MPS, as the details surrounding these were very often incomplete. They tended to name either the drug given or the presenting disease but very rarely provided information necessary to identify the patient's condition and the specific drug treatment that ultimately resulted in the litigation case. The case notes did however contain a set of standardised allegations devised by the MPS, such as: failure to diagnose, delay in referring, medication and prescribing errors. This made it easier to identify the alleged negligent act and was useful when cross-referencing with information provided in the narrative. The case notes did not contain any information about the sex of the individual, the status of the claim (i.e. whether open or closed) and what damages had been or were expected to be awarded. The layout format was a spreadsheet, which was clear to work through. The style throughout the notes was consistent, suggesting that a form of standardisation had been implemented for the purposes of formulating the data set. Despite this, the MPS database proved

time-consuming to work from, due to the high frequency of inconsistency within the notes which made correct identification of the patient's specific details a difficult process.

41% of cases initially sampled from Capsticks could not be coded. This meant they contained at least one error type, as described in the methodology section. The main reason for exclusion was incompleteness, meaning that too little information was provided about each episode of care to assign codes for the patient's presenting disease, treatment, alleged error or outcome. The second most common reason for exclusion in this database was repetition/duplication of notes relating to the same case. However, inconsistency within the source document was not evident within Capsticks data sample.

The case notes were set out clearly. Each one gave a brief description of the patient's episode of care, but the amount of information given did vary from case to case, highlighting a lack of standardisation concerning what should be included in case notes intended for coding purposes. These descriptions were mainly statements that were relatively precise and to the point. The speciality within which the negligent act occurred was set out clearly and the organisation provided a key of the specialities with the case notes. The main uncertainty within the case notes was the sum of money recorded against each case: it was not clear whether the amount stated was a reserve figure, the claimant's expected settlement or the actual settlement

18% of cases sampled from the NHSLA database were found to have some form of error or fault making them unsuitable for coding and analysis. The most common error was an inadequate/incomplete document. No cases were duplicated.

The layout of the NHSLA's case notes were easy to read, but tended to cut off descriptions of a patient's episode of care, leaving vital information for coding absent. This was made even more evident by the lack of consistency between the information provided in the description of the incident and the information in the alleged error and outcome columns. This lack of consistency is perhaps due to the organisation having access to more detailed data about patients' episodes of care, from which they depicted what the error and outcomes were. In order to maintain consistency across our data sets, information regarding the error and outcomes were always taken from the descriptive summary provided. This however means that they do not always necessarily reflect the full account of the case as the amount of information contained in the descriptive summary is limited.

32% of the sample drawn from the Oxford database contained errors or inadequacies that made it difficult to code or analyse these cases. The most frequent problem was inadequate information to be able to extricate relevant details relating to the patient's episode of care. The Oxford databases tended to focus more on the legal processes of the case rather than detailed clinical data. The second most common reason for excluding cases from the initial Oxford sample was "irrelevance" of the case, meaning that no clear allegation of clinical error was involved in the case. In addition it was sometimes noted from looking through the cases that there were inconsistencies within the source documents. It was evident that different people were entering the case notes. This was reflected in the focus within the case notes changing and different styles of writing. This highlighted a lack of standardisation.

3.3 Frequency of errors and outcomes of errors

3.3.1 Primary care databases

Table 2 shows the frequency count of errors in the MDU and MPS primary care databases. The table is ranked in descending order of total frequency. In this database as in the secondary care databases, failures or delays in diagnosis/misdiagnosis and referral account between them for about 60% of all errors. Failures involving medication prescription, administration and side effects account for about a further 15% of errors recorded in the MDU database.

Table 2: Errors classified by standard error code in MDU and MPS primary care databases

Code	Error Description	Frequency	(%)
14	Failure/delay in diagnosis	494	50.05%
48	Medication inappropriately prescribed	56	5.67%
23	Failure/refusal/delay in referral	51	5.17%
46	Failure to warn/recognise side effects of drug	50	5.07%
22	Failure to monitor condition	46	4.66%
41	Unsatisfactory performance of a procedure	42	4.26%
47	Incorrect/inappropriate dosage of medication prescribed/administered	36	3.65%
15	Failure/delay in diagnosing fracture	34	3.44%
35	Misdiagnosis of condition	28	2.84%
50	Failure to diagnose complications in pregnancy	24	2.43%
32	Inappropriate/inadequate treatment	21	2.13%
31	Inappropriate/inadequate examination	19	1.93%
33	Injury, pain and suffering caused by injection	9	0.91%
52	Failure to diagnose complication following a surgical procedure	8	0.81%
24	Failure/refusal to treat/visit/examine	7	0.71%
44	Failed sterilization	7	0.71%
18	Failure to act upon abnormal findings	6	0.61%
53	Failure to provide adequate follow-up care	6	0.61%
2	Failure to inform patient of abnormal test results	5	0.51%
11	Delay in hospital admission	5	0.51%
12	Delay/failure to treatment	5	0.51%
20	Failure to diagnose likelihood of self-harm	3	0.30%
27	Failure to warn patient of potential complications	3	0.30%
38	Premature cessation of treatment	3	0.30%
45	Inappropriate contraceptive advice	3	0.30%
19	Failure to arrange x-ray/scan	2	0.20%
39	Unintentional puncture or laceration during procedure	2	0.20%
42	Unsterilised equipment used during a procedure	2	0.20%
49	Medication inappropriately administered	2	0.20%
3	Abnormal test results given to healthy patient	1	0.10%
10	Burn caused by preparatory agent	1	0.10%
21	Failure to obtain patient's/parent's consent	1	0.10%
25	Failure to recognise complication of treatment	1	0.10%
34	Lack of adequate facilities/equipment	1	0.10%
40	Retained swab	1	0.10%
51	Failure to remove IUD	1	0.10%
54	Inappropriate post-procedural medication	1	0.10%

3.3.2 Secondary care databases

Table 3 shows the frequency count of errors across the NHSLA, Capsticks and Oxfordshire secondary care databases, with a summary column showing the total numbers and percentages across the two national databases NHSLA and Capsticks[3]. The table is ranked in descending order of total frequency. Only errors in which at least 2 cases were recorded across the national databases are shown. In all three databases, failure/delay to diagnose and unsatisfactory performance of a procedure are the two most common causes of error, and the overall rankings are similar in all three databases.

Table 3: Errors classified by standard error code in NHSLA, Capsticks and Oxfordshire databases

Code	Error Description	NHSLA		Capsticks		Oxfordshire		NHSLA and Capsticks combined	
		No	%	No	%	No	%	No	%
23	Failure/delay to diagnose	79	22.13%	71	19.35%	52	13.79%	150	20.72%
42	Unsatisfactory performance of a procedure	61	17.09%	72	19.62%	67	17.77%	133	18.37%
40	Puncture or laceration of organ or tissue during a procedure	20	5.60%	19	5.18%	25	6.63%	39	5.39%
14	Negligence during delivery not specified	14	3.92%	24	6.54%	11	2.92%	38	5.25%
33	Inappropriate treatment	16	4.48%	16	4.36%	18	4.77%	32	4.42%
10	Failure to monitor labour/act upon complications during labour	16	4.48%	15	4.09%	6	1.59%	31	4.28%
56	Inadequate/inappropriate post-procedural care	13	3.64%	17	4.63%	19	5.04%	30	4.14%
1	Failure/delay to diagnose fracture	15	4.20%	12	3.27%	20	5.31%	27	3.73%
35	Misdiagnosis of condition	10	2.80%	15	4.09%	8	2.12%	25	3.45%
51	Failure to diagnose complications in pregnancy	13	3.64%	10	2.72%	3	0.80%	23	3.18%
45	Failed sterilisation	10	2.80%	7	1.91%	6	1.59%	17	2.35%
9	Delayed delivery	5	1.40%	10	2.72%	2	0.53%	15	2.07%
21	Delay in treatment	10	2.80%	5	1.36%	17	4.51%	15	2.07%
48	Medication inappropriately prescribed/administered	9	2.52%	4	1.09%	8	2.12%	13	1.80%
24	Failure to obtain patient's/parent's consent	5	1.40%	6	1.63%	9	2.39%	11	1.52%
28	Failure to warn patient of potential complications	6	1.68%	4	1.09%	10	2.65%	10	1.38%
29	Foreign body left in situ following a procedure	7	1.96%	2	0.54%	10	2.65%	9	1.24%
8	Damage caused by forceps/ventouse	2	0.56%	6	1.63%	5	1.33%	8	1.10%
19	Injury to bone, muscle, ligaments during a procedure	5	1.40%	3	0.82%	7	1.86%	8	1.10%
26	Failure/refusal to treat	3	0.84%	5	1.36%	7	1.86%	8	1.10%
41	Retained swab	4	1.12%	4	1.09%	4	1.06%	8	1.10%
22	Deprivation of oxygen	0	0.00%	7	1.91%	1	0.27%	7	0.97%
55	Failure to provide adequate follow-up care	6	1.68%	1	0.27%	2	0.53%	7	0.97%
54	Failure to diagnose complication following a procedure	3	0.84%	3	0.82%	2	0.53%	6	0.83%
4	Failure to inform patient of abnormal test results	3	0.84%	2	0.54%	2	0.53%	5	0.69%
36	Operation on wrong body part	4	1.12%	1	0.27%	2	0.53%	5	0.69%
12	Incorrect administration of epidural	0	0.00%	4	1.09%	1	0.27%	4	0.55%
20	Injury caused during oral intubation	3	0.84%	1	0.27%	3	0.80%	4	0.55%
37	Poor suture of wound/tear	0	0.00%	4	1.09%	2	0.53%	4	0.55%
11	Failure to remove products of conception	2	0.56%	1	0.27%	1	0.27%	3	0.41%
25	Failure/refusal to refer	0	0.00%	3	0.82%	3	0.80%	3	0.41%
31	Inadequate intra-operation monitoring	3	0.84%	0	0.00%	1	0.27%	3	0.41%
34	Infected with virus during procedure	0	0.00%	3	0.82%	2	0.53%	3	0.41%
50	Failed abortion	0	0.00%	3	0.82%	1	0.27%	3	0.41%
2	Incorrect level of anaesthesia administered	2	0.56%	0	0.00%	2	0.53%	2	0.28%
5	Abnormal test results given to healthy patient	1	0.28%	1	0.27%	0	0.00%	2	0.28%
13	Insufficient pain relief during delivery	1	0.28%	1	0.27%	3	0.80%	2	0.28%
39	Premature cessation of treatment	1	0.28%	1	0.27%	6	1.59%	2	0.28%
46	Inappropriate contraceptive advice	2	0.56%	0	0.00%	1	0.27%	2	0.28%

[3] It is likely that NHSLA overlapped Oxfordshire database, therefore the latter was not included in the combined exercise to avoid potential double counting and to ensure a representative sample.

Table 4 shows a frequency count of outcomes for the MDU and MPS primary care database, in descending order of frequency. Only outcomes in which at least 3 cases were recorded are shown. In this database the main outcomes associated with errors were death, deterioration in a clinical condition, and unnecessary pain.

Table 4: Outcomes by standard outcome code in MDU and MPS primary care databases

Code	Outcome Description	Frequency	Percent
33	Death	178	20.70%
35	Deterioration in clinical condition	50	5.81%
86	Unnecessary pain	34	3.95%
99	Surgical excision of organ	34	3.95%
3	Amputation of limb	31	3.60%
95	Open reduction/ internal fixation	28	3.26%
100	Surgical excision of reproductive organs	27	3.14%
88	Appendicectomy	23	2.67%
52	Impaired/total loss of vision	21	2.44%
10	Brain damage	20	2.33%
61	Mastectomy	18	2.09%
6	Aneurysm	16	1.86%
125	Injury resulting from procedure	16	1.86%
118	Complication of the skin and subcutaneous tissue	15	1.74%
130	No description	15	1.74%
50	Hospital admission	14	1.63%
117	Wrongful birth (as result of failed sterilisation)	13	1.51%
94	Hysterectomy	12	1.40%
92	Excision of neoplasm	11	1.28%
120	Infection of -internal/external	11	1.28%
47	Haemorrhage	10	1.16%
51	Impaired/total loss of hearing	10	1.16%
93	Exploratory/access incision surgery	10	1.16%
101	Surgical reconstruction	10	1.16%
12	Burn of multiple and unspecified sites	9	1.05%
77	Renal damage/failure	9	1.05%
78	Scarring	9	1.05%
81	Stroke	9	1.05%
8	Behavioural disorder	8	0.93%
36	Deterioration in organ function	8	0.93%
54	Infertility	8	0.93%
2	Addiction	7	0.81%
74	Psychotic episode	7	0.81%
97	Radiotherapy	7	0.81%
5	Anaphylactic shock/allergic shock/allergy	6	0.70%
38	Disability	6	0.70%
63	Nerve damage	6	0.70%
113	Pregnancy	6	0.70%
34	Depression	5	0.58%
96	Organ transplant	5	0.58%
98	Repair of ligament/muscle	5	0.58%
105	Developmental/chromosomal abnormality	5	0.58%
119	Contraction of infectious diseases	5	0.58%
121	Inflammation of organ/tissue	5	0.58%
37	Diarrhoea/vomitting	4	0.47%
40	Drowsiness, lethargy, fatigue	4	0.47%
89	Biopsy/bone biopsy	4	0.47%
114	Premature birth	4	0.47%
124	Extended healing/rehab period	4	0.47%
15	Cardiovascular condition	3	0.35%
18	Colostomy bag	3	0.35%
39	Drainage of fluid	3	0.35%
41	Emotional/psychological damage	3	0.35%
71	Paraplegia	3	0.35%
82	Suicide	3	0.35%
102	Suture of wound/tear/rupture	3	0.35%
103	Abortion	3	0.35%
104	Cerebral palsy	3	0.35%

Table 5 shows the frequency count of outcomes across the NHSLA, Capsticks and Oxfordshire databases, with a summary column showing the total numbers and percentages across the two

national databases. The table only shows outcome codes for which a total of at least 2 cases were recorded across the combined NHSLA and Capsticks databases, and is ranked in descending order. It is evident that there is a fairly high degree of agreement between databases in terms of relative importance, with unnecessary pain, death, cerebral palsy, need for further treatment and brain damage ranking high in all three databases.

Table 5: Outcomes by standard outcome code in NHSLA, Capsticks and Oxfordshire databases

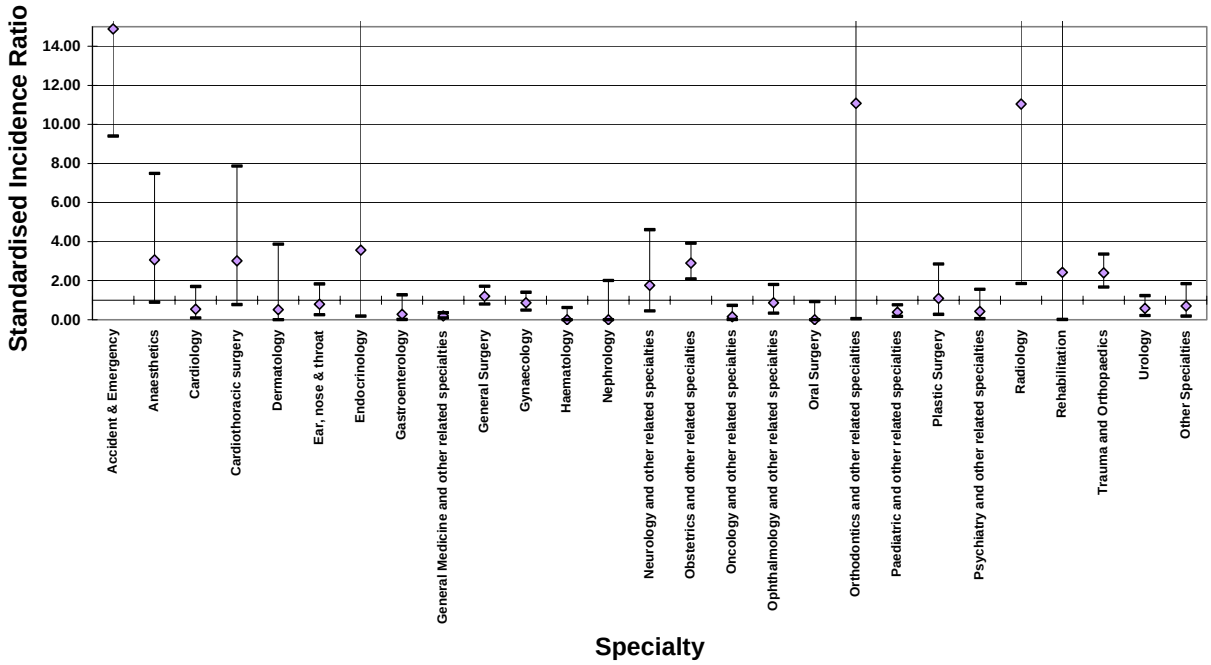
Code	Outcome Description	NHSLA		Capsticks		Oxfordshire		NHSLA and Capsticks combined	
		No.	%	No.	%	No.	%	No.	%
81	Unnecessary pain	50	15.43%	14	5.11%	34	10.43%	64	10.70%
35	Death	28	8.64%	29	10.58%	37	11.35%	57	9.53%
85	Cerebral palsy	18	5.56%	24	8.76%	8	2.45%	42	7.02%
7	Brain damage	20	6.17%	16	5.84%	9	2.76%	36	6.02%
112	Need for further surgery/treatment	13	4.01%	15	5.47%	18	5.52%	28	4.68%
83	Worsened condition	15	4.63%	5	1.82%	7	2.15%	20	3.34%
56	Nerve damage	11	3.40%	8	2.92%	5	1.53%	19	3.18%
94	Wrongful birth (as result of failed sterilisation)	11	3.40%	8	2.92%	3	0.92%	19	3.18%
37	Emotional/psychological damage	8	2.47%	9	3.28%	9	2.76%	17	2.84%
107	Infection of -internal/external	10	3.09%	7	2.55%	16	4.91%	17	2.84%
49	Impaired/total loss of vision	9	2.78%	6	2.19%	6	1.84%	15	2.51%
73	Scarring	7	2.16%	8	2.92%	2	0.61%	15	2.51%
100	Poor outcome of procedure	5	1.54%	8	2.92%	3	0.92%	13	2.17%
88	Erb's Palsy	4	1.23%	8	2.92%	4	1.23%	12	2.01%
20	Damage to bladder	2	0.62%	8	2.92%	0	0.00%	10	1.67%
36	Disability	5	1.54%	5	1.82%	12	3.68%	10	1.67%
86	Developmental/chromosomal abnormality	3	0.93%	7	2.55%	3	0.92%	10	1.67%
21	Damage to bowel	3	0.93%	6	2.19%	7	2.15%	9	1.51%
2	Amputation of limb	5	1.54%	3	1.09%	3	0.92%	8	1.34%
95	Damaged joint	7	2.16%	1	0.36%	1	0.31%	8	1.34%
6	Blood clotting	4	1.23%	3	1.09%	5	1.53%	7	1.17%
9	Burn of multiple and unspecified sites	4	1.23%	3	1.09%	3	0.92%	7	1.17%
16	Other complications of surgical/medical care	3	0.93%	3	1.09%	5	1.53%	6	1.00%
44	Haemorrhage	2	0.62%	4	1.46%	0	0.00%	6	1.00%
51	Incontinence	4	1.23%	2	0.73%	1	0.31%	6	1.00%
60	Paraplegia	2	0.62%	4	1.46%	5	1.53%	6	1.00%
93	Stillbirth	4	1.23%	2	0.73%	2	0.61%	6	1.00%
106	Contraction of infectious diseases	2	0.62%	4	1.46%	5	1.53%	6	1.00%
10	Cancer	4	1.23%	1	0.36%	4	1.23%	5	0.84%
18	Cosmetic disfigurement	4	1.23%	1	0.36%	1	0.31%	5	0.84%
53	Limb deformity	2	0.62%	3	1.09%	1	0.31%	5	0.84%
108	Inflammation of organ/tissue	2	0.62%	3	1.09%	1	0.31%	5	0.84%
111	Extended healing/rehab period	3	0.93%	2	0.73%	5	1.53%	5	0.84%
31	Damage to teeth/tooth N.S	4	1.23%	0	0.00%	3	0.92%	4	0.67%
40	Fall from bed	2	0.62%	2	0.73%	3	0.92%	4	0.67%
91	Infertility	1	0.31%	3	1.09%	0	0.00%	4	0.67%
84	Abortion	3	0.93%	1	0.36%	2	0.61%	4	0.67%
98	Fractured limb	2	0.62%	2	0.73%	1	0.31%	4	0.67%
11	Cardiac arrest	1	0.31%	2	0.73%	4	1.23%	3	0.50%
25	Damage to face	1	0.31%	2	0.73%	1	0.31%	3	0.50%
32	Damage to testicle/s	1	0.31%	2	0.73%	1	0.31%	3	0.50%
115	Damage to urethra	2	0.62%	1	0.36%	0	0.00%	3	0.50%
41	Fistula	0	0.00%	3	1.09%	0	0.00%	3	0.50%
48	Impaired/total loss of hearing	2	0.62%	1	0.36%	2	0.61%	3	0.50%
57	Numb limbs following procedure	2	0.62%	1	0.36%	2	0.61%	3	0.50%
64	Quadriplegia/tetraplegia	0	0.00%	3	1.09%	7	2.15%	3	0.50%
75	Spinal damage	0	0.00%	3	1.09%	4	1.23%	3	0.50%

3.4 Standardised incidence ratio of errors by specialty

Figures 1-3 show the standardised incidence ratios of errors in relation to activity rates in each standard specialty for the NHSLA, Capsticks and Oxfordshire databases respectively.

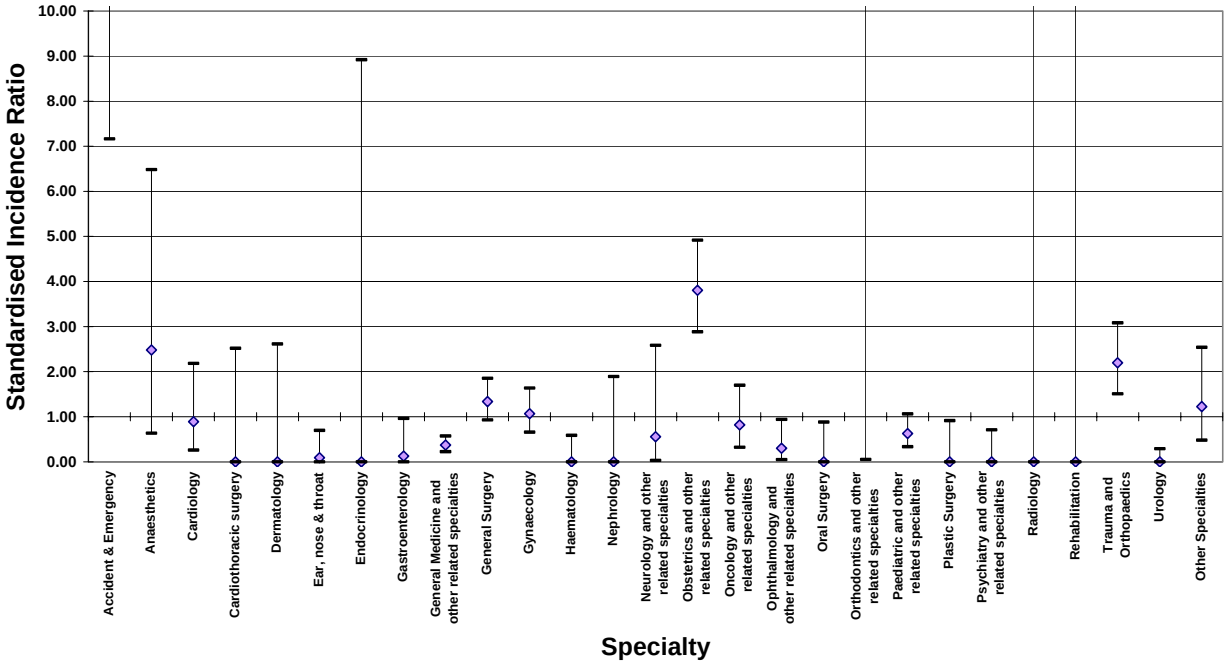
In the NHSLA database (Figure 1), only three specialties have a standardised incidence ratio of an error significantly greater than 1: accident and emergency (SIR 14.9, 99% c.i. 9.4, 22.3), obstetric and other related specialties (SIR 2.9, 99% c.i. 2.1, 3.9) and trauma and orthopaedics (SIR 2.4, 95% c.i. 1.7, 3.3). It is possible that the accident and emergency result is partly a consequence of national HES data recording patients who enter hospital through an accident and emergency department by the specialty they are eventually admitted to, whereas the errors recorded in the NHSLA database reflect the location in which an error is alleged to have been made, rather than the specialty in which care was primarily received. However, further light is cast on this by the ICD chapter analysis below.

Figure 1: Standardised incidence ratios of errors in relation to national activity rates (HES) in each standard specialty for the NHSLA database



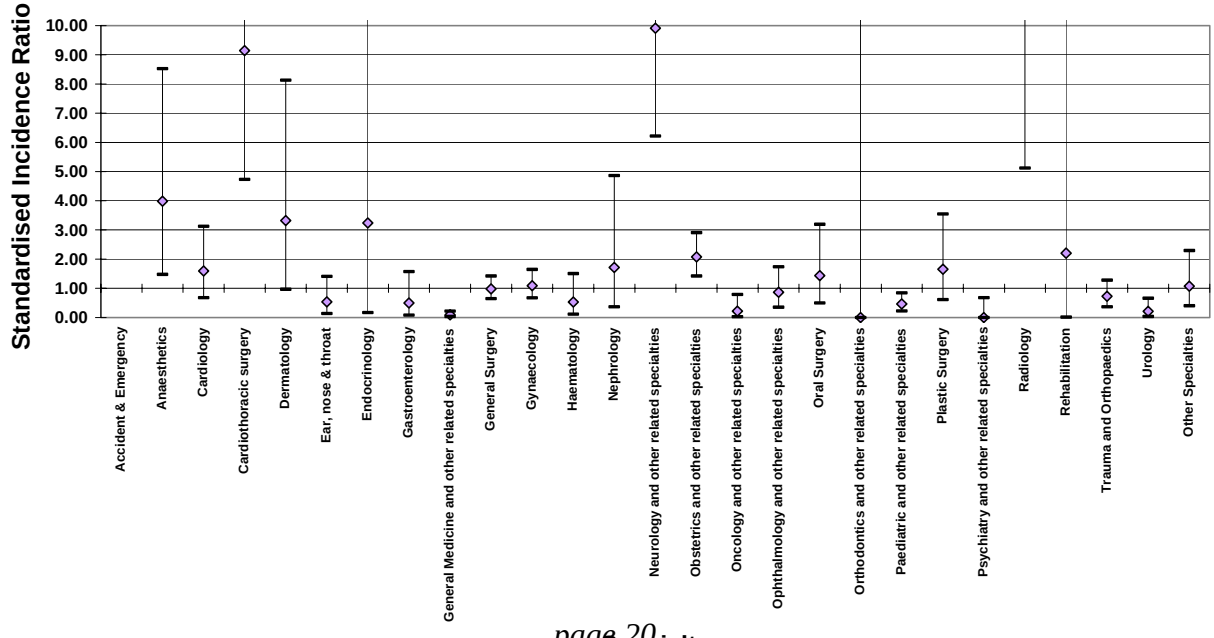
In the Capsticks database (Figure 2), the same three specialties have a standardised incidence ratio of an error significantly greater than 1: accident and emergency (SIR 11.9, 99% c.i. 7.2, 18.4), obstetric and other related specialties (SIR 3.8, 99% c.i. 2.9, 4.9) and trauma and orthopaedics (SIR 2.2, 99% c.i. 1.5, 3.1).

Figure 2: Standardised incidence ratios of errors in relation to national activity rates (HES) in each standard specialty for the Capsticks database



In the Oxfordshire database (Figure 3), six specialties (including two of the three noted above in the NHSLA and Capsticks databases) have a standardised incidence ratio of an error significantly greater than 1: accident and emergency (SIR 16.1, 99% c.i. 10.6, 23.3), anaesthetics (SIR 4.0, 99% c.i. 1.5, 8.5), cardiothoracic surgery (SIR 9.1, 99% c.i. 4.7, 15.8), neurology and other related specialties (SIR 9.9, 99% c.i. 6.2, 14.9), obstetric and other related specialties (SIR 2.1, 99% c.i. 1.4, 2.9) and radiology (SIR 17.6, 99% c.i. 5.1, 43.1). Again, it is likely that some of these differences result from coding procedures: for example, relatively few patients have anaesthetics or radiology coded as their main specialty in HES data, whereas the errors recorded in the Oxfordshire database reflect the location in which an error is alleged to have been made.

Figure 3: Standardised incidence ratios of errors in relation to national activity rates (HES) in each standard specialty for the Oxfordshire database



It should also be noted that local datasets such as that for Oxfordshire will be subject to other factors such as the presence or absence of regional specialties that may inflate or deflate the numbers of patients treated in particular specialties, or the case mix within specialties, in comparison with national averages.

3.5 Standardised incidence ratios of errors by diagnostic grouping

In order to facilitate the interpretation of the standardised incidence ratios of the alleged errors show below, Appendices 6 and 7 list the ICD-9 and ICD-10 chapter codes respectively.

3.5.1 Primary care databases

Figure 4 shows the standardised incidence ratios of errors in relation to national activity rates recorded in the 4th general practice morbidity survey by ICD 9 chapter for the MDU primary care databases. Five ICD chapters have a standardised incidence ratio of an error significantly greater than 1: Chapter II Neoplasms (SIR 16.3, 99% c.i. 12.3, 21.0), Chapter VII Diseases of the circulatory system (SIR 1.6, 99% c.i. 1.0, 2.3), Chapter IX Diseases of the digestive system (SIR 1.9, 99% c.i. 1.1, 2.9), Chapter XI Complications of pregnancy, childbirth and pueperium (SIR 5.9, 99% c.i. 2.5, 11.5) and Chapter XIV Congenital Anomalies (SIR 14.4, 99% c.i. 5.9, 28.9).

Figure 4: Standardised incidence ratio of errors in relation to national activity rates recorded in the 4th general practice morbidity survey by ICD 9 chapter for the MDU primary care databases

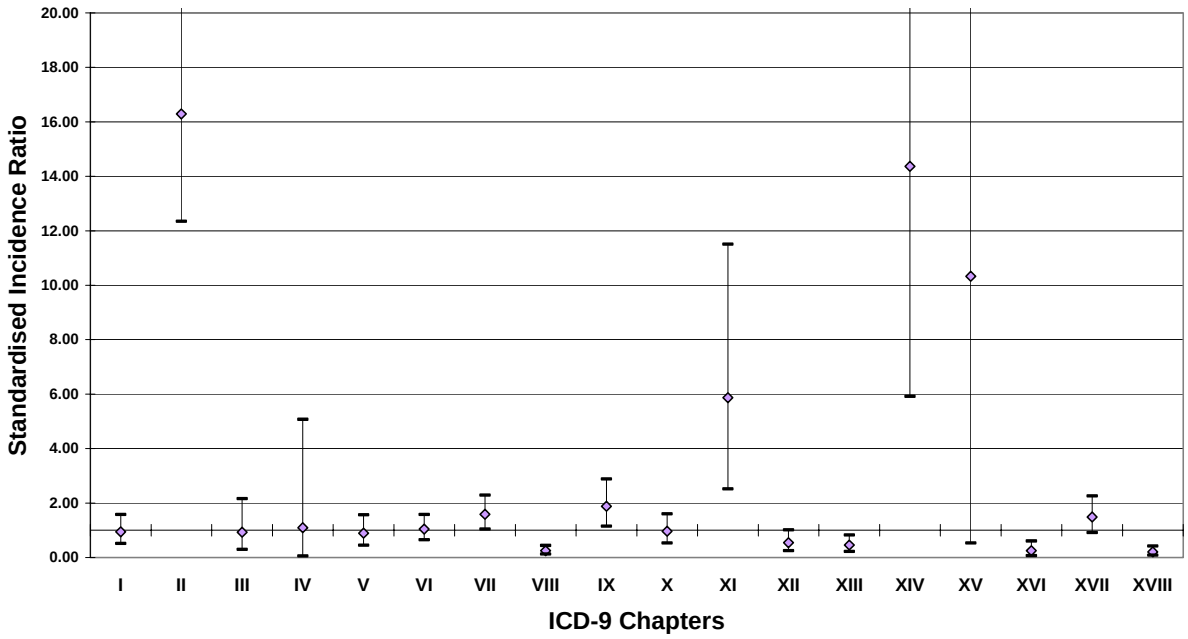


Figure 5 shows the standardised incidence ratio of errors in relation to national activity rates recorded in the 4th general practice morbidity survey by ICD 9 chapter for the MPS primary care databases. Five ICD chapters have a standardised incidence ratio of an error significantly greater than 1: Chapter II Neoplasms (SIR 16, 99% c.i. 12.0, 20.7), Chapter III Endocrine, nutritional

and metabolic diseases and immunity disorders (SIR 2.7, 99% c.i. 1.8, 4.5), Chapter VII Diseases of the circulatory system (SIR 1.8, 99% c.i. 1.2, 2.7), Chapter IX Diseases of the digestive system (SIR 2.6, 99% c.i. 1.7, 3.7) and Chapter XI Complications of pregnancy, childbirth and puerperium (SIR 9.1, 99% c.i. 4.7, 15.8).

Figure 5: Standardised incidence ratio of errors in relation to national activity rates recorded in the 4th general practice morbidity survey by ICD 9 chapter for the MPS primary care databases

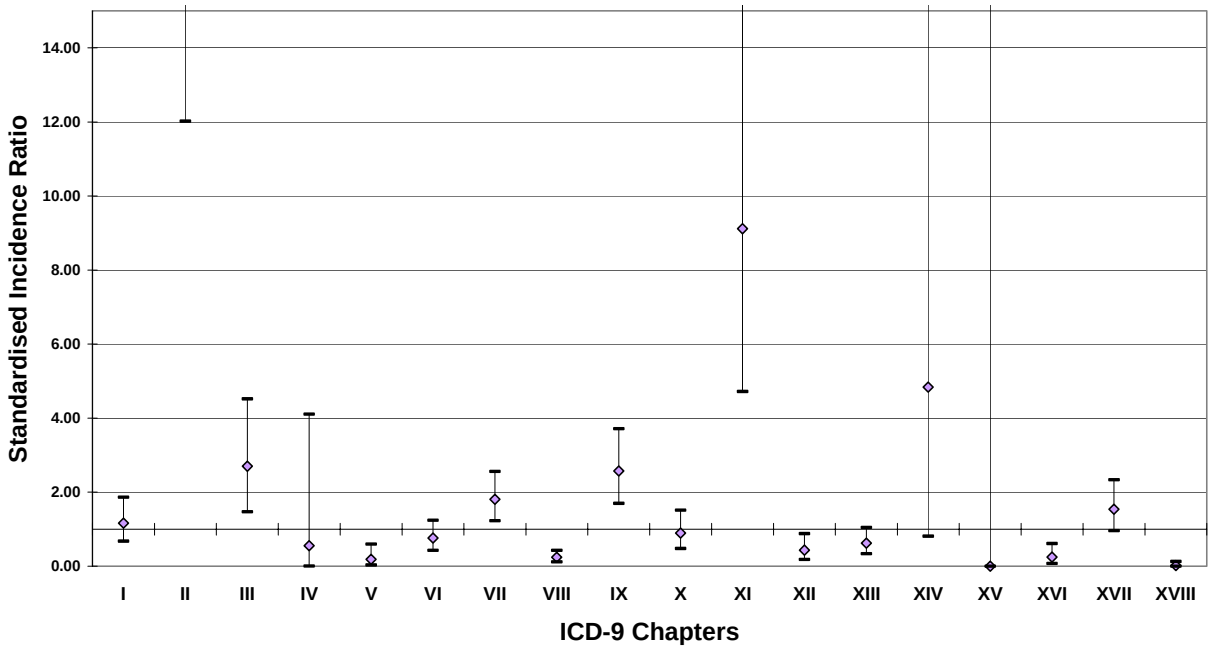
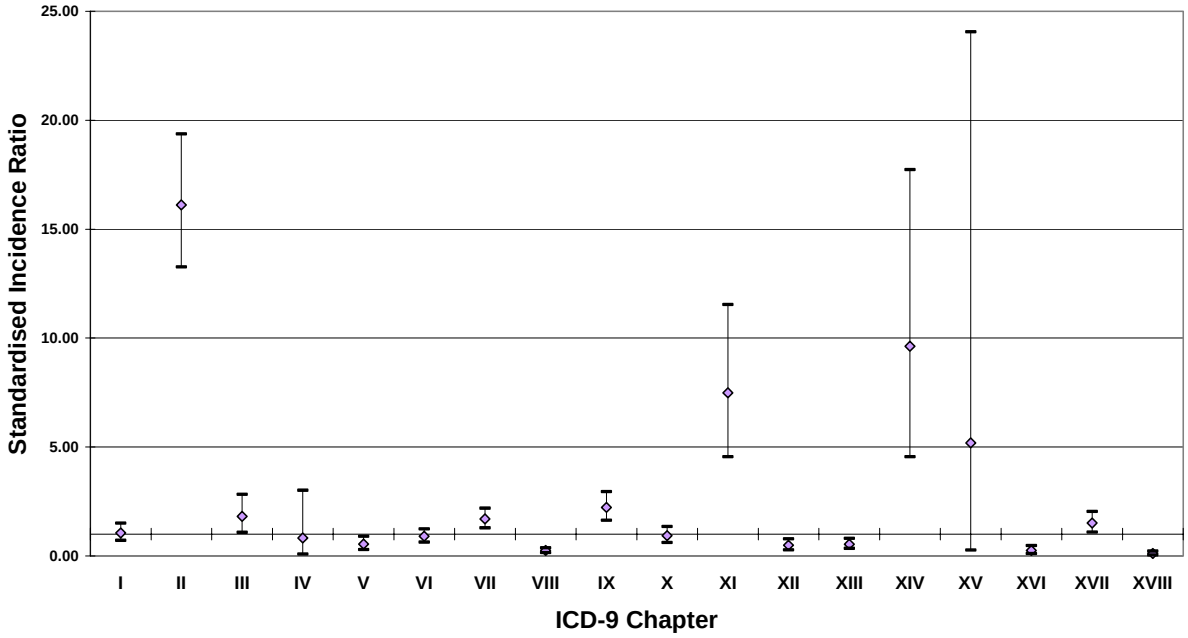


Figure 6 shows the standardised incidence ratios of errors in relation to national activity rates recorded in the 4th general practice morbidity survey by ICD 9 chapter for the pooled MDU and MPS primary care databases. Seven ICD chapters have a standardised incidence ratio of an error significantly greater than 1: Chapter II Neoplasms (SIR 16.1, 99% c.i. 13.2, 19.4), Chapter III Endocrine, nutritional and metabolic diseases and immunity disorders (SIR 1.8, 99% c.i. 1.1, 2.8), Chapter VII Diseases of the circulatory system (SIR 1.7, 99% c.i. 1.3, 2.2), Chapter IX Diseases of the digestive system (SIR 2.2, 99% c.i. 1.6, 2.9), Chapter XI Complications of pregnancy, childbirth and pueperium (SIR 7.4, 99% c.i. 4.5, 11.5), Chapter XIV Congenital Anomalies (SIR 9.6, 99% c.i. 4.5, 17.7) and Chapter XVII Injury and poisoning (SIR 1.5, 99% c.i. 1.1, 2.0).

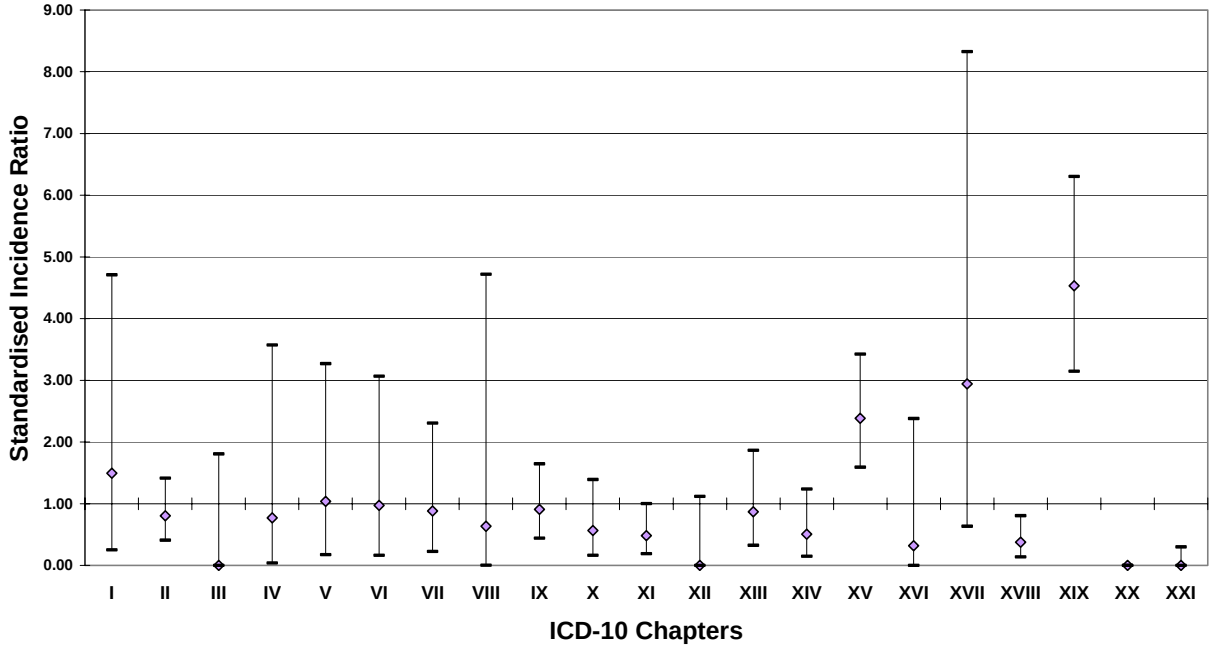
Figure 6: Standardised incidence ratio of errors in relation to national activity rates recorded in the 4th general practice morbidity survey by ICD 9 chapter for the pooled MDU and MPS primary care databases



3.5.2 Secondary Care Databases

Figures 7, 8 and 9 show the standardised incidence ratios of errors in relation to activity rates by ICD-10 chapter for the NHSLA, Capsticks and Oxfordshire databases respectively.

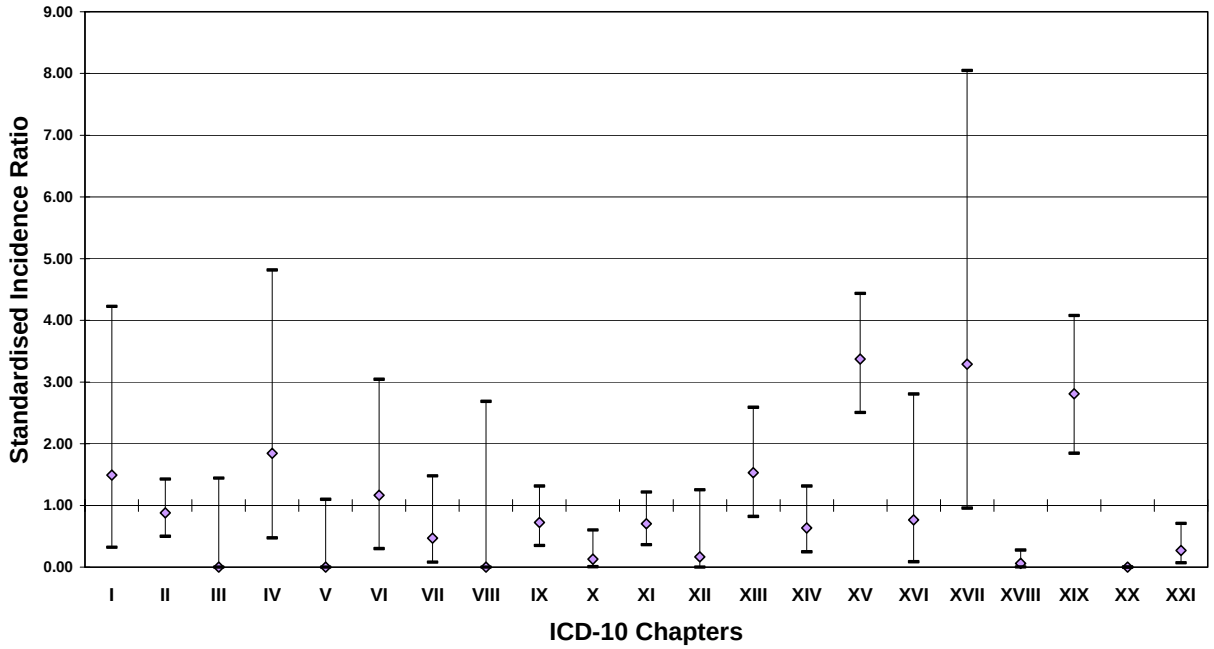
Figure 7: Standardised incidence ratios of errors in relation to national activity rates (HES) by ICD-10 chapter for the NHSLA database



In the NHSLA database (Figure 7), only two ICD 10 chapters have a standardised incidence ratio of an error significantly greater than 1: Chapter XV Pregnancy, childbirth and puerperium (SIR 2.4, 99% c.i. 1.6, 3.4), and Chapter XIX Injury, poisoning and certain other consequences of external causes (SIR 4.5, 99% c.i. 3.1, 6.3). It was noted above that the higher standardised incidence ratio of errors in the accident and emergency specialty was partly a consequence of national HES data recording patients who enter hospital through an accident and emergency department by the specialty they are eventually admitted to, whereas the errors recorded in the NHSLA database reflect the location in which an error is alleged to have been made, rather than the specialty in which care was primarily received. However, this ICD-based analysis does suggest that injuries as a cause of admission are associated with a higher risk of error.

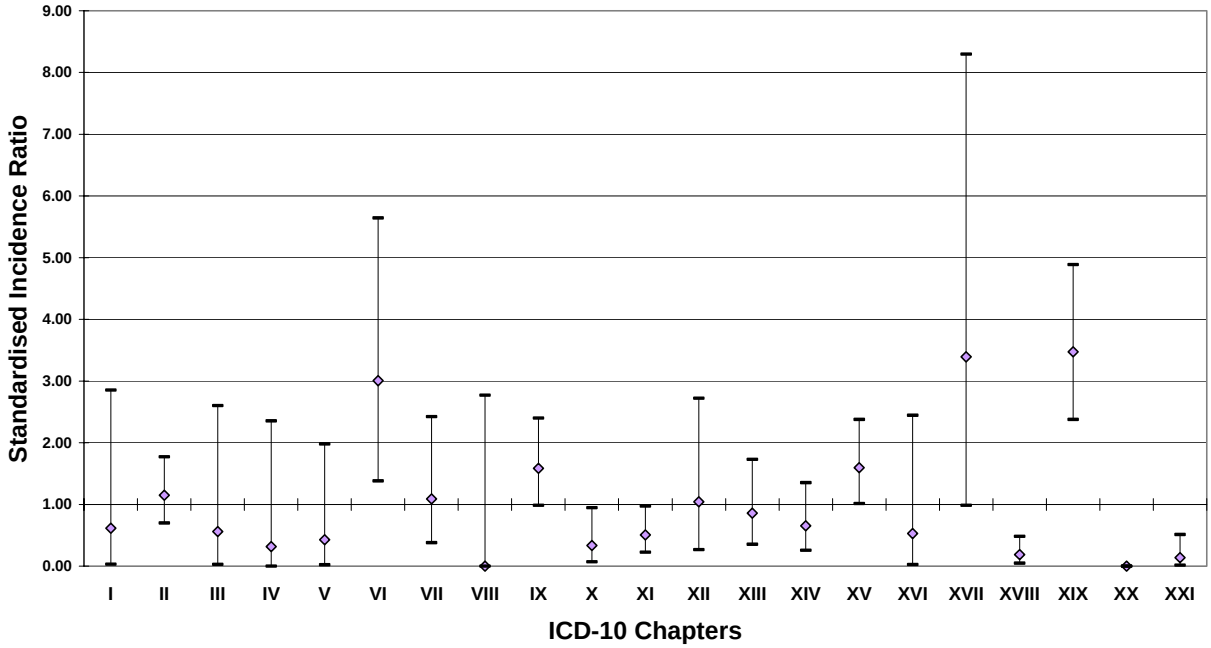
In the Capsticks database (Figure 8), the same two ICD 10 chapters have a standardised incidence ratio of an error significantly greater than 1: Chapter XV Pregnancy, childbirth and puerperium (SIR 3.4, 99% c.i. 2.5, 4.4), and Chapter XIX Injury, poisoning and certain other consequences of external causes (SIR 2.8, 99% c.i. 1.8, 4.1).

Figure 8: Standardised incidence ratios of errors in relation to national activity rates (HES) by ICD-10 chapter for the Capsticks database



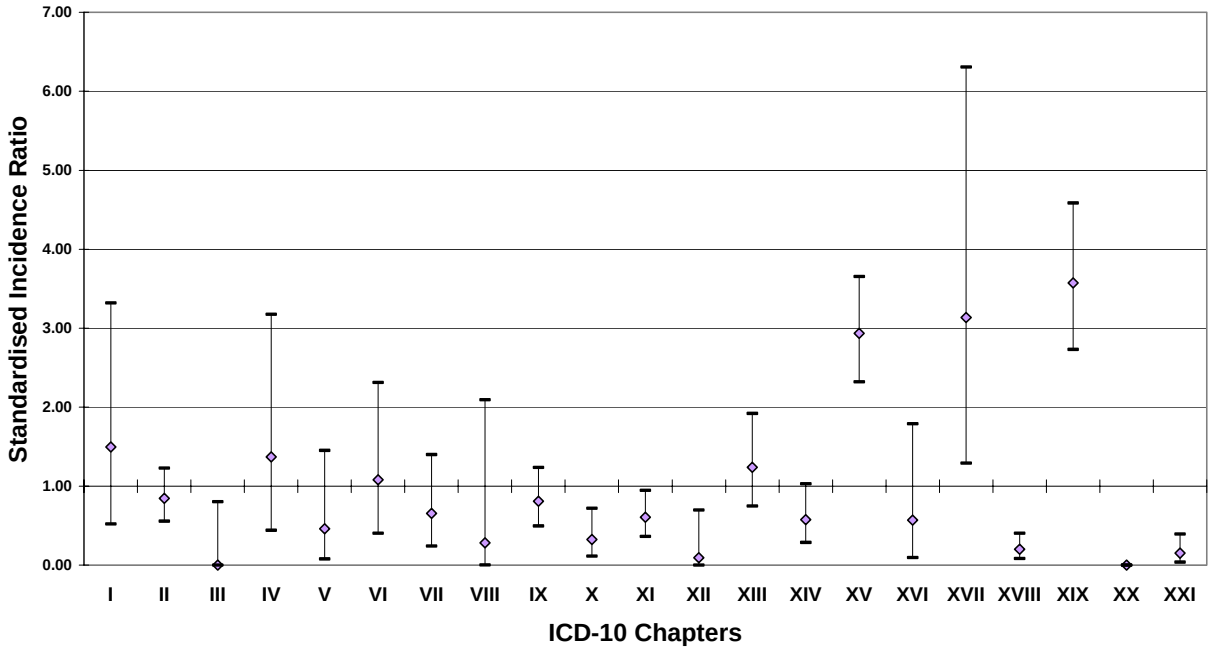
Finally, in the Oxfordshire database (Figure 9), four ICD 10 chapters (including the two noted above in the NHSLA and Capsticks databases) have a standardised incidence ratio of an error significantly greater than 1: Chapter VI Diseases of the nervous system (SIR 3.0, 99% c.i. 1.4, 5.6), Chapter IX Diseases of the circulatory system (SIR 1.6, 99% c.i. 1.0, 2.4), Chapter XV Pregnancy, childbirth and puerperium (SIR 1.6, 99% c.i. 1.0, 2.9), and Chapter XIX Injury, poisoning and certain other consequences of external causes (SIR 3.5, 99% c.i. 2.4, 4.9).

Figure 9: Standardised incidence ratios of errors in relation to national activity rates (HES) by ICD-10 chapter for the Oxfordshire sample



Finally, Figure 10 shows standardised incidence ratios in relation to national activity rates (HES) by ICD-10 chapter for the two national secondary care databases pooled.

Figure 10: Standardised incidence ratios of errors in relation to national activity rates (HES) by ICD-10 chapter for the NHSLA and Capsticks samples pooled

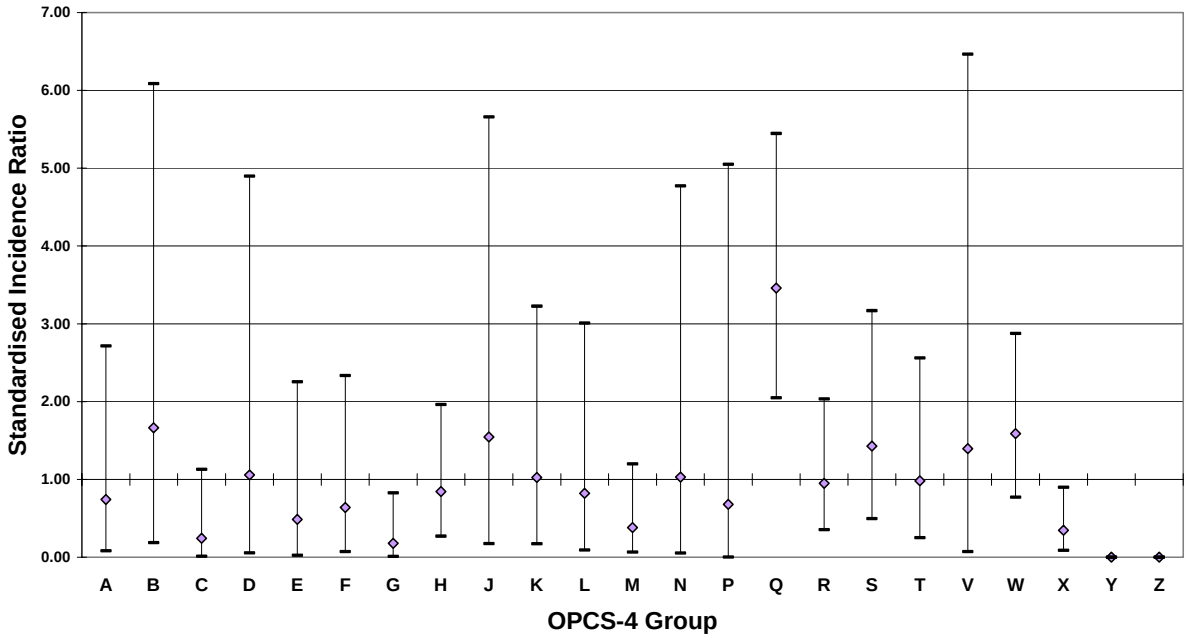


3.6 Standardised incidence ratios of errors by procedure category

Figures 11, 12 and 13 show the standardised incidence ratios of errors in relation to activity rates by OPCS-4 procedure code for the NHSLA, Capsticks and Oxfordshire databases respectively. (Appendix 8 lists the OPCS-4 procedure codes used to facilitate the chart interpretation.)

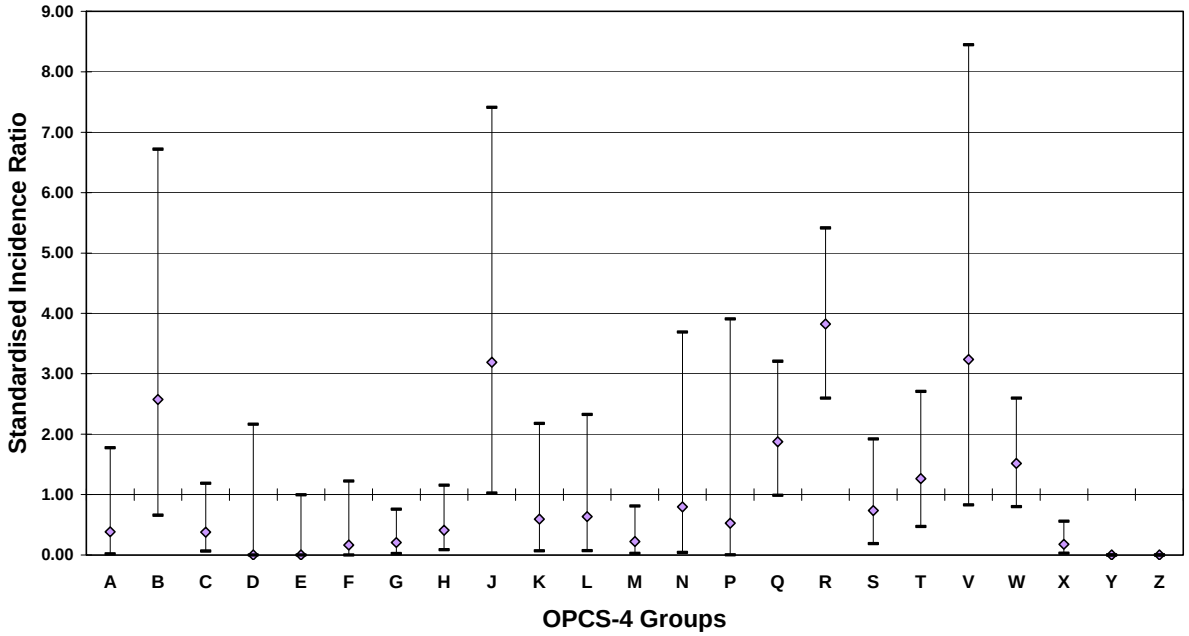
In the NHSLA database (Figure 11), the only OPCS-4 category with a standardised incidence ratio of error significantly greater than 1 is category Q Upper Female Genital tract (SIR 3.5, 99% c.i. 2.0, 5.4).

Figure 11: Standardise incidence ratios of error in relation to national activity rates by OPCS-4 procedure code for the NHSLA database



In the Capsticks database (Figure 12), three OPCS-4 categories have a standardised incidence ratio of error significantly greater than 1: category Q Upper Female Genital tract (SIR 1.9, 99% c.i. 1.0, 3.2), category J Other Abdominal Organs (SIR 3.19, 99% c.i. 1.0, 7.4) and category R Female genital tract Associated with Pregnancy (SIR 3.8, 99% c.i. 2.6, 5.4).

Figure 12: Standardised incidence ratio of error in relation to national activity rates by OPCS-4 procedure code for the Capsticks database



Finally, in the Oxfordshire database (Figure 13), two OPCS-4 categories have a standardised incidence ratio of error significantly greater than 1: category J Other Abdominal Organs (SIR 3.0, 99% c.i. 1.0, 6.7), and category V Bones and Joints of Skull and Spine (SIR 5.9, 99% c.i. 2.5, 11.5).

Figure 13: Standardised incidence ratio of error in relation to national activity rates by OPCS-4 procedure code for the Oxfordshire database

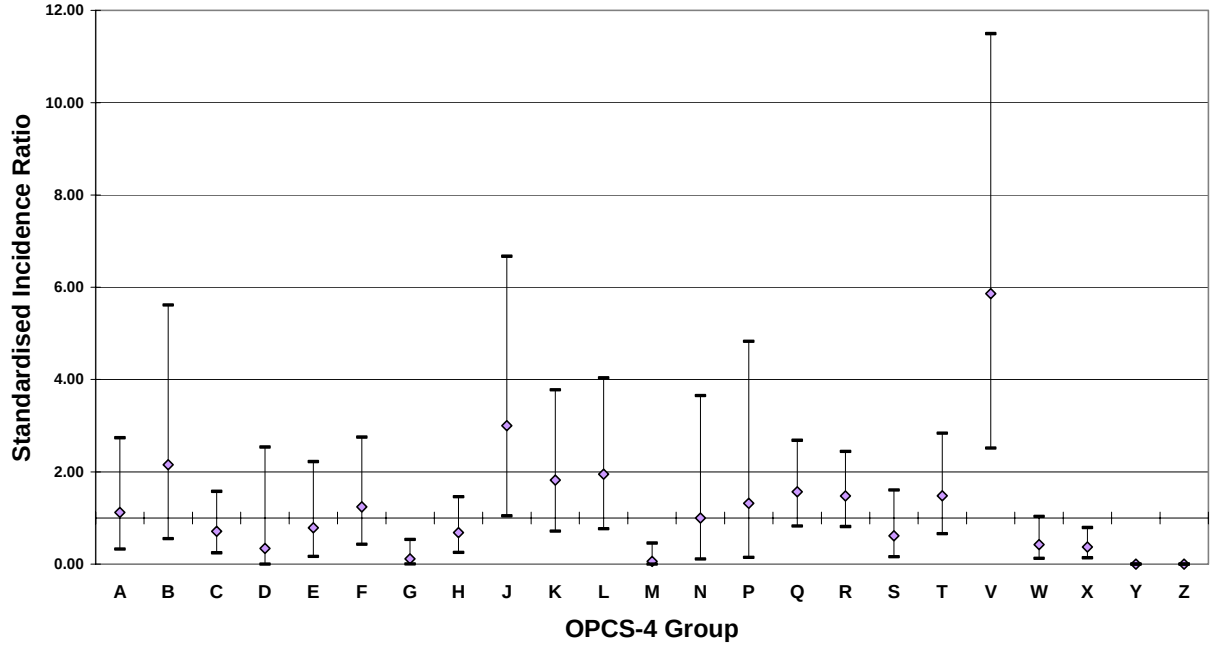
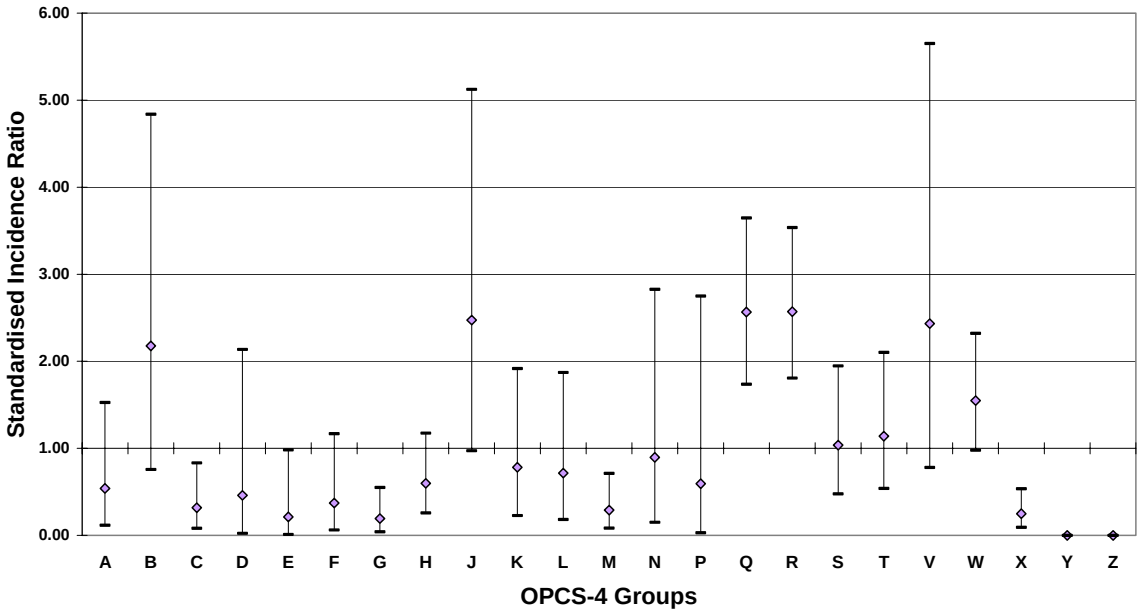


Figure 14 shows relative risk by OPCS-4 code for the two national secondary care databases combined. The two categories significantly above 1 are category Q Upper Female Genital tract (SIR 2.6, 99% c.i. 1.7, 3.7), and category R Female genital tract Associated with Pregnancy (SIR 2.6, 99% c.i. 1.8, 3.5).

Figure 14: Standardised incidence ratio of error in relation to national activity rates by OPCS-4 procedure code for the NHSLA and Capsticks samples pooled



3.7 Relative risk of errors by diagnostic and procedure code

The analyses above reported standardised incidence ratio estimates at a relatively high level of aggregration: ICD chapters, OPCS-4 groups, or specialties. However, it is possible that the events of interest to this project are concentrated within these aggregations, and that a more refined level of analysis can precisely identify the specific areas of medical care at particularly high risk of having a medical claim. Consequently, we proceeded to conduct an analysis of standardised incidence ratio at the lowest level of aggregation at which significant numbers of patients had been sampled from the databases: ICD-9 3 digit codes, ICD-10 4 digit codes and OPCS procedure group 4 digit codes. In each case, codes were only selected if at least 5 cases on the ICD codes and 4 cases on the OPCS codes had been recorded in them, and to further increase statistical reliability, analyses were only conducted on the primary care databases (MPS and MDU) combined and the secondary care databases (NHSLA and Capsticks) combined.

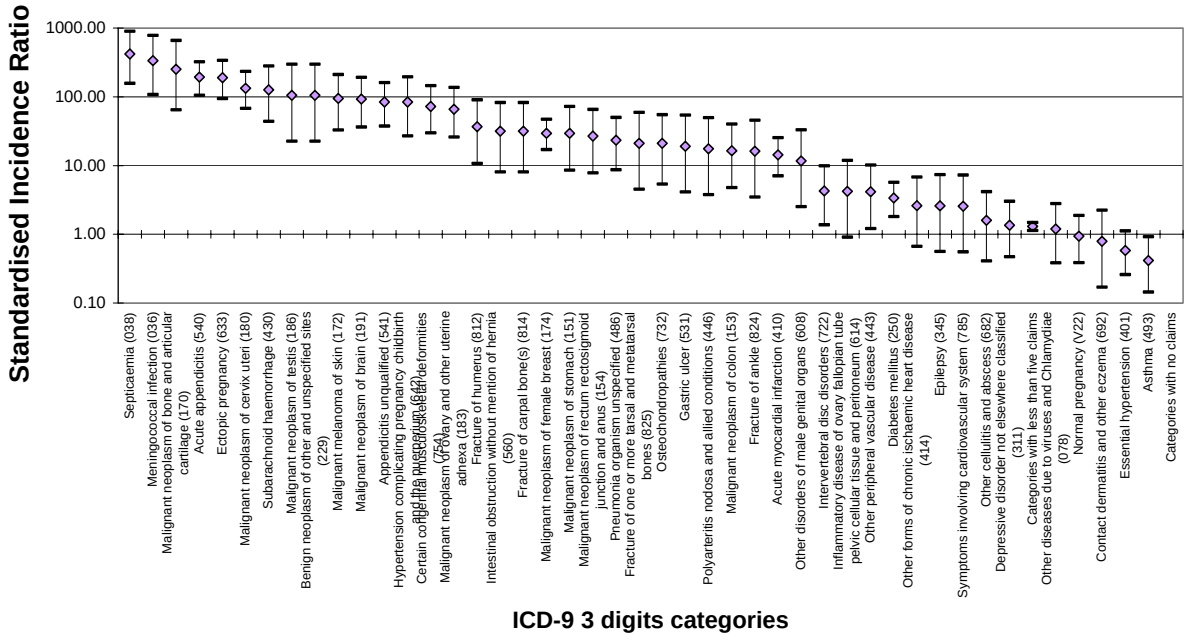
In addition, to minimise the possibility that spurious findings might be generated because of differences in the way cases had been coded at this lower level of aggregation, an attempt was made to remove catch-all categories such as "Other" and "not otherwise specified". For example, in the secondary care analysis the Capsticks and NHSLA database analysis produced substantial numbers of cases assigned to categories such as *O759 Other complications of labour and delivery NEC Complications* from the ICD 4 digits coding and Q279 Open bilateral

occlusion of fallopian tubes unspecified from the OPCS 4 digits coding; these in turn would have produced very high standardised incidence ratios because national hospital statistics made less use of such catch-all categories, suggesting a spurious excess error rate. Such categories were therefore excluded as far as possible form analysis. Standardised incidence ratio and associated confidence intervals were then calculated and ranked in descending order. The figures show the results on a log scale of standardised incidence ratio to facilitate presentation.

3.7.1 Primary care databases

Figure 15 shows the standardised incidence ratio of errors in relation to national activity rates recorded in the 4th general practice morbidity survey by ICD-9 3 digits for the pooled MDU and MPS primary care databases.

Figure 15: Standardised incidence ratio of errors in relation to national activity rates recorded in the 4th general practice morbidity survey by ICD-9 3 digits for the pooled MDU and MPS primary care databases.



A large number of categories present standardised incidence ratio significantly greater than 1. *Septicaemia (038)* and *Meningococcal infection (036)* show the highest standardised incidence ratio among these categories. Two categories present standardised incidence ratio significantly smaller than 1, *Essential hypertension (401)* and *Asthma (493)*. In terms of absolute number of claims, *Acute appendicitis (540)* and *Malignant neoplasm of female breast (174)* show the highest figures with 23 and 28 claims respectively.

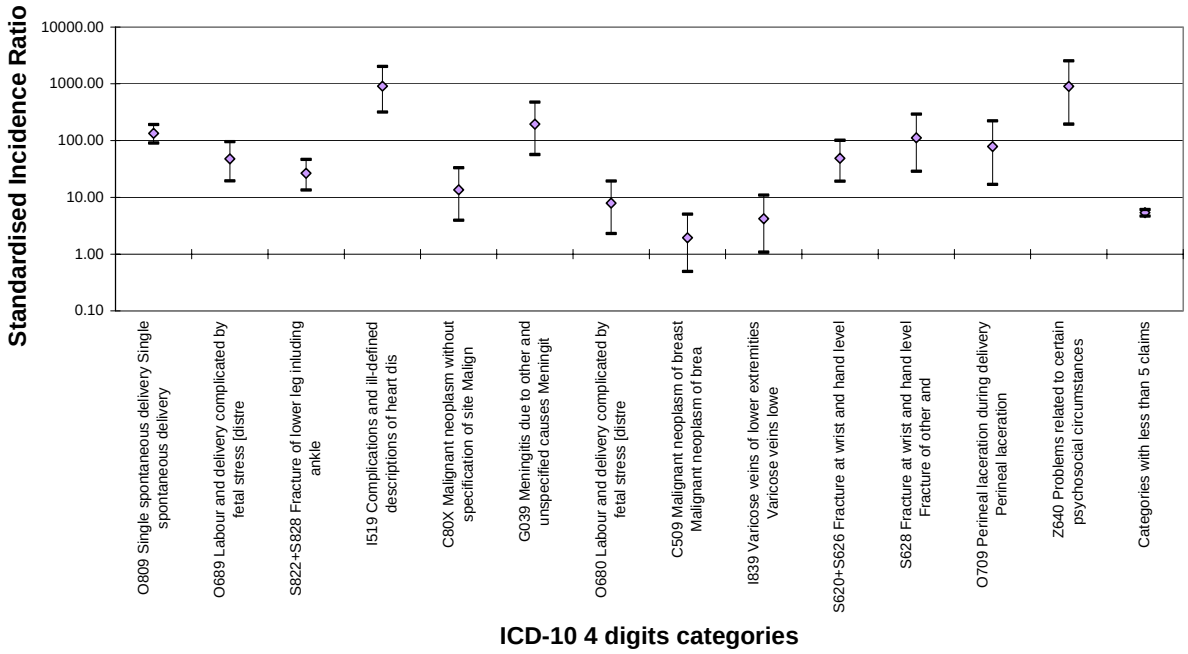
3.7.2 Secondary care databases

As mention above, a coding system for the data provided by the NHSLA and Capsticks was developed. In both cases, the ICD-10 codes for the presenting disease and the OPCS-4 codes for

the procedure were used for each claim. Four digits categories were identified to allow detailed comparison between the databases and the national activity rates.

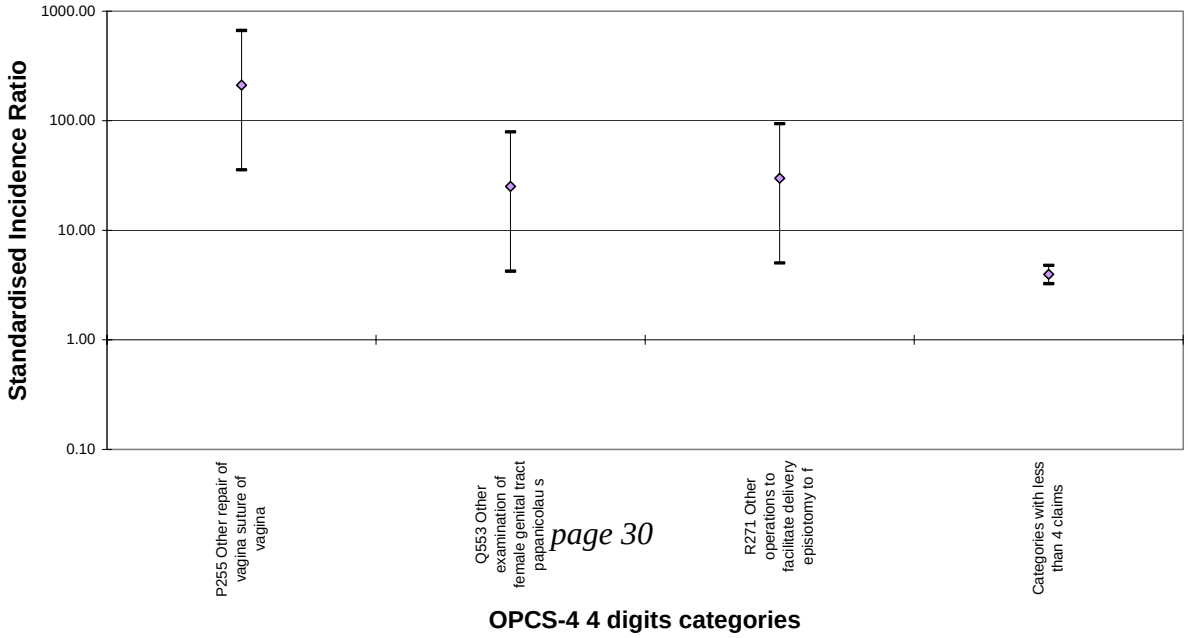
Figures 16 and 17 show the standardised incidence ratio of errors in relation to activity rates by ICD-10 4 digits and OPCS-4 4 digits for the secondary care databases NHSLA and Capsticks combined.

Figure 16: Standardised incidence ratio of errors in relation to national activity rates recorded in HES by ICD-10 4 digit codes for the pooled NHSLA and Capsticks secondary care databases.



In Figure 16, all the categories have a standardised incidence ratio significantly greater than 1 except *C509 Malignant neoplasm of breast* and *I839 Varicose veins of lower extremities*.

Figure 17: Standardised incidence ratio of errors in relation to national activity rates recorded in HES by OPCS-4 4 digit codes for the pooled NHSLA and Capsticks secondary care databases.



Only one category in figure 17 presents a standardised incidence ratio significantly greater than 1, *P255 Other repair of vagina suture of vagina*, and again this was a remaining "other" category which may be particularly prone to the generation of spurious results.

Finally, to repeat a warning made in a number of places throughout this report, the approach we have adopted does provide the possibility of identifying areas of above average and below average risk, but at present is also susceptible to generating results that are artefacts of the way in which data have been collected and coded. Improvements in the coding systems across the databases would be needed to achieve reliable answers. Therefore the results presented in this section of the report must be read with some caution.

4. Conclusions and policy implications

It has been recognised for some time within the NHS that the quality of patient-based information is of primary importance. Accurate information is vital for patient care, for planning and managing services efficiently, and for accountability. Modern clinical practices mean that patients are often cared for by large teams, so it is important that decisions are based on a common, reliable database. Coded data allows statistical analysis to take place, which is essential when identifying high risk areas within healthcare.

Outside the NHS, medico-legal organisations also have access to patient-based information, when dealing with litigation claims made against hospitals. By their nature, negligence claims are potentially good indicators of high-risk areas within healthcare. However, the data collected by medico-legal organisations are typically obtained with a view to monitoring the litigation process, and not for coding purposes to enable statistical analysis. In this phase of our study we have attempted to explore the possibilities for the latter.

Some features of the approach clearly warrant further research: for example we have assumed that missing data (for example, cases excluded because of incomplete data) are missing at random, but it is quite possible that this is not the case. There may well be other biases present in the reported data. It would also be of interest to extend the analyses in certain ways: for example, to consider the actual and expected costs by specialty or procedure associated with negligence cases. The potential association between litigation and mortality rates within or following hospital stays would also repay further investigation.

In general, the statistical results outlined above show that it is possible to obtain statistically valid findings on the areas of medicine which are most prone to adverse events leading to allegations of clinical negligence. The overall findings are, on the whole, unsurprising and predictable given the level of aggregation necessitated in our study. However, we would argue that they should be seen as part of a demonstration project; if coding was undertaken systematically for large numbers of claims across all available databases, the results would be statistically more robust and informative. In particular, it would be possible to make statistically valid estimates of relative risk at a much more disaggregated level due to the effect of increased numbers. Consequently, it could emerge that specific procedures involved in treating specific conditions were responsible for more complaints and claims than might be expected, and this could trigger a clinical review of practice. The same could of course be done for error types and outcomes of errors if similar hierarchical coding systems were developed and adopted nationally. We believe the benefits from developing such systems could be substantial.

Our study therefore suggests a need to develop a common minimum data set of information on cases of clinical negligence. It would be the responsibility of different agencies working in the area to agree such a common data set, perhaps under the overall direction of a national agency such as the National Patient Safety Agency. The common data set would clearly entail use of an agreed standard approach to the coding of diagnoses, procedures, specialties, errors, causes of error and outcome of error, and the evidence presented above suggest that this could be based largely on coding frames already in use in some organisations.

In terms of the lessons to be drawn from our exercise about the practicality of any future work of this nature, the first point to emphasise is that within hospitals there is normally a good link between clinical and administrative systems. However within medico-legal organisations there has previously been very little emphasis on data being assessed in a clinical format suitable for coding. Recommendations as to how medico-legal organisations can formulate databases so that it is clinically documented could be derived from guidelines set down in hospitals. Medico-legal organisations could adopt national coding guidelines (ICD and OCPS-4). However, the organisations can only provide accurate, complete and legible data if they themselves have been provided with accurate patient-based information. So whilst improvements can be made to further the reliable use of databases for coding purposes from medico legal organisations, this also implies that the NHS that has to ensure that the staff involved have received the necessary training and are equipped and supported properly.

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Appendices

Appendix 1: Specialty codes used by Department of Health (England), Hospital Episode Statistics - 2000/01

Not known
100 General surgery
101 Urology
110 Trauma & orthopaedics
120 Ear, nose & throat
130 Ophthalmology
140 Oral surgery
141 Restorative dentistry
142 Paediatric dentistry
143 Orthodontics
150 Neurosurgery
160 Plastic surgery
170 Cardiothoracic surgery
171 Paediatric surgery
180 Accident & emergency
190 Anaesthetics
191 Pain Management
300 General medicine
301 Gastroenterology
302 Endocrinology
303 Haematology
304 Clinical physiology
305 Clinical pharmacology
310 Audiological medicine
311 Clinical genetics
313 Clinical immunology & allergy
314 Rehabilitation
315 Palliative medicine
320 Cardiology
330 Dermatology
340 Thoracic medicine
350 Infectious diseases
360 Genito-urinary medicine
361 Nephrology
370 Medical oncology
371 Nuclear medicine
400 Neurology
401 Clinical neuro-physiology
410 Rheumatology
420 Paediatrics
421 Paediatric neurology
430 Geriatric medicine

450 Dental medicine
460 Medical ophthalmology

501 Obstetrics for patients using a hospital bed or delivery fcilts. only
502 Gynaecology
560 Midwife Episode
610 General practice - with maternity function
620 General Practice - other than maternity
700 Mental handicap
710 Mental illness
711 Child & adolescent psychiatry
712 Forensic psychiatry
713 Psychotherapy
715 Old age psychiatry
800 Clinical oncology, alias radiotherapy
810 Radiology
820 General pathology
821 Blood transfusion
822 Chemical pathology
823 Haematology
824 Histopathology
830 Immunopathology
831 Medical microbiology
832 Neuropathology
900 Community medicine
901 Occupational Medicine

Appendix 2: Primary care error codes used in study

Code	Error description
	Anaesthetic
1	Inadequate pain relief used during a procedure
	Communication errors
2	Failure to inform patient of abnormal test results
3	Abnormal test results given to healthy patient
	Delivery
4	Delayed delivery
5	Failure to monitor labour/act upon complications during labour
6	Insufficient pain relief during delivery
7	Negligence during delivery not specified
	Dental
8	Damage to teeth during a procedure
	General errors
9	Breakage of equipment injuring patient
10	Burn caused by preparatory agent
11	Delay in hospital admission
12	Delay/failure to treatment
13	Deprivation of oxygen
14	Failure/delay in diagnosis
15	Failure/delay in diagnosing fracture
17	Failure/delay in arranging an appointment
18	Failure to act upon abnormal findings
19	Failure to arrange x-ray/scan
20	Failure to diagnose likelihood of self-harm
21	Failure to obtain patient's/parent's consent
22	Failure to monitor condition
23	Failure/refusal/delay in referral
24	Failure/refusal to treat/visit/examine
25	Failure to recognise complication of treatment
26	Failure to refer to patient's medical records/history
27	Failure to warn patient of potential complications
28	Foreign body left in situ following a procedure
29	Improper delegation to nursing staff
30	Inadequate medical records
31	Inappropriate/inadequate examination
32	Inappropriate/inadequate treatment
33	Injury, pain and suffering caused by injection
34	Lack of adequate facilities/equipment
35	Misdiagnosis of condition
36	Poor suture of wound/tear
37	Poor sterilisation of wound/tear
38	Premature cessation of treatment
39	Unintentional puncture or laceration during procedure
40	Retained swab

41	Unsatisfactory performance of a procedure
42	Unsterilised equipment used during a procedure
	Gynaecology
43	Failure to recognise complication associated with IUD
44	Failed sterilisation
45	Inappropriate contraceptive advice
	Medication errors
46	Failure to warn/recognise side effects of drug
47	Incorrect/inappropriate dosage of medication prescribed/administered
48	Medication inappropriately prescribed
49	Medication inappropriately administered
	Pregnancy errors
50	Failure to diagnose complications in pregnancy
51	Failure to remove IUD
	Post procedural errors
52	Failure to diagnose complication following a surgical procedure
53	Failure to provide adequate follow-up care
54	Inappropriate post-procedural medication

Appendix 3: Secondary care error codes used in study

Code	Error description
	Accident & Emergency
1	Failure/delay to diagnose fracture
2	Incorrect level of anaesthesia administered
3	No anaesthetic used during a procedure
	Communication errors
4	Failure to inform patient of abnormal test results
5	Abnormal test results given to healthy patient
6	Communication error between medical staff causing adverse event
	Delivery
7	Burn caused by preparatory agent during delivery
8	Damage caused by forceps/ventouse
9	Delayed delivery
10	Failure to monitor labour/act upon complications during labour
11	Failure to remove products of conception
12	Incorrect administration of epidural
13	Insufficient pain relief during delivery
14	Negligence during delivery not specified
	Dentistry
15	Extraction of wrong tooth/teeth
	General errors
16	Blood transfusion errors
17	Breakage of equipment injuring patient
18	Burn caused by preparatory agent
19	Injury to bone, muscle, ligaments during a procedure
20	Injury caused during oral intubation
21	Delay in treatment
22	Deprivation of oxygen
23	Failure/delay to diagnose
24	Failure to obtain patient's/parent's consent
25	Failure/refusal to refer
26	Failure/refusal to treat
27	Failure to refer to patient's history
28	Failure to warn patient of potential complications
29	Foreign body left in situ following a procedure
30	Improper delegation to junior staff
31	Inadequate intra-operation monitoring
32	Inappropriate dosage/administration of radiotherapy
33	Inappropriate treatment
34	Infected with virus during procedure
35	Misdiagnosis of condition

36	Operation on wrong body part
59	Operation on wrong patient
37	Poor suture of wound/tear
38	Poor sterilisation of wound/tear
39	Premature cessation of treatment
40	Puncture or laceration of organ or tissue during a procedure
41	Retained swab
42	Unsatisfactory performance of a procedure
43	Unsterilised equipment used during a procedure
	Gynaecology
44	Failure to recognise complication associated with IUD
45	Failed sterilisation
46	Inappropriate contraceptive advice
	Medication errors
47	Incorrect dosage of medication prescribed/administered
48	Medication inappropriately prescribed/administered
	Pregnancy errors
50	Failed abortion
51	Failure to diagnose complications in pregnancy
52	Failure to remove IUD during pregnancy
	Post procedural errors
53	Failure to administer the correct level of anti-coagulant
54	Failure to diagnose complication following a procedure
55	Failure to provide adequate follow-up care
56	Inadequate/inappropriate post-procedural care
57	Inappropriate post-procedural medication
58	Insufficient pain relief following a procedure

Appendix 4: Primary care outcome codes used in study

Code	Outcome description
	General outcomes
1	Abscess
2	Addiction
3	Amputation of limb
4	Anaemia
5	Anaphylactic shock/allergic shock/allergy
6	Aneurysm
7	Arterial damage
8	Behavioual disorder
9	Blood clotting
10	Brain damage
11	Bruising
12	Burn of multiple and unspecified sites
13	Cancer
14	Cardiac arrest
15	Cardiovascular condition
16	Chest infection/problems
18	Colostomy bag
19	Coma
20	Complications with breathing
21	Cosmetic disfigurement
22	Damage to digestive system
23	Damage to eye/s
24	Damage to face
25	Damage to fallopian tube/s
26	Damage to joint/muscle/ligaments
27	Damage to ovary/ies
28	Damage to spine/spinal cord
29	Damage to teeth/tooth N.S
30	Damage to testicle/s
31	Damage to vocal cords
32	Damage to womb
33	Death
34	Depression
35	Deterioration in clinical condition
36	Deterioration in organ function
37	Diarrhoea/vomitting
38	Disability
39	Drainage of fluid
40	Drowsiness, lethargy, fatigue
41	Emotional/psychological damage
42	Emphysema
43	Epileptic fit/epilepsy
44	Fall from bed
45	Fistula
46	Foot drop
47	Haemorrhage
48	Hallucinations
49	Hernia
50	Hospital admission
51	Impaired/total loss of hearing

52 Impaired/total loss of vision
53 Incontinence
54 Infertility
55 Internal bleeding
56 Jaundice
57 Kidney stone
58 Limb deformity
59 Loss of hair
60 Loss of sexual function
61 Mastectomy
62 Menstrual irregularity
63 Nerve damage
64 Numb limbs following procedure
65 Numbness to face/mouth
66 Osteoporosis
68 Panic attacks
69 Paralysis of face
70 Paralysis of other body parts
71 Paraplegia
72 Perineal tear
73 Pneumonia
74 Psychotic episode
75 Quadriplegia/tetraplegia
76 Removal of swab/foreign body left in situ
77 Renal damage/failure
78 Scarring
79 Speech impediment
81 Stroke
82 Suicide
83 Swelling
84 Tissue damage
85 Unnecessary investigations
86 Unnecessary pain
87 Weight gain/loss

Surgical/medical procedures

88 Appendicectomy
89 Biopsy/bone biopsy
90 Brain surgery
91 Chemotherapy
92 Excision of neoplasm
93 Exploratory/access incision surgery
94 Hysterectomy
95 Open reduction/ internal fixation
96 Organ transplant
97 Radiotherapy
98 Repair of ligament/muscle
99 Surgical excision of organ
100 Surgical excision of reproductive organs
101 Surgical reconstruction
102 Suture of wound/tear/rupture

Pregnancy/birth related outcomes

103 Abortion
104 Cerebral palsy
105 Developmental/chromosomal abnormality
106 Downs syndrome

107	Ectopic pregnancy
108	Erb's Palsy
109	Facial palsy
110	Flat baby
111	Miscarriage
112	Newborn with infectious disease
113	Pregnancy
114	Premature birth
115	Spina Bifida
116	Stillbirth
117	Wrongful birth (as result of failed sterilisation)
	Infection related outcomes
118	Complication of the skin and subcutaneous tissue
119	Contraction of infectious diseases
120	Infection of -internal/external
121	Inflammation of organ/tissue
122	Re-opening of wound-internal/external
	Miscellaneous outcomes
123	Blood transfusion needed
124	Extended healing/rehab period
125	Injury resulting from procedure
126	Pacemaker installation

Appendix 5: Secondary care outcome codes used in study

Code	Outcome description
	General outcomes
1	Abscess
2	Amputation of limb
3	Anaphylactic shock/allergic shock/allergy
13	Aneurysm
5	Arterial damage
6	Blood clotting
7	Brain damage
8	Bruising
9	Burn of multiple and unspecified sites
10	Cancer
11	Cardiac arrest
12	Cardiovascular condition
14	Change in personality/behaviour
15	Colostomy bag
16	Other complications of surgical/medical care
17	Complications with breathing
18	Cosmetic disfigurement
19	Damage to bile duct
20	Damage to bladder
21	Damage to bowel
22	Damage to cervix
23	Damage to digestive system
24	Damage to eye/s
25	Damage to face
26	Damage to fallopian tube/s
118	Damage to gall bladder
28	Damage to kidney/s
119	Damage to liver
29	Damage to lung
120	Damage to organ/tissue
30	Damage to ovary/ies
31	Damage to teeth/tooth N.S
32	Damage to testicle/s
115	Damage to ureter
33	Damage to vocal cords
34	Damage to womb
35	Death
36	Disability

37 Emotional/psychological damage
39 Epileptic fit/epilepsy
40 Fall from bed
27 Fatigue
41 Fistula
42 Foot drop
44 Haemorrhage
45 Hallucinations
46 Hernia
47 Hysterectomy
48 Impaired/total loss of hearing
49 Impaired/total loss of vision
51 Incontinence
91 Infertility
52 Internal bleeding
116 Jaundice
53 Limb deformity
54 Loss of sexual function
55 Mastectomy
56 Nerve damage
57 Numb limbs following procedure
58 Numbness to face/mouth
122 Paralysis of face
59 Paralysis of other body parts
60 Paraplegia
61 Perineal tear
62 Pneumonia
63 Pressure/bed sores
64 Quadriplegia/tetraplegia
65 Removal of appendix
66 Removal of bladder
67 Removal of cervix
68 Removal of fallopian tubes
69 Removal of kidney
70 Removal of lung
71 Removal of testicle/s
72 Renal damage/failure
73 Scarring
74 Speech impediment
75 Spinal damage
76 Stroke
77 Suicide
78 Swelling
80 Tissue damage

81	Unnecessary pain
82	Weight gain/loss
83	Worsened condition
	Pregnancy/birth related outcomes
84	Abortion
85	Cerebral palsy
86	Developmental/chromosomal abnormality
87	Downs syndrome
88	Erb's Palsy
89	Facial palsy
90	Flat baby
117	Miscarriage
92	Spina Bifida
93	Stillbirth
94	Wrongful birth (as result of failed sterilisation)
	Fractures/dislocation and sprain outcomes
95	Damaged joint
97	Fracture-face/head
98	Fractured limb
99	Fractured spine
100	Poor outcome of procedure
101	Strain/pulled muscle
	Infection related outcomes
102	Complication of the skin and subcutaneous tissue
106	Contraction of infectious diseases
107	Infection of -internal/external
108	Inflammation of organ/tissue
109	Re-opening of wound-internal/external
	Miscellaneous outcomes
110	Blood transfusion needed
111	Extended healing/rehab period
112	Need for further surgery/treatment
113	Organ transplant
114	Pacemaker installation

Appendix 6: International Classification of Diseases 9 (ICD-9) by chapters.

	ICD-9 Chapters
I	Infectious and parasitic diseases
II	Neoplasm
III	Endocrine, nutritional and metabolic diseases and inmunity disorders
IV	Diseases of the blood &blood forming organs
V	Mental disorders
VI	Diseases of the nervous system and sense organs
VII	Diseases of the circulatory system
VIII	Diseases respiratory system
IX	Diseases of the digestive system
X	Diseases of the genito-urinary system
XI	Complications pregnancy, childbirth and pueperium
XII	Diseases of the skin and subcutaneous tissue
XIII	Diseases of the musculoskeletal system and cognitive tissue
XIV	Congenital Anamolies
XV	Certain conditions originating in the perinatal period
XVI	Symptoms, signs and ill-defined conditions
XVII	Injury and poisoning
XVIII	Supplementary Classification of factors ingluencing health status and contact with Health Services

Appendix 7: International Classification of Diseases 10 (ICD-10) by chapters.

I	Certain infectious and parasitic diseases
II	Neoplasm
III	Diseases of the blood &blood forming organs & inmune system
IV	Endocrine, nutritional and metabolic diseases
V	Mental and behavioural disorders
VI	Diseases of the nervous system
VII	Diseases of the eye and adnexa
VIII	Diseases of the ear and mastoid process
IX	Diseases of the circulatory system
X	Diseases of the respiratory system
XI	Diseases of the digestive system
XII	Diseases of the skin and subcutaneous tissue
XIII	Diseases of the musculoskeletal system and cognitive tissue
XIV	Diseases of the genitourinary system
XV	Pregnancy, childbirth and pueperium
XVI	Certain conditions originating in the perinatal period
XVII	Congenital malformations, deformations & chromosomal deformities
XVIII	Symptoms, signs and abnormal clinical & laboratory findings NEC
XIX	Injury, poisoning and certain other consequences of external causes
XX	External causes of morbidity and mortality
XXI	Factors affecting health status and contact with health services

Appendix 8: Office of Population, Censuses and Surveys Classification of Surgical Operations and Procedures - 4th revision (OPCS-4)

	OPCS-4 Groups
A	Nervous System
B	Endocrine System and Breast
C	Eye
D	Ear
E	Respiratory Tract
F	Mouth
G	Upper Diggestive Tract
H	Lower Digestive Tract
J	Other Abdominal Organs
K	Heart
L	Arteries and Veins
M	Urinary
N	Male Genital Organs
P	Lower Female Genital Tract
Q	Upper Female Genital tract
R	Female genital tract Associated with Pregnancy…
S	Skin
T	Soft Tissue
V	Bones and Joints of Skull and Spine
W	Other bones and Joints
X	Miscellaneous operations
Y	Subsidiary Classification of methods of operations
Z	Subsidiary classification of sites of operation

Appendix 9: Coding procedures in each database.

Primary care databases (MDU, MPS)

In the primary care databases alleged errors were categorised into four main groups:

1. Allegations made about the quality of care eg: a treatment given to a patient that resulted in damage being caused to the patient or negative side effects of a treatment.
2. Allegations made about the timeliness of care eg: the failure to diagnose a condition or failure/delay in referring them to a specialist or hospital.
3. Misdiagnosis of a condition eg: diagnosing a patient as having condition A when they have condition B.
4. Medication errors eg: prescribing a patient with the wrong drug, failing to recognise side effects of drug etc.

Errors associated with the quality of care
Cases where the GP was alleged to have been negligent in the administration of a treatment were assigned an error code from the pre-determined list. The framework applied to such cases was the same as for the majority of negligence cases in secondary care. The presenting disease or condition was the disease/condition for which the associated treatment was alleged to have been negligent. In some cases more than one disease or condition may have been recorded. This was the case when the alleged negligent treatment was for the simultaneous management of more than one disease/condition. Likewise more than one negligent treatment may have been recorded.

Timeliness of care
A large number of allegations related to the timeliness of treatment, rather than the quality of care. For these types of claims the presenting condition was recorded as the condition/disease for which the patient alleged that the speed of care was not satisfactory. For example, the GP may have failed to recognise the signs of an ectopic pregnancy or alternatively he/she may have failed to diagnose meningitis. In these examples ectopic pregnancy and meningitis would be recorded in the presenting condition column.

Since the allegations related to the timeliness of care, rather than the quality of care we were not concerned with recording information on the 'eventual treatment'. Therefore, for such claims the treatment column was completed as none.

Misdiagnosis
This error occurred when a GP had wrongly diagnosed a condition resulting in unnecessary treatment, or subsequent treatment not being administered due to failure to note the seriousness of condition. Such cases were presented with the actual disease (even if doctor had not recognised it) being recorded in the presenting disease column and the 'diagnosed disease' in the misdiagnosed column. For example if a patient had a brain tumour but the doctor diagnosed them as having migraines, migraines was entered into the misdiagnosed column and brain tumour into presenting disease. Both the actual and misdiagnosed diseases were recorded, as it will help to show any similarities between conditions that are frequently mistaken for each other. In most misdiagnosed cases the treatment was recorded as none or not specified N.S. as the

source of error was not surrounding treatment given but due to an incorrect diagnosis being made leading to serious implications.

Medication errors
Where medication was the only treatment offered to a patient and this was alleged to have been negligent this was recorded as follows:

M-Y43.6

(M) shows that the treatment is medication
Y43.6 is the code for the medication taken from ICD 10 (table of drugs and chemicals). If no code exists then the name of the medication was recorded instead.

The drug type was also recorded and the alleged error code was always coded as a medication related error.

Post surgical care
In some cases when a patient visits a doctor following surgical/hospital treatment post surgery is recorded in the presenting disease column as often the initial disease/condition for which the treatment was for is not specified and the cause of error is related to post surgical care.

Vaccines and routine contraception

When a patient has made a claim surrounding a vaccine jab or routine contraception given by the doctor/nurse the presenting disease is recorded as none. These cases are highlighted as the drug type is specified (vaccine or oral contraceptive).

Outcome

The consequence of the alleged negligence was recorded in the outcome column. This outcome is the final state/condition in which the patient was left. For example, if a GP failed to diagnose meningitis and the patient had to receive emergency hospital treatment and their condition deteriorated and finally resulted in death, death was the outcome recorded rather than hospital admission or deteriorated clinical condition.

The status of the claim was recorded as open or closed.

Damages

For closed claims, the total of any damages awarded to the patient was recorded. For open claims, the reserve amount was recorded.

Date of claim

This was recorded as the date that the relevant organisation received notification of the patient's intention to pursue financial compensation for an alleged adverse event.

Secondary care databases (NHSLA, Oxford, Capsticks)

In the secondary care databases the information surrounding negligent claims was sorted primarily under 5 main headings
1.Presenting disease/condition
2.Treatment
3. Alleged error
4.Outcome
5.Status of claim

Presenting diseases or conditions

A patient may have received treatments for numerous diseases or conditions during one episode of health care. The presenting disease/condition recorded was always the one associated with the treatment that was alleged to be negligent.

Where the alleged negligent treatment was for the simultaneous management of more than one disease/condition then all of the diseases/conditions were recorded.

Some conditions employ a dual coding system. Where this was the case the two codes were treated as one code, according to ICD 10 coding guidelines, and entered into column one together (see example 1)

Example 1.

Presenting disease/condition 1	PD/C 2
A39.0+ G01 (Meningococcal meningitis)	

For obstetric claims where the labour was assisted e.g. forceps, ventouse delivery, but the mother or foetus' condition was not mentioned it was assumed that a complication had occurred. Therefore in these cases O75.9 (complication of labour and delivery N.S) was recorded as the presenting condition.

Treatments

During an episode of health care a patient may receive several treatments for the management of a disease/condition. The treatment column includes information of only the alleged negligent treatment. All other treatments patients received were deemed to be irrelevant, regardless of the quantity of resources they utilised.

Sometimes a patient alleged that they received multiple negligent treatments. Where this occurred all the allegations of negligent treatments were recorded in the treatment columns. In order to be able to identify the error attached to each treatment, T1, T2, or T3 were recorded after the error codes. See Example 2.

Example 2

Treatment 1	Treatment 2	Treatment 3	Alleged Error 1	Alleged Error 2
Excision of lesion of breast	Reconstructive surgery		Incomplete excision (T1)	Unsatisfactory performance (T2)

Where medication was the only treatment offered to a patient and this was alleged to have been negligent the code M was placed before the drug code to highlight it as a medication case (see example 3).

Example 3.

Treatment 1	Treatment 2
M-Y43.6	

Y43.6 is the code for the medication taken from ICD 10 (table of drugs and chemicals). If no code existed then the name of the medication was recorded.
Medication administered following a procedure was treated as a post-procedural error, see example 5.

Alleged errors

A code for the alleged error, extracted from a list of error code descriptions, was allocated to each claim.

If a patient claimed that more than one error had taken place, each resulting in a different outcome, the codes E1,E2 and E3 were assigned after the relevant outcomes signifying which outcome related to each error.

Sometimes patients claimed that a negligence act occurred following, rather than during, a procedure. For such cases a list of post-procedural error codes were devised. Treatments that patients had received, though not alleged to have been negligent, were recorded as usual. For example if a patient went into hospital to have their impacted wisdom teeth removed and then fell from their bed in the recovery room resulting in them fracturing their spine the information would be coded as shown in example 4.

Example 4

Presenting condition/disease	Treatment	Error	Outcome 1	Outcome 2
Impacted wisdom teeth	Removal of impacted wisdom teeth	Inadequate/ Inappropriate post procedural care	Fall from bed	Fractured spine

Where negligence was alleged to have occurred following a procedure in the form of medication given to a patient the information was recorded as shown in the example below.

Example 5

A patient with coronary heart disease had heart bypass surgery on day 1. On day 2 the consultant prescribed Warfarin, an anti-coagulant drug. The patient subsequently had an embolism and died. The patient's family alleged that the level of Warfarin was insufficient and that this had caused the patient's death.

Presenting cond./disease	Treatment 1	Treatment 2	Error	Outcome
Coronary heart disease	Heart bypass surgery	M-Y44.2	Failure to administer the correct level of anti-coagulant (T2)	Death

There were several cases of undiagnosed fractures, particularly in A&E. These were treated separately to other cases of failure/delayed diagnosis and were assigned a unique code specifically related to fractures.

Claims where the negligence related to a delay in treatment were assigned a different error code to those alleging a 'failure to treat'. The treatment column for such claims was filled in as NONE since the allegation was not surrounding the quality of treatment, moreover the timeliness.

Cases where a patient alleged that the medical staff's decision not to offer treatment was unwarranted were coded as a failure or refusal to treat. Again the treatment column was filled in as NONE since this was not relevant.

Claims relating to a hospital's failure to diagnose a condition often specified that the hospital had either completely failed to diagnose a condition (which was diagnosed elsewhere) or that the hospital had merely delayed the diagnosis. For the purpose of this study such cases were grouped together under the error code, failure/delay in diagnosis. This is because it was often impossible to ascertain from the case notes whether a hospital had completely failed to diagnose a condition or merely caused a delay in the diagnosis of a condition.

Codes of *misdiagnosed condition* related to cases where a patient had been diagnosed as having disease/condition A when in fact they had condition B. In such cases the presenting disease/condition recorded was always the misdiagnosed condition, eg: If a patient had irritable bowel syndrome but was diagnosed by the hospital as having bowel cancer the presenting disease recorded was bowel cancer. To highlight the case as an error of misdiagnosis the presenting disease code was preceded by the code MD.

Infections

Allegations levied by patients that they were infected with a virus during a procedure were assigned error code 34, (infected with virus during a procedure). The outcome code attached to

such claims was 106, contraction of infectious diseases, followed by the name of the disease, e.g. 106-Hepatitis.

Some patients alleged that they received negligent treatment for the sterilisation of wounds, which had subsequently resulted in an infection. Such claims were allocated error code 38, (poor sterilisation of wound) and were usually assigned injury code 107, (infection – internal/external).

Cases where a patient alleged that they had contracted an infection to a post surgical wound as a result of negligent care on the ward or subsequent visits to the hospital were assigned error code 56, (Inadequate/inappropriate post-procedural care). The corresponding outcome code was 107, (infection - internal/external).

Finally, cases alleging that a patient had contracted an infectious disease whilst recovering on the ward, i.e. because of a failure to place infectious patients in quarantine, were allocated error code number 56. The outcome code allocated to such claims was 106, followed by the name of the disease, e.g. Meningitis

Outcomes

The consequence of the alleged negligence was recorded in the outcome column. Where multiple consequences existed, all of these were recorded. The status of the claim was recorded as open or closed.

For closed claims, the total of any damages awarded to the patient were recorded. For open claims, any settlements made to date, along with expected future settlement were recorded. The date of the claim was be recorded as the date that the relevant organisation received notification of the patient's intention to pursue financial compensation for an alleged adverse event.