THE UNIVERSITY of MANCHESTER

Patient safety: lessons from litigation

Case studies in litigation: claims reviews in four specialties

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Contents

EXECUTIVE SUMMARY

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

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

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

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

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

This report which is the third report of the Lessons from Litigation project describes the results of the in depth study of claims spanning primary care, medicine and surgery, mental health and obstetrics. The purpose of this stage of the project was to assess the feasibility of whether it was possible to analyse individual medico-legal case reports from a range of specialties – some of which had never been examined in detail before (general practice and mental health). We wanted to assess how easy it was to access the information, what sort of information the case records contained and whether any useful lessons could be learnt from this type of structured analysis.

We therefore sought to examine the potential of reviewing claims documentation for learning meaningful lessons about the cause of adverse events, to draw clinical lessons where possible and to assess the value and feasibility of reviewing the claims data on an ongoing basis. The results have been summarised in the second report. This third report contains the full reports from each of the specialty reviews. The reports therefore contain

a lot more detailed information on the findings relevant to the individual specialties. However, it should be pointed out that this report is very much based on the subjective views of the four specialist reviewers. What their reports show are the richness of the clinical information that can be obtained from a structured analysis of medico-legal case reports and the fact that lessons can be learnt from the scrutiny of these reports. However, the broader question of whether such an investigation is worthwhile is not considered in the individual reports nor is the generalisability of the findings. The reader should therefore read these reports as part of a feasibility study and recognise the limitations of the methods used.

The reviews were carried out by five experienced clinicians, each with medico-legal and research experience. A sample of cases from each of the four specialty areas were reviewed using a standard proforma which is included as Appendix 1. The generic proforma was developed by the modification of review forms from three sources. These included protocols developed from retrospective reviews, review instruments from specialty reviews and from a protocol for the investigation and analysis of clinical incidents. The process is described in detail in the second report.
The claims analysis in this report cover the following areas:

Specialty review	**Specialty reviewer**	**Topic covered**
General Practice	Dr Aneez Esmail	Diabetes, meningitis, cancer of the female genital tract, ischaemic heart disease
Medicine and Surgery	Professor Graham Neale	General medical and surgical cases-missed diagnosis
Mental Health	Professor Jenny Firth Cozens and Caroline Davy	Parasuicide/suicide, Medication errors
Obstetrics	Professor Max Elstein	Shoulder dystocia, cerebral palsy

Each report is a stand-alone document and the reviewers draw conclusion relevant to their own specialty area.

Methods

The process of case selection and the procedures used are summarised in the second report. Primary care cases were obtained from the Medical Protection Society databases. These were cases that had been part of an in house review of a cohort of 1000 claims from July 1996 onwards. Secondary care (obstetric and general medicine/surgery) cases came from Capsticks solicitors. Mental Health involved both primary and secondary care cases and were supplied by Capsticks and the Medical Defence Union.

We aimed to review 50 cases in each specialty. However, many cases did not contain sufficient information for review. This was generally because these cases had not

proceeded to litigation and the file did not contain the expert review that formed the basis of the analysis. We were also limited by the funding that was available. Although we had hoped that we might be able to analyse 50 cases each, it generally took a lot longer than we had estimated and this restricted the number of cases that we could analyse. The only exception was in Medicine and Surgery where the expert reviewer had asked Capsticks to select cases that proceeded to some outcome rather than claims that did not proceed. In this respect, claims for medicine and surgery had been pre-selected and therefore cannot be used to assess the overall usefulness of claims analysis data. This does not affect the analysis of individual claims.

The original purpose of the project was to assess the value and feasibility of reviewing claims data. The advantages and disadvantages of using these data in comparison to other forms of inquiry have been described in detail in the second report. However it is worth noting that the reports in this section represent the subjective views of the assessors. The aim was to assess whether the claims data contained useful information and in that respect, this study represents a feasibility study. We did not set out to assess the reliability of the process nor did we subject the conclusions to independent scrutiny. Ideally, if the process we developed to analyse claims data is to be generalisable then the reviews will need to be assessed by two reviewers. This would introduce an important element of reliability in the process. The conclusions drawn about each case and in particular the potential for learning would also need to be subject to scrutiny by an independent panel in much the same way that some of the confidential inquiries scrutinise the findings obtained from local reports. None of these methods were developed for this study – our brief was interpreted quite narrowly to assess the usefulness of claims data – but not to subject the analysis or our findings to independent review.

Overall conclusions

The nature of claims data and the complexity of the clinical situations that gave rise to the claims, together with the need to assess several expert reports and balance the sometimes differing views expressed by experts made the task of reviewing the cases difficult and time consuming. The richness of the clinical information present is not in doubt but the value of assessing what is in fact historical data is more difficult to judge. This raises the important question of how and if claims data has any role to play in reducing errors and improving the quality of care.

As pointed out in the second report there are now several mechanisms for analysing information from critical incidents. Although not specifically discussed, the Confidential Enquiries are an important mechanism for learning from adverse critical incidents – usually deaths, but more recently their remit has expanded to cover morbidity from specific procedures or interventions. The Confidential Enquires in Maternal and Child Health (CEMACH), the National Confidential Enquiry into Patient Outcome (NCEPOD) and Deaths and the National Confidential Inquiry into Suicide and Homicide by people

with Mental Illness (CISH) are important examples of inquiries into adverse events following specific procedures or events.

CEMACH is the oldest of the confidential enquiries and started in 1952 as the confidential enquiry into maternal deaths. It reported triennially. It was recently combined with the confidential enquiry into sudden deaths in infancy and its remit now covers both infant and perinatal deaths together with maternal deaths.

NCEPOD was originally set up by surgeons and anesthetists to review surgical and anesthetic practice in three regions of the United Kingdom. In 1988 it moved to a national level. Its studies have ranged from measuring the percentage of patients dying within 30 days of surgery to looking at deaths within a specific age range.

The funding of all three Confidential Enquiries has now been taken over by the National Institute for Clinical Excellence and their remit has been expanded. NCEPOD has expanded its remit to cover medical patients and primary care and will not only cover deaths but near misses as well. CEMACH is currently working on developing a new programme of national confidential enquiries on child health and is also carrying out a major investigation into diabetes in pregnancy using case control methodology. CISH will continue to focus on suicides and homicides by people with mental illness.

Both CEMACH and NCEPOD use similar methods for collecting information with local reporters obtaining information using a proforma. The evidence is then collated by locally paid coordinators. The data are then compiled nationally and an independent committee of clinicians reflect on the data and develop recommendations based on the findings. CISH has a three stage process of data collection. Stage 1 requires the collection of a comprehensive national sample, irrespective of mental health history. In Stage 2, individuals within the sample who have been in touch with the mental health services are identified. In stage 3, clinical data is collected about these individuals. On identifying a person who committed suicide and who was in contact with the mental health services, a suicide questionnaire is sent to the consultant with responsibility for the patient who is asked to fill in the questionnaire in consultation with the mental health team. In addition families and other informants are also interviewed in order to corroborate related to the suicide or homicide using a well established technique known as the psychological autopsy method.

What therefore distinguishes the confidential enquiries from the process that was used in this study is the closeness of the investigation to the incident being studied, the comprehensiveness of the data collection and the way in which the findings are studied and commented on by a committee of appropriate clinicians. The involvement of practicing clinicians in all stages of the process gives the Enquires local legitimacy and also means that the work and the recommendations of the Enquiries have a greater chance of being acted on and implemented. An independent review of NCEPOD in 1998 found that 1700 of 2195 consultants responding said that NCEPOD had influenced their clinical practice. The impact of the Confidential Enquiry on Maternal Deaths has also been

significant with audits showing that key recommendations on maternal risk in pregnancy have been implemented in most obstetric units in the country.

Viewed from the perspective of assessing the utility of information contained in the medico-legal databases, it seems clear that the information obtained from the confidential enquiries is more immediate and certainly more comprehensive and extensive. As a mechanism for identifying ways in which the quality of care can be improved, they have been extremely important. In contrast, analysis of individual cases in the medico-legal databases suffers from the analysis taking place at a time quite distant from the original incident, the over reliance on the perspectives of experts (this is particularly problematic in the case of mental health) and the subjectiveness of the analysis. The analysis of cases based solely on the fact that they have been litigated may also mean that certain types of incidents are more likely to be studied. This is in contrast to the Confidential Enquiries which select their investigations on the recommendations of steering groups which include members from all the medical specialties, the professions allied to medicine and also include lay representatives.

So what is the value of claims data based on our attempt to analyse individual case reports? As pointed out earlier, the richness of clinical data contained in the reports is not in doubt, but its value is reduced because of the long time delay between the incident and the analysis. Much medical practice changes over a period of 5 years – better investigative techniques are developed, clinical audit is widespread and the introduction of clinical governance means that the profession generally is much more reflective and willing to consider improvements in the quality of care.

Apart from the value of considering the impact of cases through publicity and the size of awards, its seems unlikely that the detailed analysis of cases in the medical legal databases will add to the existing processes of clinical governance. However, the value of using the epidemiological data in the claims database, as identified in the first report, as a mechanism for surveillance and for identifying areas of clinical care which need further investigation should be explored. Furthermore, the lessons learnt from critical incidents related to rare cases, in the absence of any national surveillance, is one of the areas where the analysis of individual case reports may have utility. This is discussed in more detail in the report on primary care.

Another factor which needs to be considered is the impact that recent legislation and guidance will have on studies of this kind. As pointed out earlier, research ethics approval was given for this study and the research team signed confidentiality agreements with each of the defence organisations in order to carry out this study. In most cases, the defence organisation was able to redact the records so that data identifying the individual complainant or the clinician being complained against was not available. Each of the expert reviewers signed confidentiality agreements with the medical defence organisations before being given access to the information. However one interpretation of the Health and Social Care Act 2001 and the Data Protection Act 2001 together with recent guidance on research governance produced by the Department of Health suggests that studies like this will not be able to be carried out in future without the explicit

consent of the patients and practitioners involved. If this study had started a year later, it is quite possible that ethical approval would not be given without the patients and practitioners consent. The National Confidential Enquiries have obtained Section 60 dispensation from the Secretary of State for Health for their studies into critical incidents. This allows patient identifiable data to be used whilst alternative methods of data collection/obtaining consent are being implemented. If case analysis of medico-legal reports is developed in a systematic way, then this is an issue that will need to be explored because obtaining consent would almost certainly restrict the feasibility and utility of such studies.

Conclusions related to case analysis

Overall only about 70% of cases selected randomly were suitable for selection for further analysis. The figure was lowest for primary care in which 58% of cases were suitable for analysis. This raises issues about the value of systematically analysing medico-legal databases in terms of cost and information obtained. These issues are discussed in depth in the second report.

Each individual report discusses in depth the clinical lessons that need to be learned from the analysis of this group of cases. There were few surprises when a detailed root cause analysis was undertaken. As a mechanism for identifying errors and changing systems to reduce errors, the use of litigation databases is therefore limited. The exception may be in the analysis of rare events. However, the way that current databases have been created and the unstructured way in which data is collected means that currently they are not suitable for this purpose. The potential is for the litigation databases to become a national quality assurance system, albeit without a denominator. In order for this to happen, there will need to be consistency in the collection and recording of data by the medico-legal organisation. This is discussed in the first report.

The reviewers identified the following points, based on their analysis of cases. Readers are invited to read the individual reports for more specific comments: It should be emphasised that this is a subjective analysis based on the analysis of individual claims. The conclusions are based on the assessment by one individual of the potential lessons that can be learnt from a random selection of cases. However, what is clear is that there are issues that need to be addressed at a national level both in relation to the future surveillance and in the assessment of critical incidents related to rare diseases.

General Practice

- Difficulties in making diagnoses is an important problem especially for rare diseases.
- Computerised decision aids may help in the diagnosis of rare diagnoses.
- Systematic analysis of adverse events for rare diseases at the local level may provide a mechanism for learning and reducing the risk for errors.
- Systems failures related to organisational issues e.g. poor record keeping, lack of communication between primary and secondary care and failure to follow protocols for chronic disease management remain an important cause of adverse events.

Surgery and General Medicine

- History taking and clinical examination remain vital to the art of diagnosis.
- Assessment at the time of discharge with clear guidelines for follow-up both by GPs and specialists is an important safeguard.
- Consideration of rare diseases remains important in the differential diagnosis.
- An awareness of the changing epidemiology of previously rare diseases, for example TB is important.
- Specialists must seek advice on cases outside their area of interest.
- Junior staff must not take full responsibility in outpatient clinics.

Mental Health

- Observation of patients on section needs to be defined in care plans.
- Psychiatric referral needs to be more easily accessed so that at risk patients can be seen quickly.
- Nursing notes need to be amalgamated into medical notes so that a full assessment can be made including a list of observations, past history, current stresses and symptoms.
- More and better training needs to be put in place for diagnosis and alternative models of describing the case if diagnosis is difficult need to be developed e.g. psychological formulation or functional analysis.
- The doctor/patient relationship was highlighted as playing a role in many of the cases reviewed
- Emergency resuscitation equipment needs to be available, in working order and staff trained to use it.

Obstetrics

- Problems in monitoring intra-partum care are once again highlighted as a significant problem. Training in CTG interpretation and acting on results is critically important.
- Failure to adhere to guidelines remains a problem in the genesis of adverse events.
- Problems with the systems of care, with doctor patient relationships and with teamwork/supervision continue to play a role in the genesis of adverse events on the obstetric ward.
- All levels of staff can be responsible for poor judgement – it is not the prerogative of junior staff.

1 Analysis of claims in general practice

1.1 Introduction

Why study general practice?

It is often stated that 80% of contacts in the health service occur in primary care, mainly in GP surgeries. In contrast to hospital care, the care delivered in general practice is often described as 'low tech', with an associated assumption that things are less likely to go wrong in primary care when compared to hospital settings. This assumption is reflected in the research agenda on patient safety, which has concentrated primarily on the study of factors which enhance or reduce patient safety in secondary care. The emphasis of the National Patient Safety Agency in its early work has been on the introduction of reporting systems for secondary care and on the development of analytical tools which are primarily used in the situations when things go wrong in the hospital setting. This emphasis on secondary care is understandable. The complexity of the organisations, the severity of illness in patients presenting to hospitals and the complexity of the technological interventions that are frequently necessary in the treatment of illnesses in this setting means that there is a greater propensity for things going wrong. However, it is a misnomer to think of primary care as an environment where things do not go wrong. The organisation of primary care is complex because it is the main area where the health care of the individual is co-ordinated and in the majority of cases where the health problems involving an individual are treated. The disease process of many acute illnesses begins in primary care. Care delivered through primary care will frequently involve tertiary and secondary care services, other primary care professionals and pharmacists. The outcomes of the care received by patients will frequently depend on the quality of services, the quality of the organisation and the skills and knowledge of the general practitioner and the primary care team. In all these areas things can go wrong and in some cases, when things go wrong, they have catastrophic consequences. Failing to diagnose a child with meningitis, failing to act on a test result which might be a pointer to the early detection and treatment of cancer, inadequate control of a diabetic patient or failing to diagnose a heart attack can all have disastrous consequences.

What do we know about claims in general practice.

In a literature review of 15 studies of medical error in primary care, we estimated that errors occurred in 0.8 per cent of consultations (1 in 120) with errors in diagnosis and prescriptions accounting for 78 per cent of all problems (Sandars and Esmail, 2003). Up to 42 per cent of errors concerned delayed or inappropriate treatment. Between 60 to 83 per cent of errors were probably preventable.

In a recent study of complaints notified to the MDU and presented at a conference sponsored by the RCGP and the NPSA, the MDU analysed 202 randomly selected complaints. They found that diagnostic delays were the most common reason for the complaint with poor communication between doctor and patient being the most common root cause.

However, there are few detailed studies of patient safety in primary care(Sandars and Esmail, 2003) and one of the most readily available sources of information to study this area are the claims databases. We sought to assess the usefulness of this data.

1.2 Methods

How GP claims are organised

Within the NHS, general practitioners are independent contractors and are therefore not covered by crown indemnity for medico-legal cases. When NHS indemnity was introduced in the mid- 1980's, general practice was excluded from this arrangement and general practitioners still have to purchase their own individual indemnity insurance. General Practice claims are exclusively dealt with by three medico-legal defence organisations – the Medical and Dental Defence Union of Scotland, the Medical Defence Union (MDU) and the Medical Protection Society (MPS). These three organisations therefore hold all details of claims made against general practitioners in the UK.

We agreed that we would only study organisations based in England and Wales and approached the MDU and MPS for help. Both organisations signed a memorandum of understanding with us, allowing us access to their records.

In Phase 1 of the study, we assessed the epidemiology of error in general practice using data from these two organisations. We established a clear understanding of the way in which data was collected and the ease with which we could obtain the data. We also discussed with both organisations their perceptions of what were the main areas of medical practice that resulted in claims.

Developing the instrument for root cause analysis

When things go wrong in a healthcare setting, there are several tools available for identifying the underlying or root cause of the adverse event. The aim of root cause analysis is to look beyond the immediate cause of the adverse incident and look for contributory factors which may have contributed to the incident but which are not immediately apparent. There is virtually no published work on how to carry out a root cause analysis of error in primary care. There is a well established mechanism for doing this in secondary care but none for primary care. The organisation of care in general practice is completely different when compared to the organisation of care in the

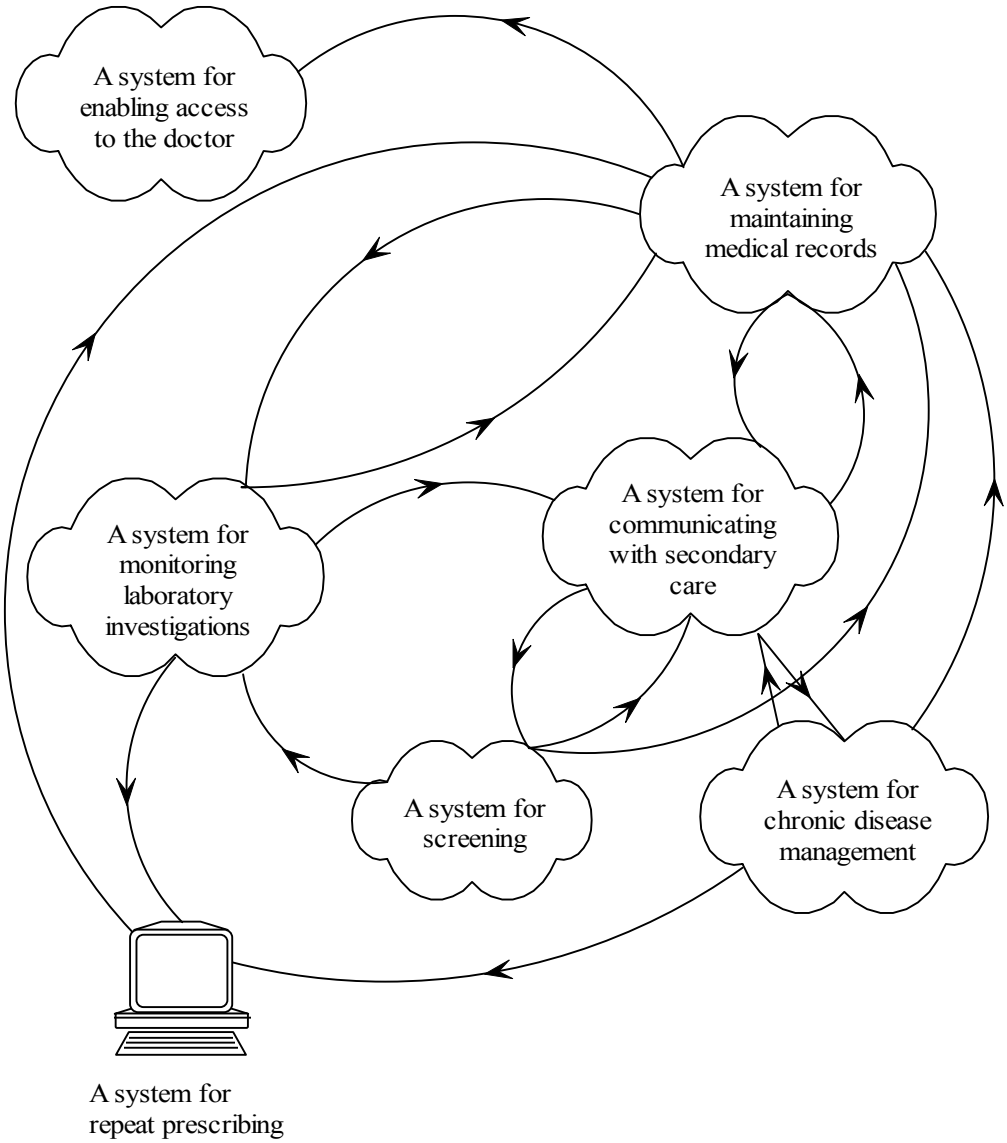
secondary care setting and tools developed for use in hospital are unlikely to be appropriate for use in general practice. It was therefore important to develop a framework for root cause analysis for use in general practice. There were several stages to this process:

A small pilot study I was involved in, attempted to assess whether GPs would be willing to report errors that occurred in primary care. We had a total of 63 reports over a period of 3 months. Together with colleagues from the USA (Dovey *et al.*, 2002) who carried out a similar study, we categorised the reported errors into two broad areas – the organisation of care and errors related to the knowledge and experience of the doctor. Within each of these areas, we subdivided the type of error into categories dependent on the location of where the error took place – for example, an error in record keeping or in the ordering of laboratory investigations. The categorisation of errors in this way was similar to work that Vincent and colleagues (Vincent *et al.*, 2001) had already carried in secondary care. However, we felt that there were inadequacies in this categorisation of error chiefly because it did not reflect the manner in which patients presented with problems in general practice. It was therefore difficult to determine where the problem was occurring. Discussion with Vincent and colleagues who were developing a modification of their own instrument suggested that a way forward may be to think of care in the primary care setting in terms of a patient journey through the health care system. They had found that identifying the phase of care during which the adverse incident occurred (for example in A&E, the Admission Ward, Ward care, Discharge arrangements etc.) made it much easier to develop a framework for identifying the root cause of the incident. Obviously health care in primary care is located in one locality but the concept of a patient journey in terms of how a patient presents with a problem, is assessed by a general practitioner and has his/her symptoms investigated or treated can be viewed as a patient journey. This formed the basis of developing a root cause analysis for general practice.

We also identified in more detail the different systems of organisation within general practice with a view to categorising errors in a way that more clearly reflected the manner in which care was organised. The outcome of these deliberations is shown in Section G (which is specific to general practice) of the Analysis of Claim Form

Organisational analysis and development of the symptom flow chart

Based on our experience from the international pilot study we attempted to categorise the different systems within a general practice which were an integral part of the way that care was organised and delivered. Because we had already determined that there were a significant number of adverse incidents attributed to the organisation of care, part of our analysis was aimed at identifying the different systems within a local primary care organisation. *Figure 1* attempts to categorise the different systems that were conceptually identified as being integral to the organisation of care.



PRACTICE ORGANIZATION AND ITS RELATIONSHIPS

Figure 1

Following Vincent's example of categorising the phase of care, we developed a conceptual model of symptom flow. This was based on the assumption that patients consult their GP's with symptoms as opposed to pre-existing conditions. The GP then has to translate that symptom into a medical problem, develop a plan for its diagnosis and treatment which may include arranging further tests and investigations or referral for a specialist opinion. Within each of these stages, there is a potential for an adverse incident to occur and it is possible to categorise the factors which contribute to that incident in each of these stages of symptom flow.

Table 1 shows how a more detailed contributory factor analysis can be developed. A worked example is shown in *Appendix 2.*

Stage of patient flow process	**Activity being undertaken**	**Factors contributing to potential adverse event**
Arranging to be seen by GP	Accessing GP surgery	▪ Organisation of 'out of hours care' ▪ Triaging of advice ▪ Organisation of practice - Appointment system
Formulation of symptoms into medical problem	Assessment of presenting complaint	▪ Communication skills of doctor - Ability to take a good history
Assessment of medical problem	Assessment of findings from history and clinical examination	▪ Knowledge and skills of doctor ▪ Organisation of practice - Level of organisation of medical records
Formulation of management plan	Combining knowledge and skills with assessment of findings	▪ Knowledge and skills of doctor ▪ Organisation of practice - Record keeping
Arranging investigations	Investigation	▪ Knowledge and skills of doctor ▪ Communicating with secondary care ▪ Organisation of system for local investigations ▪ Organisation of practice - Referral policies - System for follow-up
Formulating a diagnosis	Diagnosis	▪ Knowledge and skills of doctor ▪ Communicating with secondary care ▪ Organisation of practice - Record keeping - System for follow-up
Development of a treatment plan	Treatment	▪ Knowledge and skills of doctor ▪ Communication skills of doctor ▪ Communicating with secondary care ▪ Up to date information on drugs and interactions ▪ Organisation of practice - Record keeping - System for follow-up - Health promotion system - Chronic disease management system

Table 1: Symptoms and their relationship to potential adverse events. A conceptual model.

Notes:
1. These seven stages could form a possible categorisation for a pathway of care in Primary Care.
2. There is some possible overlap between the formulation if symptoms into a medical problem and the assessment of the medical problem, but I wanted to identify separately the role of communication skills.

To test the appropriateness of this model of root cause analysis, five randomly selected cases were chosen from the cases provided to us by the Medical Protection Society and analysed. Minor modifications to the list of contributory factors were made as a result of this pilot work.

Sample selection

From Phase 1 of the study, it became apparent that there was little significant difference in the type of claims that both organisations (MDU and MPS) dealt with. We had intended that the Phase 1 study would identify the type of cases that we would analyse. However as pointed out in our first report, inadequacies in the coding system used by the defence organisations meant that apart from identifying the broad disease categories we would not be able to identify other features which we could use to identify cases. Furthermore there was broad agreement by both organisations as to the type of claims that we should investigate in more depth. The MPS had already carried out an analysis of 1000 consecutive claims as part of an internal study and had created an electronic database of these records that could easily be redacted and provided to the project. The MDU did not have the same database and obtaining records for further analysis from them would have been difficult and costly. The project team therefore decided to obtain records provided solely by the MPS. Based on work done in the pilot phase of this study, it was felt that the information present in the MPS database would fulfil the requirements of the study. No added benefit would be obtained by considering additional cases from the MDU.

It is important to understand the way that the MPS data were collected. The 1000 claims chosen for inclusion within the MPS database and which was made available to me, represent the first 1000 claims made against MPS' UK GP members starting from 1st July 1996. The 1000 claims are therefore better described as a population or cohort of claims rather than a sample. By definition, the 1000 claims include claims both settled with a payment to a patient and those that have been successfully defended. A handful of claims in the database remain active and some were never progressed. The MPS definition of a claim is, as we understand it, similar to the definition of a claim that is applied by the NHSLA. Some of the claims never progressed beyond an initial letter from the plaintiff's solicitor. This inevitably means that the amount of information in each case will vary depending on how the claim was progressed within the MPS.

Based on a discussion with both the MPS and MDU we identified four categories of diseases which they felt may benefit from more detailed analysis. This was partly based on their perception of the kind of problems that they felt kept on recurring and formed a large part of their claims both in terms of frequency and in the settlement costs. In total I was provided with a list of 121 cases.

Selection of diseases categories for analysis

The cases supplied covered the following areas:

- Delay in diagnosis of meningitis - amongst GP claims these are typically the greatest cost in terms of settlement - 21 case details supplied.
- Diagnosis and management of ischaemic heart disease - amongst GP claims more deaths were related to this topic than any other - 34 case details supplied.
- Delays in diagnosis of ovarian cancer and cancer of cervix (most common cancer in MPS series of cases) - 25 case details supplied.
- Diagnosis and management of diabetes mellitus (we included this because it was both a commonly featured problem and as an area where primary care has undergone changes since the study) - 41 case details supplied.

The cases were supplied on a CD ROM as scanned documents. Each group of cases were in their own electronic folder. I was also given a printed list of these cases. After consultation with the project review team it was decided to sample from this list and every third case was assessed.

1.3 Data quality

The way that the data had been collected by the MPS meant that the availability of the documentation was not the issue. It is however important to understand that I was in fact analysing information from a data set that had already been developed as part of special study that they had carried out. Repeating the study with a different data set would therefore be costly and difficult. Categorising the data and selecting cases would not be straight forward as outlined in Phase 1 of our study and identifying and reading the legal summaries could only happen by examination of individuals case note folders. Currently systems and resources do not exist for this exercise to be done on a routine basis.

My assessment of the causal sequence of events or the underlying root cause of the incident was based on my own experience as a practising clinician. In that respect I am applying a value judgement based on my understanding of best practice and also my knowledge of the natural history of the disease. The protocol we used did allow me to make a judgement as to whether some incidents were inevitable and were caused by the disease process alone, but as I shall point out, this only occurred in a few cases.

I had also assumed that in order to make a judgement on cases I would need a large amount of clinical information which would not necessarily be available from the GP notes. However, the legal summaries in effect consisted of a summary of the witness statements together with a summary of the expert statements or sometimes an expert statement which had obviously be collected by reference to some sort of witness statement. There was therefore a richness of information that I had not expected. It is difficult to assess how difficult it is to get to this stage of assessment because it is essential if a more detailed root cause analysis is going to be carried out.

Even though the data was easily accessible, interpretation of data was time consuming. Reading the material, thinking about the likely cause of the adverse incident and applying the pro forma that was developed took on average about two to three hours per case. I did feel during the analysis that the benefit of discussing the findings with a group would have been beneficial and paradoxically may have reduced the time taken to analyse each case, though the total 'whole time equivalents' to analyse the case may have stayed the same.

Because we analysed notes randomly we believe that we can make estimates of how useful the analysis of a cohort of cases presenting as claims to a defence organisation can be. However it is important to understand that the way that data is being collected and categorised is undergoing significant changes based on our experience of working with the defence organisations in Phase 1 of our study. Our estimates of the usefulness and completeness of the data may therefore need to be revised. We made specific recommendations in the Phase 1 report which we believe will improve the usefulness of the data that is collected by the defence organisations for research purposes.

1.4 Results

General observations

Before looking at each of the individual disease categories, it is useful to summarise some aspects of all the cases that I reviewed so that they can be compared with claims arising from obstetrics, general medicine and mental health. It was not possible to obtain information on all the 39 cases analysed (excluding the 5 cases analysed for the pilot phase of the study) because some of the information contained in the case record was incomplete. Twenty-three cases out of the total of 39 were analysed using the same protocol as the other researchers. Therefore approximately fifty-eight per cent of cases in primary care are suitable for in-depth analysis. This figure gives the best estimate of how many cases based on a cohort of sequential cases presenting to the defence organisations can be analysed for more detailed root cause analysis. However a further seven cases contained sufficient information for me to draw some conclusion on the cause of potential adverse events and have therefore been included in the discussion on the specific topic. The totals referred to in the discussion of the specific topic areas will therefore vary.

The underlying cause of the injury can be attributed to either the disease process, healthcare management or an interaction of the two. This is shown in Table 2.

Table 2: Cause of Injury

	Frequency	Percentage
Healthcare Management	6	26%
Healthcare and disease process	14	61%
Disease Process	3	13%
Total	23	100%

Table 2 shows that in nearly 13% of cases, I felt that the adverse event was caused by the disease process. This suggests that there was no failure in the healthcare process. It remains a cause for concern that in a significant minority of cases there appears to be no basis for the claim and these claims may represent a breakdown in communication between the litigant and the healthcare professional rather than a poor outcome from an adverse event.

There is an underlying assumption that because care in general practice is 'low tech' care, then if things go wrong, they will not be serious. Table 3 shows that serious adverse outcomes, with death being the most common are probably the most common reason why claims are made against GPs.

Table 3: Impact of Injury

	Frequency	Percentage
Disability	2	9%
Death	11	48%
Pain	1	4%
Other Complication	6	26%
Unclear	3	13%
Total	23	100%

The consequences of adverse events that do not result in death are also significant as shown in Table 4.

Table 4: Additional Procedures as a result of Incident

	Frequency	Percentage
Additional Procedure	10	43%
Additional Medications	4	17%
Additional Treatments	6	26%

The vast majority of claims were the result of failure to diagnose, assess the overall condition of the patient or monitor the presenting symptoms of the patient. This will be discussed in more detail when the root cause analysis of the disease specific adverse events are analysed. In relation to failure to diagnose, assess or monitor, prescribing related errors were far less common. This is shown in Table 5.

Table 5: Factors leading to Incident

	Definite N (%)	**Probable N (%)**	**Possible N (%)**	**Not Present N (%)**
Failure/delay to diagnose or assess correctly	16 (70%)	1 (4%)	3 (13%)	3 (13%)
Failure/delay to appreciate the patient's overall condition	15 (65%)	1 (4%)	2 (9%)	5 (22%)
Failure/delay in clinical monitoring/management	13 (56%)	0	2 (9%)	8 (35%)
Failure/delay to prevent/control infection	0	1 (4%)	0	22 (96%)
Related to the prescribing of drugs/fluids	1 (4%)	0	0	22 (96%)
Misfiled Report	1 (4%)	0	0	22 (96%)

Results related to each of the disease categories

Ischaemic heart disease

Ischaemic heart disease was chosen as a category for root cause analysis because it was a common condition which resulted in a large number of claims for negligence. In epidemiological terms, ischaemic heart disease is one of the major causes of mortality and morbidity in the UK. It is important to understand reasons as to why this condition results in a large number of claims of negligence – approximately four percent of all claims of negligence in the cohort of 1000 cases.

We were provided with 34 cases from the 1000 claims series. We analysed 11 cases randomly selected from this series. There was one case in which there was insufficient evidence to carry out a root causes analysis. In the one case in which there was insufficient information, the case record consisted of a letter from a GP explaining that the patient had died suddenly from a myocardial infarction. The GP was concerned that there might be a claim against him because he had seen the patient 48 hrs previously with a flu-like illness. There was no other documentation, presumably because no complaint

was made. We assume that the case was logged because of the letter received from the GP.

This case highlights one of the problems of using claims related databases that aren't coded in order to distinguished claims which are not pursued – currently, the MPS database cannot identify such cases. Furthermore, information is not collected so that a root cause analysis can be carried out. The important point to make is that lessons can be learnt from such cases and claims analysis should not only be restricted to cases in which a claim is pursued.

In the remaining ten cases that were analysed, eight resulted in death. In the two other cases, one was due to a prescription error in which there was no adverse outcome. In the second of these cases, the adverse outcome was heart failure resulting from a myocardial infarction which was not diagnosed.

We have chosen to analyse these cases by grouping them into prescription error and delay in diagnosis.

- Prescription error
  There was no adverse outcome in this case which resulted from the issuing of one prescription which failed to note that the doses of anti-hypertensive drug prescribed should have been higher (one tablet per day was prescribed when the dose should have been two tablets per day). The system of prescribing and repeat prescribing was obviously at fault. Details of the actual system were not described, but this incident could properly be described as a near miss. More detailed analysis of the cause may have revealed flaws in the current system of repeat prescribing and changes could have been instituted which may have prevented other potentially more serious incidents.

- Delayed diagnosis of myocardial infarction.
  There were nine cases in this series, with death being the outcome in eight. In all of these cases, the principle nature of the problem was a failure to diagnose or assess the patient correctly with a subsequent failure to appreciate the gravity of the patients overall condition and subsequent failure in the clinical management of the patient. In all cases, the presenting complaint was chest pain. In one of the cases the patient died suddenly at home without a doctor being called. However in this case, the patient had presented on a separate occasion with chest pain which was not investigated despite a strong family history of ischaemic heart disease (IHD), the contention being that if he had been investigated he would have been found to have IHD and preventative treatment instituted. In eight cases the general practitioner was directly responsible for the care of the patient and in one case it was a combination of the GP and the hospital which was responsible for the adverse outcome.

It was not possible to ascertain the age of the patient from the records in one of these cases. In seven of the cases, the patients were under sixty years of age, the youngest being 34 yrs old.

In all cases there was a history of ischaemic heart disease with additional risk factors for IHD in seven of the nine cases. This makes the failure to diagnose the cause of the chest pain surprising. In terms of the involvement of the general practitioner, the problem in all cases was related to how the GP failed to recognise that the chest pain was a significant factor in the presenting symptom and failed to take appropriate action.

In a more detailed root cause analysis which was possible in all these cases, the lack of knowledge and skills of the doctor was a significant factor in the genesis of the adverse event in eight out of the nine cases. In only two of the cases was out of hours care a factor which suggests that in seven out of nine cases the patient was being looked after by their own practice.

Some aspect of the system of practice organisation was also a contributory factor in all of these adverse events with the system for maintaining medical records and the system for chronic disease management being implicated in all cases.

In epidemiological terms ischaemic heart disease is a common condition and one of the major causes of death and morbidity in this country. Analysis of this small series of adverse events suggests that there are potentially preventable factors which can be identified in all litigated cases. The failure to diagnose with the lack of skills and knowledge of the treating general practitioner being a contributory factor in the majority of cases was a surprising finding because unlike cases like meningitis and cancers of the female genital tract, the condition is not rare. Although chest pain is a very common presentation, the finding that risk factors for ischaemic heart disease were present in the majority of cases suggests that better diagnosis may have prevented death in many of these cases.

With advances in treatment and in particular the widespread use of thrombolytic drugs the early diagnosis and treatment of chest pain is very important. Balancing non-cardiac causes of chest pain with cardiac causes is an important determination for the doctor to make. However in all the studied cases, it appears that a cardiac cause was the most likely cause of chest pain and yet appropriate diagnosis and treatment was not made, resulting in disastrous consequences for the patients. Almost all the cases were from the early 1990's when the treatment of chest pain due to cardiac causes was well established which makes the failure to diagnose even more worrying.

The analysis of claims data suggests that root cause analysis can identify remediable contributory causes. Because the frequency of the condition is so widespread, analysis at a practice level of all referrals to hospital of patients with chest pain with a particular emphasis on those patients who receive thrombolysis or who subsequently have a myocardial infarction, will raise important questions in terms of the standard of preventive care and the quality of acute care.

The level of public knowledge about the possibility that chest pain may be due to cardiac causes is widespread and many patients now refer themselves directly to hospital, by-passing the doctor. In circumstances when the doctor is called to see a patient with chest pain, the use of diagnostic aids such as such as algorithms can help greatly in improving the diagnostic certainty as can the use of biochemical markers for cardiac pain, many of which are available rapidly.

It is unlikely that incidents where patients with suspected myocardial infarction who are referred to hospital by their general practitioner are analysed in any systematic manner by general practices. As can be seen from this sample analysis, incidents in which mortality is an outcome highlight the fact that there are preventable factors in most cases which are amenable to change. The outcome may not change but the process of care can almost certainly be improved – better record keeping, clearer protocols for the diagnosis and treatment of chest pain in the community are two areas where improvements could be made. Review of such cases at practice level using well developed models of significant event audit will ensure that lessons are learnt.

Meningitis

Meningitis is a rare disease. The incidence is approximately 3 cases per 100,000 people per year and in their lifetime of practice, most general practitioners will probably see one or two cases. However failure to diagnose this condition can have devastating consequences and in situations where the patient survives, brain damage can be an important outcome. This is one of the main reasons why it appears in negligence claims and represents area where large settlements are frequently made.

There were 21 cases in the series of 1000 consecutive claims related to delays in the diagnosis of meningitis. We analysed 7 cases randomly selected from this series. There were four cases in which there was sufficient information to carry out a root cause analysis. In the 3 cases in which there was insufficient evidence, one was due to illegible records, and three were because they were cases in progress with insufficient information available to carry out a detailed analysis.

In two of the four cases in which we carried out a root cause analysis, the outcomes – death and loss of digits – were entirely the result of the disease process. There were no identified preventable causes and in one of these cases, although the child died, the care in general practice was exemplary. We can only assume that because the outcomes are so devastating, there is sometimes a tendency to assume that they could have been different. In such circumstances it is not surprising that families seek recompense – in the case of death in which the care was exemplary, the defence societies (two GPs were involved belonging to different societies) settled the case for £5000 to avoid costly legal wrangling.

In the one remaining case, there was a delay in diagnosis resulting in severe brain damage in one case and deafness in the other.

In this case, the incident occurred in 1992 but the claim was lodged in 1999. The child was 3 weeks old at the time of the adverse incident. Root cause analysis shows that the cause of the problem was the lack of knowledge and skills of the doctor with an additional contributing factor being the system for enabling access to the doctor and the system of out of hour's care.

Without having to make a comment on the issue of negligence, it is clear that the doctor lacked the knowledge and skills to assess new-born infants.

Meningitis is a very rare disease and most GPs will only see one or two cases in the lifetime of their practice. Successful immunisation campaigns have also reduced the incidence of meningitis and it is likely that in future most GPs will never see a case in their clinical practice. Maintaining a balance between recognising how rare the illness is and a high degree of suspicion is crucial. The difference in care ascertained from the case described above in which the child died and the one in which the child ended up brain damaged is instructive. In the former there was evidence that the child was followed up regularly and examined thoroughly on several occasions and when the diagnosis made, prompt action and treatment instituted. In the other, the records are incomplete, an inappropriate diagnosis of a throat infection in a 3 week old baby is made and there was inadequate follow-up and monitoring.

There is no easy way to compensate for the lack of knowledge and skills by the doctor but because of the possible tragic consequences of meningitis and the difficulty in elucidating symptoms in very young children and especially babies, mechanisms to trigger suspicion and to ensure follow up where the diagnosis is uncertain are critical, especially in babies.

As a learning tool for practices, periodic review of babies admitted to hospital as part of a significant event audit may raise issues in which the personal care can be reviewed together with improving knowledge and skills in the diagnosis of serious illness in babies and young children.

Delay in diagnosis of meningitis was highlighted by the defence societies as an area of care in general practice in which they were frequently large settlements and in which there were potential lessons in improving safety. However, it is clear from our limited analysis that the information contained in the medico-legal records is incomplete in the vast majority of cases and is likely to remain so until the case is resolved. Because the litigation process is likely to be complex and take a long time, lessons may take a while to emerge. A more useful model may be for all cases of meningitis in young children to be analysed in multi-disciplinary settings involving primary care and secondary care teams. The condition is rare and if such learning were to be carried out at a PCT level, it would involve the detailed analysis of about three to four cases in any one year. It is something that the NPSA may which to consider as a sentinel condition which may benefit for further analysis.

It is also important to make the point that in half the cases that I analysed, the outcomes in my analysis were related to the disease process and not the result of any failure in the health care management yet they still resulted in being litigated. Whilst I accept that I was only analysing a limited amount of information in relation to the cases, it is worth noting that failures in communication or a breakdown in trust together with problems in the provision of services for handicapped patients may be one of the reasons the cases are being subject to litigation.

Diabetes

Like ischaemic heart disease, diabetes is a common condition and its prevalence is increasing. It is a chronic condition which is almost wholly managed in the primary care setting. Because it is a chronic condition good record keeping, good communication with other agencies and health care workers and a high level of patient self-care are pre-requisites of good quality healthcare. There are many areas where the healthcare management process can be compromised.

There were 41 cases provided by MPS. This represented 4 percent of the total number of cases in the series of 1000 cases collected by the MPS. We analysed 13 cases in total and there was sufficient information in 10 of these cases in which we were able to carry out a more detailed analysis.

In the three cases in which there was insufficient evidence, one was because the claim against the doctor was withdrawn when it was determined that the negligence was the responsibility of the hospital. In the second case, the GP defendant died and because there was no long term adverse outcome, the case was not pursued. In the third case, there was only a letter of complaint from a solicitor but no subsequent information.

4 cases were due to a delay in the diagnosis of diabetes. In three of these cases, the delay in diagnosis was related to children presenting with symptoms and signs which were only attributed to diabetes after a considerable delay. In one case, an adult presented with rapidly progressing cellulitis following an injury to his foot. It was diagnosed and treated appropriately, but the patient still required amputation of the forefoot. In this case the patient was 58, previously healthy and had no signs and symptoms suggestive of diabetes. He had never accessed primary care health services until he had the injury. In this case I determined that the adverse event was due to the disease process and that there were no failures related to health care management.

In the case of the three children, the principal problems were a failure to diagnose and assess correctly, a failure to appreciate the patient's overall condition and a failure in the clinical monitoring and management.

In the root cause analysis of these three cases, the knowledge and skills of the doctor, aspects of practice organisation and task factors were all responsible for causing the adverse event. The diagnosis of diabetes in a child is difficult unless a high degree of suspicion is maintained. It is a rare condition but its diagnosis in the general practice

setting is easy (checking a urine sample) provided the index of suspicion is maintained. In my opinion, the knowledge and skills of the doctor were paramount in the genesis of the adverse incident.

Five cases were associated with problems related to the management of people who already had a diagnosis of diabetes. I judged that in one case, the adverse event was due solely to the disease process and that there were no failures of healthcare management. In the remaining four cases, the principal problems were a failure to assess, failure in clinical monitoring and a failure to appreciate the overall patient's condition. In one of these cases, there was a failure to control and manage an infection.

In terms of the care delivered by the GP, the principal problem was in not having a clear management plan or a treatment plan for the continuing care of the diabetes. In the root cause analysis, in three out of four cases, the knowledge and skills of the doctor played a part in the adverse incident. Aspects of practice organisation were relevant in all cases (for example the quality of record keeping and the system for chronic disease management). In all cases the system for communicating with secondary care was a relevant factor in the genesis of the adverse event. In two cases there was clear evidence for not following established guidelines or a protocol for the management of diabetes.

Poor team working relationships were also identified as contributory factors in three out of four cases.

What is clear from the root cause analysis of these cases is the contribution of practice organisation (record keeping, communicating with secondary care, team working and use of protocols) in the development of the adverse incident. Good systems for the management of chronic diseases are critical in the delivery of safe care. The quality outcomes framework in the new GP contract make a contribution to improving safety in this area because it will provide incentives for good organisational structures in the management of diabetics.

There was only one case out of the ten cases reviewed in which there was a prescribing error. Contributory factors related to the prescribing error were poor record keeping, the system for repeat prescribing and the use of a locum who did not know how to use the prescribing system of the practice.

Analysis of claims in this area suggests that if a system of root cause analysis were applied to negligence claims related to diabetes care, then important lessons related to improving patient safety can be learnt.

The diagnosis of diabetes in children is difficult because in the young it is a relatively rare disease. The development of decision aids which can highlight the possibility of diabetes when certain symptoms (for example weight loss, polyuria or frequency of urine) are typed into computerised records of patients under 16 may help to identify potential cases by prompting the doctor to consider the diagnosis.

The majority of cases resulting in adverse events in diabetes were the result of failures in the ongoing management of adults who already had a diagnosis but who were receiving their continuing care from the general practitioner. The importance of robust systems for the organisation of care (good record keeping, communicating with secondary care and the use of protocols) cannot be underestimated. Continuing audit of care in this area will provide important pointers for practices to monitor the quality of care that they deliver. Incentives in the new GP contract may help in improving quality and patient safety because of the explicit criteria by which chronic disease management in diabetic care will be monitored and rewarded.

Cancers of female genital organs

We were provided with 25 cases by MPS and analysed eight cases from this sample. We were able to carry out a root cause analysis in six cases. In one case there was insufficient information available to carry out a root cause analysis. In the second case in which there was insufficient information, the patient died and the assumption is that the case was not pursued. However, in this case I made the judgement that the cause of death was due to the disease process with no adverse events identified. A woman presented with menstrual irregularity for which she was promptly investigated and discovered to have ovarian cancer from which she died.

In the remaining six cases, five were due to the delayed diagnosis of cervical cancer and one case was due to the delayed diagnosis of choriocarcinoma.

Choriocarcinoma is a very rare cancer of the female genital tract. The incidence is 1 in 40,0000 normal pregnancies. It therefore falls into the category of a very rare disease which most GPs are never likely to encounter in their professional working lives.

The clinical history was of a young woman who continued to bleed after a miscarriage and was not examined or investigated adequately despite the presence of important clinical signs. The outcome was a delayed referral to hospital with more intensive treatment required than if the condition had been diagnosed earlier. Contributory factors were related to the lack of knowledge and skills of the doctor, the system for keeping records, recording investigations and communicating with secondary care.

Analysis of the delay in this case was due to a failure to diagnose and assess correctly and a failure to appreciate the patients overall condition. In the context of general practice the adverse event occurred because of failure of assessment by the GP and the failure to investigate properly.

As with most rare conditions, the knowledge and skills of the clinician are critical in the diagnosis of such a condition and clinicians must maintain a high index of suspicion. In this case there was an inadequate examination and assessment of the problem which was compounded by poor systems for record keeping.

It is unlikely that exhortation to be aware of the likelihood of rare conditions will make much impact in reducing the risk of the sort of case described but the potential for discussing such a case as part of a significant event analysis would offer a more useful learning experience.

There were a total of five cases of delayed diagnosis of cancer of the cervix in which we carried out a more detailed root causes analysis. These five cases could be divided into two broad categories – one related to the failure to investigate gynaecological symptoms which subsequently turned out to be cancer. The other category was failure to act on the results of cervical cytology.

In both cases of failure to investigate, the patients were over 50 years of age and presented with menstrual irregularities. There was a failure to investigate in both these cases. Contributory factors included mis-diagnosis due to lack of knowledge, record keeping and evidence of not following guidelines. In one case, the patient received repeated prescriptions for anti-fungal creams with no follow-up as to why so many prescriptions were being issued.

In three cases, abnormalities in cervical cytology were reported which all required action at the primary care level. In one case, a report was mis-filed, and in the other case there was no follow up of a suspicious smear. In the third case, although a referral for investigation was made following a smear showing severe dyskarriosis, an appointment was not given for at least six months by the hospital.

All these three cases showed failures in the system for screening and communicating with other agencies. There are now fail-safe mechanisms in place for the follow up of abnormal smear results and it is likely that such adverse events would no longer occur in current systems. However, without any systems for quality assurance the continuing existence of such adverse events cannot be excluded.

Detailed analysis of this series of cases related to cancers of the female genital tract show that systems failures related to deficiencies of the call recall system for cervical screening are responsible for an important group of adverse events. Screening programmes are being extended – for example in breast cancer screening - and are also being considered in other areas such as Down's Syndrome and Prostate Cancer. The potential causes of failures in existing systems need to be understood and analysed if they are not be repeated in these other areas. Analysing failures is an important part of the quality assurance process and the danger is that because they are sporadic and not usually grouped by locality, then lessons from adverse events will not be assimilated. There may be a case for all newly diagnosed cases of cervical cancer to be reported to PCT's where a comprehensive root cause analysis can be carried out as part of the quality assurance process of the screening programme.

Cervical cytology is part of a national screening programme with the screening taking place in primary care. The percentage of the population screened is an established quality indicator and general practices are rewarded on the level of population screening that

they have achieved. The level of population screening is also one of the indicators against which primary care trusts are assessed.

The level of public knowledge about screening is therefore high and all practices have established call and recall systems for carrying out population based screening. It is therefore surprising that delayed diagnosis of cervical cancer was one of the conditions identified by the defence organisations as an area where there was a high level of claims and where there were probably lessons which could be learnt from more detailed root cause analysis.

What is clear from this preamble is that there are incentives by which primary care organisations are judged in terms of the success of their population based screening programmes but there are virtually no programmes to assess the quality of those programmes at the primary care level. There have been well publicised examples of the investigation of secondary care systems where failures have been identified – for example in the reporting of results – but no investigations of systems failures at the general practice level. This is almost certainly because when failures do occur they are based around individual cases.

Systems to carry out significant event audit of all newly diagnosed cases of cervical cancer would identify cases where despite high levels of population based screening, women were being diagnosed with cancer as a result of failures in the organisation of the screening process. The use of medico-legal records in these cases is too slow (the adverse incident in most of the cases in the series that was examined occurred in the mid 1990's even though the claim was being contested several years later) for lessons to be learnt, which in the case of population based screening programmes need to be implemented fairly rapidly.

The use of decision support tools in the diagnosis of rare conditions can be important and the Problem Knowledge Coupler as described by Lawrence Weed (Weed, 1997) is a good example of a decision support tool which would help clinicians in making diagnoses in rare conditions.

1.5 Conclusion

Summary of clinical findings & emerging clinical themes

In any case analysis of thirty cases, it would be unwise to make generalisable claims about the quality of care or to try and draw out specific lessons from individual cases. The reality is that I analysed four cases of meningitis, ten cases of myocardial infarction, ten cases of adverse incidents in diabetes and six cases of delayed diagnosis in cancers of the female genital tract.

The purpose of the root cause analysis was to show that more detailed and systematic analysis of adverse events can result in a better understanding of why something went wrong and suggest changes to processes which may prevent things going wrong in the future. Whilst they are more established mechanisms for doing this in secondary care through mortality and morbidity meetings, such processes for reflection are not so widespread in primary care. Significant event audit does take place but there are no reliable estimates as to how widespread it is or at what level it is carried out. In most practices in England, there is no systematic consideration of groups of cases in the primary care setting apart from the use of audit which is more about raising the standard of care rather than learning from adverse events. A combination of audit and significant event audit using a system of root cause analysis such as that suggested in this review may offer an improved mechanism for quality improvement.

The generalisable lessons are not surprising, better record keeping, better communication with other agencies, and better use of protocols and guidelines in the management of chronic diseases.

The specific lessons related to general practice can be considered under the disease categories

Disease Category	Clinical lessons
Ischaemic heart disease	• Failure to consider ischaemic heart disease (IHD) as a cause of chest pain remains the most common cause of adverse events. • In all cases, presence of additional risk factors should have alerted the physician to consider (IHD) as a differential diagnosis.
Meningitis	• Too few cases analysed to draw any firm conclusions. • Strategies to learn from rare diseases need to be developed.
Diabetes	• Adverse events were mainly related to organisation of care (record keeping, communicating with secondary care and use of protocols
Cancers of female genital organs	• Most failures related to deficiencies of call recall system

The value of claims data in assessing adverse events in general practice

The data that we analysed in this phase of the project was collected primarily for administrative and litigation purposes. Its main aim is to enable the defence organisations support and defend their members. The defence organisations also have a long term interest in reducing adverse events and have been keen to use the data that they have to inform a programme of education and risk reduction. However, as we have described in

other reports from this study, there are still major problems in the way they collect, categorise and store the data which makes detailed analysis more difficult.

An additional problem which is related to the purpose for which the data is collected also limits its usefulness – and this was clearly identified in many of the cases that I analysed. Because the data is collected for litigation purposes the amount of data which is collected both in terms of expert reports and detailed examination of the circumstances leading to the adverse event, is determined by the size of the claim and the outcome. Furthermore, the data that we analysed was dominated by evidence provided by expert reports on behalf of the defendants. From my observations based on analysis of this case series, especially in relation to deaths from ischaemic heart disease, and adverse events in diabetes, the evidence appeared to by dominated by trying to show that death was inevitable and that the event resulting in the complaint was therefore the result of the disease process rather than any shortcomings in the medical care provided. Inevitably the information was constrained in this respect because the primary purpose for which it was collected was to defend the doctor. In some cases, unless the plaintiff was determined to pursue the claim it was frequently settled in a way that minimised the liability of the defence organisation. It is important to point out that the defence organisation would not defend the indefensible. However some settlements were dominated by the need to reduce costs with the result that the information that was collected was also limited.

The root cause analysis that I carried out was an individual exercise but I felt that it may have been more useful if the case and the root cause analysis could have been discussed in a team setting. In most models of root cause analysis described in the literature, root cause analysis is carried out as a team exercise and in the case of primary care should have been carried out by a multi-disciplinary team. The underlying cause may not be altered when a team considers the root cause but the solutions discussed would have benefited significantly when considered from different perspectives. This remains a significant limitation in the analysis that I carried out.

Irrespective of these limitations, in analysing the data for the purposes of this study I was surprised how useful the information was (when it was complete) in helping identify what went wrong and allowed me to assess, using the developed root cause analysis, to identify the cause of the potential failures. This was helped by the fact that my primary purpose was not to identify who was to blame but to try and understand why something went wrong. Claims data is therefore useful but we need to understand its limitations and also recognise that other sources of data may be more useful. The key question to answer is to identify in what way claims data will be useful.

Reflections on quality

As pointed out previously, the quality of the information was variable and dependent on the disease category being studied. The amount of information present was good for diabetes and ischaemic heart disease and less good for cancers of the female genital tract and meningitis, probably because these are rare diseases. As pointed out above, if the patient dies then the information is restricted and in many cases, costs are limited because

of death. It is cases of brain damage that attract large settlements but a poor unemployed person who dies because of poor care is unlikely to obtain a large settlement and it will invariably be settled, sometimes with little investigation into why the adverse incident took place.

In some cases, the long delay between the incident and settlement of claim makes the information less relevant because healthcare has moved on – there may be better diagnostic tests, improved systems and better public awareness so that the circumstances resulting in the adverse event is less likely to occur. Many patients with chest pain now directly refer themselves to accident & emergency departments where improved diagnostic tests mean that it is easier to distinguish between cardiac and non-cardiac causes of chest pain. Systems improvements in the call-recall system for cervical screening mean that abnormal results are more closely followed up. This does not mean that adverse events in these areas will disappear but causes may change and hopefully they will become less common.

One of the problems I identified was related to the fact that *'lack of knowledge and skills'* was a contributory factor in the root cause analysis. I had not anticipated that this particular contributory factor was going to be present in so many adverse events. The root cause analysis broke this down into execution of the clinical task, mis-diagnosis, wrong treatment decision or prescribing error. The problem is that this is not a sufficiently developed analysis to understand why this contributory factor is present in so many cases and we need to disentangle what this means. This is certainly one of the lessons that we have learnt from this analysis because it was not revealed in the pilot study when we asked physicians to prospectively identify adverse events. What seems surprising to me is that when we asked GPs to prospectively collect information on adverse events they did not identify their lack of knowledge and skills as a contributory factor. However, in this retrospective analysis it featured in the large majority of cases as one of the contributory factors. It is important to understand why because this is an area that is directly attributable to an individual and not obviously related to a systems failure. A multi-disciplinary discussion around the root causes of the adverse incident may well have identified other issues related to this contributory factor and as pointed out earlier, remains a limitation of this study.

Some systems that have been developed to improve clinical performance have directly addressed this problem(Weed, 1997). If we are going to prevent lack of knowledge and skills being a contributory factor to adverse events, then this needs to be understood in a lot more detail that the root cause analysis that we developed.

Assessing the quality of care

One of the reasons for studying issues of safety is that it provides a handle to improve quality of care. How useful is the analysis of claims data for identifying issues related to improving safety and quality of care?

Overall the analysis of claims data is less useful than I thought before starting this study. The key to improvement in primary care is to get local 'buy in'. Local practitioners need

to be involved in the identification and analysis of adverse events and it is unlikely that claims data can be made available for analysis at a local level because of issues related to confidentiality. Significant event audit at a practice level is probably the most useful mechanism for doing this. The great strength of using significant event audit is that it forces organisations to look at the process of care when compared to other methods of quality improvement such as audit. More detailed analysis of patients that are referred for investigation and treatment of cancers at a practice level for example, may identify areas for improvement. Similar mechanisms could be introduced for admissions to hospital for chest pain. Analysis of claims data at this level is unlikely to be a substitute for significant event analysis.

Using the root cause analysis developed for this study will provide a useful basis for carrying out a systematic root cause analysis for adverse events. For it to be really useful, it will need to be used by a multi-disciplinary team with further development of some of the underlying causes behind the contributory factors.

However, there is a potential role for the analysis of claims data at identifying trends so that organisations such as the NPSA can identify areas for improving patient safety which may need more detail and action at a local level. This is particularly true of rare events such as meningitis and some cancers of the female genital tract. As pointed out in the analysis related to both these areas, most general practitioners are unlikely to come across these groups of diseases in their working careers. Analysis of these adverse events at a national level may identify areas for improvement and the development of learning action plans for implementation at a local level probably through PCTs.

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2 Analysis of claims in general surgery and general medicine

2.1 Introduction

In all general hospitals general medicine and general surgery are core services, and cover most emergency admissions. By definition such patients are acutely ill and thus are at high risk for adverse events (AEs). In the Harvard study of AEs in hospital practice 38% admissions were classified as general medical (and these were associated with 42% of AEs) and 22% general surgical (23% AEs) (Brennan et al, 1991). However, in American studies fewer than 10% of preventable AEs led to claims and so it is not possible to get an overall picture of AEs in hospital practice from a study of claims. It is probable that claims are more likely to arise from events concerning:

- younger patients
- obvious error e.g. wrong side surgery
- significant delay in diagnosis (especially with malignant disease)

and less likely with regard to errors in

- monitoring a patient's progress
- providing care in an ongoing illness
- the care of the sick patient with complicated pathology
- the care of the elderly

This report on the value of claims data is made with these initial reservations.

2.2 Methods

The study was undertaken to test the feasibility of abstracting useful information from medico-legal claims and to make a simple assessment of the quality of such data. It was planned to study 25 cases drawn from General Surgery and 25 from General Medicine.

Choice of cases

It was decided to select cases for which the claim was based on wrongful diagnosis because:

- The findings might be applicable across specialist boundaries
- It is possible for an experienced hospital general physician to assess both medical and surgical cases without seeking specialist advice
- It might be possible to show clustering even though the number of cases entered into the study was small.

Cases were selected solely from the Capsticks database because a preliminary survey suggested that the associated records were more likely to contain useful information than those from alternative sources. It was not possible to take a random sample of Capsticks'

records because of their uncertain availability. So essentially this became a study of 'closed' records that were reasonably easily available at the time of the study.

The size of files and the amount of information contained in the records was very variable (mostly around 250 A4 sheets but in some cases well over 1000). Fortunately most of the paperwork on legal information was filed together in date order and could be ignored.

Clinical information was abstracted as quickly and as efficiently as possible by looking for specific items of evidence especially expert witness reports and legal summaries (particularly when these summaries included a reasoned medical opinion). The assessor was helped by his considerable experience of assessing medico-legal claims both for claimants and defendants (several hundred cases over 15 years); and of analysing computer-recorded data from these studies (Neale, 1993, 1998a, 1998b).

The data was recorded on pre-determined questionnaires with additional comments, in free script at the end of each questionnaire, about the quality of practice and the preventability of the adverse event.

Logistically there were few problems, largely because of the co-operation of the Capsticks staff in general and Brian Captick's personal assistant (PA) in particular. The PA cut through an administrative tangle and always succeeded in producing case notes that contained sufficient useful information. To this extent the case records were selected by their suitability for detailed review. The filing within individual records was variable and it was sometimes difficult to pick out key documents. However, in an individual case it was always possible to define the issues within one hour.

2.3 Data quality

The material available for each case was much as expected. Unfortunately the evidence used by the claimant in making a claim was limited. In essence most case records started with a letter of intent from the claimant solicitors which was followed by reports gathered from the Trust. The quantity and quality of these reports was very variable. It was difficult to assess clinical histories in cases in which

- the claim was discontinued
- the NHSLA or Trust decided to settle at an early stage of the proceedings

As a case developed more information became available – statement of claim, expert witness report(s) for the defendant, statement of defence and finally expert witness report(s) for the plaintiff. A legal summary might be made at any stage but usually after receipt of the expert witness report(s) for the defence.

Copies of case records were rarely available (<10% cases) – presumably these were held by risk managers at Trust level. In some cases it would have been helpful to check statements in reports against those available in the contemporaneous written record.

Expert witness reports were usually very informative and it was particularly helpful to be able to abstract data from report(s) commissioned by both claimant and defendant. A summary of informative material available is tabulated below.

Table 6

Material available	Surgery (27 cases)	Medicine (25 cases)	Total
Expert witness reports	19 (12 C+D (7D only	17 (4 C+D; 2 C only (11 D only	26 (50%)
Internal Trust correspondence	5	7	12 (23%)
Legal summaries	17	22	39 (75%)
Case records	3	1	4 (8%)
Witness statements	19	20	39 (75%)

C = claimant D = defendant

In most cases (25/52 = 48%) enough information was available to provide a firm statement on the quality of care and in a further 20 (= 38%) there was probably enough information to make an assessment that was reasonably accurate. In only 1 case (medical) was there insufficient evidence; but in a further 6 cases more information would have been useful. Additional expert witness report(s) and/or case records would have been needed to make a better informed assessment.

2.4 Results

Cases were selected for possible errors in diagnosis. Half the diagnostic errors were either due to failing put together signs and symptoms to form any physical diagnosis (12 missed diagnoses) or noting signs and symptoms but arriving at incorrect diagnoses (11 wrong interpretations). These types of error were evenly spread between medicine and surgery.

Factors underlying other potential errors could not be grouped satisfactorily (Table 7).

Table 7

Basis of claim	Medicine (n=25)	Surgery (n=27)	Total (n=52)
Wrong diagnosis	2 (8%)	0	2 (2%)
Missed diagnosis	6 (24%)	6 (22%)	12 (23%)
Delayed diagnosis	10 (40%)	10 (37%)	20 (38%)
Incomplete diagnosis and other factor(s)	1 (4%)	2 (7%)	3 (6%)
Delayed diagnosis (uncooperative patient)	1 (4%)	1 (4%)	2 (3%)
Misunderstanding by claimant - minimal delay in diagnosis/ no case to answer	5 (20%)	0	5 (9%)

Impact of incidents on patients

Inevitably many cases had serious outcomes (33% death; 21% physical disability) (Table 3) although usually these outcomes were due primarily to an extension of the disease process rather than a direct effect of health care management.

Example: A 68 year old man presented with perineal pain and difficultly with micturition. Assessment in an outpatient clinic revealed a hard knobbly tender prostate gland. Prostate specific antigen was moderately elevated and on clinical grounds the patient was diagnosed as suffering the effects of chronic prostatitis. He was treated with antibiotics for 2 months before a further assessment revealed inoperable cancer of the prostate. Almost certainly this delay in diagnosis made no difference to the patient's prognosis.

There were no obvious differences between medical and surgical cases although pain was a problem in 4 surgical cases occurring only once in medical cases.

Table 8

Impact of AE	Medical cases (n=25)	Surgical cases (n=27)	Total (n=52)
Death	7 (28%)	10 (37%)	17 (33%)
Cognitive impairment (CI)	0	1 (4%)	1 (2%)
Physical disability (PD)	6 (24%)	5 (18%)	11 (21%)
CI and PD	1 (4%)	0	1 (2%)
Infection	0	1 (4%)	1 (2%)
Pain	1 (4%)	4 (15%)	5 (9%)
Other	5 (20%)	6 (22%)	11 (21%)
None	2 (8%)	0	2 (4%)
Uncertain	3 (12%)	0	3 (6%)

Additional procedures performed as a result of incidents

Adverse incidents occurring as a result of healthcare management led to the need for corrective procedures in 19 cases (37%) with major surgery required in 8 (15%) - 6 surgical and 2 medical (Table 9). Additional medication was noted in 10 cases (19%) but in a further 4 cases the evidence was uncertain (Table 10). Other interventions were required in 3 cases and in 11 cases (21%) the hospital stay was significantly prolonged (Table 11).

Table 9:

Add'l procedure required	Medical cases (n=25)	Surgical cases (n=27)	Total (n=52)
Major surgery	2 (8%)	6 (22%)	8 (15%)
Minor surgery	0	2 (7%)	2 (4%)
Intensive care	1 (4%)	1 (4%)	2 (4%)
Other	3 (12%)	1 (4%)	4 (8%)
None	19 (76%)	15 (56%)	34 (65%)
Uncertain	0	2 (7%)	2 (4%)

Table 10:

Add'l medication required	Medical cases (n=25)	Surgical cases (n=27)	Total (n=52)
Yes	3 (12%)	7 (26%)	10 (19%)
No	16 (64%)	12 (44%)	28 (54%)
Uncertain	6 (24%)	8 (30%)	14 (27%)

Table 11:

Add'l treatment required	Medical cases (n=25)	Surgical cases (n=27)	Total (n=52)
Yes	3 (12%)	0	3 (6%)
Extended stay	2 (8%)	9 (33%)	11 (21%)
No	16 (64%)	11 (41%)	27 (52%)
Uncertain	4 (16%)	7 (26%)	11 (21%)

Period of care during which the incident occurred

Incidents stemmed more commonly from events in Outpatient clinics (18 – 35%) than from those in Admission Wards (12 – 23%) or in Accident and Emergency (A&E) departments (7 – 13%) (Table 12). Considering the data from Admission wards and

A&E together there was no difference between the incidence of medical and surgical cases. The high rating for adverse events stemming from Outpatient Clinics probably reflects the psychology of making claims rather than the overall pattern of incidents. For example patients and relatives are probably less likely to make a claim after a poor outcome arising from an emergency situation than from, what they may regard as, a considered opinion in an Out-patient clinic.

Table 12:

Stage of care	Medical cases (n=25)	Surgical cases (n=27)	Total (n=52)
General practice	0	1 (4%)	1 (2%)
OP clinic	8 (32%)	10 (37%)	18 (34%)
Pre-admission (unspec.)	2 (8%)	0	2 (4%)
A & E	5 (20%)	2 (7%)	7 (13%)
Admission ward	3 (12%)	9 (33%)	12 (23%)
During procedure	1 (4%)	2 (7%)	3 (6%)
Ward care	4 (16%)	0	4 (8%)
Discharge	0	1 (4%)	1 (2%)
Post-discharge	1 (4%)	0	1 (2%)
Uncertain	1 (4%)	2 (8%)	3 (6%)

Members of staff involved in the care of patient at time of incident

Consultants were directly involved in the care of patients in which half the incidents occurred (25 cases) and less directly in a further 8 cases (Table 13). This correlates with the high number of AEs stemming from Out-patient clinics. The next most numerous group were ward doctors (i.e. house staff up to and including SHO's) – 21% cases direct involvement and 21% indirect or subsidiary involvement.

Table 13:

Staff involved	Medical cases	Surgical cases	Total
House staff (incl. SHO's)	5 (+ 5)	6 (+ 6)	11 (+11)
Registrars	2 (+ 2)	4 (+ 2)	6 (+4)
Consultants	12 (+ 4)	13 (+ 4)	25 (+8)
Locum reg.	0	1	1
Team	1 (+ 2)	3 (+ 6)	4 (+8)
GP	0	(+ 1)	(+1)
Nurse	(+ 1)	0	(+1)
Other	3	0	3
Uncertain	0	2	2

Figures in brackets indicate numbers of grade of staff apparently involved at a secondary level.

Nature of the problem underlying the incident (note each case may fall under one or more category)

As cases were selected primarily based on claims of wrongful or delayed diagnosis, diagnosis was the major issue in possible faults in care (47 of 52 cases – 90%). In addition in 13 cases (25%) there were definite or probable problems in monitoring the progress of patients and in 11 cases (21%) in their general assessment. Procedural problems were identified in only 3 cases (6%) (Table 14).

Table 14:

Nature of problem	Medical cases (n=25)				Surgical cases (n=27)			
	Diag.	**Assess**	**Monitor**	**Proc**	**Diag.**	**Assess**	**Monitor**	**Proc**
Definite	13	1	4	1	10	3	3	2
Probable	3	5	2	0	9	2	4	0
Possible	5	1	3	0	7	1	1	2
Total	**21**	**7**	**9**	**1**	**26**	**6**	**8**	**4**
Not contributory	4	18	16	24	1	21	19	23

Commentary on surgical cases

For general surgery the pattern of cases in which there was diagnostic error was much as expected except for the high proportion of rare conditions – 9 out of 27. This may be

related to the length of delay in diagnosis (data not collected). The following comments appear appropriate for specific conditions:

Cancer of the breast is a common condition but, despite well-defined means of making the diagnosis, errors still occur. The 2 cases of definite fault were in patients examined by junior staff who either did not have or did not follow a reasonable protocol. The one probable fault occurred in the management of a patient in whom both she and her GP thought that they could define a lump which the surgeon was unable to identify – mammography was negative and the surgeon did not follow-up. 10 months later there was an obvious cancerous lump in the same segment of the same breast.

Appendicitis remains a difficult diagnosis especially in young women. For the past 6 years publications in the medical literature (Paulson, Kalady and Pappas, 2003) suggest that examination by **spiral CT will identify >95% cases** of acute appendicitis and will provide alternative diagnoses in many cases with normal appendixes. (Sensitivity and specificity for acute appendicitis >95%). Examination by ultrasound is much less certain. Very few hospitals in the UK have the resources to offer the appropriate CT service.

Definite or probable faults in diagnosis were in patients with hidden appendixes (2 pelvic; one retro-caecal; one not specified) and appropriate examinations were not performed (e.g. pelvic assessment by digital examination; ultrasound).

Perforated peptic ulcer is a much less common diagnosis than it was several years ago. It is difficult to know **how to raise awareness of this condition** that often goes undiagnosed until necropsy. It is missed especially in elderly patients although in the survey the ages were 48, 58 and 72 years. In the first patient the casualty officer diagnosed a pulled muscle (inadequate history and interpretation of clinical findings); in the second there was delayed assessment by a surgical registrar and then over-reliance on what was said to be a normal CXR; in the third case the patient was seen in the middle of the night by a house doctor who made a tentative (correct) diagnosis but left the patient for action on the morning ward round.

Unclassified disorders In this series there were 12 examples of 'isolated' misdiagnosis. 3 were misdiagnoses of common conditions – Ca prostate (initially thought to be chronic prostatitis); a bleeding DU (dreadfully mismanaged by ward doctors over a weekend); and a fractured skull (with delayed recognition of deteriorating consciousness and a CSF leak). The 9 other cases were misdiagnoses of rare conditions (5 rare neoplasms; 3 unusual disorders due to vascular pathology; and one drug-induced condition - NSAID cystitis misdiagnosed as a colo-vesical fistula). However, in each of 7 of these rare diagnoses there were certain or probable faults (delays) in making the correct diagnosis.

> Examples: In 4 of the 7 cases non-specialist staff were out of their depth and did not seek appropriate help (GI bleed left for 60 hours; odd lump in cheek sent for day surgery; missed deterioration in patient with head injury (including leak of CSF); failure to obtain CT scan in a patient known to have a compressed ureter). In the other cases specialist surgeons appear to have been working on 'auto-pilot' and failed

to examine/investigate patients appropriately (an ENT surgeon missed an acoustic neuroma; an orthopaedic surgeon failed to do a neurological examination in a patient with nerve root symptoms progressing to paraparesis; a general surgeon defunctioned a patient's colon for a presumptive colo-vesical fistula despite appropriate radiological examination that showed no defect. Subsequently the patient was found to have drug-induced cystitis). 1

These unclassified cases show recurring themes in the art of diagnosis including:

- *assessing the patient as he/she walks through the door* (e.g. an orthopaedic surgeon should be able to spot a likely 'neurological' gait)
- *concentrating on elucidating the main symptoms* – often details in the patient's story hold the key to diagnosis (e.g. a patient with a lump under her jaw demonstrated that pressure on the lump caused her to cough. This was ignored and the lump was diagnosed as simply ectopic salivary gland tissue. In fact she had a deep-seated paraganglionoma that could have been diagnosed by scanning at the time of presentation.)
- *collecting all the key symptoms, signs and results of investigations and assessing the overall pattern*. It is all too easy to leap to a diagnosis and to ignore evidence that doesn't fit the picture (e.g. A man presented with dysuria, frequency of micturition and bladder inflammation seen on cystoscopy. He might have had a colo-vesical fistula but the radiological examination using contrast media failed to show a fistula. This virtually excluded the diagnosis – so the surgeon should not have proceeded to laparotomy but should have re-assessed the evidence. Had he done so he might have noted that the patient was taking a drug (NSAID) known to cause cystitis). The discipline of writing a differential diagnosis is too often ignored.
- *getting a second opinion when in doubt* – a rule that applies especially to inexperienced clinicians but should not be ignored by consultants (and would have been appropriate in the case described above).
- *reviewing case notes and thought processes at the end of a clinic* – having second thoughts is often helpful.

Commentary on medical cases

As in general surgery the pattern of cases was fairly predictable. Delays in recognising tuberculosis may become a significant problem as the number of cases increase especially amongst immigrants living in urban areas (Davies, 2003). Diagnosing rare tumours is always going to be a problem although one that can often be resolved by using an appropriate scanning technique.

Issues noted regarding specific conditions are as follows:-

Cardiac pain. The main problem in the cases reviewed was the inability to recognise ECG abnormalities. I suspect that only cardiologists have a high degree of competence

in reading ECGs. However, ECG technicians can become very good and computer analyses should not be ignored. In the literature there is evidence to show that ECG technicians perform better than SHOs and junior registrars (ref). There is a case to be made for, whenever possible, an ECG to be reported on by the trained technician taking the tracing.

Subarachnoid haemorrhage. The diagnosis of acute headache is a perennial problem. Curiously the 5 cases in this study were all somewhat atypical. However two well-recognised issues emerged.

- A careful history is vital and diagnoses of tension headache and migraine should be made with caution especially when there is no longstanding history
- There is a serious lack of neurological and neuro-radiological expertise in district general hospitals.

Tuberculosis. The present generation of doctors were not educated in the era when TB entered the differential diagnosis of most non-acute diseases. Errors in diagnosis occur at all levels from failure to consider the possibility in a chronically ill patient, to failure to look at radiographs, to poor quality histopathology. It may be necessary to raise the profile of TB in undergraduate and postgraduate teaching in view of the recent resurgence of cases in the UK (mostly in immigrants and patients with AIDs).

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

Over the next 12 months the patient's health deteriorated progressively and he lost 2 stones weight and became unable to work. He was referred to a 'top' unit for infectious disease where he was told that he had "chronic fatigue syndrome". (Errors: failure to undertake a full physical re-assessment; making a diagnosis of a functional/psychological/psychiatric disorder without excluding organic disease)

A year later the patient became unable to walk. This was regarded as a back problem super-imposed on chronic fatigue and poor posture. A consultant rheumatologist diagnosed spondylitis. A further 6 months went by before it was recognised that the patient was actually very sick. A chest radiograph showed evidence of advanced pulmonary tuberculosis.
(Error: failure of specialist to look at the 'whole' patient as well as the area of special interest)

Acute abdomen Most cases of acute abdominal disease are referred directly to surgeons. In the 2 cases in this series the patients had other disorders – one was an alcoholic (who developed pancreatitis) and the other was on high dose prednisolone for polymyalgia (leading to a perforated peptic ulcer). The abdominal diagnoses were unnecessarily delayed and the learning point must be that a surgical opinion should be obtained promptly for all cases of severe abdominal pain.

Non-ischaemic heart disease. As for tuberculosis, now that rheumatic fever has virtually disappeared valvular heart disease has become much less common and most doctors have failed to acquire the auscultatory skills to make a clinical diagnosis of structural cardiac pathology. However ultrasound examination of the heart is very effective, readily available and should be used whenever there is doubt.

Rare tumours. It is interesting that the delayed diagnosis of rare tumours appeared as a common cause of claim (5 in the surgical series and 5 in the medical series). Again this leads back to the art of diagnosis (see above under surgery). Humans are much better at following a routine than at considering one-off problems

Others. One case concerned a child with renal hypertension who ruptured a berry aneurysm but the available evidence was too scanty to make a valid judgement about the quality of care. The final case was mildly diverting – a man misled a rheumatological team and a consultant neurologist when he complained of increasing immobility. He underwent many tests and efforts at rehabilitation before he was referred to a psychiatrist who labelled him as suffering primarily from conversion hysteria with overtones of malingering. The patient sued on the grounds of having received unnecessary physical treatment!

2.5 Conclusions

This was an interesting exercise but too cumbersome, I think, for routine use.

Although the analysis of claims against NHS Hospital Trusts cannot provide an accurate picture of the quality of health care in general hospitals the method may be useful in identifying clusters of events leading to claims; and in bringing together unusual cases that occur sporadically (e.g. the injection of vincristine into the CSF, a procedure that had terrible consequences for patients but overall was occurring just once a year in the U.K.)

Strengths of method

I have considerable confidence in conclusions from cases that had been fully assessed. Expert witnesses have had access to all the clinical material (case notes, GP records, correspondence, witness reports and radiographs) and the standard of assessment was usually reasonably meticulous. On the other hand the reports are designed to establish a position with respect to medical negligence and they take no account of contributory factors.

Severity of outcome is probably an important precipitant for making a claim. Curiously incidents arising from care in an out-patient clinic equalled those arising in A&E and admission wards put together. This suggests that claims are proportionately less likely to arise in the care of the acutely sick (perhaps because the general public are more likely to expect the worst following admission to hospital as an emergency).

It was equally surprising to find that consultants were directly involved in 50% of the incidents leading to claims (and indirectly involved in a further 16%). This must be related to selection of cases but does show that clinicians remain vulnerable to error even after they are regarded as fully trained.

By collecting data from claims it is possible to show some degree of clustering. This offers the opportunity of making some statements of general value.

Weaknesses of method

The cases are highly selected and one can only guess at the processes influencing the decisions to make claims.

The quality of available evidence is variable. In most cases arising from hospital management it is possible to form an opinion regarding the overall standard of care but in depth analysis is not possible.

The cases are far from contemporaneous. It is probable that most cases are not closed until 5 or more years after the event. So we have been analysing what happened in the mid nineteen-nineties.

Clinical commentary

The clinical themes emerging from this study reveal little new. Nevertheless the general thesis that the art of diagnosis remains firmly rooted in following basic principles – taking a detailed history (especially of factors surrounding symptomatology), combining this with a careful clinical examination and ending with a differential diagnosis that takes account of all the evidence – remains paramount.

Interestingly doctors who undertake medico-legal work often state that their own standard of practice has been improved by analysing adverse events. Perhaps this provides a lesson. Audit of hospital practice is fragmentary and inadequate. Introducing this into the working life of hospital doctors in a coherent manner might lead to practice that is more thoughtful and of higher quality.

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3 Analysis of claims in psychiatry

3.1 Introduction

Safety issues in mental health services are often seen as addressing two principal areas: (1) the risks due to staff, to other patients and to the public, as a result of the patient's disorder; and (2) the risk of suicide and parasuicide by the patients themselves. However, mental health patients suffer many of the other risks faced by patients in general and, in particular, medication errors with drugs that are powerful and dangerous if given wrongly. They are nevertheless different to other patients in that they are often very willing parties to the harm they cause themselves, certainly in suicide, but sometimes also in terms of medication, since they are frequently reluctant to take the drugs prescribed.

Suicide and Parasuicide

Most suicide (84%) takes place outside hospital care (National Confidential Inquiry into Suicide and Homicide by People with a Mental Illness, 2001). Nevertheless, around a quarter of suicides have been in contact with mental health services in the year before their death, and the commonest drugs used to overdose are those prescribed to treat their mental disorder. From the National Confidential Inquiry (2001), it is clear that groups most at risk are those in their first year of illness, particularly those who also have alcohol and/or drug abuse and who self-harm. Half of the suicides in this inquiry had been in contact with mental health services in the week before their death, and in 85% of cases their immediate risk of suicide was judged to be low or absent.

Only 16% of suicides are in-patients, usually by hanging; and a quarter of suicides occur within three months of discharge, particularly in the first week.

Medication Errors

Medication errors are as likely to occur within mental health services as elsewhere. However, there are particularly risky drug interventions in psychiatry; for example, in the long-term use of lithium, where there is inadequate monitoring or overdose.

As Grasso et al (2003) point out, psychiatry would benefit from more investigation into adverse drug events and medication errors. Their review of papers in the period 1996 - 2003 found few reports on the incidents and characteristics of medication errors in psychiatric hospitals. Although sparsely documented in the literature, lithium prescription error resulting in toxicity is a well known clinical problem. Lithium toxic patients suffer serious morbidity, and the length of time they spend in hospital makes it a worthwhile investigation on cost issues too (Oakley et al, 2002). In addition, discussions with Capsticks and the MDU highlighted this issue as a good example of mental health litigation from their databases.

3.2 Methods

These two areas - suicide/parasuicide and errors of psychiatric medication - were considered the most useful foci for the study of litigation bases involving mental health services. The focus on suicide will let us study via litigation data an unusually distinct but common cause of death or serious injury while under NHS care. This is also a key government target area for reduction of those who die. On the other hand, studying medication errors in mental health services lets us look for commonalties with, as well as distinctions from, other types of healthcare.

Cases for analysis were selected by requesting Capsticks solicitors (for secondary care) and the Medical Defence Union (for primary care) for all files of closed suicide/ parasuicide and medication error litigation cases since 1985.

The two reviewers were Chartered Clinical Psychologists and one (JFC) was also a Chartered Occupational Psychologist. CD analysed 41 (72%) of cases, and JFC analysed 16 (28%). Initially they spent two days analysing cases together so that discussion about any ambivalent material could take place, encouraging greater reliability in the review process. After these joint reviewing sessions the rest of the cases (N=32) were analysed by CD alone.

Each case was analysed using a version of the review form designed and used previously in clinical case reviews and adapted by the authors for use with mental health litigation cases (see Appendix 1). After establishing what documentation was available, the reviewer was first required to judge whether there was sufficient information to provide useful evidence. Types of documentation included: plaintiffs' or defendants' expert witness reports, legal summaries, or staff statements or reports. If none of these existed, then this was recorded and the analysis went no further.

3.3 Data quality

The two organisations produced 57 cases which accorded with our selection criteria. Of these, 33 (58%) were suicide or parasuicide, and 22 (39%) were medication incidents, while the remaining two cases (3%) were judged to involve other mental health issues.
The files reviewed contain primarily solicitors' letters and costings with very few reports.

Reports

Table 15 sets out the type of professionals who gave these reports; there may have been multiple reports for some cases. Expert witness reports existed in 19 (35%) cases for the defence (13 cases in parasuicide/suicide cases and 7 for medication errors) and 19 (34%) cases for the plaintiff (9 cases in suicide/parasuicide and 10 in medication incidents). Other types of reports were present in 37 (66%) cases, including statements of claim (11

cases, 20%), coroners' reports (2 cases, 4%), legal summaries (10 cases, 18%) and, in two cases (4%), copies of actual clinical notes.

Table 15: Professions of expert witnesses

Professions of expert witnesses	Plaintiff	Defendant
Psychiatrist	14	10
Orthopaedic Surgeon	4	2
GP	7	5
Clinical Psychologist	1	0
Physician	2	2
Other	3	6
Nurse	0	2

File sizes varied considerably ranging from one to between 5-9 large folders for those that went to litigation. Files were rarely organised, except for costs, and it was often unclear whether the case had been settled, gone to court or indeed was still ongoing. The quality of the notes appeared to vary according to whether claims were seriously pursued or not and whether they went through to a judgement or settlement. Where legal liability was absolute (because, in suicide/parasuicide cases, Mental Health Act surveillance protocols were breached), there were particularly brief, poor data.

3.4 Results

Of the 57 cases, 39 (67%) had sufficient documentation for review, and all data which follow come from this group of cases. Of these, 24 (61%) concern suicide/parasuicide and 15 (39%) medication errors. These are set out in Table 16, divided for in-patient/community and male/female. Mean age of male suicides/parasuicides was 33 (sd 11.7 years), of females it was 32 (sd 11 years). For medication errors, the mean age of males was 32 (sd 3.5 years) and of females it was 46 (sd 15 years).

Table 16: Frequency of patients (or relatives) with claims regarding medication errors or suicide/parasuicide actions

	Inpatient		Community	
	Males	**Females**	**Males**	**Females**
Parasuicide/Suicide	5	7	6	4
Medications Error	0	2	6	7

Suicide and parasuicide

The principal diagnoses for those cases of suicide or parasuicide were schizophrenia (7, 29%) or depression (7, 29%). In addition, there were four cases of affective/bipolar disorder, three of personality disorders, one combined depression and anxiety, and one with no diagnosis in the records.

Ten people died as a result of their suicidal act. Hanging accounted for four cases, two people threw themselves under trains and one died by self immolation. The three other cases did not specify how the patient had died although two had previously attempted suicide, one by slashing his wrists. In terms of parasuicide, the injuries suffered varied according to which method the patient used: two cases (5%) had spinal injuries and broken limbs resulting from falls from great heights; and a further two cases (5%) had brain damage due to hanging. Other injuries that were sustained through parasuicide included one patient with burns and eight cases of multiple injury, and two further cases of fractures.

Causes of injury

In 16 (67%) cases, the injury or death was judged as caused by healthcare management interacting with the condition, namely the suicidal intent of the patient. In two cases it was judged as caused solely by the process of the illness. In five cases, the reviewer was unable to judge.

In 9 (39%) cases those named as being most closely involved in the incident were nurses, followed by six (25%) general practitioners, two (8%) Consultant Psychiatrists, and two (8%) junior doctors, and one other member of staff. There were no identified members of staff in the other cases.

Table 17 sets out the definite, probable or possible cause of the incident (note: some causes possible in other conditions were not applicable in any mental health cases).

Table 17: Cause of Incident (Suicide/Parasuicide)

	Definite n (%)	Probable n (%)	Possible n (%)	Not present n (%)
Failure/delay to diagnose or assess correctly	10 (41%)	2 (8%)	7 (30%)	5 (21%)
Failure/delay to appreciate the patient's overall condition	14 (58%)	2 (8%)	5 (21%)	3 (13%)
Failure/delay in clinical monitoring/management	13 (54%)	5 (21%)	2 (8%)	4 (17%)
Related to prescribing of drugs/fluids	0	0	3 (13%)	21 (87%)

Medication Incidents

Of the 15 medication incident cases the diagnosis was affective/ bipolar disorder in four cases (27%), followed by two cases each with diagnoses of depression, anxiety, and schizophrenia. Various mental health diagnoses were given for each of the other five cases.

Of the medication error cases, seven (45%) concerned the prescription or monitoring of Lithium. The others included a variety of antipsychotic medication: three (20%), Carbamazepine; and one (7%) each of Respiridone, Pethidine, Largactil, and Benzodiazepines.

Through medication error the injuries suffered included neuroleptic malignant syndrome (6, 40%), other mental health problems (3), one suicide attempt and one addiction/dependency problem. Two cases resulted in renal damage, and one case each of liver damage and heart block.

Causes of injury

Twelve cases (80%) involving medication errors were judged to be due to a combination of healthcare management plus the disease process, whilst only one case was judged to be solely a healthcare error, one a disease-only process, and one was unable to be judged.

In terms of staff named as most closely involved with the incident in two cases these were nurses, in nine they were GPs, and three were consultant psychiatrists, with no named staff for one case.

Table 18 sets out the definite, probable or possible nature of the incident (note: some causes possible in other conditions were not applicable in any mental health cases).

Table 18: Nature of Incident (Medication errors)

	Definite N (%)	Probable N (%)	Possible N (%)	Not Marked N (%)
Failure/delay to diagnose or assess correctly	0	1 (7%)	3 (20%)	11 (73%)
Failure/delay to appreciate the patient's overall condition	1 (7%)	3 (20%)	1 (7%)	10 (66%)
Failure/delay in clinical monitoring/management	3 (20%)	1 (7%)	3 (20%)	8 (53%)
Directly related to a problem with an operation or procedure?	1 (7%)	0	0	14 (93%)
Related to prescribing of drugs/fluids	8 (53%)	1 (7%)	1 (7%)	5 (33%)
Directly related to administration of drugs/fluids	1 (7%)	0	0	14 (93%)
Related to monitoring of drugs/fluids	7 (46%)	0	1 (7%)	7 (46%)

Causative or contributory factors in mental health cases

Most causative or contributory factors noted from the data in both categories of claim involved the patient; for example, 53% noted personality or social factors; 69% previous treatment history of high risk or non-compliance; 59% with previous personal history of suicidal attempts, etc, and 23% of other relevant personal factors. The latter included seven instances of poor doctor-patient communication, one of missed important cultural factors and one caused by external events (watching a film of the Dunblane massacre) triggering a patient response.

In terms of organisational or staff-related factors, 44% involved the failure to use guidelines or protocols that existed (particularly the Mental Health Act), 16% involved inadequate supervision, 20% poor written communication, and 31% were cases where the incident involved referral to another agency or team member.

3.5 Case examples

Example 1: Parasuicide/Suicide

This example is a mistake by a senior house officer with six months experience.

The patient, a man of 40, had a psychiatric history 20 years previously. He presented at A&E with badly lacerated wrists. He was assessed but sent back to the caravan where he was living which was splattered with blood from his suicide attempt. The SHO gave him a letter addressed to his GP to take home with him, presumably for the patient to deliver personally.

The patient was due in court the next day. He had written a suicide note and disposed of his money to friends. This was evidence of behaviour that is associated with suicide, as was his clear suicidal intent and recent attempt. In the circumstances, it seems that obtaining advice or detaining the patient would be the obvious decision for a junior member of staff. The accumulation of clinically significant signs and behaviours suggested a serious risk of further self harm or suicide attempts.

The outcome was that although the GP referred the patient to a psychiatrist (whether or not this was as a result of the SHO's letter is not clear), the patient committed suicide before the appointment date.

As a result of the claim, the patient's parents were awarded compensation.

Example 2: Suicide case.

An example that highlights how poor communication can play a major part in tragic events is the case of a 51 year old academic who committed suicide by self immolation.

This patient had attended his GP surgery over many years on an irregular basis because of "lecture anxiety". His mother had committed suicide. He had been prescribed Propanolol (a beta blocker) on these occasions.

In the two week period leading up to his suicide he consulted his GP four times because of symptoms of anxiety and depression. The GP prescribed Seroxat and told him that it would take time for the medication to work. Apparently the GP did not ask the patient if he had any suicidal thoughts. The patient's wife said that she told the GP that her husband had mentioned suicide to her.

Although a referral letter was written to a psychiatrist, it was not sent, the reasons for this are unclear. The patient was under the impression that it would take a long time for an appointment to be sent and the next day set fire to his car whilst sitting inside it. He died of his burns.

The witness statement of the patient's wife gave an account of the GP consultation that was totally at odds with the GP's defendant statement. They appeared to have a completely different understanding of what had been said at the consultation the day before the patient's death.

The legal outcome of this case was not clear.

Example 3: Medication error.

A female patient was diagnosed with post-natal depression following the birth of her son in 1965. The symptoms continued and the patient was diagnosed by the GP as having bipolar disorder. He treated her for 20 years with Lithium.

In July 1995 the patient was prescribed a diuretic. This resulted in her having an acute toxic state attributed to the long-term side effects of Lithium and Prothiadine (an anti-depressant) plus the interaction with a diuretic. Her symptoms included lethargy, slurred speech, diarrhoea, trembling, poor coordination, decreased libido and loss of confidence. After the diuretic, which is contra-indicated with Lithium, the patient became incoherent.

Admission to hospital led to blood tests being taken and the patient's toxic state being diagnosed. She required a number of follow-up visits over the next fortnight.

Eventually the patient's medication, both anti-psychotic and anti-depressant, was withdrawn totally. One of the patient's complaints was that she had been advised not to have further children whilst taking Lithium. She had very much wanted more children.

The GP had misdiagnosed bi-polar disorder and then failed to monitor serum levels. He was under the impression that he had supported this patient through many difficult years. The patient felt he had not listened to her when she had tried to tell him about the symptoms she was getting.

Evidence for this case included a GP and psychiatrist report. The consensus of opinion was unequivocal in support of the plaintiff.

Example 4: Medication error.

This case illustrates racial issues and misunderstanding of "florid" type behaviour.

A 24 year old male psychiatric patient diagnosed with schizophrenia was the victim of poor inter-hospital communication and probable misinterpretation of his behaviour.

An increase in his disturbed behaviour led to an escalating spiral of anti-psychotic medication. This patient was transferred between different hospitals in an attempt to contain his behaviour. As a result of miscommunication and missing notes, there was poor case management. The patient's behaviour became more and more desperate but met only with a rigid medical response.

This patient's case was broadcast by the BBC as a part of a series about Black/Asian issues. The consultant involved in his care was given a written warning by the Health Authority about his racist attitudes towards patients.

The litigation case was brought by the patient's parents since he had suffered liver damage and severe anaemia as a result of the over-prescription of anti-psychotic medication. However, the case did not proceed to become an active claim.

Evidence for review of this case came from notes of an internal hospital inquiry.

Example 5: Suicide

A 29 year old female patient diagnosed with psychotic depression hanged herself while on an inpatient ward.

An initial psychiatric opinion had failed to note how low the patient was and simply prescribed anti-depressants with no follow up. She was not fluent in English. The subsequent psychiatric admission revealed that the patient's mood was "flat, low and preoccupied". Her unkemptness and weight loss were noted. A care plan was drawn up agreeing close observation, but this was not defined.

The patient was found hanging. Emergency resuscitation equipment was inadequate and the staff were not trained to use it.

This case was the subject of an "untoward incident" inquiry at the hospital concerned.

3.6 Discussion

Quality of Litigation Data

There were fewer psychiatric claims during the period under study than any of the other clinical areas we considered. A review of actual and potential claims by the MDU from a randomly selected year revealed approximately 1% were Mental Health cases. Moreover, the quality of case notes in the litigation cases dealing with mental health issues was very poor indeed - in particular those regarding suicide or parasuicide – in terms of their usefulness in exploring in any depth the causes behind the incident. There are a number of possible reasons for this. First, there is the problem of absolute liability where protocols regarding surveillance have been breached; for example, where a nurse has left a patient for 20 minutes while surveillance was required every 10 minutes. This means that suicide cases usually do not continue beyond the first few solicitors' letters, which makes it very unlikely that expert witnesses are called. Where these exist, they are principally from psychiatrists, and fairly equally for plaintiffs and defendants. The material within the legal notes is therefore largely clinical rather than addressing service issues.

Second, by the nature of their illness, mental health patients are frequently reluctant to be treated and may see treatment as an attack. Because of their reluctance they are perhaps more likely to give insufficient information to staff and so, in some way, they may

contribute substantially to what goes wrong, and this leads to legal cases being dropped. However, this lack of compliance is clearly part of the nature of their illness, so in patient safety terms this is not an issue. Their treatment needs to involve the use of safe ways to deal with their reluctance.

Finally, there may be fewer cases overall – and fewer which go any distance – because relatives understand the problems of treating individuals with severe mental health problems and so do not pursue claims so vigorously as they might do incidents of poor physical health care. Even where the case might be sound, the patients themselves may be less likely to bring cases because of their own disordered states which make the long pursuit of satisfaction more difficult to achieve. Although details on the amounts claimed and/or awarded were often difficult to find in the notes, it seems clear that these were relatively small, and pursuing a claim to settlement or judgment was rare. Where a case does not proceed, it would be useful if in future the reason for this was included in the notes.

Thirty-nine cases had data of sufficient quality to form our sample. It can be seen that most of the incidents leading to medication error cases take place in the community, while the suicide/parasuicide cases are primarily concerning in-patients, completely contrary to the fact that most suicides take place in the community. This might lead to the interpretation that community suicides are more personal affairs, less influenced by healthcare, were it not for the finding in the National Confidential Inquiry that half have been in contact with mental health services in the week before their deaths. In reality, it is more likely that the larger number of litigation claims which arise from inpatient treatment is the result of the absolute liability under the Mental Health Act when a patient is sectioned. This means that litigation data have considerable limitations in terms of understanding the causes of suicide and parasuicide while under care within the community.

Medication cases are almost all within the community, perhaps reflecting (as one of the case studies illustrates) that general practitioners do not always diagnose severe mental illnesses accurately, nor prescribe for them correctly, nor monitor regularly.

Other material in some files was useful in making expert judgments. This was particularly the case with legal summaries and statements of claim. Where patient case notes were included, this provided considerably more useful information in terms of background issues such as staffing levels, rarely mentioned in the reports of expert witnesses. However, going through patient case notes is a cumbersome process.

Suicide and Parasuicide

Eleven of the 24 cases in this group had succeeded in killing themselves, using the usual methods, in particular by hanging. The injuries of the others were often considerable, involving multiple fractures, paraplegia, substantial burns and brain damage due to being rescued by staff while hanging.

In terms of expert judgment from the case notes, in 16 (67%) cases the injury or death was seen as caused by healthcare management interacting with the suicidal intent of the patient, which was a substantial part of his or her illness, whatever the formal diagnosis. In only two cases was it judged as caused solely by the illness itself – that nothing could have been done to stop the attempt. In five cases there were insufficient data to make any judgement.

Looking at the litigation notes, it is clear that these provide a description of only those staff involved around the actual incident – primarily nurses, particularly in the in-patient cases, or general practitioners who had seen the patient fairly close to the event.

The principal causes of the events involved a failure or a delay to appreciate how depressed and/or actively intent on suicide the patient actually was, either through monitoring them less closely than was stipulated, or failing to diagnose or assess correctly in the first place. Although there are usually only individual examples of the ways this occurred, these still provide some potential lessons for healthcare in cases where the notes were good. For example, in two cases people had been transferred around a variety of mental health units and real knowledge of the seriousness of their intent was not communicated well. In another case, just the contrary: the patient was extremely well known to staff, had been in and out of the hospital for years, and it seemed more that they never expected him to do anything outside his routine: "he always went to the shop on his own".

What the litigation notes almost always fail to provide is anything more than the very immediate cause of the incident except where hospital case notes are included. From these notes other possibilities emerge. For example, in a case where a young woman had tried (and failed) to hang herself, thereby suffering severe and irreversible brain damage, the hospital notes revealed that she had been having a long series of electro-convulsive therapy prior to this act and that, as a result, she had come out of her manic state and was getting "very low". The influence of her ECT, and the fact that the lowering of her mood was seen as a beneficial result of it, was apparently never viewed as a causative factor in her subsequent attempt. Nor was it noted in any of the legal notes that the dangerously low staffing on the ward had been reported by a student nurse but left unchanged. The nurse who should have been supervising the patient was dismissed, but the actual treatment of ECT and drugs was not questioned.

Medication errors

The number of medication errors in the sample is small, and nearly half of them concern the use of lithium. Almost all take place in the community and involve primarily general practitioners' inaccurate diagnoses, wrong drug combinations and poor monitoring (one case study involves all three of these). Neuroleptic malignant syndrome is the most common outcome for these patients on lithium; for example, when the dose was administered twice within a short time in hospital, or where it was poorly monitored.

Oakley et al (2002) consider that lithium toxicity is an iatrogenic problem in patients with predisposing factors. They analysed retrospectively 97 cases of lithium poisoning treated at a regional centre over a 13 year period. Findings suggested that neurotoxicity occurs in patients who had identifiable risk factors such as older age, abnormal thyroid function, impaired renal function and nephrogenic diabetes insipidus. According to the data available to us, our sample had none of these characteristics. This might reflect the generally poor data available from litigation; our own small sample size; or it may suggest a gap in knowledge and understanding of lithium prescription errors. As Oakley et al state, after 50 years of medical experience of lithium, and despite the fact that they have identified that neurotoxicity occurs usually in the context of chronic therapeutic administration rather than overdose, there remains worryingly little research in this area.

Medication errors studied by litigation data have apparent causes which are very similar to those in other conditions, studied by other methods. They do, however, highlight the inadequacies of general practitioners in diagnosing, prescribing and monitoring these drugs. Nevertheless, there have been a number of educational initiatives during this period (for example, the 1993 Defeat Depression campaign) which are likely to have resulted in somewhat better management of serious mental illness taking place now within primary care.

Causative factors

What is very clear in the litigation data relating to mental health, is that the causative factors focus primarily on the patient and his or her condition, previous history, social factors, etc., rather than on anything beyond the immediate incident itself. In this sense the defence against litigation has strong indications of "blaming the patient" who was described as badly behaved, who failed to do as he or she had said they were doing, or failed to seek help. This highlights the problems of reporting the causes of poor care in a behaviourally based condition rather than one that is purely physical.

3.7 Conclusions

In terms of factors beyond the patient or the immediate incident we saw only faint glimpses of evidence around teamwork, the referral process (whether between agencies or at the primary/secondary interface), and poor communication as contributory factors. There were a number of cases where existing guidelines or protocols had not been used, but this was inevitable in cases involving The Mental Health Act.

Overall, this form of data does not help us to understand individual cases any better than – or as well as – other forms of in-depth analysis such as national audits, internal or external reviews or ward- or practice-based root cause analyses. Although individual cases do bring out occasional safety lessons, as described above and in the case studies, the lessons learned need to be considered in relation to the enormous amount of work it currently takes to find the data within the files. Were systems of analysing all errors by

the Trusts concerned made available within the files; and were the legal files themselves changed in ways to make the evidence more systematic and accessible, then it might be possible that this means of understanding patient safety became more appropriate. At the moment this is not the case.

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4 Analysis of claims in obstetrics

4.1 Introduction

Obstetric claims account for over 70% of all NHS litigation expenses with average cost as a result of cerebral palsy cases being approximately £1.5 million. Indeed birth related brain damage (including cerebral palsy) alone accounted for just over 5% of medical litigation cases in which damages were paid and 60% of all annual expenditure on medication litigation (DOH 2003, p9). The current estimate is that obstetric claims will amount to £400 million of total costs of £600 million to the NHS (Wood, L., 2003). The highest payment in a cerebral palsy case to date is £5.5 million paid in February 2003 (DOH 2003, p50).

It has been estimated that a 10% reduction in the number of adverse events from which the claims arise, could save the NHS at least £20 million annually (DOH 2000).
A retrospective study of the data base of obstetric cases in an organisation conducting the defence of obstetric claims has the potential for providing valuable information for root cause analysis in order to identify clinical issues and problems in the system of providing midwifery/obstetric care.

4.2 Methods

The study was undertaken to ascertain whether useful information might be obtained from an analysis of medico-legal records of approximately 50 cases. The selection of cases was based on the premise that cerebral palsy and shoulder dystocia constituted most of the major compensation awards in this area. Cases were selected solely from the Capsticks database rather than alternative sources because of their availability. The study was based on closed cases over the period 1985 – 2001.

There was considerable variability in the number of files, their size and distribution of the information. Files per case ranged from 1 – 15 (mean 3). There were 9 cases with files in excess of 5; and 23 with a single file. Most of the cases with a single file did not proceed to litigation (21 of the 23 cases); of the remaining 2 cases, there was obvious liability one of which was settled and in the remaining case it was unclear whether the case progressed. Case records were not available, reliance being on the legal documents provided.

4.3 Data quality

The files were established for documenting a legal process. The material therefore had not been prepared for the type of retrospective analysis undertaken of the evaluation of the shortcomings in clinical care and the system of management. The initial plan had been to rely on the expert reports. However, in the event other documentation proved to be necessary. Indeed in 8 (16%) of cases the analysis could not proceed because of a lack of and inappropriate data. The organisation of the material was repetitive; all drafts were included and not identified clearly. The information was confounded by details of the legal process and the financial implications of the case which were not indexed for ease of reference. In the few complex cases with many and diverse expert reports, the differences of opinion resulted in difficulty in coming to a conclusion. Some of the most useful information was found in the legal summaries prepared for Counsel.

Of those cases on which an evaluation was made, the expert report, be it on behalf of the claimant or for the defence, was seminal in providing relevant information. All cases without expert reports did not proceed.

Witness statements of the medical and midwifery staff provided useful information and added insight into the clinical situation and, to some extent of the system of care in which the adverse event took place. In all cases that provided them, legal summaries were the most valuable documents in identifying the issues of the case. In particular, the shortcomings of the staff concerned and their work environment were revealed.

There was considerable variability in the time taken to analyse the documents ranging from 15 minutes in 3 cases that had inadequate information and did not proceed, to 2-3 hours in the 6 most complicated cases (average number of files – 7). Duration of work required averaged 60 minutes in the cases reviewed.

4.4 Results

Of a total of 49 cases, 41 (84%) had sufficient documentary evidence to review the case. These were divided into 34 cerebral palsy cases (83%) and 7 shoulder dystocia cases (17%).

Healthcare Management

<u>For Mother</u>
In 80% (33) of all reviewed cases there was an injury or complication. In 15% (6) of cases it was judged that no injury/complication was evident and in 2 cases (5%) the reviewer was unable to judge.
The injury or complication was attributed to healthcare management (5 cases or 12%), healthcare management plus the process of labour/delivery (16 cases or 39%) and to the process of labour/delivery only (13 cases or 32%). This left 17% of cases (5) where it

was difficult to judge what the injury/complication could be attributed to. Two cases (5%) were missing.

For Baby
The figures for the injury/complication to the baby are 34 cases (83%) whilst in 1 case (2%) the reviewer was unable to judge and in 3 cases (7%) there was judged to be no injury to the baby. 3 cases (7%) were missing.
The injury/complication was judged to be due to healthcare management only in 7 cases (17%), healthcare plus process of labour/delivery 16 cases (39%) and process of labour/delivery only 14 cases (34%). 4 cases were missing (10%).

The Nature and Impact of the Adverse Event

Table 19: Nature of injury due to adverse event

	Frequency	**Percentage**
Fatality	2	5%
Cerebral Palsy	22	58%
Other Obstetric	11	28%
Prematurity	1	3%
Stillborn	1	3%
Shoulder Dystocia	3	8%
Total	39	100%

The impact of the injury/complication was disability in 14 cases (36%) or cognitive impairment plus disability in12 cases (31%), or cognitive impairment alone in 4 cases (10%).

The adverse events resulted in additional procedures being carried out in 82% of cases reviewed, and in 4 more cases there was more than one additional procedure. The nature of these additional procedures included surgery (major four cases and minor in one case), two caesarean sections and ten emergency procedures.

Additional medications were also required in ten of the cases (26%). While additional treatments were also necessary in ten of the cases (26%). One case resulted in an extended hospital stay.

Stage of care

The period of care during which the injury/complication occurred was most commonly when the mother was in the labour ward (42%, 16 cases) or at the antenatal clinic (29%, 11 cases). If there was a further contribution to the incident/adverse event (40%, 15 cases), this was most likely to be procedure related (21%, 8 cases) or in the labour ward (18%, 7 cases).

Factors involved in Adverse Event

Although the sample size was small, a number of factors were highlighted. The most frequent were:
In 29% of cases (12) staff were judged to have failed to diagnose or assess correctly. In 27% of cases (11), there was a failure or delay in monitoring or clinical management. There was a failure to appreciate deterioration in the mother/baby's condition in 10% of cases (4). Table 2 describes the reviewer's judgement of the evidence available. In 14 (35%) of the cases the reviewer judged that there were additional problems during the period of care in which the adverse event occurred.

Table 20: Factors leading to Incident

	Definite N (%)	**Probable N (%)**	**Possible N (%)**	**Not Marked N (%)**
Failure/delay to diagnose or assess correctly	12 (29)	5 (12)	4 (10)	20 (49)
Failure/delay to appreciate the patient's overall condition	4 (10)	2 (5)	3 (7)	32 (78)
Failure/delay in clinical monitoring/management	11 (27)	2 (5)	2 (5)	26 (63)
Failure/delay to prevent/control infection	0	1 (2)	0	40 (98)
Related to a problem with an operation or procedure	10 (24)	2 (5)	1 (2)	28 (69)
Related to monitoring of drugs/fluids	1 (2)	0	1 (2)	39 (96)
Related to resuscitation procedure	1 (2)	1 (2)	0	39 (96)
Other	1 (2)	1 (2)	0	39 (96)

Deficiencies in CTG knowledge

There were eight examples of failure to interpret the CTG appropriately and seek advice in at risk cases. This would indicate that training in CTG interpretation was likely to be deficient.
Case example 1
A gestational diabetic, controlled by diet, was induced at term. There were abnormalities in the CTG trace at the end of the first stage of labour that became worse in the second stage. The registrar accepted these changes and allowed labour to continue without intervention or a fetal blood sample to check for abnormal bio-chemistry. Immediately prior to normal delivery, the trace was even more abnormal, with meconium staining in

the liquor which was aspirated. The child was born with poor Apgar scores and manifested hypoxic ischaemic encephalopathy (HIE) with subsequent gross signs of cerebral palsy.

Problems in the system of care

25% (10) of cases were judged to demonstrate a lack of staff skills and knowledge or staff working outside their expertise/experience. Similarly, 25% (10) of these claims were procedure related. A failure to use guidelines was identified in 25% (10) of case. Issues of poor teamwork/relationships perhaps related to inadequate supervision accounted for 6.5% of cases but this was very difficult to judge from the limited data. Many service issues were not evident because they are not raised in the litigation process. Another example of this is the lack of documentation regarding the doctor /patient relationship or, more probably, the midwife/mother relationship.

Case example 2
The client/mother sometimes contributed to the adverse event by insisting on a home delivery or delivery in a unit close to home where it was inappropriate for delivery to take place. A mother, who was a nurse, insisted on having her baby delivered at home although the consultant deemed this was inappropriate particularly as her second baby was over 4kg in weight. After 24 hours of ruptured membranes at home, the mother still refused transfer to hospital. There was a delay of 14 minutes after the delivery of the head. The domiciliary midwife did not have the skills to manage the shoulder dystocia adequately. Once delivered, she valiantly resuscitated the baby and transferred her for intensive neonatal care. The baby died 3 days later.

Case example 3
This is contrasted with a primigravida who requested a home delivery as she wanted a low key intervention as her sister had had a prolonged labour with forceps delivery. There was a family history of diabetes and she had a borderline glucose tolerance test. A compromise was reached with arrangements made for a domino delivery. A forceps delivery was performed after a prolonged labour of 22 hours. The child was born with good Apgar scores and a birth weight of over 4 kg.
Moderate shoulder dystocia was managed appropriately although an Erb's palsy with subsequent substantial recovery occurred.

Case example 4
In another case, the mother with a previous caesarean section requested delivery in the local maternity unit having had a subsequent normal delivery. In this labour, there were abnormalities in the CTG trace in the first and during the second stage these were obvious. The SHO was called at this late stage and agreed with the interpretation. He subsequently summoned the registrar who delivered the baby by forceps 80 minutes after commencement of the second stage. The baby was severely asphyxiated. Additionally, the facilities in this unit were inadequate for this "at risk pregnancy" and the paediatric cover was 1 hour away. As a consequence of this adverse event disaster, CTG training of

the midwifery staff was instituted and better paediatric cover was arranged, pending the closure of the potentially hazardous facility.

Staff Involved

The grade of staff involved in these cases of mother/baby injury was 18% midwife and other nurses, 18% senior obstetric training grades. In only 8% of cases was there consultant involvement. However, some judgements of the consultant/midwifery staff left much to be desired.

Case example 5
A woman of 32 was successful in her fourth attempt to achieve pregnancy by assisted reproduction i.e. IVF. Intra uterine growth retardation (IUGR) was diagnosed at 34 weeks as a "borderline small baby". At 38 weeks she had a show with painful abdominal contractions and she was advised to stay at home. There was no record of this telephone consultation, which was evident in other cases also. Nor was there any clear documentation in the notes that this was an "at risk" pregnancy. Five days later there was an intrauterine fetal death.
In the pathologist's opinion, the baby would have survived an apparent hypoxial event superimposed on the chronic IUGR had delivery taken place before 38 weeks. Failure to institute monitoring of fetal condition from 34 weeks onwards was evident.

Case example 6
In one such incident, the locum registrar did not respond to calls from a midwife who was concerned about a lady with an occipito-posterior position who had a prolonged end of first stage and second stage of several hours. Had she informed the consultant directly of this uncooperative junior obstetrician, it is likely that the resulting severe asphyxia and the subsequent cerebral palsy would have been prevented.

It was surprising to observe that there was clear evidence that in only 4% of cases locum staff were involved. However, the data did not record whether other junior staff were locums or the duration of their experience and tenure of their post.

4.5 Discussion

A retrospective analysis of these medico legal cases which were selected because of their unfavourable clinical outcomes reflects events occurring over the last two decades. Over this time period, improvements in the quality of care directed towards risk management should have been evident , yet the problem remains (DOH, 2003).

This research has identified deficiencies in the way in which healthcare was managed, particularly in the labour ward or the antenatal clinic. Factors attributing to the adverse event, on which the litigation was based, included failures of the staff to diagnose or assess the potential hazard correctly or refer to the appropriate senior clinician appropriately for consultation or advice; inadequate or inappropriate monitoring of the

clinical situation; failure to appreciate deterioration in the parameters reflecting fetal/maternal well-being; and delays in implementing necessary intervention. There was evidence of deficiencies in the skills of the health care professionals faced with critical clinical events, such as an inability to perform certain procedures or working beyond their level of expertise or difficulty to interpret CTG traces appropriately. Although there were problems in the system of care, these were difficult to judge from the data derived from the material studied. Poor team relationships and inadequate supervision was implicated as an underlying issue in many of the cases.

Although there was a failure to use guidelines in 10% of cases, the material collected did not evaluate whether guidelines were present or were being adhered to. Furthermore, as these data were collected for the purpose of defending litigation in cases of cerebral palsy and shoulder dystocia, they were not primarily directed towards examining the system of care or for defining issues in which risk management might be improved and thus be used for implementing appropriate strategies to obviate critical incidents. Nevertheless, in spite of the limitations of the information gleaned, it was clear that the findings of previous research were confirmed and useful lessons could be learned and applied (Ennis & Vincent, 1990).

Emerging clinical themes

Healthcare management

Obstetrics concerns the care of two patients, the mother and her child(ren), either antenatally or in the labour ward. In 32% of the cases the mishap was related to the process per se; in nearly 40%, i.e. the majority, the process of labour/delivery was compounded by deficiencies of the healthcare provided. In the minority (12%), the problem was the management of care alone. However, the quality of the data was such that it was not possible to make a judgement in 17% of cases.

Lack of experience and skills

In the assessment of the factors involved in the adverse events, there was good evidence indicating deficiencies in diagnosis and assessment of the deteriorating clinical situation resulting in critical delays in management of most of the cases (Table 2 ; case examples 2 & 3). This is in keeping with the findings of Murphy et al (1990) who found that there was a lack of knowledge in the interpretation of CTG's and a slowness to react to abnormalities. This was evident in this analysis with the implication that training in CTG interpretation was deficient. Clearly there is a need to address these anomalies (case examples 1 & 4).

Deficiencies in the system and use of staff

Issues reflecting deficiencies in the system of care were implicit but did not feature in the data since they were not pertinent to the litigation process. Inadequate staffing, poor deployment of existing staff to situations beyond their level of training, lack of training or opportunities to acquire necessary skills could not be ascertained from this information. Inadequate supervision of junior staff, who were slow to consult their seniors was apparent but not explicitly recorded. Midwives were reluctant to appeal for help from consultants when the system was such that the initial referral had to be to an SHO who might be very inexperienced and who would defer to a registrar, further delaying a critical situation. This could be compounded by "consumer pressure" from the mother requesting a "low index for intervention" in an inappropriate situation (compare case example 3 & 4).

When there was a fraught situation of an uncooperative registrar, the midwife did not feel empowered to insist on the registrar's attendance or to appeal directly to the consultant on call (case example 6). The midwifery supervisor supported her inaction. In another case in which a domicillary delivery was insisted upon, even though there was a history of a large baby, the midwife was out of her depth dealing with shoulder dystocia with disastrous outcome, yet her failure to manage the unforeseen emergency was vindicated as "she did her best". The information did not indicate whether she was provided with updating training.

Lack of consultant involvement

Direct consultant involvement in the emergency situation was infrequent (in only 2 of the cases reviewed). In one, the consultant was called too late because an inexperienced SHO was left to deal with a complicated situation without guidance.

In the other the consultant was at hand and successfully delivered shoulder dystocia. In case examples 5, the consultant's misjudgement was aggravated by poor documentation and inadequate assessment. In general the data did not accurately indicate whether the consultants' advice was sought in these cases.

This is a well recognised problem in obstetric practice and the RCOG has recommended that consultants should have dedicated sessions in the delivery suite. The reduction of working hours for junior trainees as a consequence of the European working time directive has resulted in the priority need to increase the number of consultants to make them available for direct involvement in intrapartum care. In the chapter on reducing risk in obstetrics, Drife (1995) sets out a clear programme to implement the necessary improvements in obstetric care, a need for which has been identified in this study.

Midwifery Issues and Deployment

The data obtained did not identify midwifery staffing shortages or inappropriate deployment of skills (case example 7). A trainee midwife was conducting a delivery when there was difficulty with delivery of the shoulders, the senior supervising midwife took over and successfully delivered this large baby (4.55kg) with good Apgar scores. However, the child had a transient Erb's Palsy and fractured clavicle. This readily defendable action proceeded to an economic settlement!

This study has failed to identify issues of midwifery staffing and deployment. It did identify inadequate skills in CTG interpretation and emergency manoeuvres for shoulder dystocia. Although it has been recognised that a national shortage of midwives exists (Dimond 1998), despite government targets to increase the number of midwives, the shortfall remains (RCM, 2003)

4.6 Conclusions

Investigations into medico-legal databases in order to conduct root cause analyses to identify remedial issues in the system of care provision in midwifery/obstetrics has distinct limitations because of the way in which the information is collected, being primarily directed towards the legal process. However, relatively simple modifications on how the data are kept and information about the system of care provided, would be helpful. Clinicians should be encouraged to identify and to carefully and fully document critical incidents

Adverse events should be investigated and documented at the time they occur or shortly thereafter. In particular the grade of the healthcare professional and the length of time they have been in the unit and their training record should be noted. The value of the summaries prepared by the lawyers for submission to the NHSLA were evident and have a potential application for risk management issues. It would be helpful if these were separately identified and chronologically filed.

The CNST recommendations will have facilitated further improvements (Wood, L. 2003) This study has been of interest and its value would be increased by a prospective investigation, in particular since these data were prepared for the litigation process rather than identifying remedial problems and deficiencies in the system of care. Studies based on contemporaneous observation of events in maternity units are more likely to reveal areas in which risk factors might be addressed (Ashcroft et al, 2003).

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Appendices

Appendix 1. Analysis of Claims Form

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

Inspection of electronic document	☐
Visit to organisation	☐

Source of Information:

M.D.U.	☐
M.P.S.	☐
Capsticks	☐
NHSLA	☐

Documents used (please tick):

How many plaintiff expert reports? ……

Professions of experts
(Please specify)

…..…….
……..
…….…….

How many defendant expert reports? ……..

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

……

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

How many legal summaries? …….

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

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

Section A – patient information and background to incident

Patient name/identifier……

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

Principal Specialty involved in care……

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

	Yes	No	Unable to judge
Was there a patient injury/complication?			
Was the injury/complication caused by:			

i)healthcare management			
ii) healthcare management interacting with a disease process/condition			
iii) solely by disease process/condition			

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

Nature of Injury…….
…….
…….

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

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

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

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

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

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

Post discharge
Re admission ☐

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

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

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

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

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

Section E

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

Case summary including reviewer's own judgement of events.
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Any additional comments on claims review process stemming from this case?
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Notes for Reviewers

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

Appendix 2. An example of a contributory factors analysis

Mrs B came to see her GP because she was feeling tried and lethargic. Her symptoms were non-specific. The doctor took a full history, examined her and formulated a working diagnosis that she may be slightly depressed. He decided to check a FBC and other biochemical markers and agreed that Mrs B would be reviewed with the results. The FBC showed that she was slightly anaemic with an iron deficiency picture. The result was acknowledged but was not linked with the patient's symptoms in her computerised records. Mrs B saw another colleague on several other occasions but with different symptoms. The occurrence of persistent bowel symptoms caused a review of previous investigations, the iron deficiency anaemia, which was further investigated. Mrs B was found to have a large bowel tumour. It is highly likely that if the iron deficiency was investigated earlier, then the tumour would have been picked up earlier.

The problem occurred in the following processes.

1. Assessment of medical problem
   Knowledge and skills of doctor – Possibly relevant

   Organisation of practice
   A system for maintaining medical records – Somewhat important

2. Formulation of management plan
   Organisation of practice
   A system for maintaining medical records – Somewhat important

3. Arranging investigations

Organisation of practice
A system for monitoring laboratory investigations – Very important

4. Formulating a diagnosis

Organisation of practice
A system for enabling access to the doctor – Possibly relevant
A system for monitoring laboratory investigations – Very important

5. Developing a treatment plan

Organisation of practice
A system for enabling access – Possibly relevant
A system for monitoring laboratory investigations – Very important
A system for medical record keeping – Somewhat important

Section G – Primary Care:

What is the principal nature of the problem?

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

Problem	Definite	Probable	Possible
Arranging to be seen by GP			
Formulation of symptoms into medical problem			
Assessment of medical problem			
Formulation of management plan			
Arranging investigations			
Formulating a diagnosis			
Development of a treatment plan			

Appendix 3. Rating quality of care and preventability in medicine and surgery

I noted the degree of confidence I had in making assessments (based on the methodology we used for retrospective case record review in the London study (ref). These are plotted against the estimates of quality of care in table 2.

Table 2

Quality of Degree care of confidence	Unequivocally poor care	Probably poor care	Possible defect in care	Acceptable care
High degree of confidence (25)	9M + 7S = 16	5M + 2S = 7	1M + 1S = 2	0
Reasonably confident (20)	0	4M + 7S = 11	5M + 4S = 9	1M
Some reservations (6)	0	0M + 3S = 3	0M + 3S = 3	0
Not confident (1)	0	1M	0	0

Findings

In general surgery 19/27 (71%) AEs were assessed as probably preventable with a standard quality of care; in general medicine the proportion was virtually identical at 18/25 (72%).

Diagnostic error by disease process- surgery

Diagnosis	Number of cases	Definite Fault	Probable fault	Possible fault	No fault
Ca breast	6	2	1	3	0
Appendicitis	6	2	2	2	0
Perforated ulcer	3	2	1	0	0
Other	12	4	3	5	0
Total	27	10	7	10	0

Diagnostic error by disease process- medicine

Diagnosis	Number of cases	Definite fault	Probable fault	Possible fault	No fault
Ischaemic cardiac pain	5	2	1	1	1
Intracranial bleed (SAH)	5	1	2	2	0
TB*	3(5)	1	1(2)	1(2)	0
Acute abdomen	2	1	1	0	0
Non-ischaemic heart disease	2	2	0	0	0
Rare tumours	5	1	3	1	0
Other	2	0	1	1	0
Total	24(26)	9	9(10)	6(7)	1

*One case of tuberculosis presented on 3 occasions to 3 different specialties (general surgery, infectious diseases unit; rheumatologist) and on each occasion the diagnosis of TB was missed. On the first occasion there was definite fault (failure to look at CXR/report); on the second occasion probable fault (poor assessment) and on the third occasion possible fault (failure to look at the whole patient).