

Detection of Adverse Events in Surgery by Record Review

By

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Abstract

Surgery has a strong tradition of professional self-assessment which has developed into the current practice of auditing specific elements of care and outcome. Despite the growing recognition of error it has been difficult to engage individual clinicians in measurement and analysis of error in their own practice.

The different methods for identifying adverse events and critical incidents in hospital care each have their own strengths and limitations. Record review has become the internationally recognised gold-standard for detecting and assessing the incidence of adverse events in hospital care to address patient safety.

This thesis describes the development of a method of detecting adverse events and also critical incidents which build on the surgical tradition of peer assessment and audit; it therefore includes surgeons in the data collection. It is an adaptation of traditional retrospective record review.

A series of studies were undertaken to develop and test this methodology in different settings. The initial study tested the methodology reviewing 134 case records at the time of discharge from three surgical units involving both nurses and doctors involved in the care and using a structured review tool. The findings of record review of 288 medical and surgical patients were compared with findings of incident reporting and active surveillance of medication errors. In addition a training programme in record review for clinicians was developed and tested. The work of this thesis also led to some indirect outputs in terms of use of the training program and capacity for supervision of record review projects.

This research concludes that real-time record review by surgeons is feasible and supplies results which are both trusted locally and can lead to change in the delivery of surgical care. Training in record review is essential to improve the validity and reliability of results.

The work for this thesis would not have been undertaken had it not been for the inspiration and encouragement from Graham Neale who got me started on the track of patient safety.

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To Tim and Isak I apologise for the many missed trips swimming, time playing or spent as a family. I promise to do better.

The work described in this thesis is the result of my personal efforts and where this has been contributed to by others it is fully acknowledged in the thesis

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List of Abbreviations

AE	Adverse event
ALARM	Association of Litigation and Risk Managers
ASA	American Society of Anaesthesiologists
CEPOD	Confidential enquiry into peri-operative deaths
CI	Critical incident
CMIFS	Californian Medical Insurance Feasibility Study
DVT	Deep Vein Thrombosis
EMRF	Electronic modular review form
GI	Gastro intestinal
HDU	High Dependency Unit
HMPS	Harvard Medical Practice Study
ICU	Intensive care unit
ITU	Intensive Therapy Unit
MI	Myocardial Infarction
NCEPOD	National confidential enquiry into patient outcome and death
NPSA	National Patient Safety Agency
PCE	Potentially compensable events
PE	Pulmonary embolus
PRHO	Pre-registration house officer
QAHCS	Quality in Australian Healthcare study
RF	Review form
RTRR	Real-time record review
RTRR-MRF	Real-time record review – Modular review form
RRR	Retrospective record review
SASM	Scottish Audit of Surgical Mortality
SHO	Senior house officer
SpR	Specialist Registrar
TMRF	Training modular review form
UTCOS	Utah and Colorado Study

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Chapter 1

1. A historical perspective on Safety and Quality in healthcare

1.1 Introduction

The concept of healthcare being potentially harmful is not new although it has been at the forefront of public debate for only the past 5-10 years. Recognition of this aspect of healthcare has been brought about by the emergence of a number of factors. In western society there has been a general drift away from blind trust in authorities and paternalistic practices allowing the public to question and even challenge the fallibility of the medical profession both in the individual doctor patient relationship and in the media (Kennedy, 2001;Smith, 1998;Riddell, 2001;Smith, 1998). This has led to widespread publicity of a few serious events of harm from treatment with tragic outcomes such as the deaths from intrathecal vincristine(Toft B, 2001) and wrong site surgery in the UK (Dobson, 2000;Dobson, 2000). At the same time epidemiological studies of the scale of harm from hospital care have been published in a number of developed countries often followed by heated political debate and publication of government reports on action needed for patient safety in the US "To err is human" (Linda T.Kohn, 1999), and in the UK "An organisation with a memory" (Department of Health Expert Group, 2000).

Although there are many reports of large scale epidemiological studies of harm with a validated systematic approach (Baker, 2004;Brennan, 1991;Brennan, 1991;Davis, 2003;Davis, 2002;Gawande, 1999;Leape, 1991;Thomas,

2000;Vincent, 2001;Wilson, 1995) there is currently no standardised way to assess the scale and nature of harm at a local level by clinicians themselves. The work of this thesis will be to develop a new methodology of systematic record review which can be used at a local level by practising surgeons to assess the safety of all aspects of surgical care. This chapter will describe the beginnings of patient safety in healthcare in general but with particular emphasis on surgery and the measurement and systematic assessment of harm.

1.2 First do no harm

In the mid eighteenth century, when the practice of medicine emerged as a professional endeavour, it had significant potential for causing harm. As an indirect response to this the phrase of a doctor's duty to 'First do no Harm' was introduced in the mid 1800's. This was a twist of the original wording of the Hippocratic Oath. (Sharpe, 1998;Vincent, 2006). This was a time when there was tension between proponents of natural healing (letting the body and the power of nature be responsible for health improvement) and "heroic medicine". Heroic medicine is a term used to describe attempts by doctors to counter act disease by undertaking dramatic interventions such as bloodletting as a cure against major infection such as Yellow fever. During the same era surgery was particularly traumatic to patients in the absence of audit, proper training, carefully designed tools, sterilisation and anaesthesia.

1.3 Early pioneers of patient safety

During the second half of the 1800's there was growing recognition of the potential of harm stemming directly from both treatments and healthcare in a wider sense. The notion of hospitals being potentially dangerous places was becoming more widespread but not generally accepted by the medical and surgical establishment as exemplified by the fate of Semmelweiss ,a Hungarian doctor practising in an obstetric hospital in Vienna In 1847.

Dr. Ignaz Semmelweiss observed a high rate of mortality from childbirth fever amongst the patients on a ward attended by medical students compared with a midwifery led ward and those who gave birth before arriving at the hospital i.e. patients who were not examined by doctors or medical students. Based on these observations and from watching a colleague die from an identical set of symptoms following a wound sustained during an autopsy, Semmelweiss drew the conclusion that the high mortality was linked to contamination by cadaverous particles carried on the hands of medical students and doctors. He immediately instituted a disinfecting procedure whereby physicians were required to wash in a chloride of lime solution after attending necropsies and with soap and water between patient visits. Doctors also had to change into clean coats before examining patients. As a result, hospital mortality rates from infectious diseases were dramatically reduced.

Unfortunately, Semmelweiss's call for reform of medical practice was met by hostility by many of his contemporaries many of whom rejected the results of his work. Semmelweiss lost his job in Vienna and became increasingly more isolated in medical circles and answered his critics by writing a harsh criticism of

the European medical establishment. With the permission of his family, he was involuntarily committed to an insane asylum where he died in 1865.

The story of Semmelweis is still taught in medical schools today usually as an example of the folly of the past of failure to accept the obvious basic precautions in the light of clear evidence. One may argue that with the upsurge in hospital acquired infection with multi-resistant organisms such as MRSA this tale has never been more relevant and should act as a reminder of the importance of hand hygiene(Jarvis, 1994).

Although Semmelweis was ridiculed and ostracised by his peers he was not the only contemporary voice recognising the potential dangers of hospitalisation. In 1863 the well respected and honoured Florence Nightingale noted that 'the actual mortality especially in hospitals in larger crowded cities is very much higher than any calculation founded on the mortality of the same class of diseases among patients treated outside hospital' (Vincent, 2006)

In surgery there was also a growing recognition of the high mortality from sepsis. Lister was the first British surgeon to experiment with sterilisation in surgical practice. He did not subscribe to the popular theory at the time which stated that sepsis was caused by 'bad air' or contact between oxygen and subcutaneous tissues. When, in 1865, Louis Pasteur suggested that decay was caused by living organisms in the air, which on entering matter caused it to ferment, Lister made the connection with wound sepsis. He considered that microbes in the air were the likely cause of the putrefaction he had observed in sepsis and should be destroyed before they entered the wound. Lister now began to clean wounds

and dress them using a solution of carbolic acid which he believed would kill the microbes described by Pasteur. As a result his wards at the Glasgow Royal Infirmary became remarkably clear of sepsis.(Francoeur, 2000;Lidwell, 1987;Newsom, 2003;Sakula, 2005)

Although his methods were initially met with indifference and hostility, surgeons gradually began to support his antiseptic techniques and German surgeons adopted the use of steam sterilisation of surgical instruments and dressings with great success from the 1870's.

1.4 A Pioneer of Measurement of Harm in Surgery

The first surgeon to take major steps to systematically detect and understand failures in treatment was the Boston surgeon Ernest Codman. Dissatisfied with the standard of care and lack of willingness to evaluate and address the outcome for patients undergoing surgery, he resigned from his position as staff surgeon at Massachusetts General Hospital in 1911 to start his own private hospital which he called the "End Result Hospital". Here he recorded diagnostic and treatment errors and linked these errors to outcome in order to make improvements. From 1911 to 1916 he recorded 123 errors in the 337 patients discharged from the "End Result Hospital" by measuring the end results for all these patients.

His classification of errors is not dissimilar from those seen today namely errors due to lack of knowledge or skill, poor surgical judgment, lack of care or equipment, and lack of diagnostic skill. In addition to the errors there were four "calamities of surgery" used to describe those accidents and complications over which surgeons have no known control. These should be acknowledged to our

selves and to the public and study directed to their prevention". Codman was a pioneer, not only by measuring harm from surgical care, but also by openly publishing these in print. All errors were described in the annual report of his hospital which he paid for out of his own pocket so that patients could judge for themselves the quality and the outcome of care. He even sent copies of his annual reports to major hospitals throughout the country challenging them to do the same (Neuhauser, 1990;Neuhauser, 2002).

Although Codman's efforts to get his peers to adopt similar methods of ongoing assessment and improvement were met by hostility at the time, some of his suggestions were adopted by the American Surgical Society and he helped found the American College of Surgeons and its Hospital Standardization Program. His work has left an important legacy which is felt both in surgery and in healthcare in general today. Codman is credited by holding the first M&M (morbidity and mortality) meetings for internal evaluation which still remains a strong tradition in the US. The most important current legacy however is the formation of the Joint Commission on Accreditation of Healthcare Organisations (JCAHO) from the Hospital Standardization Program in the US (Joint Commission for Accreditation of Healthcare Organisations, 2006). JCAHO is the world largest hospital accreditation organisation and helps regulate and standardise care across a multitude of private care facilities in a market where there is little government ownership or regulation. The JCAHO continue to pay strong tribute to Codman by reprinting his original hospital reports and by funding a coveted annual prize "the Ernest Amory Codman Award" to health care organisations for achievement in the use of process and outcomes measures designed to improve organisational performance and, ultimately, the

quality and safety of care provided to the public (Joint Commission for Accreditation of Healthcare Organisations, 2006).

1.5 Hazards from diagnosis and therapy

The expansion of available drugs and therapeutic manoeuvres in middle of the 20th century increased the potential for harm from delivery of healthcare. 'Iatrogenic disease' again became a topical subject. In 1955 it was brought to the fore front of the attention of the medical establishment by Barr's reading (and later publication in JAMA) of the paper titled 'Hazards of modern diagnosis and therapy – the price we pay' at the annual meeting of the American Medical Association (Barr, 1955). Barr described a long list of types of medical accidents and unfavourable responses which may arise in daily work through 'enlightened thoughtful use of diagnostic and therapeutic measures by conscientious and well-informed physicians earnestly trying to help their patients'. The list consisted of examples of accidental drug intoxication, modification of internal environment, introduction of infection, allergic reactions, special instances of intoxication and dangers from procedures. He did not include examples of poor practice arising from lack of knowledge, carelessness or misconduct, nor those arising from simple human error.

Barr described a study of 1000 patients admitted to a 'Great Hospital' over an undefined period of time. The method of data collection is not described but Barr reported 50 major toxic reactions or accidents in these patients that either arose from or caused admission to hospital. Notably this paper excluded all effects of what was regarded as poor practice, carelessness or misconduct. He concluded that major accident or sequelae occurred in 5% of admitted patients,

making 'iatrogenic disease' one of the commonest conditions encountered in hospital practice. Although Barr largely accepted that there is a price of potential danger from advances in medicine, he also advocated that physicians must carefully consider the need for intervention and choice of diagnostic or treatment modality in order to minimise the hazards to patients (Barr, 1955).

1.6 The Beginning of Systematic Assessment of the Scale of Harm Caused By Healthcare

Following the renewed acceptance and interest in medical harm systematic studies of the scale of harm from healthcare began to emerge in the 1960's. In 1964 Schimmel (Schimmel, 1964) described a detailed study of the incidence and causation of iatrogenesis during hospital admissions to the general medical service of a teaching hospital. Data was collected for 8 months on all patients admitted to his service. Schimmel relied on reporting by junior doctors from his team to highlight any harm from medical interventions both for diagnosis and treatment. To avoid sensitivity about the reporting of errors or mistakes by staff these were excluded from data collection. As a result these data included only events stemming from accepted normal clinical practice. He found that 198 patients of 1,252 admissions (16%) suffered one or more iatrogenic events during their stay. The 240 identified events were categorised as reactions to diagnostic procedures (29, 12%), therapeutic drugs (118, 49%), transfusions (31, 13%), therapeutic procedures (24, 10%); acquired infections (23, 10%); and other hospital hazards (14, 6%). A similar study was conducted a few years later by McLamb and Huntley (1967) (McLamb, 1967) who studied 240 patients admitted to the general medical department of a general hospital and found 47 these patients (20%) suffered one or more iatrogenic events during their admission - a

total of 63 such events was found. Again, drug reactions were the commonest form of iatrogenic event (28, 44%). Both authors acknowledge that they may have underestimated the incidence of iatrogenic events because of the likelihood of underreporting.

The first major study relying on the patient's medical record as the source of data on which to determine the scale of harm from healthcare was the Californian Medical Insurance Feasibility Study which is described in detail in Chapter 3 (California Medical Association, 1977, Mills 1978). This study had the explicit aim of determining the likely annual incidence of potentially compensable events (PCE) to evaluate if a system of no-fault compensation would be financially viable in the face of spiralling costs of malpractice insurance. Much of the methodology developed for this study is the foundation on which later retrospective record review have been built. The authors of the study reported an incidence of 4.2% of PCE in hospital admissions.

This study was followed by Steel et al (1981) who examined all patients admitted to a teaching hospital medical service over a five months' period, using prospective structured review of all patients' records complemented by questions to the clinical staff and other hospital information sources (Steel, 1981). They found that 290 patients (36%) of 815 admissions suffered one or more iatrogenic events during their hospitalisation. A total of 79 patients (9%) had a major complication. Of the 497 iatrogenic events found, 208 (42%) resulted from drug therapy, 175 (35%) from diagnostic or therapeutic procedures, and 114 (23%) from other areas, particularly patient slips and falls. In 15 patients (5% of those

with iatrogenic events, and 2% of all patients admitted) the iatrogenic event was believed to have contributed to the patients' death.

1.7 The first published studies of adverse events in surgery

In the same edition of the New England Journal of Medicine as Steel's paper, Couch et al described a one year prospective study focused on serious errors in care in the general surgical service of a large teaching hospital - what the team termed surgical mishaps (Couch, 1981). Over the period 5,612 admissions were screened for mishaps, with flagged cases being discussed by the clinical team. Data was collected on patients who had suffered a complication which was discussed at a routine weekly service meeting. Only poor outcome stemming from 'a surgical misadventure resulting from a decision which was a clearly an error in the field of general surgery' were included in this study. The author revealed 36 (0.6%) patients who suffered a total of 56 serious errors, of which 9 (16%) were diagnostic errors and 47 (84%) were therapeutic. That these cases represented only the most serious instances of avoidable iatrogenic disease is shown by the poor outcomes for the patients involved - 20 (56%) died, and 5 (14%) suffered serious physical disability. This study was done before a full understanding of potential influence of systems failure on outcome. Couch stated that the errors found had five main causes, all of which were related to behaviour and performance of clinicians: misplaced optimism about patients' state of health or physicians' own ability; unwarranted urgency in undertaking procedures; the urge for perfection resulting in unnecessary surgery; the use of vogue therapies of unproven effect; and insufficient restraint and deliberation before making diagnostic and therapeutic decisions.

In the mid to late 1980's CEPOD (confidential enquiry of peri-operative deaths), acting as an independent charitable organisation, undertook study of postoperative deaths in 3 NHS regions in the UK (Devlin, 1988;Spence, 1988). Data was collected from both surgeons and anaesthetists to establish the 30 day in-hospital mortality in patients who had undergone surgery. Following this trial a national enquiry was set up in 1988 with NCEPOD (national CEPOD) as an independent body funded in part by the Department of Health. It studied data from England and Wales on 30 day in-hospital mortality following surgery to identify remediable factors in the practice of both anaesthesia and surgery. NCEPOD's purpose was to assist in maintaining and improving standards of surgical care for the benefit of the public by reviewing the management of patients, by undertaking confidential surveys and research, by maintaining and improving the quality of patient care and by publishing and generally making available the results of such activities (NCEPOD, 2006).

In the last 15 years NCEPOD has continued to highlight a number of unsafe practices and made recommendations on how to avoid these. An example is highlighting the problem of comparatively poor outcome from emergency surgery carried out by unsupervised junior surgeons during the night. This has led to the current policies of carrying out only life or limb saving operations after 11pm and the introduction of dedicated daytime theatre lists for emergency surgery (NCEPOD, 1997). Following the success of the work of NCEPOD it's remit was extended first to include all invasive procedures and now also other aspects of medical care.

At the same time a similar project was initiated in Scotland led by the surgical profession. The initial project was started in 1988 and a similar study in the Greater Glasgow Health Board started in 1989. These two parallel studies worked closely together and amalgamated into the Scottish Audit of Surgical Mortality (SASM) in 1994. Currently this audit reviews the in-hospital mortality reviewing all deaths from all but 2 surgeons in Scotland (SASM, 2006). Both the work of SASM and NCEPOD's work will be described on more detail in chapter 2.

1.8 Summary

As shown in this chapter the problem of harm arising from healthcare management is not new nor is the interest in this. What has changed in the past 10-20 years is the general acceptance of the need for measurement and assessment of the scale and causes of harm followed by interventions to improve the safety of healthcare. The scale of harm has been estimated at regional or national levels in major studies of adverse events in industrialised countries. Surgery has a strong tradition for professional self-assessment and audit of narrow topics and outcome. There has been a growing general acceptance of need to study error in medicine and develop methods of reducing error, rather than simply seeing it as a character fault or deficiency in training or competency. This has largely been born out of developments in other industries and is slowly beginning to take root in surgery. Despite this recognition it has been difficult to engage individual clinicians in measurement and analysis of their own practice. Nationally and internationally there has been no real attempt to solve the problem of unsafe healthcare by radical redesign of the systems of delivery of healthcare. Any change has thus far predominantly been in the form of suggestions to change isolated aspects of practice such as the placement of

nasogastric tubes (National Patient Safety Agency, 2005) or timing and use of prophylactic antibiotics to reduce wound infections (Berwick, 2006).

Chapter 2

2. An overview of methods of detection of adverse events and critical incidents in surgery

2.1 Introduction

Patient safety research became an accepted field of research in the 1990's largely born out of studies such as The Harvard Medical Practice Study (Brennan, 1991; Leape, 1991) to assess the liability to litigation and the publication in the US of the report 'To Err is Human' (Kohn 1999). Since then much effort has been invested in methods for assessing the incidence of adverse events. Epidemiological large scale record reviews have been carried out in a number of countries to assess the incidence of adverse events and existing practices such as morbidity and mortality (M&M) meetings and surgical audits have been re-examined. Healthcare has also looked to other industries for lessons to be learned and as a result incident reporting systems have been widely introduced. New methods such as direct observation of care and trigger tools are being developed to detect cases with errors or adverse events. Much debate has since ensued regarding which method is best in terms of reliability, validity and feasibility.

This chapter will examine methodologies available to detect and describe adverse events in surgical care with a predominate focus of UK practice. It will examine both methods in use as routine tools in clinical practice in the NHS and methods currently reserved for research. Each method will be explained and evidence of its use presented. The likely value will be examined after an

evaluation of strengths and weaknesses of each method. This is not an exhaustive list and some methods of less relevance to the core subject matter of the thesis will only be mentioned briefly.

2.2 Routine activities current used in surgery

Morbidity and mortality meetings

The traditional way for doctors and in particular surgeons to address deficiencies and mishaps in their care is through Morbidity and Mortality (M&M) meetings. This is typically a departmental forum of surgeons where all cases of patients suffering morbidity or death as a result of medical care or surgical procedures are presented and discussed. The aim is to analyse cases and address any aspects of care found to be deficient in order to prevent the future occurrence of similar events. This approach fits the mould of the traditional surgical culture of self-regulation with review of standards by peers but without open sharing of results to a wider circle of partners such as patients, other healthcare professionals or hospital management.

Several studies have been published exploring the value of data presented at M&M meetings in the US and Canada. A study by Feldman and colleagues published in 1997 compared the proportion of adverse events (AE) as determined by prospective observation and record review with those presented at the units M&M meetings over a 6 month period (Feldman, 1997). The impact of feedback to surgeons on patterns of adverse events was also evaluated. This study looked only at patients who had undergone an operation. Only 29 of 106 patients identified as having suffered a complication were presented at M&M

meetings. The percentage of patients identified as having complications presented at M&M increased with the severity of the complication with 87.5% of deaths presented. These findings are mirrored by a Canadian study published in 2000 where only 29 of 144 complications identified by prospective observation and chart review from surgical admissions were presented at M&M (Wanzel, 2000).

Attempts has been made to improve M&M meetings after surveys of surgical trainees found that they regarded these as non-educational (Harbison, 1999). One example of this is the study by Hamby and colleagues published in 2000 (Hamby, 2000). In an attempt to include more complications for presentation at M&M meetings and to present overall trends of complications, they set up a computerised registry of these. This tracked all complications as identified by nurses using an identification tool. The data was presented at M&M and where clusters of complications were identified, these were discussed with regards to what action might be required to prevent similar problems. This new format was well accepted but although there was a trend toward falling complication rates, no significant data on this was presented.

Although potentially a useful forum for the sharing of and learning from mistakes, M&M meetings have rarely adapted a perspective of system of care analysis or understanding of the complex matrixes of contributing factors and events which play a role in causation (Laffel, 1989). They therefore run the risk of concentrating on apportioning individual blame or resign to a position of acceptance of consistently poor systems of care within the organisation

(Berwick, 1989). M&M meetings are still common place in the US but are decreasing in the UK where in many places they have been replaced by 'Audit Meetings' in which specific audit data is presented. For M&M meetings to reach their full potential for sharing and learning from mistakes and mishaps in surgery, much depend on the inclusion of cases and the nature of the discussion of these. There is a tendency toward examining cases of extreme poor outcome and selection of cases of patients who have undergone surgery. This data will only show a fraction of care problems of any surgical unit. At present few surgeons have received training in systematic analysis of care problems. This reinforces the risk of focusing on individual failings rather than on more complex contributing factors.

Large scale Morbidity and Mortality Audits

There is a longstanding acceptance of professional or peer organised reporting or audit systems in surgery. Regional and speciality based morbidity and mortality audits exist in the UK such as the North West London Breast Cancer audit. National initiatives include the Scottish Audit of Surgical Mortality (SASM) covering all surgical specialities and hospitals in Scotland and the National Confidential Enquiry of Preoperative Deaths now National Enquiry into Patient Outcome and Deaths (NCEPOD) in England and Wales. All of these rely on individual surgeons recording their outcome and feeding this into a larger data collection system with central analysis of data.

The principal precursor to NCEPOD was a confidential and anonymous pilot study of mortality associated with anaesthesia carried out by Lunn and Mushin in 1978 (Lunn, 1982). This covered inpatients from five regions in England,

Wales and Scotland. Its aims were to assess peri-operative care in order that the clinical practice of anaesthesia might be improved and to provide comparative figures between regions to facilitate this. A further important objective was to establish an index of contemporary standards of care to permit future comparisons. It was hoped that this study might be a combined surgical and anaesthetic enterprise but this proved impossible at the time.

Following the success of the pilot study and the subsequent publication of the report, the way was paved for a collaborative anaesthetic and surgical project. In 1982 the joint venture between surgical and anaesthetic specialties was initiated, the original Confidential Enquiry into Perioperative Deaths (CEPOD). This reviewed surgical and anaesthetic practice over one year in three regions. In 1988 the National Confidential Enquiry into Perioperative Deaths (NCEPOD) was established supported by government funding, and its first report was published in 1990. NCEPOD has strong professional involvement and the Royal College of Surgeons of England was actively involved in the creation of this. It has since been expanded to include assessment of non-surgical care and now operates as an independent charity and a company limited by guarantee (NCEPOD 2006).

Eighteen reports have since been published by NCEPOD. Samples for study have ranged from a random sample of all deaths within 30 days of surgery, to all deaths observed within a specific age range, or specific procedure. Two specific studies have been undertaken (NCEPOD, 1997; NCEPOD, 2003) into the pattern of operating within hospitals regardless of outcome to assess what level of staff are involved in the operating case load a different times of day and

to relate this with operative outcome. These studies have shown a comparatively poor outcome from emergency surgery carried out by unsupervised junior surgeons during the night. Other reports have described problems with communication and assignment of responsibility for perioperative care between surgeons and anaesthetists (NCEPOD, 2002) and the organisation of surgical practice (NCEPOD, 2001).

SASM was created in 1994 by the amalgamation of Lothian Surgical Audit and a similar study in the Greater Glasgow Health Board both of which had been running since the late 1980's. SASM in contrast to NCEPOD has remained strongly focused on surgical care and today enjoys a much stronger feeling of professional ownership by surgeons. SASM identifies all deaths that occur in hospital under the care of a surgeon, whether an operation has taken place or not. Data is collected by the individual surgeons under which care the patient has died and where appropriate also the involved anaesthetist. The forms then undergo a peer review process carried out by virtually every practising clinician within the audited specialties on behalf of their colleagues (SASM, 2006, Thompson 2005a). SASM reports are published annually and contain data on the number of deaths but also highlight areas of concern such as hospital acquired infection and senior staff involvement in care and surgery (SASM, 2005, Thompson 2005b). By assessing all surgical deaths rather than just those following anaesthesia SASM has been able to report on more general problems such as inadequate access to intensive care and poor care at the end of life to terminally ill patients (SASM 2005, Thompson 2005b).

The advance and subsequent success of these initiatives are based on the confidentiality and professional involvement in the Audits. Both have achieved very high response rates as a result. Important data have emerged from both including the high rate of events associated with unsupervised trainees operating at night. This has in turn resulted in guidelines being issued and working practices changed so that non-life or -limb saving surgery no longer takes place as a routine after 11pm. Despite their success in improving surgical patient safety, both of these audits are currently limited by only assessing care of patients who die and hence may fail to address the wider problems in ward care and assessment of surgical patients.

Systems for critical incident reporting in surgery

Reporting systems for near misses, 'close calls' or critical incidents have been pioneered in the aviation industry over the past 30 years. This has led to the development of reporting systems in many high risk industries (see box 3.1). Most of these are confidential and offer the reporter incentives to reporting such as regular specific feedback and immunity from non-criminal offences provided the incident is reported within a specified time frame (Helmreich, 2000;Barach, 2000). The success of these has led to improved aviation safety through a series of specific initiatives resulting from specific information obtained through reporting. These include both redesign of aircrafts and air-traffic control systems, introduction of crew resource management and changes to pilot and cabin crew training. These lessons have successfully been adapted to several other high-risk industries including nuclear power production, petrochemical processing and military institution (Helmreich, 2000;Barach, 2000;Barach, 2000).

Box 2.1 Reporting systems for in industries for near-misses and safety related incidents

Aviation

- Aviation safety reporting system (ASRS)
- Aviation safety airways program (ASAP)
- Air Altitude Awareness Program
- Canadian aviation safety reporting system (CASRS)
- British Airways safety information system (BASIS)
- Air safety report (ASR)
- Confidential human factors reporting program (CHFRP)
- Special event search and master analysis (SESMA)
- Human factors failure analysis classification system (HFACS)

NASA

- Safety reporting system

Petrochemical processing, steel production

- Prevention and recovery information system for monitoring and analysis (PRISMA)

Nuclear (nuclear power and radiopharmaceutical industries)

- Licensing event reports (LER)
- Human performance information systems (HPIS)
- Human factors information system (HFIS)
- Nuclear Regulatory Commission allegations systems process (NRCAS)
- Diagnostic misadministration reports—regulatory information distribution system (RIDS)

(Barach & Small 2000a; Vincent 2006a)

In the past decade incident reporting has been introduced to the healthcare provision in developed countries but with varied success. It is now the norm for individual hospitals to have a local incident reporting system and some national system have been set up such as the National Reporting and Learning System by the National Patient Safety Agency in the UK, the Agency for Healthcare Research and Quality in the US and the Australian Incident Monitoring System (AIMS). National systems have the advantage of collecting limited details on a large number of cases thereby being able to detect trends and identify rare serious events. Examples of how these have lead to changes at a clinical level can be seen in box 2.2.

Box 2.2 Examples of changes institutes as a result of incident reporting

- Risk of cardiac arrest have following in advertent intravenous injection of concentrated potassium chloride led to the removal of all vials of this to be removed from general wards in the UK. Intravenous fluid now comes with pre-added and clearly labelled potassium chloride. Where potassium chloride is kept in intensive care wards this is store in a locked cupboard of controlled drugs rather than stored freely on the ward.(National Patient Safety Agency 2002)
- Intrathecal injection of chemotherapy designed for intravenous use lead to severe injury or death of patients. Following recognition of this being a rare but recurring problems national guidelines have been issued on the prescription, dispensing and administration of intra-theal chemotherapy in the UK.(Barach & Small 2000a;Toft B 2001)
- Placement of nasogastric (NG) tubes is commonplace for nutritional supplementation of treatment of surgical disease. Misplacement of tubes is relatively common but patients rarely come to direct harm. A review of the national incident reporting database by the NPSA revealed several cases of death following misplaced NG tubes. This has lead to development of national guidelines on checking position of NG tubes after placement. (National Patient Safety Agency 2005a;National Patient Safety Agency 2005b)

AIMS was originally developed as a system for collecting data on anaesthetic incidents and was first launched in 1989. Its use since grew to include other related specialties such as intensive care medicine and medical retrieval. In 1996 the Australian Patient Safety Foundation developed a generic AIMS for use across specialties to provide a mechanism for reporting any incidents or accidents in the health care system by using a single standard incident report form. This information could then be recorded using the AIMS software and a range of reports can be generated to indicate problem areas. This analysis of data can both be carried out locally and nationally (Spigelman 2005). There have been clear early benefits of the system in anaesthesia such as learning from several problems including problems with equipment, vascular access, intubation and human errors in anaesthetics (Williamson 1993, Webb 1993, Singleton 1993, Szekely 1993). Although there has been great success with the long established speciality versions of AIMS with an established reporting tradition, full benefit of the national generic system still remains to be seen. The main limitations of the system are typical of other reporting systems and include under-reporting of incidents, poor reporting levels from medical staff and problems with the interface and inability to modify reports for local use (Spigelman 2005).

A recent development in surgery has been the establishment of the confidential reporting system in surgery by the Association of Surgeons of Great Britain and Ireland in 2005 (CORESS 2006, Lewis 2006). This is developed as a complement to other reporting systems. Surgeons are encouraged to report cases with potential safety lessons on line or via a postal form. Cases are

analysed and general learning communicated via a newsletter with serious or recurrent problems represented as case presentations with comments. This is an example of a profession led reporting system.

Local systems however have the advantage of often containing more detail and reflect problems particular to the individual institution. Local incident reporting systems vary in their design and in the UK are still commonly paper based. Increasingly computer or web based reporting is being introduced. Reporting is commonly voluntary but may be mandatory for a set of defined clinical or non-clinical incidents such as violence against staff or incidents relating to potassium chloride. Most voluntary systems are based on a set form including details of the nature of the incident, consequences to the patient, staff involved in the incident, immediate action taken and the identity of the reporter. Reports are typically submitted initially to the unit manager for intermediate action and subsequently to the risk management department of the institution where they are all entered into a database and also analysed in detail if severe. Any feedback to clinical staff is determined by individual hospitals or institutions but is commonly lacking.

Voluntary incident reporting in healthcare has not mirrored the success of the aviation industry in terms of completeness of reporting (O'Neil, 1993; Barach, 2000). Few studies have compared the rate of events reported with other means of identifying AE or critical incidents (CI). The most important study was that carried out by Brennan and colleagues at Brigham and Women's Hospital, Boston in 1993 (O'Neil, 1993). This compared traditional hospital initiatives for identification of AE with prompted physician reporting and record review. The

study found that only 1.5 % of events detected by record review were reported through usual spontaneous incident reporting. The study did not comment on the profession of the reporters. Interestingly this study also investigated prompted physician reporting of adverse events which was compared to both record review and routine reporting of incidents to the risk management department. Prompted physician reporting using the hospital's electronic mailing system identified the same rate of adverse events as record review (2.8% of all admissions) although there was only moderate correlation between the events identified ($\kappa = 0.52$; CI, 0.47 to 0.57). This finding supports the impression that doctors, although able to recognise deficiencies in care and poor patient outcome, generally do not report these occurrences through standard incident reporting systems.

Kingston and colleagues investigated both doctors and nurses attitudes to incident reporting in Australia in 2002 (Kingston, 2004). 14 doctors and 19 nurses were included and attitudes were assessed by separate facilitated focus groups for doctors and nurses. Staff were recruited from 3 different hospitals and the specialities of medicine, surgery and intensive care. General barriers to reporting were identified from staff and are summarised in box 2.3.

Box 2.3 Barriers to doctors participating in incident reporting

- Lack of knowledge about the process and what constitutes an incident
- Perception by doctors that an incident reporting form is a “Nursing Form”
- Time constraints and complexity of reporting form
- Lack of feedback after a report had been submitted
- Lack of legal privilege afforded to the reporting process
- Perceived culture of blame
- Perception of no value of incident reporting in terms of patient care improvement
- Perception of reporting data being outside professional control

In contrast to nurses, doctors did not have a culture of reporting. They simply did not consider reporting. Only junior doctors occasionally did so but only when prompted by nurses in specific instances. Doctors felt it was disloyal to team members to report and junior doctors were concerned that it led to loss of face amongst peers and embarrassment to publicly disclose mistakes. Nurses were more concerned about blame being apportioned as a result of incident reporting and that this might lead to punishment. The negative consequence which doctors were most concerned about was laying themselves open to litigation as a result of disclosing error. A similar study from the UK carried out in 2004 reported on doctors' attitudes to reporting critical incidents (Waring, 2005). Data were collected by semi-structured interview of general and rehabilitation physicians, anaesthetists, surgeons and gynaecologists. All groups of doctors accepted the potential benefit of incident reporting for improving both the service in general and patient safety. All groups, apart from surgeons, were involved in local or collegiate reporting of adverse events or critical incidents.

The hospital wide reporting system was regarded as managerial, non-medical and 'faceless'. Therefore clinicians had little confidence or support for this approach to reporting. Departmental or collegiate systems of reporting in contrast were accepted as contributing both to service improvement and professional development. Surgeons' attitudes in this study presented an extreme position of unfamiliarity with and suspicion of and even hostility towards reporting of critical incidents to hospital management. Surgeons favoured a less formal departmental approach to communicating safety concerns and analysis of care such as direct contact with the clinical director and discussion of cases of at departmental morbidity and mortality meetings.

A barrier to incident reporting not addressed in the above papers is clinicians' ability to recognise defects in care in the first instance. It is often the case that poor outcomes for patients are not detected until after discharge from hospital. Some poor outcomes in hospital are caused by a complex chain of minor errors or deficiencies in care which culminate to have a severe impact on patients (Reason, 2005). Often this is not reported as no particular 'incident' has been perceived by the clinical staff.

Root cause analysis

Root cause analysis as it is often known as in the US is one of a number of detail methods of analysis of adverse events, incidents of patient harm or serious near misses. It is based on similar methods of investigation of incidents in industries such as aviation and nuclear power. The main aims of a Root Cause Analysis is to find out what happened, why did it happen and what to do to prevent it from happening again (Vincent 2006). It can be used as a tool for

identifying prevention strategies and has been seen as a process that is part of the effort to build a culture of safety and move beyond the culture of blame. A particularly detailed and wide spread system of root cause analysis has been developed by the Veterans Administration(VA) in the US and had been in use since 2000 (Bagain 2002). It has been widely disseminated through the VA system both for local learning but the results of individual case analysis are being further used in aggregate analysis which provides a systematic process for analyzing high-priority, frequent events (Neily 2003). Other analysis protocols have been developed by other groups including the “the London Protocol” for systems analysis following individual events (Adams 2004) and the NPSA are providing day seminars in root cause analysis for clinicians and clinical risk staff in the UK. Whichever protocol is used the main aim and principles of investigation remain the same. A team of investigators access a wide range of sources of information including the medical record, procedures and protocols in place and interview with staff involved or present at the time of the incident in order to establish what happened, why it happened and what the contributing factors were so that preventative action can be taken.

2.3 Methods for adverse events detection currently used as research tools

In addition to routine data collection on adverse events and care problems a number of research methods have been developed for detection of adverse events in hospital admissions. Those most relevant to surgery and the aim of this thesis, to develop a method of detection and analysis of adverse events involving practicing surgeons, have been reviewed in this section.

Record review

The development and methodology of retrospective record review will be addressed separately in chapter 3. Only a brief outline of the methodology and results will be presented here.

The methodology for retrospective record review was initially developed in the 1970's to estimate the incidence of negligent harm to patients in the Californian Medical Insurance Feasibility Study (California Medical Association, 1977; Mills, 1978). This methodology was adapted and expanded in a series of large scale epidemiological studies aimed at assessing the incidence of adverse events in hospital care. The landmark study was the Harvard medical practice study carried out in the late 1980's (Leape, 1991; Leape, 1991; Brennan, 1991). Similar studies have since been replicated in Australia, the UK, Canada, New Zealand and Denmark with some variability in the methodology employed (Baker, 2004; Vincent, 2001; Wilson, 1995; Davis, 2003; Davis, 2002; Schioler, 2001). The main point in the traditional methodology is a 2-stage review process carried out 6-24 months after discharge. Nurses or medical record clerks screen the notes for predefined occurrences shown to be associated with poor patient outcome such as readmission to hospital, transfer to intensive care or death. Screen positive notes are subsequently reviewed by doctors for the occurrence of adverse events which are described and the preventability assessed. There has been wide variability in the rate of adverse events determined by individual investigators depending on the setting and methodological variations. Rates vary from 2.9-16%. Although the methodology has been popular for epidemiological studies and has aided the general understanding of adverse

events it has been criticised for being too expensive and time consuming to be suitable for ongoing review and quality improvement (Murff, 2003;Thomas, 2002).

Observation of care

Prospective empirical studies of adverse events have been undertaken in an attempt to avoid many of the methodological pitfalls of retrospective analyses by not solely relying on the information recorded in the case records as the complete and true account of occurrences in care delivery. Methodologies in prospective and observational studies of adverse events vary widely but may include direct observation of care delivery, attendance at ward rounds or morbidity and mortality conferences and interviews with clinical staff (Michel, 2004;Murff, 2003;Andrews, 1997). These studies were undertaken during acute hospital admissions. This gives the advantage of being able to access multiple sources of information on occurrences and possible causative factors of AE. It also opens up the opportunity for direct learning and feedback to clinical staff on the number, types and causes of adverse events occurring in their care, bringing closer the ultimate aim of the study of adverse events - improvement of patient safety. Observational studies of adverse events have their own limitations including cost and time constraints, the need for large numbers of subjects, and difficulty controlling, measuring, or accounting for the complex interdependent clinical and environmental factors likely to play a prominent role in patient safety (Thomas, 2003). Despite this prospective data collection remain important methods of detection of adverse events.

Observations have been used in the context of determining the incidence of adverse events, evaluating the punitive effect of contributory factors such as sleep deprivation or potential benefit of patient safety initiatives such as improved handover arrangements (Gottlieb, 1991; Van Eaton, 2005)

A study of observations of care in ten surgical wards within a single hospital in the US was reported by Andrews in 1997 (Andrews, 1997). This used a different approach to retrospective record review but with similar results. Instead of bringing in external observers to identify adverse events, this methodology consisted of observing clinical staff during ward rounds, nursing shift changes, case conferences and morbidity and mortality meetings discussing and addressing adverse events clinical staff themselves had detected. All incidences of inappropriate care taking into consideration the facts known to the healthcare provider at the time of decision making were included in this study. When linking this to disability or death to the patients 17.7% of patients included in the study experienced adverse events as defined by the standard taxonomy for record review.

A study of surgical patients in Canada, reported in 2000, reviewed care of consecutive general surgical admissions over a 2 months period in a single hospital (Wanzel, 2000). This included prospective monitoring of all complications through daily chart reviews, attendance at ward rounds and during surgical operations, patient visits and interviews with consultant surgeons, trainee surgeons, nurses and other health care staff. A complication was defined as an unintended, adverse outcome that occurred after medical

management or a surgical procedure and not caused by the underlying disease and which resulted in 'impaired health'. If disagreement among investigators arose, the final decision was made by a medical student in order to reduce potential bias on the part of the clinician involved. It was noted whether each complication was recorded in the patient's records, and if so by whom (doctor, nurse or both), and whether it was reported at the departmental morbidity and mortality meeting. One hundred and ninety-two patients were observed over 1277 patient-days. Seventy-five patients (39%) suffered a total of 144 complications. Of the 144 complications, 9 (6%) were not documented in patients' records. Only 29 (20%) of the 144 complications were presented at weekly morbidity and mortality rounds. Of the 26 complications that were attributed to error, 13 were discussed at the weekly rounds.

A different type of observational studies of error in surgery is exemplified by the work of De Leval (Catchpole, 2006) who has conducted observations made in the operating theatre during paediatric cardiac surgery. Observations were made by a human factors researcher who noted the types of minor and major events (errors and problems) as they occurred. Minor events were errors that alone were not expected to have serious consequences for the patient; these included instrument handing errors by the scrub nurse, positioning and tension errors by the surgical assistants, and communication problems in the theatre team. Major events were more serious errors, such as accidental injury of a coronary artery and severe laceration of a pulmonary artery branch requiring patch repair. Clinical data on patient and procedural variables were also collected. Major events were found to be closely related to death ($P < .001$) and

death and/or near misses ($P < .001$). Appropriate and timely action to mitigate these error however, sharply reduced the risk of death ($P = .003$). The total number of minor events was also closely related to death and also death and/or near misses ($P < .001$). In addition the study produced some important insights into errors and near misses during surgery.

Record review by clinicians

Wolff has in Australia developed a system of medical record screening following discharge by clinicians to highlight potential adverse events. His work stems back to 1991 (Wolff 1992) and had since been refined as is known as the Wimmera risk management model. Of interest to this thesis is the medical record review carried out by medical staff following the discharge from hospital.

Admissions were screened for 8 screening criteria:

1. Death.
2. Return to operating theatre within 7 days.
3. Transfer from general ward to intensive care unit.
4. Unplanned readmission within 28 days of discharge.
5. Cardiac arrest.
6. Transfer to another acute-care facility.
7. Length of stay greater than 35 days (reduced to 21 days in 1993-1994).
8. Theatre booking cancelled.

Medical records which screened positive underwent further review by a senior doctor who would determine if an adverse occurrence had happened. The definition of this was different from other studies and was: "an untoward patient event which, under optimal conditions, is not a natural consequence of the patient's disease or treatment". The causation of medial care was determined on a confidence scale similarly to that used in traditional retrospective record review.

The result of this method of detecting adverse events, its integration with other detection methods such as critical incident reporting has been published in a series of papers (Wolff 2002, Wolff 2001, Wolff 1996). The detection rate adverse patient occurrences using this method of record review of 1.35%-0.58% has however been significantly below other published rates. It is not clear if this is due to differences in definitions or screening and review methodology. There have not been published reports from other institutions using the same methodology. There are however other similar in-house risk management systems which utilise record review such as a long running system at Sydney's Royal North Shore Hospital (personal communication Wilson).

Interview with clinical staff

Michel and colleagues carried out an interesting study in France reported in 2004 (Michel, 2004). The study was set across 37 wards in three public and four private hospitals including the specialties of medicine, surgery and obstetrics. It compared the detection of adverse events by retrospective record review, prospective analysis and cross sectional survey. The methodology used for prospective study consisted of investigators visiting the ward on day one of the survey and on two other occasions during the first seven days followed by weekly visits for up to a month. An additional medical investigator visited the ward at the end of the first week of the study period and then when the last patient was discharged or on day 30 of the study if patients were still present. Patients with adverse events detected on the first day were confirmed by two different doctors one week apart. Data was collected by speaking to the ward

staff of the unit and observation of care. The adverse event rates found by the prospective and retrospective methods were similar however the incidence of preventable adverse events assessed prospectively was 25% higher than that assessed retrospectively.

Recent developments and emerging techniques

A brief mention will be made of the more recent developments in terms of detection of adverse events and potential for patient harm.

The concept of a "trigger" or a sentinel word to identify adverse events in the medical record was introduced by Jick in 1974 (Jick 1974). The approach has been refined and automated using electronic triggers with an integrated hospital information system to isolate adverse events in the US (Resar 2003). In this system, specific events including the ordering of certain drugs, orders for antidotes, certain abnormal laboratory values, serve as triggers to initiate a more detailed review of the case. These can also be used for manual review of health records although this is time consuming.. "Trigger tools" have been developed and championed by the Institute of Health Improvement in the US. Examples of the triggers developed by the IHI for their global trigger tool include positive blood cultures, insertion of chest tubes in ICU, complaints from patients or relatives and for their adverse drug event tool include use of naloxone or vitamin K, raised digoxin level and isolation clostridium difficile. Trigger tools do not replace record review but can act as "screening" to identify the records most likely to contain adverse events and this strategy is likely to prove its benefit in relation to future electronic patient records in the UK. .

Electronic medical records and integrated electronic patient record, test result and computerised prescription systems have long been the norm in the US but the UK had lagged behind in this area. This is however set to change with the NHS program “Connecting for Health” which is planned for completion in 2014. This program aim to create a single electronic record for each patient which can be accessed by any GP or hospital facility in the UK.

The introduction of an electronic medical record opens new avenues for detecting problems in hospital care. Systematic ‘mining’ of data, electronically, and the use of ‘triggers’ may lead to closer analysis of individual episodes. The potential of these developments has yet to be ascertained but some studies of electronic recognition of adverse drug errors have been promising (Classen 1991, Cohen 2005, Bates 2003).

2.4 Comparison of methods of detection of adverse events and problems in care delivery

Thomas and Petersen have discussed the relative value of different methods of detection of adverse event and errors in health care (Thomas, 2003). They described each method in relation to reliability, validity and ability to detect different types of errors. Errors in health care can be divided into separate categories according to the part of the system of care delivery they describe. Latent errors include systems defects such as poor design, faulty maintenance, poor supervision arrangements and inadequate staffing. These are difficult to measure as they do not occur at set point in time but are never the less important as they contribute to deficiency in care which may later result in

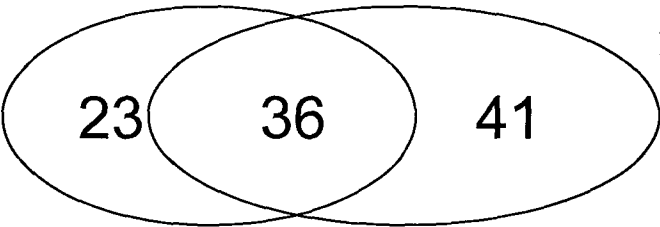
adverse events. Active errors are easier to measure as they occur at the point of care delivery such as wrong site surgery. Thomas and Petersen suggest that although some methods of detection of error may detect both active and latent errors each method will focus on a specific area of the spectrum from latent to active error.

Morbidity and mortality meetings have long been the standard method for surgeons to examine and discuss complication. The weakness of these is that the format has largely remained unchanged and rarely includes review of adverse events in patients who have not undergone surgery or ward based common events. The analysis of complications is often limited and there is still a risk of discussions concentrating on individual blame. Observational studies based in the operating theatre examine error resulting from both technical and non technical aspects of the surgeons work. In addition they have the potential to detect both latent errors (failings from lack of available equipment) and active errors (resulting from the action of clinicians). They are however by their very nature limited to detect only events stemming from surgery and do not include problems in diagnosis or ward care.

The methodology and taxonomy of observational and interview studies of adverse events are not standardised making comparisons difficult. It seems however that observation and/or interview of clinical staff is able to detect a higher rate of adverse events than traditional retrospective record review and may capture important events for improvement of patient safety by detecting a higher rate of preventable events. The study by Michel and colleagues was able to address this question by directly comparing the events detected by

retrospective record review and prospective observation combined with interview in the same patient cohort (Michel, 2004). This revealed, as can be seen in fig 2.1, that although the rates of detection of adverse events were similar for retrospective record review and prospective observation the cases identified had only a 50% overlap.

Fig 2.1 Adapted Venn diagram from Michel (2004) (surgical patients only)



Prospective observation Retrospective record review

Table 2.1 Evaluation of different methods of detection and description of adverse events and critical incidents

Method for detection	Strength	Weakness
Morbidity and mortality meetings	Can suggest latent errors. Familiar and acceptable to surgeons	Reporting bias Hindsight bias Often poor analysis of events Risk of apportioning blame
Reporting systems	Can detect latent errors Relatively cheap and can run as routine system	Reporting bias Hindsight bias Lack of acceptance and participation by surgeons
Record review	Use already available data source- notes. Can yield detailed information on events Can detect active and latent errors	Rely on information in notes Hindsight bias
Prospective/real time review	Use already available data source - notes. Can yield detailed information on events Can detect active and latent errors Potential to involve staff who participated in care delivery to gain information not recorded in the notes.	Relatively expensive. Open to hindsight bias but less so than retrospective record review. To be most effective require input from clinical teams delivering care.
Observation	Provide data not recorded elsewhere Good at detecting active errors	Expensive Logistical problems Poor at detecting latent errors

Adapted from Thomas and Petersen 2003 (Thomas, 2003)

2.5 Conclusion

This chapter has shown that there are many ways of identifying adverse events and critical incidents in hospital care. No method can be described as ‘the best’ or most valuable method for detection of adverse events or problems with care delivery in surgery. All of the described methods and systems each have their own benefits and weaknesses in terms of cost, work involved and spectrum of events identified. Incident reporting systems are relatively low cost and once set up can run continuously collecting data for years. National systems may pick up rare serious events not appreciated as part of a pattern on a local level. Information on details of contributory factors and preceding events, important to understanding of future prevention, is often lacking in such systems. Local morbidity and mortality meetings have the potential for detailed discussion of adverse outcomes. Often however these review only a fraction of events with an emphasis of serious rare cases rather than the common minor events that constitute the majority of patient harm. Record review has been used as an epidemiological tool for estimating the incidence of adverse events in several countries. It has the disadvantage of relying solely on information recorded in the patient records and has been relatively costly to do at a large scale. Prospective observation has the advantage of being able to integrate several data sources such as staff interview, observation of care delivery, case notes, staff meetings and ward rounds. This is however costly and labour intensive and suffers logistical difficulties.

The choice of method for the investigation of adverse events must be tailored to the problem to be addressed and a balance of financial and logistical constraints.

Chapter 3

3. Methodology of record review

3.1 Overview

This chapter presents the main findings of my literature search and analysis of methodologies of retrospective record review from the international literature. I will here present the development and evolution of record review methodology paying particular attention to the seminal studies which are described in detail. The conflict between the litigation and the first quality driven studies are explored before examining how these have influence further studies. The recent evolution in record review methodologies will be presented at the end of this chapter.

3.2 The Medical record as a research instrument

The medical record holds a written account of the assessment and treatments of a given patient during interactions between the patient and hospital. It acts both as a record of care delivery but also as source of background information on which to base clinical decisions about care of the patient and as a tool of communication between healthcare professionals. A good and adequate medical record will be clearly structured and contain sections on communication with other healthcare providers, in- and outpatient treatment episodes, nursing and allied professions records, observation and fluid charts, prescription charts and results of investigations in clearly marked sections. In the UK the medical record is a legal document which may not be altered once written and remains

the property of the institution of origin which has a duty to retain health record even for a time after the death of a patient.

Not surprisingly for decades the medical record has been widely used as a source of information for retrospective studies (Schuller, 1977; Nazarian, 1993; McNamara, 1997; Maniscalco, 1991; Leland, 1993; Landers, 1975; Harchelroad, 1988; Beard, 1992; Bass, 1981). A wide range of studies have made use of information extracted retrospectively from case records for assessment of clinical outcomes and quality of care. Such studies have been undertaken in a large number of specialities including medicine, emergency care, surgery and obstetrics and gynaecology. Most of these studies assess defined outcomes or specific elements of care rather than the full spectrum of quality or safety of care (Worster, 2005; Linn, 1983; Cocanour, 1998; Meehan, 1997). Record review has also been used in many industrialised countries to estimate the incidence of adverse events in healthcare. These studies were initiated in the US as a response to the rapidly increasing cost of malpractice insurance in order to assess the expected cost of litigation for negligence but the methodology has since evolved to assess the incidence of adverse events with an aim to improve patient safety.

A search strategy was carried out searching Medline from inception to 2005 with the aim of identifying all papers describing the methodology of studies of retrospective record review for identification of adverse events using the following search terms “adverse events” or “retrospective record review” or “record review” or “patient safety” or “Medical Error”. A full search of the

references listed in all suitable papers was also made as was searched of the published work of the lead authors of the main retrospective record review studies. The literature in English on the methodology of retrospective record review consists of at total of 11 papers describing the 8 main national or regional epidemiologically based studies or pilot studies assessing the incidence of adverse events using retrospective record review. In addition to these papers there is a body of 5 papers concentrating on the methodology, reliability and validity of the studies. In addition to the papers relating the methodology there are additional papers describing further results for most of the large scale studies presenting the result in additional detail for all or a selected group of patients or specialities such as surgery. A large number of papers comment on the findings of the main studies of record review but without presentation of data. For the purposes of this thesis those papers describing the original and evolving methodology and those which make significant contribution to the reliability and validity assessment of retrospective record review are described in detail.

3.3 Record review studies for assessment of the cost of compensation

Californian Medical Insurance Feasibility Study.

Record review for identification of adverse events was first used in the 1970's in the Californian Medical Insurance Feasibility Study (CMIFS). This first study of the epidemiology of malpractice in healthcare was undertaken in California in 1974, in response to dramatic rises in malpractice litigation with spiralling costs for legal fees and compensation which led to a crisis in the insurance market in making malpractice insurance unaffordable to some medical specialities. The

CMIFS was set up by the Californian Medical Association to examine the incidence and causation of malpractice, with a view to evaluate if alternatives to a tort based system for patient compensation would be cost effective (Mills, 1978). The methodology used in this study later became the model on which the Harvard medical practice study was based.

A sample of 20,864 inpatient admissions were selected, designed to be representative of the 3 million patients admitted to Californian hospitals during 1974. The main outcome measure was detection of *potentially compensable events* (PCEs). A PCE was defined as “a temporary or permanent impairment of physical or mental function (including disfigurement) or economic loss in the absence of such impairment, which is caused by healthcare management” (Mills 1978). It is worth noting that this definition is different from that of adverse events used in subsequent epidemiological studies. The review methodology consisted of 2 stages with an initial screening stage by non-medical personnel and subsequent review of screen positive records by doctors. The screening was performed using a structured list of 20 generic PCE types, which were used to flag records for further review. The screening eliminated 50 percent of the sample charts while missing less than 1 percent of the PCE's. The remaining 50 percent of case records were then reviewed by one or more of the investigators to determine the presence or absence of PCE's. All positive findings were reviewed in group sessions to confirm the presence of a PCE.

In this study 970 patients (4.6%) had a PCE, of which 796 (82%) resulted from the adverse effects of treatments or procedures; 144 (15%) involved incomplete or

delayed diagnosis or treatment; and 30 (3%) resulted from incomplete protection or prevention. Overall, 94 patients (9.7% of those with PCEs) died as a result of their PCE, and 165 patients (17% of those with PCEs, and 0.79% of all patients in the study) suffered a PCE for which the researchers judged the healthcare provider was legally liable. The 2 main causes of PCEs were therapeutic procedures (641, 66%) or drug therapy (182, 19%). Most (696, 72%) occurred or originated in the operating theatre (Mills 1978).

The Harvard Medical Practice Study (HMPS)

This study is often quoted as the seminal study of adverse events (AE) and the methodology employed here has become the model for subsequent epidemiological studies. This study will therefore be described in detail to give a full picture of the methodology and acts as a benchmark against which to compare future adaptations and development of the methodology of record review.

The main objective of the study was to assess the financial feasibility of a no-fault compensation system in the state of New York. In order to assess the feasibility of such a scheme the study provided an examination of the incidence and causation of malpractice, with a focus on the relationship between malpractice and litigation. The study had four main aims (Hiatt 1989; Brennan 1991; Leape 1991):

1. To establish a population based measure of the incidence of adverse events and “negligent adverse events”
2. To assess the economic effects of these events on patients

3. To determine what proportion of these events actually lead to litigation
4. To examine whether the threat of litigation has any value in deterring malpractice

For comparison it is important to note that 'negligence', as used here, is a narrower term than 'preventable' which has been used in subsequent studies.

Methodology and definitions of the HMPS

The methodology of the study is described in detail in Hiatt and Brennan's (Hiatt, 1989, Brennan 1990) paper from 1989 published ahead of the main findings of the study. A 2 stage methodology based on that of the CMIFS was used. Case records from 30,121 randomly selected admissions were screened by specially trained nurses and medical record clerks/analysts. The records were screened using a generic instrument similar to that applied in the CMIFS to identify records more likely to contain evidence of adverse events. Each adverse event discovered was reviewed by a team of doctors using a structured analysis process designed to gather information about its nature and causation as well as assessing liability.

The definition for AE used in the Harvard study has been adapted in subsequent epidemiological studies of record review in other countries.

Box 3.1 Definition of Adverse Event

An AE needs to fulfil all of these 3 criteria:

1. There must be definable injury to the patient caused at least in part by the medical management.
2. The injury must have produced measurable disability that prolonged the admission or was present at discharge or led to the death of the patient.
3. The injury must be unintended and not part of the planned treatment

An example of an AE would be a wound infection leading to breakdown of the wound requiring packing and closure by secondary intention. This is an unintended injury causing the patient to need prolonged treatment and discomfort. It was not intended and would not have occurred had the operation not been performed. The fact that the patient may have been worse off without the operation is not relevant in relation to this definition. In contrast an amputation of an ischaemic limb where no other treatment is feasible is not an adverse event even though there is disability as a result of treatment.

This definition was chosen to suit the aim of the study, which was to gain evidence to estimate the cost of an alternative to the tort legal system. In the legal system the patient had to be able to prove injury as a result of medical treatment which led to loss of earning or significant pain and suffering. In addition to this the claimant also needed to prove that the medical practitioner had been negligent and failed to provide care of a standard which could be expected by the average physician of his or her standing.

The reviewer was asked to indicate their confidence that the injury was caused by healthcare management rather than the disease process on a 6 point scale, the causation confidence scale. This scale is similar to that used for confidence in negligence seen in box 3.3. If the rating was 4-6 the causation was due to healthcare management and this part of the definition of for adverse event fulfilled.

Similarly the definition of a negligent AE was chosen to mirror the legal position of failure to meet accepted standard of care. The exact definition of negligence used in the study is seen in box 3.2:

Box 3.2 Definition of negligence

'Injury caused by failure to meet standards reasonably expected of the average physician, other provider or institution'

In judging negligence the study used a 6-point confidence scale, if the confidence was indicated at 4-6 on the scale the AE was classed as negligent.

Box 3.3 Confidence scale for negligence

1. Virtually no evidence for negligence
2. Slight to modest evidence for negligence
3. Negligence not quite likely; less than 50-50 but a close call
4. Negligence more likely than not; more than 50-50 but a close call
5. Strong evidence for negligence
6. Virtually certain evidence for negligence

Stage 1 review or screening stage

The review process consisted of 2 stages with the first being a screening stage aimed at selecting records with high likelihood of AE for further in-depth review. This was undertaken by medical record clerks screening the notes for a list of explicit criteria or occurrences in the care of the patient as recorded in the notes. This methodology was an adaptation of that used in the Californian Insurance Feasibility Study, and the screening criteria were largely taken from those previously used but with some changes and adaptations. A full list can be seen in box 3.4

Box 3.4 Screening criteria used in the Harvard Medical Practice Study

1. Hospitalisation within the previous year for patients less than 65 years old and previous six months for older patients
2. Admission to any hospital after this (*the index admission's*) discharge
3. Previous failure of medical management or unfavourable results
4. Trauma incurred in hospital
5. Unfavourable drug reaction in hospital
6. Transfer to general care to specialist care unit
7. Transfer to another acute care hospital
8. Return to operating theatre during this period of hospitalisation
9. Treatment for organ damage after an invasive procedure
10. Acute myocardial infarction, cerebrovascular accident, or pulmonary embolus during or after an invasive procedure
11. Neurological deficit at discharge
12. Death
13. Temperature of 38.3 C the day before or on the day of discharge
14. Cardiac or respiratory arrest
15. Five minute Apgar score <6 or complications of abortion or delivery and labour
16. Other undesirable outcome
17. Evidence of litigation in the medical record
18. Length of hospital stay over 90th percentile for diagnosis-related group in patients under 70 and 95th percentile in those 70 or older

The selected records were referred for implicit review by physicians to determine whether or not they contained evidence of an AE or a negligent AE.

Second stage or Physician review

The second stage review team consisted of doctors in the research team acting as supervisors and reviewers who were board-certified (fully trained) general physicians, surgeons and GPs from the local areas. These were trained in record review and the use of an 'Adverse Event Analysis form' designed for the study. The reviewers were asked to determine if an adverse event has taken place and if this was negligent. In addition to this they were also asked to give an assessment of the degree of disability caused and to describe the care problem leading to the adverse event. Reviewers had access to a panel of experts in specialised fields whom they could consult in complex cases with regards to the medical treatment, however the judgment on regarding whether there was an AE and whether an AE was due to negligence rested with the reviewer. All case records underwent review by 2 independent reviewers and in cases of disagreement these were referred for review by a supervising reviewer who made the final decision.

Results of the HMPS

Case records from 51 randomly selected hospitals in New York State in 1984 were sampled and accessed a minimum of 12 months after discharge. The screening process selected approximately 7800 or 25% of the case records by these fulfilling one or more of the screening criteria. In the 30,121 admissions case records reviewed in the study, 1,278 (4.2%) patients suffered an adverse event during hospitalisation, of which 280 (22%) were judged to have been

caused by negligence. Extrapolating these figures to all admissions to New York hospitals in 1984 indicates that 3.7% of all patients admitted to hospital suffered an adverse event, and that 27.6% of all adverse events were due to negligence. Thus 1.0% of all admissions to hospital were judged to have been complicated by a negligent adverse event. Most adverse events resulted in minimal or short-term disability but 14% caused or were implicated in the patient's death (of which 51% were judged to be negligent). Almost half (48%) of adverse events resulted from an operation - including wound infections (14%) and technical complications (13%). Medication errors (19%) and diagnostic errors (8.1%) were the most common non-invasive causes of adverse events.

The Utah and Colorado study (UTCOS)

A second US study was initiated by the lead investigators of the HMPS to see if the results found in New York state were generalisable to the rest of the US (Thomas, 2000;Gawande, 1999). This study was set in 1995-96 in Utah and Colorado states in hospitals interested in evaluating the possibility of a no fault compensation scheme. Although it is not a landmark study in terms of methodological development it is mentioned here as it was carried out at the same time as the Quality in Australian HealthCare Study (QAHCS) but with markedly different findings. This led to a separate study by the authors of the UTCOS and QAHCS to explore methodological differences (Thomas, 2000;Runciman, 2000).

Main methodological variations from HMPS

The definitions of AE and negligence were identical to those used in the HMPS as was the 2 stage review process. The screening criteria were identical except for 2

additional criteria relating to conversion of laparoscopic procedure to open and patients admitted as day care spending more than one night in hospital. Nurses undertook the screening process and physician review was carried out by board-certified family practitioners and general internists with previous experience in assessing medical care for litigation purposes. Each case record was only reviewed by one physician but quality control was carried out on reviewers with aberrant adverse review rates (Thomas, 2000).

Main results

Of 15000 cases selected for the study 14700 were screened and of these 2820 records were reviewed by doctors. Adverse events occurred in 3.9% of admissions in the study, equivalent to 2.9% all hospital admission in the states sampled and negligent adverse events constituted 32.6% of all AE in Utah and 27.4% in Colorado. Most (44.9%) of AE were classed as operative and 19.3% as drug related.

3.4 Record Review Studies for Assessment of the Quality of Care

The initial US studies setting down the corner stone of the methodology of retrospective record review were both driven by assessing negligence in a medico-legal context. However the focus of the research group behind the HMPS turned towards understanding and assessing harm from a patient safety perspective as can be seen in subsequent publications by the authors of this study (O'Neil, 1993;Schiff, 1994;Petersen, 1998;Garnick, 1991;Burstin, 1993;Brennan, 1991;Brennan, 1991;Bates, 1994).

In the mean time the publication of the HMPS in the early 1990's sparked debate in other countries regarding the quality of care. The first country to replicate the HMPS as a national study of AE was Australia. The question of the feasibility of no-fault compensation was not addressed by the Australian research team. Instead the focus of this study was to assess the scale of preventable harm from healthcare. This was the first study carried out with a quality of care perspective from the outset and as a result the team made some adjustments to the HMPS methodology.

The Quality in Australian Healthcare Study (QAHCS)

This was the first record review study of adverse events undertaken with the aim of understanding the scale of harm caused by healthcare and gain data on which improvements to patient safety could be made. In the wake of the publication of the HMPS researchers and the health authorities in Australia became interested in repeating a similar study but with the specific aim of gathering information which could lead to quality improvement (Wilson, 1996; Wilson, 1995). The objective of the study was to estimate patient injury and its direct consequences as caused by healthcare in Australian hospitals. For logistical reasons only hospitals from 2 Australian states were sampled. The methodology was very similar to that used in the HMPS study but some modifications were made. These will be discussed in detail later in this chapter.

Methodology of the QAHCS

The methodology followed 2 stages as in both the CMIFS and HMPS. The initial screening stage was carried out by nurses screening case records for the

occurrence of 18 screening criteria. These were slightly different to those used in the HMPS. Some criteria were rephrased but others completely restructured. The main differences are highlighted in box 3.5.

The screening team consisted of 9 registered nurses who each reviewed between 636 and 2683 notes against a set of 18 explicit criteria.

Box 3.5 Variations in screening criteria used in Australian study form the HMPS

1. Criteria 1: Unplanned admission before the index admission as a result of injury from healthcare management (at any time)
 - a. This replaced criteria 1 and 3 form HMPS
2. Unplanned removal, injury or repair of organ during surgery
 - a. Wider than HMPS were treatment for organ damage or removal is required
3. Criteria 9 : Other patient complications (AMI,CVA,PE etc)
 - a. This was widened beyond the original limitations of only AMI,CVA and during or after invasive procedure only to any new complication and also unrelated to surgery
4. Criterion 12: Inappropriate discharge to home
 - a. This is much wider than in HMPS where it is limited to raised temperature prior to discharge
5. Criterion 15: Hospital acquired infection/sepsis
 - a. Additional criterion
6. Criterion 16: Dissatisfaction with care documented in the notes
 - a. Additional criterion
7. References to length of stay removed from list of criteria

Case notes which were screened positive by first stage screening were reviewed by a team of 21 doctors all specialists with a minimum of 10 years clinical experience. The background of the reviewers varied and included medicine, surgery, anaesthetics, obstetrics and paediatrics. In addition reviewers had access

to a panel of 22 specialists who could provide medical or technical advice in complicated cases. As in the HMPS the decision of the presence of adverse events and preventability rested with the reviewer and the expert panellists had no role in this. The review was implicit but data was recorded on a structured form and included demographic information, the presence and preventability of any AE, the disability caused, the effect on hospitalisation and details of the event. Each case was reviewed independently by two doctors. In cases of disagreement on the presence or preventability of an AE the 2 reviewers would meet to discuss the case with a third reviewer (expert reviewer) before a consensus was reached. The reliability and validity of the review process is addressed in detail separately in chapter 4.

Since the emphasis of this study was on quality improvement rather than negligence and litigation, reviewers were asked to comment on the preventability of AE rather than whether or not they were caused by negligence. The definition of preventability used was 'an error in management due to failure to follow accepted practice at an individual or system level', accepted practice being 'the current level of expected performance for the average practitioner or system that manages the condition in question'. As in the HMPS the reviewer was asked to indicate the confidence in preventability on a 6 point scale similar to that seen in box 3.3

Results of QAHCS

The sample size for this study was calculated based on an estimate that 3.5% of admissions would be associated with adverse events. 31 hospitals were selected

at random to form a representative sample of hospitals types in the regions included. Data was collected from 28 hospitals (one hospital refused and 2 had unsuitable format of notes). 14,179 admissions from 1992 were included in the study.

The screening process selected 6210 (43.7%) case notes which were referred for physician review. 16.6% of patients suffered an adverse event, of whom 46.6% suffered no or minimal disability, 48.8% suffered some moderate temporary or permanent disability, and 4.9% died. Reviewers judged that 51% of adverse events were highly preventable, 29.8% had low preventability and 19.0% were not preventable at all. Most adverse events happened in the operating room (46.8%) and 25.1% happened on the wards. 50.3% of AE were associated with operations, 13.6% with diagnosis and 12% with non interventional therapy.

3.5 Comparing findings from litigation oriented and quality driven studies

After the publication of the QAHCS results and the AE rate of 16.7%, in contrast to the rate of 3.7% in New York, a heated political debate followed in Australia. Questions were raised about both the research methodology in the Australian study and of the quality of health care in Australia. As the second US study, UTCOS, was carried out at the same time and both reviewed admissions from the year 1992, a close comparison of the 2 studies was suggested. To counter some of the criticisms of the QAHCS a separate study was set up by the investigators of the UTCOS and QAHSC studies to determine some of the methodological or other reasons for the discrepancy between the 2 studies (Thomas, 2000;Runciman, 2000). It is important to understand the results of this study and

the wider differences and evolution in the methodology to understand the subsequent use and choice of review methodology. This section will explore these methodological differences.

The 4 initial studies are summarised in table 3.2 and table 3.3 below. The main structure of the methodology of retrospective record review, with a screening stage carried out by technicians or nurses with the aim of selecting case record with high likelihood of an AE to reduce the time required for doctor review and thereby the overall cost, originate from the Californian study. The exact screening tool and the screeners background has however been changed which may alter the sensitivity and specificity of the screening stage. The definition of the main outcome measure changed from PCE in the Californian study to AE in the Harvard study but has remained constant since then, as has the use of a confidence scale of causation of the healthcare management to aid the stage 2 reviewers' decision making. As the focus changed from litigation to patient safety, the second outcome measure changed from negligence to preventability. Although the wordings of the definition of the two terms are similar, the 2 concepts may be very differently interpreted by reviewers. It may well be easier for a doctor to think of a colleague's poor outcome as preventable rather than negligent, a term which has more sinister connotations.

While the Californian and Harvard studies are broadly in consensus, about both the incidence of adverse events and the proportion of negligent adverse events, the Australian study has rather different findings. In this study adverse events are almost four times as common in Australia compared to the USA, and almost half

are judged preventable compared to about 25% in the US studies. How much of this difference was due to methodology or a reflection of the safety of healthcare has been the object of much debate and study. The investigators of the UTCOS and QAHCS set up a study to determine some of the methodological or other reasons for the discrepancy between the 2 studies (Thomas, 2000; Runciman, 2000). A number of methodological differences were found relating to hospital selection and the context of the studies. Differences in the screening criteria have been described above but the difference in the rate of case records screened positive (UTCOS=19.5%, QAHCS=43.7%) could not be explained solely by these. A major difference was interpretation of the confidence scale. Although the same scale was used in both, the QAHCS study included cases with an average score of 2 or more by the 2 reviewers whereas the US studies required a score of 4 or more. There were also differences in the inclusion of AE depending on the temporal relation to the index admission. The QAHCS included all AE related to the index admission whereas UTCOS counted only those that led to the index admission or those that occurred and were discovered during the index admission. After adjustment for these factors the Australian data was reanalysed and the rate of AE found to be 10.6%.

Table 3.1 Comparison of methodology of Record Review

Study	Setting	Main outcome measures	Stage 1 reviewers	Stage 2 reviewers
Californian Medical Insurance Feasibility Study	23 hospitals in California	Potentially compensable events 2. Negligence	No information in paper	No information in paper
Harvard Medical Practice Study	51 hospitals in New York State	1. Adverse events 2. Negligence	Medical record clerks	Board-certified general physicians, surgeons and GPs
Utah and Colorado	28 hospitals in 2 states in the US	1. Adverse events 2. Negligence	Nurses	Board-certified general physicians, surgeons and GPs
Quality in Australian Healthcare	28 hospitals in 2 states in Australia	1. Adverse events 2. Preventability	Nurses	Hospital doctors with a broad experience and knowledge base

Table 3.2 Comparison of results

Study	Episodes examined	Proportion of notes screen positive	All adverse events	Negligent or preventable adverse events	Negligence / preventability(%)
Californian medical insurance feasibility study	20,864 admissions		970 (4.6%) of admissions	165 (0.79% of admissions)	17%
Harvard Medical Practice Study	30,121 admissions	25%	1,278 (4.1%) of admissions	280 (0.93% of admissions)	22%
Quality in Australian Healthcare	14,179 admissions	44%	2,353 (16.6%) of admissions	8.3% of admissions (note - preventability used, not negligence)	51.2%
Utah and Colorado	14,700 admissions	19%	587 (3.9%) of admissions	181 (1.2% of admissions)	30.9%

By the late 1990's the methodology and quality approach of QAHCS to adverse events study was accepted by the wider research and patient safety community. The UTCOS study had become a footnote in the evolution of record review seen

as a validation study of lesser importance than the HMPS and the Harvard group investigators had largely moved on in terms of their research agenda. When a 3rd wave of record reviews studies were launched in other countries, these were driven by a wish to assess the scale of harm from healthcare in order to improve patient safety. Both the Australian and Harvard methodology and review tools became the foundation for new studies.

3.6 Wider use of record review

The publication of the institute of medicine report “To Err Is Human” and the resulting wider publicity of patients safety led to a move in several countries to set up national studies assess their rate of adverse events.

The methodology used in the UK, Danish and New Zealand (Schioler, 2001;Davis, 2003;Davis, 2002;Vincent, 2001) studies is similar to that used in the Australian study and the authors sought advice in conducting their national studies by contacting the Australian and US research groups directly (personal communication Wilson, Vincent).

3.7 Evolution of the methodology of record review

The methodology of retrospective record review was originally developed over 20 years ago. The remarkable homogeneity of the methodology over such a long period of time stem in part from the unique relationship between researchers in this field which is characterised by collaboration between groups and sharing of review tools rather than internal competition or conflict (personal communication Wilson).

The UK pilot study of adverse events led to a redesign of the traditional stage 2 review form which was subsequently piloted by reviewers in 8 countries and modified according to their comments and criticisms (Woloshynowych, 2003). The main rationale for modifying the review form (RF) was to make the review process clearer for the reviewer and to provide clear detail for more powerful final analysis. Furthermore the team felt that the way in which findings were presented in the traditional RF2 did not always adequately represent the clinical reality. For instance, with a standard RF2 a postoperative infection is classified as an operative event (because it occurred within 30 days of surgery) and non-technical (because it was not directly related to the operation itself). It was felt that a more accurate presentation of this occurrence would be that a postoperative chest infection would be classified as a ward based event and the problem as one related perhaps to drug administration (over-sedation), to failure to monitor (such as over a weekend), or to failure to provide physiotherapy (Woloshynowych, 2003). To allow such presentation and classification of the events the review form contained a section for description of which stage of care the principal problem occurred and a section for classification of the type of problem. A final important change was a much stronger emphasis on the broader organisational, environmental, and other factors that contribute to adverse events. While earlier versions paid some attention to these factors, the approach was not sufficiently systematic. The approach presented by Neale et al in the MRF2 is based on a previously devised framework and method of individual case analysis (Vincent, 2000). The modifications led to a new modular review form (MRF2) but the basic components of AE determination,

description of disability and preventability determination remained and these definitions were unchanged.

Progress in technology as well as a growing understanding of limitations of the traditional methodology has led to new adaptation on the methodology in terms of use of technology and the timing of access to the notes as well as integration with other information sources such as interview with local staff. The main evolutions in the methodology were introduced by the most recent studies from Canada and France. These studies will be described here.

The Canadian Adverse Event Study

This study sampled discharges from four hospitals in 5 Canadian provinces to create a sample representative of all major regions of the country. A total of 4164 admissions were sampled but only 3745 were eligible for inclusion. (Worster, 2005; Baker, 2004; Baker, 2004). The methodology was based on the HMPS and very similar to the Australian study in terms of temporal relation of adverse events to the index admission. Nurses screened the records and positive records were referred for physician review. Only one reviewer saw the notes at each stage apart from a 10% subset that underwent double review to determine the inter-rater reliability. For physician review the paper review tool used in previous studies was replaced by a computerised tool to ensure complete data entry and minimise transcription error. This also had the benefit of being linked to a data registry for automatic uploading of demographic information hence saving time spent by reviewers. All reviews were sent electronically to the coordinating centre on a regular basis to minimise loss of data.

French Study of Adverse Events

This pilot study by Michel and colleagues differed from the above studies in terms of the data collection and information sources but used the definition of an adverse event and preventability originated in the AQHCS. In this study case notes were reviewed 30 days after discharge in a sample of patients admitted on a predetermined date (Michel, 2004). This method was chosen as the aim of the study was to compare retrospective case record review by external assessors with prospective data collection by interview of clinical staff and access to the medical record. The comparative aspects of this study have been described in detail in chapter 2 but an important aspect of the prospective data collection was the involvement of local staff through the use of interview, thereby involving local clinicians in the detection of adverse events. This was also the first major study of adverse events to use record review near the time of discharge.

A full summary of the number of patients included and rates of adverse events can be seen on table 3.3 below.

Table 3.3 Summary of all studies of record review for detection of Adverse Events

Study	Date of admissions	Number of hospital admissions	Adverse event rate (% admissions)
Litigation driven studies			
California Insurance Study	1974	20864	4.65
Harvard Medical Practice Study	1984	30195	3.7
Utah-Colorado	1992	14052	2.9
Quality driven studies			
Australian	1992	14179	16.6
United Kingdom	1999	1014	10.8
Denmark	1998	1097	9.0
New Zealand	1998	6579	11.2
Canada	2000	3745	7.5
France	2002	778	14.5

Adapted from Vincent 2006 (Vincent, 2006)

3.8 Training in record review

Information on how reviewers were trained to perform record review is sparse in the papers describing retrospective record. Table 3.4 below list the comments on training in the main publications from each of the major studies. There are no papers describing, nor are there published, protocols on teaching record review to clinician reviewers. The study teams setting up the major studies have mainly devised their own teaching programmes of reviewers by learning from the experiences of previous studies (personal communication with Neale, Vincent, Wilson). Generally this has been done by supervised review of standardised or

anonymised case records and by providing reviewers with a manual in the review process (personal communication, Neale, Vincent, Wilson).

Table 3.4 Training in record review

Publication year	Lead author	Country	Comments on teaching
1989	Brennan	US (NY)	
1995	Wilson	Australia	Nurses ‘had at least 5 years clinical nursing experience; all underwent an intensive two-week training course in the study protocols and were provided with a review manual. Doctors were all specialist with at least 10 years experienceall underwent a two-day training course and were provided with a training manual.
1999	Gawande	US Colorado	‘ trained’
2001	Vincent	UK	Each reviewer screened sets of notes under supervision until they were judged to be fully conversant with the review process’
2003	Davis	New Zealand	‘trained nurses’ ‘specifically trained doctors’
2004	Baker	Canada	Provincial physician and nurse leaders underwent training and used a standard set of hospital charts and a training manual.

3.9 Summary

Record review has evolved over the past decades from being a tool to assess liability for claims or litigation from negligent medical care to become the internationally recognised epidemiological tool for detecting and assessing the incidence of adverse events in hospital care to address patient safety. The core of the methodology has remained largely unchanged but a major shift from assessment of liability to an assessment of quality led to change of the definition

of negligence to preventability. These definitions may be interpreted differently in the climate of patient safety improvement. Technology and recognition of the limitation of written documentation has led to recent adaptations. Significant questions however have been raised as a result of the wide variation of the rates of adverse events found in the epidemiological studies using retrospective record review. Even if one only compare the later studies concerned with quality of care, there are variations of the findings of more than 2 fold. The validity and reliability of the methodology crucial to understanding and interpretation of the results and is addressed further in chapter 4.

Chapter 4

4. Reliability and validity of record review

4.1 Introduction

Record review has been used to assess the scale of harm arising from healthcare management in a series of epidemiological studies as described in Chapter 3. Confidence in these results as well as those of any new diagnostic test or measurement is assessed by determining validity and reliability. When evaluating a new test one needs to answer the following questions: Is the test valid, does it measure what it is intended to or is it influenced by other factors? A clinical example of this problem is the ability of a pulseoximeter to read carbon monoxide bound to haemoglobin as oxy-haemoglobin thereby giving high SatO₂ readings when in fact there is very little oxygen bound to haemoglobin. The second question is: Is the test reliable, can one trust that the result is accurate or do results vary between tests without change in the measured property? For example; is the drop in haemoglobin of 1 g/l due to a new bleed or part of the normal variance of the machine in the laboratory? It is important to understand the reliability and validity of a measurement tool before trusting or commenting on results. However one must first fully understand the concepts and components of these. Validity and reliability describes the influence on a measure of random and non random error. A simple mathematical definition of validity is that it is inversely related to the extent of non-random error. The reliability of a measure is inversely related to the extent of random error (Carmines, 1979). The less influence of non-random error on a test, the higher

the validity. Similarly for reliability, the less influence of random error, the higher is the reliability of the test.

This chapter will explore the general theory of reliability and validity in detail before reviewing the literature describing these in relation to record review.

4.2 Theory of Reliability

Reliability concerns the random errors which occur in measurements and as such is less contentious. There are 3 types of reliability one must assess in determining the reliability of a test. Inter-rater reliability (or observer variance), intra-rater reliability (or repeatability) and internal consistency.

Inter-rater reliability

Inter-rater reliability assesses the extent to which 2 or more independent observers produce the same result when applying the same test to the same subject. It assesses the extent to which random error or variations occur when different raters apply the same measure. Naturally this is open to many influences. In the case of record review this is likely to depend on the training, supervision and time available to the reviewer for carrying out the measurement i.e. review. Inter-rater reliability is empirically measured by the correlation between the scores of independent raters.

Intra-rater reliability

Intra-rater reliability measures whether a test when applied twice by the same rater produces the same result. It assesses the random variation that arise

when the same rater applies the test on different occasions. In the case of record review this is measured by the same reviewer reviewing the same case notes at different times sufficiently far apart to minimise the effect of memory of the previous rating. Intra-rater reliability is the correlation between the results of the two measurements. This does however become meaningless as there will be a large degree of influence of memory of the case at any additional reviews.

Internal consistency

This measures how well the items in a measure which is designed to measure a particular characteristic correlate with each other. If the measure measures a single trait then a reliable measure will have a high inter-item correlation. This has no relation to record review and will not be further discussed or assessed.

The aspect of reliability which is important to and has been assessed for record review is inter-rater reliability. A high degree of inter-rater reliability is seen as essential to be able to trust results of record review as a true reflection of harm from healthcare rather than just the opinions of the individual reviewer. Many things however can affect the inter-rater reliability such as the training, clinical speciality, clinical experience and predetermined views of the reviewer.

4.3 Theory of Validity

A simple mathematical definition of validity is that it is inversely related to the extent of non-random error (Carmines, 1979). In more simple terms a test is valid if it measuring what it is intended to measure. Traditionally validity is assessed using a matrix of criterion, content, face and construct validity to

investigate the validity of methods. To understand traditional description of validity it is important to understand these concepts.

Criterion-related validity

Criterion-related validity concerns the relationship between a measure and some external variable (the criterion) with which it is expected to correlate. The correlation between the measure and some external variable or criterion (often termed the gold-standard) indicates how well the measure represents the criterion. An example is a measure of adverse events by record review) and whether it is correlated with the gold standard measure of adverse events. Unfortunately no such gold standard of detection adverse events exists.

One use of criterion-related validity used further in this thesis is in relation to sensitivity and specificity. Here it is the variable of screening outcome in the screening stage of the methodology used in relation to the criterion of the occurrence of adverse events (this is the external criterion or gold standard). Criterion-related validity provides a frame work for sensitivity and specificity. In assessing dichotomous data these concepts can be used to assess validity.

Sensitivity and specificity

Sensitivity of a test can be described as the proportion of cases positive for the criterion variable (or attribute variable) which are assessed as positive on the test (or measurement). Specificity is the proportion of cases negative for the criterion (or attribute) variable which are assessed as negative on the test (or measurement) variable. The sensitivity of a measure can in simple terms be

described as the accuracy of the measure - its ability to correctly identify those cases which are positive for the criterion or attribute. Specificity can be described as the negative accuracy of a measurement - its ability to correctly identify those cases which are negative for the criterion or attribute. The degree of variance in specificity and sensitivity, that is acceptable for a test, depends on what it measures and the circumstances. In the case of record review these issues are most important in the screening stage. The screening stage needs to be sensitive to identify all cases with adverse events but also specific so that it does not select too many records without adverse events. Hence the screening stage of record review needs a high sensitivity to include a high proportion of cases in which adverse events occurred for further analysis to achieve a high overall validity (an accurate reflection of the degree of harm to patients). Specificity at this stage is of somewhat less importance as cases with no events will be weeded out by further review at the second stage. Specificity of the screening stage mainly has resource implication by determining the number of records that need full physician review. The specificity for the review stage however needs to be high otherwise processes of care may be criticised or changed unnecessarily.

Content validity

Content validity refers to how adequately the items within a measure reflect the conceptual definition of its scope. Evaluation of content validity is a study of the measure rather than a study of the data produced by the measure. It is non-empirical and usually assessed through the comments of an expert panel on a measure or an evaluation of the measure against available literature or

previously validated methods. These steps are important in the development of a new measure to stop the investigator being drawn down a false track. One could however make the criticisms that this is not an evaluation of the validity of a measure as it does not evaluate the response behaviour but simply other investigators opinion of the measure(Borsboom 2004). Nothing has been formally published on the content validity of record review. Record review has however been used in many countries through out the world, led and trusted by both experts in patient safety and epidemiologists. Their endorsement of the method could be seen as an expression of content validity.

Construct validity

Construct validity is the extent to which a measure supports or conforms to a given theory or construct. Its use has been advocated where criterion validity is difficult or impossible due to a lack of a criterion or when this is complex or abstract. Construct validity is measured empirically by examining the results of the measure in relation to other data which can be used to evaluate the relationship predicted by the theory. The construct validity of record review has not been explicitly assessed in the literature.

Face validity

Face validity of a measure concerns the opinion of users or potential users of the instrument on whether the measure seems reasonable and produces reasonable data. It is a much criticised concept due to its subjective nature. It mirrors content validity but face validity of a measure is evaluated by its users rather than by the opinions of experts or the literature. This raises a series of

problems. One can imagine a situation where a test is valid but scores low on face validity as the users of the test have a limited understanding of the attribute measured. The same of course is true for content validity, although arguably less frequently but it is certainly possible for attributes or phenomena poorly understood by science. The converse is also possible. A test can be invalid, measuring something entirely different from the attribute intended, but the results seem plausible and hence the test may score highly on face validity. Face validity, the views of the users of the results of record review has again not been formally described in the literature and there have been many varied responses to the results of record review studies from around the globe. Some comments have been highly sceptical but in most countries where record review has been carried out, this has been followed by action to improve patient safety. This can be seen as an expression of face validity, on balance most users of the results of record review have trusted its results and acted accordingly.

4.4 Recent developments in the theory of validity

Recently there has been much discussion of the definition and role of validity theory. A simple definition from Borsboom (2004) states that all that is important when considering validity theory is the following: a test is valid for measuring an attribute if and only if (a) the attribute exists and (b) variations in the attribute causally produce variations in the outcomes of the measurement procedure.

This means that tables of correlations between test scores and other measures cannot provide more than circumstantial evidence for validity. What needs to be tested is not a theory about the relation between the attribute measured and

other attributes but a theory of response behaviour. Somewhere in the chain of events that occurs between item administration and item response, the measured attribute must play a causal role in determining what value the measurements outcomes will take; otherwise, the test cannot be valid for measuring the attribute (Borsboom 2004).

This is the essence of Borsboom's position, a simplification of validity theory away from the complex matrix of construct, criterion, content and face validity which all are proposed to evaluate different aspects of validity. Borsboom argues that these do not exist in relation to validity but describes the relation between a measure and nomological network of constructs and interpretations of test measures rather than the question of the validity of the measurement itself.

If one accept Borsboom's stand on validity, it means, that in relation to validity of record review for identification of adverse events, one should not assume that the data provide a valid measure of the quality of care delivered. This is would be to try to validate an interpretation of a measurement. What needs to be validated is record review as a measure of adverse events. To enter these terms into Borsboom's definition: The method of record review is valid for measuring adverse events if and only if (a) the adverse events exist and (b) the variation of adverse events causally produce variations in the recording of adverse events using the method of record review.

Borsboom's critique is primarily aimed at psychological and social measures where the concepts in question such as personality or intelligence are more abstract. The implications for record review are primarily that it is not crucial to assess in detail every aspect of traditional validity. The essential part is that record review need to be a meaningful reflection of actual errors in and harm arising from patient care.

4.5 Reliability and validity of Record Review

Record review (RR) has been used in epidemiological studies for over 20 years. Several studies have addressed the reliability and less so the validity of record review for the identification of adverse events. In particular the reliability of record review has been hotly debated as this has implications for comparing rates of AE between studies and for using RR as a tool for measuring changes in AE at intervals of time in the same setting. Some critics have argued that RR is too unreliable to base firm judgements of the scale of harm and prioritise improvements on and have argued that assessors in record review overestimate the preventability of adverse events by being influenced by hindsight bias (Hayward, 2001;Hofer, 2000). This has been defended by others who accept that although there are problems with reliability, RR is currently the best validated tool available for epidemiological assessment of AE and that the findings might be seen as a lower bound as some adverse events carry no written record in the case notes (Leape, 2000;Weingart, 2000). To critically assess or participate in this debate one must have an overview of the published evidence in this area. The main studies assessing validity and reliability of record review were identified by structured literature search and are presented

below before separate summaries of the findings and implications for each of the components of reliability and validity.

Californian medical association. Report on the medical insurance feasibility study, Mills 1978

The first study estimating the incidence of AE by record review was carried out in California in the mid 1970's (California Medical Association, 1977; Mills, 1978). It was a medico-legal study, where the main outcome measure was negligent PCE. The methodology has previously been described. A validity analysis of a sub-sample of screened records showed that 12% of screen-negative charts contained an adverse event. The only assessment of the validity of stage 2 was an analysis of an additional review of a sub-sample of 415 charts that has been previously assessed as not containing AE. However it is not clear from the report if the second reviewer was blinded or how the 415 charts were selected. On second review 10 of 415 or 2.4% of charts were found to contain evidence of an AE.

Reliability and validity of judgments concerning adverse events suffered by hospitalised patients, Hiatt 1989

This paper describes the development of methodology used in the Harvard study (Hiatt, 1989). It also details a pilot study with assessment of reliability and validity of the method carried out before the HMPS. Validity of the screening stage was assessed by comparing 672 pairs of medical record analyst stage 1 reviews with senior physician stage 1 reviews as the gold standards. 54 of these records with positive screening criteria were wrongly screened negative by the medical record analyst's. The sensitivity of MRA screening was 84.5% and specificity 71.8%. The screening process was also evaluated against

physician review of records. The screening was negative for 19 of 241 cases with PCE (7.9%) and 9 of 144 cases (6.3%) with negligent PCE. Negative and positive predictive value was calculated by extrapolation. Negative predictive value of the screening process was 99.5% and positive predictive value 21%.

Reliability was assessed for inter-rater reliability between physicians' reviews. This was as excellent for a 10 point confidence scale for medical causation (AE) $R=0.78$ and good to excellent on a binary scale for the same. Reliability for negligence was less but rated as good with $R=0.62$ and $R=0.51$ respectively in the 2 scales. Senior review consensus for causation was calculated with a correlation score of $\kappa=0.57$ and $\kappa=0.51$ regarding correlation on negligence. Both correlations are moderate to good.

Identifying adverse events caused by medical care, degree of physician Agreement in a retrospective chart review. Locali/Brennan 1996

The study described in the above section was a pilot validity and reliability assessment of the Harvard Medical Practice Study. The author of this paper describes a more extensive reliability assessment after completion of the HMPS (Localio, 1996). Working independently 127 paired physicians assessed 7533 inpatient admissions for adverse events. A total of 15066 reviews were done. In 10 % of cases (757) the two physicians agreed on the occurrence of an adverse event. The correlations given below are weighted kappa statistics. The rate of agreement on the presence of an adverse event for all cases was $\kappa=0.44$. For comparison purposes, this sample of reviews has a chance rate of agreement of $\kappa=0.11$. The rates of agreement differed significantly with the type of cases ($P < 0.001$). Wound infections showed the highest rate ($\kappa=0.62$). Drug reactions and

falls had markedly lower rates of agreement ($k=0.48$ and $k=0.37$, respectively). Rates of agreement were lowest when reviewers found the event was caused by a failure to diagnose ($k=0.32$) or omission of therapy ($k=0.24$). This study found that agreement were highest within pairs of physicians who had reviewed many cases prior to the date of their review of the case of interest, $\kappa=0.57$. This rate was significantly higher than that for cases assessed by less experienced reviewers ($\kappa=0.37$; $P < 0.001$).

Incidence and Type of Adverse Events and Negligent Care in Utah and Colorado, Thomas, Brennan 2000

As this study was carried out using the methodology from the HMPS under the guidance from the original authors of the methodology the reliability was assessed but not the validity (Thomas, 2000; Thomas, 2002). After completion of stage 2 review, re-review was performed on a random sample of 500 records screened positive in stage 1. The original 2:1 ratio of Colorado to Utah records was maintained (167 from Utah and 333 from Colorado). Of these records, 400 were originally judged to have no adverse event, and 100 were originally judged to have an adverse event. This mix of records was selected to provide a sample of a similar proportion of adverse events to that of the original review. Six physicians in Colorado and 4 in Utah reviewed these records; they all reviewed records that they had not previously reviewed. The reliability or validity of the nurse screening process was not evaluated. Of the 500 records chosen for re-review as part of the reliability study, 488 were located and reviewed (97 of 100 with AE and 391 of 400 without AE). The percent agreement for adverse events was 79%, and $\kappa=0.4$.

The Quality of Australian Healthcare Study. Wilson/Runciman 1995

This study had extensive assessment of both its reliability and validity assessed in anticipation of heavy criticism mainly on political grounds but also because it was the first time this methodology was used outside the US and with a particular emphasis on assessment of quality rather than for assessing the cost of litigation(Wilson, 1995). The screening stage as evaluated for inter-rater reliability and for validity in the form of sensitivity of screening. 2574 cases were independently screened by two nurses. The agreement for presence of positive screening criteria was 84% ($k=0.67$). For the 6200 cases screened positive in stage 1, two independent medical reviewers indicated if they agreed with the positive screening criteria selected by the nurse screener. In 98.7% of admissions there was complete agreement. In 0.1% both medical reviewers disagreed with the screening criteria and in 1.1% one of the medical reviewers disagreed. The sensitivity of the screening was evaluated by reviewing 413 screen negative notes. The number of adverse events found in these was used to estimate the sensitivity and specificity of the screening process. The screening stage was judged to have a sensitivity of 97.6% and a specificity of 67.3%. At the second a stage of review each case record was reviewed independently by two reviewers. In 1993 of 6200 (32%) case records there was discrepancy between the findings of the reviewers. In 1375 there were disagreement on the presence of an AE and in the remaining 618 cases there was disagreement on causation and preventability. The 1375 case records underwent a third review by an expert reviewer and in 906 (66%) an AE was found, in 469 there was no AE. In a minority of cases, 195 of 1375 (14%) the disagreement was due to violation of the study protocol. The overall agreement

on presence of AE between medical reviewers was 80% ($k=0.55$) agreement on causation was 71% $k= 0.42$. Agreement on preventability was even lower at 58% ($k=0.33$).

The Canadian Adverse Events Study. Baker 2004.

The data recording in this study was computerised in an attempted to improve reliability and ensure complete data entry. At both stages of the review process, inter-rater reliability was assessed on a random sample of 10% of the charts. The kappa statistic for the measurement of agreement on the 10% sample for the first stage of the review process (by nurses or health records professionals) was $k= 0.70$. Kappa scores for the measurement of agreement for the second stage, review by physicians, were moderate for each of several steps. On determination of whether an injury had occurred $k=0.47$, on determination of whether the injury was caused by health care management $k=0.45$ and on determination of whether the event was preventable $k=0.69$.

The French comparative study of Adverse Events, Michel 2004.

Although this study did not perform record review according to the traditional methodology it deserve particular mention here due to the important methodological developments of record review near the time of discharge and involvement of local clinicians in the identification of adverse events through interviews. The results for reliability for identification of adverse events are unprecedented with excellent agreement $k=0.83$. However the agreement on preventability was poor at $k=0.31$.

These are the most important studies of validity and reliability of record review for detection of adverse events. Several other smaller studies have been carried out each with an assessment of the screening stage and inter-rater reliability (Vincent, 2001; Davis, 2003; Davis, 2002). All have findings similar those laid out above.

4.6 Summary of Evidence on Reliability of Record Review

As can be seen from the above studies intra-rater reliability has not been assessed in any of the studies of record review.

In contrast inter-rater reliability has been extensively addressed in all the studies of RR. Most studies have given kappa correlations and some give percentages of agreement. The results are presented as 'percent of agreement overall' and 'percent of agreement in the cases where AE were found'. Correlations for the presence of AE are described as being high to moderate in the 5 studies. Correlation on preventability is lower in most studies with a grading of moderate to poor apart from the Canadian study where this was rated as good ($k=0.69$). There is little discussion apart from in the Australian study of whether some of the discrepancies between reviewers were due to real disagreement relating to the clinical facts, interpretation of the definitions of the study or an oversight of events by some reviewers.

4.7 Validity Assessments of the Record Review process

The evidence as it stands to date with regards to each point of classical validity of retrospective record review for identification of adverse events will be summarised below.

Face validity

This has not been formally presented or addressed by any of the above studies although implicitly assumed. Face validity of using record review as a tool for assessment of AE could be assumed to be good due to the large number of studies using this technique and the relative small variations in the methodology.

Content validity

The point made above for face validity can also be applied to content validity. The methodology although adjusted between studies has remained largely unchanged over two decades. Researchers in individual studies have contacted experts with previous experience in this field for evaluation the design of their individual methodology (personal communication Vincent, Wilson, Neale). However this is not explicitly described in the published literature. Previous work in this field has been carried out by Walshe and Richards (Walshe, 1998; Richards 1988). Richards et al used a panel of 3 doctors to comment on the adversity of each element of an adverse patient occurrence inventory. All doctors rated all elements as being negative and “generally agreed with one and another in their evaluations”. Walshe surveyed 150 doctors working in clinical medicine and public health in the UK and found broad support for the validity of a generic adverse events measure. The methodology used in this

study shares many similarities with that used for previous record reviews. Thomas and Petersen (Thomas, 2003) describe record review as able to detect adverse events, active and latent errors but point out the obvious disadvantages of difficulty in detection of adverse events or error in care that are poorly or not at all recorded in medical records. Review of medical records is also susceptible to hindsight bias.

Criterion related validity

Criterion validity has been extensively assessed for the screening stage of the classical methodology of record review in the form of sensitivity and specificity analysis. The screening questions vary slightly between studies as does the profession of the screeners. The sensitivity of the screening stage was found to be high in all studies reporting this, with a sensitivity of 97.6% in the Australian study and 84.5% in the Harvard Medical Practice study. As expected and accepted the specificity of the screening process was lower, with a specificity of 67.3% in the Australian study and a specificity of 71.8% in the Harvard Medical Practice study. For epidemiological studies such as these it is important that as high a number of cases with AE as possible are selected by the screening process. That relatively large number of cases without AE goes on to stage 2 review is mainly a resource issue. One important factor not mentioned in any of the above papers is whether there was a different distribution of AE in relation to type and preventability in those cases not selected by screening. This is important if the findings are used to extrapolate rates and types of AE in the wider population. Criterion validity of the overall methodology is not assessed by any of the above studies although a comparison between quality of care and

AE rates between different types of hospitals are performed by a number of studies (Wilson, 1995; Baker, 2004; Hiatt, 1989; Localio, 1991; Thomas, 2000).

Construct validity

Construct validity is not directly assessed by any of the studies of RR for identification of AE. However when the reported AE rates in the Australian study were 3 to 4-fold higher than in the 2 US studies the methodology was questioned. It resulted in a study of the differences in the methodologies which are described in Chapter 3 (Thomas, 2000; Runciman, 2000). 40% of the discrepancy in the findings of the 2 studies was attributed to methodological differences. Most of the remainder were judged to be a result the different aims of the 2 studies and due to the differences in background of the reviewers. However true differences in the rates of AE in the 2 countries could not be excluded (Thomas, 2000; Runciman, 2000, personal communication Wilson).

Comparing retrospective record review with other methods of detection of adverse events

The WHO commissioned a review of the strengths and weaknesses of methods available for detection of adverse events which was carried out by Professor Michel, lead author of the French study of adverse events, and completed in 2003 (Michel 2003). This literature review addresses amongst many other methods retrospective record review. Its conclusions on reliability are similar to those summarised above stating that reproducibility for detection of adverse events is moderate where reproducibility for preventability is poor. In terms of validity this review highlights a number of studies comparing record review to

other methods of detection of AE some of which are described elsewhere in this thesis(Wanzel 2000, O'Neil 1993, Brennan 1990, Michel 2004). Based on the evidence from these and other sources Michel concludes that although standardised medical record review is effective in estimating the nature, frequency and economic impact of adverse events, it is nevertheless likely to under estimate preventable adverse events and some specific types of adverse events such those related to medication. In addition it is unlikely to in isolation provide data for analysis of root causes of events.

4.8 Summary of evidence of validity of Record review

Through the 20 years the methodology of retrospective record review has been used there has been much less formal assessment of the validity than of reliability of the methodology. Face validity has not been formally presented or addressed by any of the above studies although implicitly assumed. This also applies to content validity. Record review is however accepted as being able to detect adverse events, active and latent errors but suffers the obvious disadvantages of difficulty in detection of adverse events or error in care that are poorly or not at all recorded in medical records and being susceptible to hindsight bias. Criterion validity has been extensively assessed for the screening stage of retrospective record review in the form of sensitivity and specificity analysis. The sensitivity of the screening stage was found to be high in all studies reporting this. Criterion validity of the overall methodology is not assessed by any of the studies although a comparison between quality of care and AE rates between different types of hospitals were performed by a number of studies.

4.9 Summary

Reliability and validity are important when evaluating new research methodologies and when assessing their impact. Differing theories of reliability and validity complicate the frontline researcher's task. The basic methodology of retrospective record review has been used in many developed countries but with results ranging from 2.9-16.7 % rates of adverse events. Even if one compare only the later studies with more uniform methods and a focus of patients safety as opposed to a liability to litigation, the variation is more than two fold (7.5-16.6%). Reliability has been an area of concern which despite many efforts has not been fully resolved. Most traditional record review studies have found poor to fair correlation between reviewers with kappa scores of 0.4-0.47 for presence of an AE and poor to good for agreement on preventability 0.33 – 0.65. Neither the validity nor the reliability of record review has been proven despite the fact that the methodology has been used in a large number countries and the results have had wide ranging consequences. There is however no alternative acceptable gold standard for detecting AE and one cannot readily compare the validity of RR with other methods such as prospective or observational studies and incident reporting.

The limitations of retrospective record review methodology lie partly in the design. Thomas and Petersen (Thomas, 2003) describe record review as able to detect adverse events, active and latent errors but point out the obvious disadvantages of difficulty in detection of adverse events or errors in care that are poorly or not at all recorded in medical records and point out that review of medical records is susceptible to hindsight bias. Adequate identification and

description of adverse events that are documented in the care records rely in great part on the selection, clinical experience, training and dedication of reviewers. The issue of training of reviewers is likely to have a great impact on the reliability of reviews. Despite this there has never been any formal assessment of training or evaluation of the training of record reviewers published from the studies described here.

Summary of Introduction and Literature review

The problem of harm arising from healthcare management is not new nor is the interest in this. Surgery has a strong tradition for internal assessment stemming back to the work of Codman in the late 19th century and in UK this has developed into the current practice of audit of narrow topics and outcome. There has been a growing general acceptance of error in medicine as being part of human nature rather than being primarily caused by a character flaw or a reflection deficiency in training or competency of the clinicians involved. This view has largely been born out of developments in other industries and is slowly beginning to take root in surgery. Despite this it has been difficult to engage individual clinicians in measurement and analysis of adverse events in their own practice. Nationally and internationally there has been no real attempt to solve the problem of unsafe healthcare by radical redesign of the systems of delivery. Any change has thus far predominantly been in the form of suggestions of change to isolated aspects of practice.

Chapter 2 illustrates how there are many ways of identifying adverse events and critical incidents in hospital care. All of the described methods and systems each have their own benefits and weaknesses in terms of cost, work involved and spectrum of events identified. Incident reporting systems are relatively low cost and once set up can continuously collect data for years, but information on details of contributory factors and preceding events, important to understanding of future prevention, is often lacking in such systems. National surgical mortality reviews such as NCEPOD and SASM have succeeded in engaging

the surgical profession in review of deaths and has led to changes in working practices. The limitation of these audits are however that they look only at the care of patients who have died and predominantly after surgery. In the case of NCEPOD not all deaths are included in the audit and the local learning from the audits is not assured. Local morbidity and mortality meetings have the potential for detailed discussion of adverse outcomes. Often however these review only a fraction of events with an emphasis of serious rare cases rather than the common minor events that constitute the majority of patient harm. Prospective observation has the advantage of being able to integrate several data sources such as staff interview, observation of care delivery, case notes, staff meetings and ward rounds. This is however costly and labour intensive and suffers logistical difficulties.

Record review has been used as an epidemiological tool for estimating the incidence of adverse events in several countries and has enjoyed a position as the internationally recognised gold-standard for detecting and assessing the incidence of adverse events in hospital care to address patient safety. Despite this position there has been criticism of the traditional methodology and despite repeated efforts to improve the reliability this remains as fair for most studies. Retrospective record review has also suffered limitations of relying solely on information recorded in the patient records and has been relatively costly to do at a large scale. There have however been recent interesting developments to improve the methodology by moving away from a reliance solely on the medical record as the source of information to involving clinical staff in detection of adverse events with improvements in the reliability as a result. The challenge

still remains to prove the validity record review as there is no independent gold standard against which to compare. It is clear however that medical record review relying purely on the written account in the medical notes will never be able to detect all adverse events.

These findings illustrate the need for a method for detecting adverse events but also critical incidents in surgery with the specific requirements that it should build on the surgical tradition of peer assessment and audit; it should therefore include surgeons in the data collection. Record review would be a suitable base for such a method as it was identified as a validated means of adverse event detection and some of its weaknesses could be addressed by involving clinicians in the review process.

Hypothesis, Aims and Objectives of Studies

The hypothesis of this thesis is that it is possible to modify the method of record review for use in real-time by clinicians in order to provide a stimulus for improvement of safety of care and provide data on which to base such changes.

The overall aim of the studies in this thesis was the development of a method of detecting adverse events and also critical incidents which build on the surgical tradition of peer assessment and audit and therefore include surgeons in the data collection. This should be an adaptation of traditional retrospective record review from a research methodology of retrospective audit to a review methodology which could be used by clinicians in real time.

The aims of study 1 presented in Chapter 5 and 6 are initially to develop the methodology and then to test it in a setting of 3 surgical units within a single hospital with duplicate review of all cases by an external reviewer to allow for validity and reliability assessment of the screening stage and to compare the findings of local clinician reviewers with that of the external reviewer.

Study 2 described in Chapter 7 has the aim of gaining a better understanding of the detection rates and to get an overview of the range and quality of data available using different systems, including real-time record review, of collecting information on problems in care based on routine activities and information systems in the same hospital.

Based in the findings of study 1 further the need for further developments in the review methodology was identified. The aim of study 3 described in Chapter 8 was to assess the effect of structured training of clinicians with no previous experience of record review for adverse events and critical incidents.

Study 4 described in Chapter 9 has the aims of firstly assessing the usability of an electronic review tool and secondly the reliability of the review process by having 2 independent external reviewers assess a subset of the case records.

Study 5 described in Chapter 10 has the overall aim of exploring the implementation of the revised methodology and electronic review tool for Real-time Record Review and as part of this compare data available from consecutive discharges with data gained from review of strictly selected cases, Further aims were to explore the difference between trained clinician reviewers and external reviewer, assess the feasibility and workload involved and lastly to record organisational changes made based on the results of the study.

The last study which is described in Chapter 11 had the aim of determining if the methodology of Real-time Record Review can be used without ongoing support from the author of this thesis and to assess if the methodology is transferable to other healthcare settings.

Chapter 5

5. Detection and analysis of adverse events using real-time record review

This chapter describes the development of the initial methodology of real-time record review (RTRR) followed by data collection and some of the results of the first study undertaken in the development of this thesis. The findings of the SpR reviewers are presented separately in Chapter 6 as is the assessment of reliability and validity of the study.

5.1 Initial development of the methodology of real-time record review

Studies of record review have been carried out in a number of countries (Baker, 2004; Vincent, 2001; Wilson, 1995; Davis, 2003; Davis, 2002; Schioler, 2001). These have primarily been epidemiological in nature and have been carried out by external investigators examining case records retrospectively on a regional or national level. Retrospective record review studies have sought to detect only adverse events where harm to the patient has been demonstrated and have not included data on near-misses or critical incidents.

To improve care and awareness of patient safety on the ground it is essential to engage clinicians caring for patients. I wanted to adapt the classical method of record review used for epidemiological studies to be used by clinicians in a local setting. It is hoped that this will achieve more detailed information of events by having the clinicians providing the care also reviewing the cases, hence having the opportunity to include information not documented in the notes but known to

the team caring for the patients. The obvious challenge of this approach was firstly to engage clinicians and get them to give up valuable time in an already pressured work schedule to perform the reviews, secondly to teach clinicians critical appraisal of medical records and care given, in order to identify adverse events (AE) and critical incidents (CI). By including data collection on critical incidents it is hoped that more problems in care, which may in other circumstances lead to patient harm, will be detected and therefore the opportunity to learn from error improved.

Aim

To develop a methodology of real-time record review which can be used in a local setting by clinicians to detect, classify and describe adverse events and critical incidents.

It is hoped that the methodology can act as a mirror to the organisation investigated, highlighting problems often overseen and allow the organisation to see patterns underlying minor problems thereby allowing these to be addressed before more serious events occur. This would enable creation of an environment which is pre-emptive rather than reactive in relation to patient safety issues.

Development

The methodology of real-time record review was adapted from the methodology for retrospective record review (RRR) using MRF2 described by Woloshynowych in 2003 (Woloshynowych, 2003) in the following ways.

Changes to review process

1. Setting

This methodology was developed for local use in a single hospital directorate or firm, where past studies were carried out on a regional or national basis.

2. Timing

Record review in this study was carried out at the time of discharge from the hospital rather than the review of notes from admissions which took place 12-18 months in the past.

3. Reviewers were members of the clinical teams caring for the patients.

4. As reviewers had knowledge of the patient care which was not recorded in the case records, they were encouraged to record this in free text on the review form.

5. Types of events

This study collected data on critical incidents as well as adverse events. It is the first study of record review to include this information.

Changes to the review form MRF2

1. Detail

Due to the local design we were able to collect detailed information and classify this according to the stage of care at which the event happened and the nature of the problem.

2. Reviewers were presented with at list of possible contributing factors based on the “London protocol for analysis of adverse events”(Vincent, 2000). Reviewers were asked to indicate the presence of contributory factors.

Table 5.1. comparison between traditional record review and this study

	Traditional record review	Present study
Nature	Epidemiological	Clinical
Rationale	Insurance ('adverse event' based)	Patient safety ('medical decision' based)
Time-scale	Retrospective (e.g. Harvard over several years)	Contemporaneous (at the time of patient discharge)
Hospitals studied	Large scale multi-hospital	Detailed study in a single hospital
Methodology	Broad-brush. Mixed taxonomy	Detailed modular (when and how)

5.2 Initial methodology of Real-time Record Review

The methodology was designed as a two stage review in line with traditional retrospective record review.

Stage 1 Screening

Initial stage in the review process is screening of the medical records for occurrences associated with adverse events and critical incidents. This will be carried out by nurses and junior doctors searching the case records for 15 screening criteria which were developed by adapting the screening criteria used in traditional RRR. In addition to the 15 criteria listed below the screeners were also encouraged to list any other aspects of care with which they were unhappy as free text on the screening form.

Screening criteria:

1. Previous admission to any hospital in past 12 months
2. Length of hospital admission longer than expected
3. Length of admission > 10 days
4. Diagnosis significantly delayed at any stage of admission
5. Unplanned event occurred during surgery/procedure/anaesthesia
6. Unplanned visit to operating theatre or elsewhere for procedure
7. Unplanned transfer to other unit or hospital
8. Required period of intensive or high dependency care
9. Hospital acquired infection/sepsis
10. Condition complicated during hospital stay by intervening event (e.g. heart failure, DVT, PE, MI, pressure sore, neurological episode, cardio-respiratory arrest etc.)
11. Adverse drug reaction or problem arising from infusion of iv fluids/blood (including cellulitis, haematoma)
12. Fall or other accident
13. Death

14. Patient or relative made complaint regarding care (please specify)
15. Doctor or Nurse unhappy about any aspect of care (please specify)

Stage 2 Record review

Records were reviewed using a modular review form – for full details see Appendix 1

Data collected included the following

Section A: detailed information on patient demographics, the specialty caring for the patient and co-morbidities. In this section the reviewer is guided to determine if the patient has suffered an AE or CI. If this is the case the reviewer will record the date and circumstances surrounding adverse events or critical incident and the adequacy of the notes. Changes made to this section from the original MRF2 include changes to the demographic data collected and more importantly the inclusion of critical incident determination.

Section B: contains information on the effects of the event on the patient and hospital resources. This data was simplified compared to the data fields of the MRF2

Section C is divided according to the stage of care where the event happened. The stages; are prior to index admission, at admission (A&E and pre-admission clinic included), procedure related, immediate post procedure (include ITU and recovery), ward care and discharge. Reviewers were asked to select only the most relevant stage of care to the occurrence of each AE/CI. Relevant details

are requested in each sub section. Only the appropriate subsection according to the event is addressed. The overall structure was maintained but data in each section were altered and simplified compared to the original MRF2. Pre-admission assessment for elective surgery was added.

Section D is divided into sections according to the nature of the event. The sections are; diagnosis, over all assessment, clinical monitoring and management, infection, technical problems related to a procedure and medication or fluid/electrolyte related. The original classification was maintained apart from “during resuscitation” which was deleted. The detailed questions in the sections were altered to suit real-time-record review.

Section E relates to causative or contributing factors and inquires about patient characteristics, team factors, individual factors, task factors, work environment and organisational/management factors. Section E also addresses preventability of the adverse events and critical incidents. Reviewers were first asked to indicate from a list of factors which they felt might have contributed to any event. Secondly they were asked to supply comments of any contributory factors to the incident that they could identify in free text.

Reviewers were asked to indicate on section E of the modular review form which factors might have had a contribution to the causation of the adverse event. For full details see Appendix1 section E. This list was adapted from Vincent’s protocol for investigation of Adverse Events and constructed to give a systems perspective of causation and to make the reviewer think beyond the

immediate link in the chain of causation. This is not an exact science and can at best be an indication of the most readily identifiable causes.

Box 5.1 Definition of adverse events and critical incidents

Definition of adverse event

An adverse event is an unintended patient injury leading to a prolonged inpatient stay, disability at discharge/death and which is caused by health care management rather than the disease process.

Definition of critical incident

A critical incident is an undesirable event in the management of the patient that could have led to harm or did so but did not fulfil the criteria of an adverse event.

5.3 Study 1 - Detection and analysis of adverse events using Real-time record review

Below is described the methods results and discussion of the first test of the methodology of real-time record review.

5.4 Method

Aim

To test for the first time the methodology of real-time record review

Setting

The study was set in 3 surgical units of an 800 bed outer-London district general hospital with full intensive care, radiology and support services on site

serving a suburban population of 300.000. The 3 surgical units were chosen to cover a wide spectrum of general surgical practice and specialised in breast and endocrine, abdominal and minimal access and vascular surgery.

Selection of setting

A senior risk manager learned about the proposed study through ALARM (Association of litigation and risk managers) and offered to pave the way for the study to be undertaken at the district general hospital where she worked. Permission was secured from the Hospital Board and local Ethics Committee. Lead clinicians from 3 general surgical firms in the form of consultant surgeons were contacted by letter, which was followed up by a personal meeting to present the study protocol and seek consent for the participation in the study of the staff and patients of the firm. Two consultants were enthusiastic and keen to meet and discuss the nature of the study. One consultant was not interested in discussing the study. All three consultants gave consent for participation of their firm. The subspecialties of the three surgical firms were breast/endocrine, minimal invasive/abdominal and vascular surgery.

Patients:

134 consecutively discharged adult patients from 3 surgical firms each providing general surgical on-call cover. A formal calculation of sample size and power calculations were not undertaken. The sample size was based on what was deemed to be the maximum number of patients (50 per participating team) which the clinicians would be willing and able to assess the case records of. Engagement in the process of evaluation of care was deemed more important than strict statistical significance in order that such work will stimulate

improvements of care. A case series of 3-4 weeks of cases such as planned represents 6-8% of the annual case load.

Procedure:

Stage 1. Screening

Following discharge from hospital the case records were screened independently by a senior ward nurse and a junior doctor of 1-3 years postgraduate experience (SHO). They would read through the notes from the current and previous admissions. A list of the 15 screening questions previously presented was drawn up based on previous studies (Brennan, 1991; Vincent, 2001). Further to the 15 screening criteria the screeners were encouraged to enter in free text any aspects of care they found unsatisfactory. Case records were regarded as screening positive if any one of the screening criteria was fulfilled or a comment was made even though none of the criteria were met.

Stage 2. Medical Review

All included case records underwent review in order to evaluate the validity of the screening process.

The case records were reviewed independently by an external reviewer (Sisse Olsen) and a specialist registrar on the firm. Before final analysis was performed all adverse events were discussed with an experienced senior reviewer and physician (Professor Graham Neale) to establish if criteria for adverse event or critical incident were met. Data collected on all patients included patient demographics, diagnosis, co-morbidities, duration of admission and presence or absence of events. In the cases where a critical incident or

adverse event was detected further information was recorded onto a modular review form. This was adapted from MRF2 developed by Woloshynowych in 2003 (Woloshynowych, 2003). The complete review form RTRR-MRF can be seen in appendix A.

Recruitment of clinical staff

Once consent was obtained from the heads of the surgical firms, contact was established with the wards where the included firms' patients were usually admitted. The ward clerk (administrator) and 2 senior nurses were recruited from each ward after consent from the nurse ward manager was obtained. The ward clerk was given a 30 min session of instruction in the aims and methodology of the study and her role in labelling and retaining the notes for review.

In total eight nurses from four wards were recruited for the study, 2 from each of the 4 participating wards. They were all giving training in screening as described below.

One junior doctor (Senior House Officer) from each team was recruited and trained in screening of patient records. The same method of training in screening was used for nurses and junior doctors.

One Specialist Registrar (SpR) from the vascular and one from the minimal invasive/abdominal firm and two from the breast/endocrine were recruited and

underwent less than one hour of training in review of medical records using the review form RTRR-MRF (see appendix A).

The pre-registration house officer in charge of keeping a record of all admitted and discharged patients from each firm was contacted and asked to supply a daily list of discharged patients to the study coordinator to monitor that all eligible patients were included in the study.

Training of staff

Case notes from a feasibility study carried out at the same hospital in the past were used in training. A variety of cases was selected, some with standard care, some where critical incidents had occurred and some where adverse events had occurred. These notes were anonymised, classified and photocopied for staff training.

Training of screeners.

The study aims and methodology were explained to the screeners and the screening form introduced. This was followed by illustration of the screening process by the trainer screening a set of teaching case notes. The screener was given opportunity to raise any questions and ask for clarification. The screener and trainer together went through a further 2 sets of training case notes. Following this the screener was asked to screen a further set of training notes and independently record the findings on the screening form. Feedback was given on the screening. The screener was left with a further 2 sets of screening notes to screen before a follow-up training session. At this session any questions regarding the process were answered. In a single case further

training was provided, all other screeners were competent at this stage. Ongoing contact was provided with the trainer throughout the study to clarify any questions. The screeners were asked that if in doubt to rate the notes "screen positive".

In total eight nurses from four wards were recruited for the study. Each nurse underwent one hour of training in screening of patient case records. The time was split between a 45 minute initial session followed by a 15 minute follow-up session to clarify any problems or uncertainties. Over all the junior doctors received only 30-45 min training split between 2 sessions due to pressures on their time from clinical duties.

Training of reviewers

The aims and methodology of the study were explained to the reviewer and the review form RTRR-MFR was introduced and explained. The trainer defined critical incidents and adverse events for the study. This was followed by illustration of the review process by the trainer using a set teaching case notes. The reviewer was given the opportunity to raise any questions and ask for clarification. The reviewer and trainer together went through a further 2 sets of training case notes. Following this the reviewer was asked to review a further set of training notes and independently record the findings on the review form. Feedback was given on the of the review process. The reviewers did not have further time available to participate in further initial training but ongoing training and feedback on completed review were given throughout the study period.

Case identification

Information on discharged patients was updated daily and obtained from the PRHOs of the firms. Each ward was visited a minimum of 3 times per week to ensure eligible notes were included in the study. When patients were discharged from wards not participating in the study the notes were collected and brought to a participating ward for screening and review. Notes were retained on the ward until screening and review was completed. Contact was made with screeners and reviewers on a twice weekly basis to remind them of the location and number on notes awaiting screening and review.

Time plan of review.

The initial plan was to review the three firms sequentially for 3 weeks to get 50 discharged patients from each firm. In practice the number of discharged patients varied from what was expected and the timing therefore had to be adapted.

SURGICAL FIRM	REVIEW START	REVIEW END
Endocrine	3/10/03	24/10/03
Abdominal	24/10/03	14/11/03
Vascular	14/11/03	7/12/03

Analysis

All data from screening forms and review forms was entered into a bespoke SPSS data base.

5.5 Results

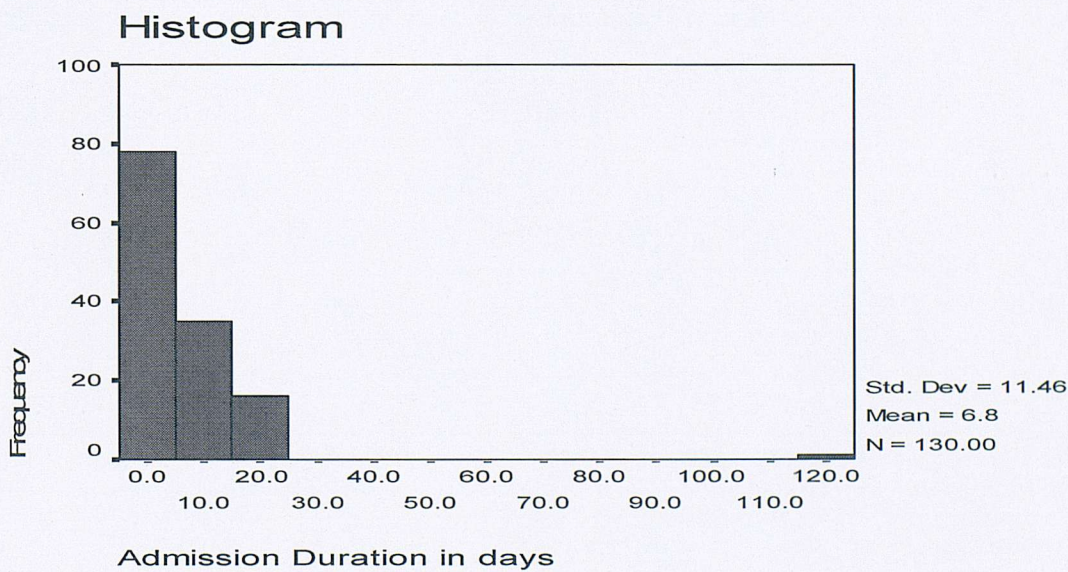
The results of this initial study are presented in detail to show the range and type of data which can be obtained from real-time record review. The initial results are the findings of the external reviewer. This will be followed by the findings of the SpR reviewers and a comparison of these.

Included Patients

In total 134 surgical patients were included in the study from the 3 surgical firms all providing general surgery emergency cover. The age ranged from 16-95, the mean age was 56 years and the median age 55 years.

Duration of stay ranged from 1-120 days, mean stay was 6.8 days and median stay 4 days. Excluding a single outlier with admission of 120 days the mean stay was 5.9 days.

Fig 5.1. Distribution of duration of admission



Distribution of patients between firms

The three firms each specialised in different types of elective surgery, each attracting specific patient types. Endocrine surgery is typically performed on younger patients under the age of 60. A large proportion is younger women with breast cancer. Vascular surgery is typically performed in older patients with multiple medical problems and multi-system vascular disease predisposing them to myocardial infarction, cerebrovascular events and renal failure. These differences are important when considering the patients' vulnerability to complications and limited reserve in resisting harm from such events.

Table 5.2 Distribution of patients between participating teams

Team	Nr of patients (n=134)	% of patients
Endocrine and general	57	43%
Abdominal and general	39	29%
Vascular and general	38	28%

Table 5.3 Distribution of patients according to admission category

	Emergency admission	Elective admission	urgent admission
Nr of patients (n=134)	72	50	12
% of patients	54	37	9

5.6 Clinical outcome results

Adverse Events and Critical Incidents

The 95% confidence intervals are given in brackets after the main outcome measures. Of the 134 surgical patients in the study 20 (15% (9.88%-21.9%)) suffered one or more adverse event. A total of 25 AE and 26 CI were identified in 134 admissions. 16 of 25 adverse events (64% (44.5%-79.8%)) were deemed preventable. 20 (15%(9.88%-21.9%)) patients experienced a critical incident in their care. 25 of 26 critical incidents (96% (81.1%-99.3%)) were preventable. In total 33 (25% (18.1-32.6)) patients experienced problems in their care in the form of an adverse event and/or a critical incident with 20 (15% (9.88%-21.9%)) of patients suffering at least one adverse event +/- a critical incident and an extra 14 (10% (6.3%-16.8%)) only a critical incident.

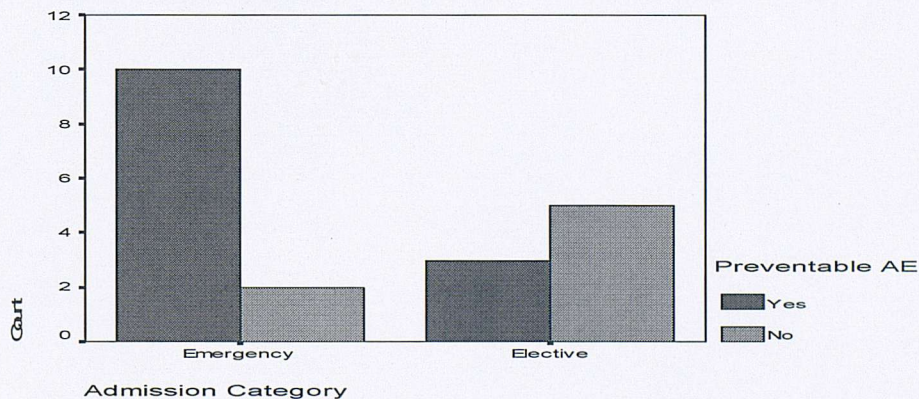
Table 5.4. Distribution of admissions with problems in care

	Patients with events (%)	preventable events (% of events)
Adverse event	20/134 (15)	13/20(64)
Critical incident	20/134(15)	19/20(95)
AE in Emergency admissions	12/72(17)	10/12(83)
AE in Elective admissions	8/50(16)	3/8(38)
CI in Emergency admissions	13/72(18)	12/13(92)
CI in Elective admission	7/50(14)	7/7(100)

The rates of adverse events were similar in emergency and elective cases however emergency cases had a higher proportion of preventable events. This difference was not seen in critical incidents as the preventability rates for both categories of admissions were very high.

When examining the relationship between admission category, emergency/elective, and the occurrence of an adverse event, there no significant relation ship although there were more adverse events in patients admitted as an emergencies (Chi sq $p=0.568$). In contrast when looking at the relationship between preventable adverse events and admission category a significant relationship is found. Patients admitted as an emergency had more preventable adverse events (Chi sq $p=0.035$)

Fig 5.2. Admission category and preventable adverse events



Examining the relationship between critical incidents and admission category, there is no significant relationship although there are more observed critical incidents in patients admitted as emergency admissions, (Chi sq $p=0.29$). The same is the case for preventable critical incidents (Chi sq $p=0.452$).

Analysis by all events

As some patients experienced more than one AE/CI the analysis of events was repeated for the total number of events rather than proportion of patients/admissions with an event.

The table below shows the distribution of all adverse events and critical incident rather than patient numbers versus the mode of admission.

Table 5.5. Total number of adverse events and critical incidents

Class of event	Total events	Preventable events
Adverse events	25/134	16/25
Critical incidents	26/134	25/26
AE in Emergency admissions	12/72	10/12
AE in Elective admissions	13/50	6/13
CI in Emergency admissions	15/72	14/15
CI in Elective admissions	11/50	11/11

Fig 5.3 Number of adverse events and admission category

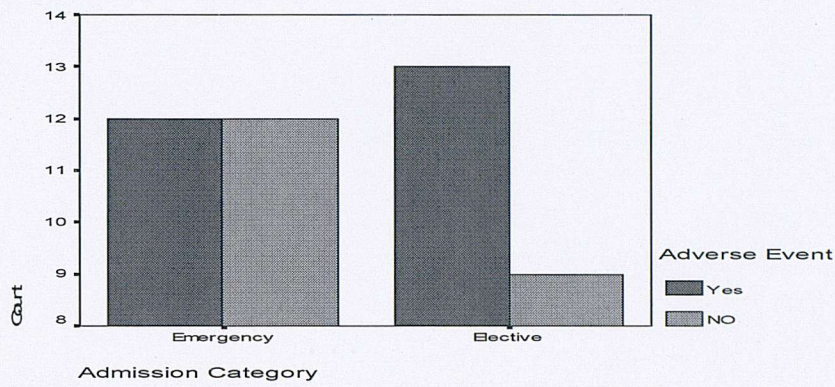
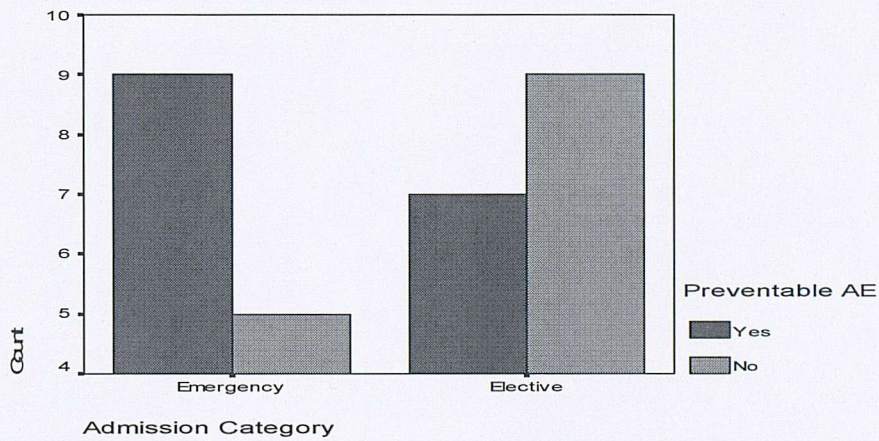


Fig 5.4 Number of preventable adverse events and admission category



Duration of stay and AE/CI.

As seen in fig 5.1 the duration of stay was of nonparametric distribution and heavily skewed. The median rather than mean is a more meaningful characteristic of the data. The median stay for all patients was 4 days. Exploration of the median stay of patients with and without events shows a significantly increased duration of admission in patients in whose care there were critical incidents or adverse events. See table 5.6

Table 5.6. Duration of stay and AE/CI

Group	Median stay	Significance Level (Mann-Whitney)
All patients	4 days	
Patients with no AE	3 days	
Patients with AE	16 days	p<0.001
Patients with no CI	4 days	
Patients with CI	7 days	p=0.01

Distribution of adverse events and critical incidents in the 3 surgical firms and specialities responsible for care

The following section will describe the distribution and number patients with adverse events and critical incidents in the three teams.

Table 5.7. Patients with events per team in percentages

Team	Adverse event	Of which preventable AE	Critical incident	Of which Preventable CI
Endocrine and general	7/57(12%)	6/7(86%)	5/57(9%)	5/5(100%)
Abdominal and general	5/39(13%)	3/5(60%)	4/39(10%)	3/4(75%)
Vascular and general	8/38(21%)	4/8(50%)	11/38(29%)	11/11(100%)

Table 5.7 shows the number of patients discharged with adverse event and critical incident from the 3 surgical firms participating in the review. When examining the relationship between events and admitting specialty it appears that the vascular team has a higher rate of adverse events and critical incidents, however this is only statistically significant for critical incidents (Chi sq $p=0.018$). The same data were analysed looking at the total number of events rather than the number of patients with AE/CI

Table 5.8. Total number of AE/CI distributed between the 3 firms

Team	Adverse event n=25	Preventable adverse events n=16	Critical incident n=26	Preventable critical incidents n=25
Endocrine and general	8	6	7	7
Abdominal and general	6	4	5	4
Vascular and general	11	6	14	14

When evaluating the relationship with Chi sq, the observed differences are not significant. It appears the vascular team has a substantially higher rate of adverse events and critical incidents as may be expected given the nature and complexity of vascular surgery and elderly patient population with multiple cardiovascular co-morbidities. To analyse this further the distribution of specialties responsible for the care of patients at the time the adverse event occurred was investigated.

Table 5.9. Specialty/team responsible for care at the time of **adverse event**

Specialty	Number of patients with AE (n=19 missing data)	Percentage of patients with AE	Number of AE (n=25)	Percentage of AE
Endocrine and general	3	16%	4	16%
Abdominal and general	5	26%	6	24%
Vascular and general	3	16%	6	20%
ITU	2	11%	3	12%
Anaesthetics	1	5%	1	4%
Medical	1	5%	1	4%
GP	1	5%	1	4%
Other	3	16%	3	12%

Table 5.10. Specialty/team responsible for care at the time of **critical incident**

Specialty	Number of patients (n=20)	Percentage of patients with CI	Number of CI (n=24 missing data)	Percentage of CI
Endocrine and general	6	29%	6	23%
Abdominal and general	2	8%	2	8%
Vascular and general	10	48%	12	46%
ITU	0	0%	2	8%
Anaesthetics	1	5%	1	4%
Medical	1	5%	1	4%
GP	0	0%	0	0%
Other	1	5%	1	4%

These data show that 36% of the adverse events and 20% of critical incidents that would have been attributed to surgical teams and surgery in traditional RRR occurred whilst the patient was under the care of other specialties.

Stage of care of events and types of problems

The stages of care where problems occurred were evaluated to get a clearer picture of where in the process of care future improvements might be focused.

Table 5.11. Distribution of events by stage of care

Stage of care	Nr of events (n= 46)	% of AE/CI (95%CI)
Before admission	6	13(6-26)
Early admission	4	9(3-20)
During procedure	10	22(12-33)
HDU/ITU	7	15(7-28)
General ward care	16	35(23-49)
Discharge	3	6(2-18)

It is clear from these findings that the majority of problems of care are related to general ward care which include ongoing medical input and decision making, ongoing investigations and actions as results of these, nursing care and pharmaceutical therapy. Only 22% of events which are traditionally attributed to surgical care are directly related to surgical procedures. The nature of events was categorised as previously described into 6 categories.

Table 5.12. Nature of problems in care for AE/CI

Nature of problem	No of AE/CI n=25 missing data	% of AE/CI (95% CI)
Diagnosis (delay/failure/wrong)	9	20% (11-34)
Assessment of overall condition	3	7% (2-18)
Ward care and monitoring incl. nursing	10	22% (13-26)
Infection related	6	13% (6-26)
Technical problem related to procedure	10	22% (13-26)
Medication or fluids/electrolytes	7	16% (8-29)

As can be seen from above table the majority of problems arise from aspects of general ward care such as medication/fluid prescribing and monitoring, hospital acquired infections and general management and monitoring of patients. Again it is clear that only the minority of problems traditionally attributed to surgical care stems directly from surgical procedures. Reaching the right diagnosis without delay was also a significant issue in this study. A proportion of diagnostic problems occurred during previous admissions and under the care of medical specialties.

During additional analysis of all events, these were classified as occurring in relation to surgical ward care (during this or previous surgical admission leading

to the index admission) or not (operation, medical, GP, etc) using this classification 52% of AE were related to surgical ward care.

Impact on patients and use of hospital resources

The majority of adverse events have minimal impact on the patients' quality of life and resolve within one month. Only 5% of cases resulted in permanent impairment and 10% of cases in the death of the patient.

Table 5.13. Consequence to patients of adverse events

Degree of disability	Nr of Pt (n=20)	% of AE
No physical impairment	6	30%
Minimal impairment for less than 1/12	10	50%
Moderate impairment for less that 1 year	1	5%
Permanent impairment	1	5%
Death	2	10%

Effects of adverse events on Hospital stay

The majority of adverse events had a negative impact on hospital resources by increasing the length of the admission or leading to readmission of the patient.

Table 5.14. Adverse events and impact on hospital stay

Effect of AE	Nr of Patients (n=20)	% of all AE
No effect on duration	1	5%
Increase in admission duration	13	65%
Re-admission	6	30%

Contributory factors

As well as recording clinical details of the AE and CI and the stage of care at which they occurred the reviewer attempted to identify more general issues which impacted on the care process. The factors were scaled in terms of likelihood of contribution to causation but in the following analysis it will be presented simply as likely/not likely because of small numbers.

Table 5.15 Frequency of indication of factors and a contribution to causation of adverse events and critical incidents

Class of factors	Total number of times indicated	Percent of all indicted factors
Patient characteristic	6	7%
Task factors	16	19%
Individual factors	29	35%
Team factors	13	16%
Work environment	3	4%
Work organisational /management	16	19%
Total	83	100%

The information indicated as free text and the factors indicated as in table 5.15 made it clear that some of the causative factor to adverse events fell in certain patterns. Based on this information a list was drawn up of contributory factors specific to this dataset and the responses on the data recording sheets re-analysed to fit one of the new set of classifications. The 2 most likely

contributory factors where appropriate were indicated. The result of this analysis is presented in table 5.16.

Table 5.16. Contributory factors based on free text descriptions

Contributing factors	Number of events where indicated
Unsupervised junior staff	6
Failure of junior to understand importance of routine task	14
Communication/handover poor	8
Opportunity for follow up arrangements poor	4
Lack of knowledge	8
Work load inappropriate	10

Almost half (43%) of the CI and AE's examined were in part caused by what was judged to be a lack of knowledge or understanding of the seriousness of failure to carry out seemingly routine task by junior staff; inadequate resources/staff such as rapid access to outpatient investigation and follow up were a factor in 27% of events. Problems with communication and handover arrangements (16%) and lack of supervision (12%) were also important contributory factors.

Based on the clinical details and contributory factors reviewers were asked to give up to 3 preventative factors for each event. A summary of these responses can be seen in table 5.17

Table 5.17 Preventative measures suggested by reviewers

Preventative measure	Cases where indicated
Education	17
Improved communication systems	7
Improved patient follow up systems	3
Improved supervision systems	7
Reduction of throughput pressure	8
Guidelines in place	11

The main preventative strategy suggested was targeted education of staff in areas of care where AE and CI occurred; this was identified as a possible preventative strategy in 50% of cases with preventable events for example; junior doctors appeared to need education targeted at understanding the importance of routine tasks such as ordering, checking and acting on routine blood tests. Other common preventative strategies suggested included improved systems of communication (22%), improved supervision of junior staff (22%) and a reduction of pressure for high throughput of patients (25%).

5.7 Discussion

It has been possible to adapt record review from a research method of retrospective audit to in real time. Adverse events in this study occurred in the care of 15% of patients, with 65% of these deemed preventable. This result lies within range of results from previous studies which have found surgical adverse events rates of 1.9% - 21.9% (Brennan, 1991; Wilson, 1995; Vincent, 2001; Michel, 2004; Gawande, 1999), and the proportion of these as preventable 48%-74% (Brennan, 1991; Wilson, 1995; Vincent, 2001; Michel, 2004; Gawande, 1999). One study describing surgical adverse events in detail have found the majority of surgical AE were related to surgical technique associated complications (24%) and infection (18%) but only a minority related to medication (7%) and diagnostic problems (3%) (Gawande, 1999). Similarly Kable et al analysing data from surgical patients in the QAHCS found 76% of AE in surgical patients to be associated with operations and 52% of these were deemed to be caused by technical problems (Kable 2002). A prospective study of complications following general, vascular and trauma surgery found that the majority of avoidable complications were caused by technical error 47-83% across the 3 specialties with the highest percentage being in general surgery (Healey 2002). We found a 22% of events relating to technical aspects of surgical procedures but the majority of events in this study related to non operative aspects of surgical care such as diagnosis, drugs and fluid prescription, monitoring and ongoing management and monitoring of patients. Our findings are along the lines of the findings of SASM in their latest reports and publications where only 5 % of surgical deaths were caused by AE and the majority of these were deemed to be systems failures rather than related to technical ability (SASM 2006,

Stonebridge 2005). There is a very little detailed data on the causes of surgical complications and mortality from large series other than the national studies of adverse events with which to compare our results but Wanzels survey of surgical complications in 2000 found that only 30% of these were related to technical problems during surgery (Wanzel 2000). The majority of adverse events had a minor impact on the patients' physical health but even this level of disability can affect the patients' psychological recovery and the doctor-patient relationship. Adverse events had a significant impact on the hospital resources and bed occupancy; in an already pressurised system this can lead to further problems arising through lack of bed space.

Important factors contributing to the occurrence of adverse events and critical incidents in this study include lack of understanding of the seriousness of failure to carry out seemingly routine task by junior doctors; inadequate resources/staff, problems with communication and handover arrangements and lack of supervision. Identification and highlighting of these areas is important in designing targeted interventions to improve safety. An example is targeted education aimed at the most junior doctors to teach the importance of "house keeping" tasks such as ordering, checking results of investigations and discussion of the findings if abnormal. Other areas where interventions are needed include improved systems to support the transfer of information at handover between teams, better integration of medical and surgical care and better opportunities of outpatient investigation and follow up.

Problems encountered

Both nurse and junior doctor screeners had night shifts during the study. This resulted in delays of up to a week in screening of the notes. In some instances this resulted in the notes leaving the ward before screening took place as the notes were needed for outpatient clinic appointment, cancer multidisciplinary meetings etc. Where ever possible the notes were recalled and returned to the ward for screening at a later date. When patients died the records were immediately send to the patient affairs office to assist with completion of death and cremation certificates and the general care of the deceased and family. Because records were needed in the patients' affairs office for prolonged periods it was not possible to return these for later screening.

The specialist registrars were under significant time pressure from clinical duties which impacted on the availability to review case records for the study. Most case notes were reviewed within a week of discharge. On occasions there was a delay of 2 weeks from discharge to review of the records. This resulted in the case records leaving the ward before screening took place as the notes were needed for outpatient clinic appointment, cancer multidisciplinary meetings etc. Where possible the case records were recalled and returned to the ward for review. Case records of deceased patients were not reviewed by specialist registrars as they did not have additional time to locate these in the patient's affairs office. These notes were however reviewed by the expert reviewer and included in the results presented above.

Data was collected by recording findings from record review onto a paper form. This was 26 pages long although not all pages were required for each review. Still this was felt to be off-putting by the registrars. All the data forms had to be read, data abstracted and entered into a bespoke SPSS data base before analysis. This was extremely time-consuming. The collection process and analysis of data collected by record review needs to be simplified if this method is to be taken up by clinicians for routine use.

Chapter 6

6. Clinicians' results, validity and reliability of Real-Time Record Review

6.1 Introduction

Reliability and validity is important when evaluating new research methodologies and assessing their potential impact. Validity gives information about a method's or clinical test's accuracy – does it measure what it is supposed to and what we are interested in knowing. Reliability gives up information about the spread of results - the measurement error one can expect from a test. Definitions and different aspects of validity and reliability are described in Chapter 4. Chapter 4 also evaluates previous studies of the evidence for reliability and validity of retrospective record review. This chapter proves a summary of validity and reliability seen in relation the real-time rapid record review.

To comment on the value of this newly developed methodology one must address the validity and reliability of the method in the following respects. The theory of validity and reliability has been presented in chapter 4. The following section will present the aspects of validity and reliability relevant for the methodology of RTRR.

6.2 Validity and reliability of RTRR

In this context the validity of the review method or components there of is the ability to detect and describe all actual adverse events and critical incidents. The reliability of the method is its ability to consistently detect the same events in same sets of notes.

Face validity in this context is whether the RTRR seems reasonable for detecting and describing adverse events and critical incidents to doctors and other healthcare workers.

Content validity in this context is whether the method of real-time record review adequately detects and describes events in care that are adverse and incidents that are critical. We have addressed previous criticisms of record review by involving the patients' clinicians in the review process in order to gain access to knowledge of care not recorded and have performed the review at the time of discharge to reduce some aspects of hindsight bias. This aspect of validity is not directly assessed in this study.

Criterion-related validity in this context is an assessment of the measurement of an adverse event or critical incident rate by record review in relation to a gold standard assessment of AE/CI. There is however no gold standard method of detection AE/CI with which to compare the results. Hence criterion-related validity cannot be assessed.

In this context Inter-rater reliability describes whether different reviewers, with the same training and time available perform to the reviews according to this methodology, identify and describe the same adverse events and critical incidents. Although there is independent review by external and registrar reviewers in this study, it would not be suitable to assess inter-rater reliability between these due to the differences in training, prior knowledge of cases and time available for review.

6.3 Evaluation of reliability of real-time rapid record review

This section will describe the evaluation of the validity and reliability in the following respects of the methodology of real-time record review undertaken in chapter 5.

This is divided into 3 parts:

1. Reliability of the screening process
 - a. Inter-observer reliability of the screening process
 - b. Inter-observer reliability on each screening criteria
2. Validity of the screening process
 - a. Validity of screening process overall and for individual professions
(results will be presented as specificity and sensitivity against the presence of and AE or CI by external review findings)
 - b. Validity of individual questions of the screening form

3. A comparison, but not formal Inter-observer reliability, of registrar and external reviewers findings can however be made to look at the number and nature of cases detected by the 2 types of reviewers.

6.4 Reliability and validity assessment of the screening process

In the following will describe the assessment of the reliability and validity of the study described in chapter 5.

6.5 Method

Evaluation of the screening process in terms of validity and reliability is important for its use in further developments of RTRR. Therefore this was part of the design of study 1 described in detail in chapter 5.

Design

To assess the screening of notes described in study 1 all notes were reviewed for the presence of AE and CI by the external reviewer to provide a gold standard against which to evaluate the screening results. All notes were screened independently by 2 different reviewers to allow assessment of reliability of screening

Cases

All 134 surgical patients in study 1 were included in this assessment. In total 121 case notes were screened

Procedure

After discharge the patients' case records were screened following a 15 point screening form as described in the method for study 1. Each case records was intended for independent review by a nurse and a junior doctor. Not all case records however were double reviewed due to in availability of some records when these were removed from the wards for use elsewhere and not returned during the duration of the study. All notes underwent full review by an external medical reviewer to provide a gold standard against which to measure the validity of screening in the form of sensitivity and specificity.

6.6 Results

Reliability of screening

A total of 121 of 134 included notes were screened (90%) by at least one screener. Nursing staff screened 108 sets of notes, 45 or 41.7% of these notes were screened positive. Of all eligible notes nurses screened 33.6% positive. SHOs screened 103 notes of which 36 (35%) were screened positive; this corresponds to 26.9% of all eligible notes. Agreement on whether notes were screen positive was achieved in 81% of the case notes screened by both a doctor and nurse reviewer. This is in line with findings of earlier studies (Brennan, 2004;Wilson, 1995). However nurse and SHO screeners agreed on all individual screening questions in only 43% of screen positive notes.

Validity of screening

In total 17 of 20 case notes or 85% of cases with adverse events were screened positive. One of 18 screened notes (7%) which contained an adverse event was

screened negative. Two of 20 notes (10%) of cases where adverse events occurred were not screened. Both of these were cases where the patient had died during admission. These notes were removed from the ward to patient's affairs office on the day of the death and were not retrieved for later screening. To assess the validity of screening in respect to sensitivity and specificity of the screening process screening results from doctors and nurses were combined and are presented in box 6.1 for adverse events and in box 6.2 for critical incidents.

Box 6.1 Validity of screening for adverse events

On intention to screen basis
• Sensitivity 85% • Specificity 71%
For screened cases
• Sensitivity 94% • Specificity 73%

When looking at doctors versus nurses individually the results for screened notes were very similar. Nurse screening alone had a sensitivity of 92% and a specificity of 64%, Screening by SHOs had a sensitivity of 85% and specificity of 72% for adverse events.

Box 6.2 Validity of screening for critical incidents

On intention to screen basis

- Sensitivity = 75%
- Specificity = 69%

For screened notes

- Sensitivity = 100%
- Specificity = 54%

The screening process has not previously been evaluated for detection of critical incidents. The results are similar to those of adverse events.

Screening by nurses had a sensitivity of 87% and a specificity of 65%, screening by doctors had a sensitivity of 66% and specificity of 68% for critical incidents calculated for screened notes rather than on intention to screen.

6.7 Comparison of registrar and expert reviews

As discussed earlier inter-rater reliability is determined by comparison of 2 independent reviewers reviewing cases under the same conditions. This condition was not fulfilled in study 1 and inter-rater reliability can therefore not be directly assessed as there were differences in training and time available for an expert and registrars. It is however important to explore the differences in the rate and nature of events detected by a registrar compared to the external reviewer. The data was collected by independent record review by the external reviewer and the SpRs of the participating clinical teams. Record review was carried out as part of study 1. The methodology of the data collection has been described in Chapter 5. The findings of the SpR's and the comparison and analysis of differences between the findings of the SpRs and the external reviewer are described here.

Aim

1. Compare number of events detected by registrars against the external reviewer.
2. Investigate if shared events were described in the same manner and if appropriate describe any differences
3. Investigate if SpR reviewers described AE or CI not detected by the external reviewer due to knowledge of care not documented in the case record.

Cases

All cases reviewed both by registrars and the external reviewer were included in this analysis

6.8 Results of review by clinicians and comparison with the external reviewer

Registrars reviewed fewer case notes than the expert reviewer. The case notes of 108 patients are included in this analysis. In the notes reviewed by registrars adverse events were detected in 8 of 15 notes where events occurred as assessed by the external reviewer. Critical incidents were described by registrars in only 4 of 14 set of notes where they occurred. The SpR reviewers did NOT identify any AE or CI not detected by the external reviewer in the medical record.

Table 6.1 Comparison of events detected by SpRs and external reviewer

	Cases assessed	Total AEs	Preventable AEs	Total CIs	Preventable CIs
SpR	108	8	3	4	3
External reviewer (same cases as SpR)	108	19	12	19	18

Comparison between all critical incidents and adverse events detected by external reviewer and registrars (Note external reviewer detected more adverse events and critical incidents than registrars in the same case notes)

The following section will present the differences in the adverse events and critical incidents detected by registrars and the external reviewer.

Table 6.3 Events detected and classification of stage of care

Stage of care	No of events expert	No of events registrars	Percent of events expert	Percent of events registrars
Before admission	3	0	8.8 %	0
A&E, admission, pre-op ass	3	1	8.8%	8%
During procedure	9	6	26.5%	50%
Post-op, ITU/HDU	6	3	17.6%	25%
General ward care	10	2	29.4%	17%
End of admission/discharge planning	3	0	8.8%	0
Total	34	12		

Table 6.3 above show the comparison between events detected by the external reviewer and the SpRs. Differences due to classification variance for the same events will be presented later. I will here explore differences in the type of events detected by the registrars as compared with the expert reviewer. The registrars did not detect adverse events occurring before the index admission, nor did they describe any of the 3 critical incidents occurring at the discharge stage of care. Registrars also failed to detect 8 of 10 events in ward care described by the external reviewer. As a proportion of all events these accounted for about half to those detected by the external reviewer. The events described by the SpRs were mainly events related to surgery and the

immediate post operative period of care. This is reflected in the nature of problems described by the registrars as seen in table 6.4 below. These relate to technical problems with surgery and infection related complications. Major problems with medication leading to adverse events were also described. Problems with diagnosis and ongoing ward management were largely missed.

Table 6.4 Classification of Nature of problem, differences in the events detected by registrars and the expert in the care notes reviewed by both.

	No of events external	No of events registrar	Percent external	Percent Registrar
Failure to diagnose	8	1	23%	9%
Failure to assess overall condition	1	0	3%	0
failure in management and monitoring incl nursing	9	0	26%	0
infection related	3	3	9%	27%
technical procedure related problem	9	5	26%	46%
failure in give medication or fluid/ electrolytes	4	2	11%	18%
Total	34	11 (1 event left unclassified)		

Seriousness of adverse events and critical incidents detected by registrars and external reviewer

As can be seen from table 6.5 the degree of seriousness of the events detected by the two types of reviewer is the same. There is no indication that registrars only detect the more serious adverse events

Table 6.5 comparison of seriousness of events detected

	No of patients exp n=12	Percent exp	Percent registrar	No of patients registrars n=7
No physical impairment	4	33.3%	28.6%	2
Minimal impairment recover 1/12	7	58.3%	57.1%	4
Moderate impairment 1 year	1	8.3%	14.3%	1

Comment

The registrars did not detect adverse events occurring before the index admission. This may be due to failure in assessing this part of the case record or it may be due to a failure to recognise events and problems in care leading to the index admission. The 3 adverse events occurring prior to the index admission was false negative cytology of the sentinel lymph node sample from an operation of wide local excision and axillary node sampling for carcinoma of the breast. This was recognised at the breast multidisciplinary team meeting

and the patient recalled for axillary clearance at the index admission. A case of failure to fully investigate a patient with right upper quadrant abdominal pain by ultrasound at a previous admission hence missing a diagnosis of gallstones and leaving the patient untreated. This led to the index admission with acute cholecystitis. The third case was failure of a GP to refer a patient with a good history of acute appendicitis to hospital, the appendix perforated before the patient self presented to hospital. The registrar reviewers did not describe any of the 3 critical incidents occurring at the discharge stage of care. Again one can only speculate about the reason for this but it is interesting to note that the registrars detected many fewer critical incidents though out all stages of care. The problems in care detected by registrars were traditional surgical complications of technical problems and infections rather than more subtle systematic problems.

Comparison between classification of stages of care and nature of problems in the adverse events and critical incidents detected by both registrar and external reviewer

Having presented differences between registrar reviewers and the external reviewer in detection of adverse events and critical incidents in the same case notes I will in the following address differences in classification of adverse events and critical incidents detected by both registrars and the external reviewer.

Table 6.6 Comparison of classification of **stage of care** between SpRs and external reviewer

Stage of care	Frequency/SpR	Frequency/ External reviewer	Percent/SpR	Percentage external reviewer
A&E, admission, pre-op assessment	1	1	8%	8%
during procedure	5	3	42%	25%
post-op, ITU/HDU	4	5	33%	42%
General ward care	2	3	17%	25%
Total	12	12	100 %	100%

It can be seen from table 6.6 that even though the events described were identical there was a difference in the classification of these events between SpR and external reviewer. Registrars classified more events as occurring during the procedure even though some of these did in fact occur during post operative management.

Table 6.7 Comparison of classification **Nature of problem** of between SpRs and external reviewer

Nature of problem	SpR No of events	SpR Percent	Expert No of events	Percentage of events
Failure to diagnose	1	9%	1	8%
infection related	3	27%	2	16%
technical procedure related problem	5	46%	4	33%
failure in give medication or fluid/ electrolytes	2	18%	1	8%
Management and monitoring	0	0	4	33%
Total	11 (data missing)	100%	12	100%

There are also differences in classifying the nature of problems. Registrars classified more events as being due to technical problems during a procedure than the expert reviewer. However when looking at the data collection forms it is clear that most of this has happened through mistaken use of the data collection forms for recording of the event. The striking difference is in the classification of deficiencies in the ongoing monitoring and management. This classification was not used by any of the registrar reviewers.

Comment

Registrars classified more events as occurring during a procedure even though some of these did in fact occur during post operative management. For example

one case concerned a post operative pneumonia that developed on the ward. Although this is related to the procedure the most likely contributing factors in this case were lack of respiratory physiotherapy on the ward and inadequate analgesia which prevented the patient from coughing or breathing deeply. Another case was aspiration related ARDS. Although this may have occurred at any time during the procedure the aspiration is most likely to have happened at extubation or in the immediate postoperative period as the anaesthetic chart did not show any evidence of increased oxygen demands indicating early aspiration.

For the events classed by the external reviewer as deficiencies in the ongoing monitoring and management, in one case there was no data completed for this section by the registrar reviewer. In another case the adverse event was ARDS developed after a prolonged laparoscopic cholecystectomy. This was classified as infection related nature of problem by the registrar. In another case the failure to monitor fluid and electrolyte prescription and checking results was classified as a medication problem. In the fourth case the event was mistakenly recorded on the part of the data collection form relating to technical problems with procedure.

6.9 Discussion

Assessment of validity and reliability is important in the development of any new measure. Validity of record review has been addressed by other investigators in the past and record review is accepted as being able to detect adverse events and active and latent errors but has the obvious disadvantage of not detecting adverse events or error in care if these are poorly recorded in medical

records. Review of medical records is also susceptible to hindsight bias. In the design of this study we addressed some of these weaknesses by involving clinicians who provided the care to gain “inside information” regarding episodes and errors not recorded. An example of a case where this led to a difference in analysis of an adverse event can be seen in box 6.3. The picture that emerged after including unrecorded observations by clinical staff is much richer and reveals multiple contributing factors including problems with planning of services, poor teamwork and problems with clinical leadership.

Box 6.3 Difference between note review alone and information available from clinical staff

Analysis of case as presented in the notes

- Elective reversal of Hartman’s procedure
- Main problem, technical failure of anastomosis gun.
- Patient needing laparostomy in ITU for 48 hours, develop MRSA wound infection and need ileostomy for 6 months.

Analysis of case by registrar present in theatre

- Same patient outcome but different causation
- List started 1.5 hours late as anaesthetist not aware that he was scheduled to do this list
- Theatre team unhappy and stressed as running late due to anaesthetic problem and difficult surgery
- Consultant joins procedure at time of anastomosis to speed things up. Not used staple gun before, does not listen to registrars instruction of use. Misuse of gun caused failure of anastomosis.
- Decided to try and patch anastomosis rather than redo as running very late. The patching procedure failed; the partial anastomosis had to be taken down and down and the revised anastomosis hand sown.

In previous studies clinician-reviewers are reported as only studying screen positive records for adverse events. In this study all case records were assessed for adverse events and critical incidents to allow an assessment of the validity of screening. However this first “real-time” study using clinicians

involved in the care of the patients suffered some methodological problems. In all 13 cases were not screened. The clinical screeners were not able due to other commitments to screen these cases before they were removed from the wards for use elsewhere. The sensitivity of screening, for the case records that were screened, was excellent at 95% for adverse events and 100% for critical incidents. The specificity was, as expected by the design, lower at 75% for adverse events and 54% for critical incidents. On the face of this the screening process seems valuable in reducing the number of full reviews needed and integrating more clinical staff in the review process without losing many events. The time needed to screen a set of notes compared to the time needed to review a short admission without events however is similar. Using clinical staff to screen may result in delay of review thereby increasing the likelihood of records being wrongly excluded from the remainder of the review process due to unavailability. These factors must be taken into careful consideration in the design of further studies of this thesis and the further development of the review methodology.

Validity in terms of the ability of the review methodology to detect all events cannot be addressed as there is no gold standard to measure against. A comparison with other methods of detection is described in chapter 7.

Reliability in terms of inter-rater reliability could not be directly assessed in this study because of the differences in time available between registrars and the expert and the limited training provided to the registrars as compared with the

expert. A series of interesting discrepancies in the results of the expert reviewer and the registrars were never the less observed. Registrars identified fewer events than the expert in the notes reviewed by both. The majority of these events occurred during invasive procedures or in the immediate post operative stage of care. Registrars did not identify events which occurred before the index admission or at the time of discharge. Not only were there discrepancies in the events detected there were also differences in the classification of identical events. These findings raise the importance of thorough assessment of reliability in the design of further studies using this methodology and provision of structured training in this review methodology. Training in the review methodology will be addressed in Chapter 8 and reliability assessment will be incorporated in the redesign of the review interface.

Chapter 7

7. A comparison of 3 methods of detection of critical incidents and adverse events

7.1 Introduction

As described in chapter 2 there are several methods of identifying adverse events and critical incidents in hospital care. All of these methods and systems each have individual benefits and weaknesses in terms of cost, work involved and spectrum of events identified. Incident reporting systems are relatively low cost once implemented but the challenge is to provide adequate reporting rates, analysing of reports and feed back to clinical staff. National reporting systems may pick up rare serious events not appreciated as part of a pattern at a local level. However data from reporting systems often lack information on details of contributory factors and preceding events, which are important for understanding and for future prevention. Local morbidity and mortality meetings have the potential of discussing adverse outcomes in detail. However these often review only a fraction of events with an emphasis on serious rare cases rather than the common minor events, which constitute the majority of patient harm. In several countries record review has been proven as a reliable epidemiological tool for estimating the incidence of adverse events. It has the disadvantage of relying solely on information recorded in the patient records and is relatively costly to do on a large scale. Prospective observation has the advantage of being able to integrate several data sources such as staff interview, observation of care delivery, case notes and staff and ward rounds. This is however costly and labour intensive and suffers logistical difficulties.

The choice of method for identifying problems in clinical care must be tailored to the problem being addressed, the context in which the project is undertaken and a balance of financial and logistical constraints. Research and epidemiological studies of iatrogenic harm have different requirements to local data collection initiatives for the improvements of quality and safety. A better understanding of what each method can achieve is therefore needed in order to select the methodology best suited to answer a given question within the resource constraints available.

To gain a better understanding of the detection rates and to get an overview of the range and quality of data available using different systems of collecting information on problems in care, a study was designed to run in parallel with the record review described in chapter 5 and 6. The objective of this study was to collect data on adverse events and critical incidents from several information sources within the same hospital. In this instance data was collected using the hospital's confidential incident reporting system, by active pharmacy surveillance of medication errors and by record review in the same patient population. The aim was to examine the number and types of care problems detected and information available on these from each of these methods to see who each method might contribute to providing a full picture of critical incidents and adverse events in hospital practice. The hypothesis was that real-time record review can detect more adverse events and possibly also more critical incidents than existing routine data sources and also that real-time record

review would provide more detailed information on the details of the events and their preventability.

7.2 Methods

This study includes both the 134 surgical patients from whom record review was carried out and an additional 155 medical patients who's care was assessed by record review in parallel with the surgical study using the same methodology.

Design

Prospective cohort study in an acute care hospital. Prospective data collection from three information sources in the same patient cohort to allow comparison of the number and types of adverse events and potential adverse events and the extent of information recorded by each method.

Setting

The study was set in a single hospital site, part of a larger acute Trust based in London. The hospital had 850 beds and around 40,000 admissions per year. The hospital covers a full range of medical and general surgical specialties backed up by full intensive care facilities. The overall annual reporting rate of critical incidents within the trust is 4% which is comparable with the UK average of 4.9% of admissions.

Patients/participants

Three separate sets of data were collected independently on 288 consecutively discharged or deceased patients from 3 general medical and 3 general surgical

teams. The teams were selected by the risk management department of the hospital based on their willingness to participate, all approached teams agreed to participate. Data was collected on all consecutively discharged adult patients for a 3 week period from each clinical team. Only adverse events and potential adverse events occurring during the index admission were included.

Data sources

Information was sought from the risk management department, the hospital senior pharmacist and the surgical firms in the hospital of existing initiatives for identifying problems on care, near misses or patient harm as a result of healthcare based on identification of these by clinical staff. The surgical firms in this hospital do not hold specific Morbidity and Mortality meetings where patient complications or outcome are discussed. Instead a monthly audit meeting takes place where specific topics or a specific case is discussed. Two routine data sources were identified: a hospital wide confidential incident reporting system and surveillance of inpatient prescriptions and administration by review of medication charts by pharmacists.

The hospital has in place a system for incident reporting through which staff are encouraged to report critical or clinical incidents. Paper reporting forms are available on all wards and in other clinical areas such as operating theatres and interventional radiology suites. Any member of staff wishing to file a report can complete these. Reporting is confidential but not anonymous. Reporting of clinical incidents is encouraged for all actual or potential patient harm with no predefined list or criteria. In addition to this, reporting is mandatory when

security staff attends a clinical area. The forms contain data fields for patient details, time and place of the incident, details of the incident, harm to the patients and what action was taken immediately following the incident. Completed reports are initially sent to ward or unit managers who must review the incidents and take immediate local action to prevent future events. This plan should be recorded on the form before it is forwarded to the risk management department for further analysis. The risk management department log all received incident forms on a computerised database. There were no additional incentives or encouragement to reporting during the data collection for this study.

The pharmacy department in this hospital routinely send pharmacists to the wards to review patient's prescription charts for medication or prescription errors. Hospital pharmacists attend the wards once each working weekday during normal working hours to review patient's prescription charts for medication or prescription errors and to ensure patient receive ongoing regularly prescribed medication. Any problems found are acted on by the pharmacists and a brief record of the error, the effect on the patients and action taken is recorded on a signed pharmacy audit form. This contains information on patient details, where the error occurred, at which stage of patient's care, which staff group was responsible for the error, to which staff group the error was reported and what action was taken as a result of this, the severity of the error and the outcome for the patient. These forms are collected and analysed centrally in the pharmacy.

The methodology of real-time record review has been described in detail in chapter 5 and 6. The data used in this study is that collected by the external reviewers.

Table 7.1 Comparison of data collected from 3 methods

Data field	Incident reporting	Pharmacy surveillance	Rapid record review
Pt demographics	x	x	x
Date and time of event	x	x	x
Classification of stage of care		x	x
Classification of type of problem		x	x
Indication of staff group involved		x	x
Section on contributory factors			x
Section for preventative measures	x	x	x
Allocation for free text description	x	x	x
Opportunity to review all aspects of care	x		x

Procedure

Stage 1.

The data collection from pharmacist surveillance was planned in cooperation with the senior clinical pharmacist in the hospital. Pharmacists were notified at department meetings, by posters in the department and by personal reminders that an audit was in progress and that all intervention forms from specific consultants must be delivered to the pharmacist liaison. Collection of intervention forms commenced 2 weeks prior to the start of inclusion of patients

for record review and ended after the last day of inclusion of patients for record review (at discharge). Audit forms for all patients under the care of the clinical teams participating in the study were collected, both patients included in the record review and patients discharged outside the recruitment period for record review (see table 7.2 for details of the time scales). All forms were forwarded to the study team and cross-referenced to the record review patient database. Forms for patients not included in record review were entered into a separate database and analysed in detail by the pharmacy department but excluded from further comparative analysis. Forms for patients in the comparative study were analysed and the nature of the medication error classified for comparison with other data sources.

Table 7.2 Time scale for data collection

TEAM WHOS DISCHARGES WERE UNDER REVIEW	PHARMACY START	PHARMACY END	REVIEW START	REVIEW END
Surgical team 1	23/9/03	26/10/03	3/10/03	24/10/03
Surgical team 2	10/10/03	14/11/03	24/10/03	14/11/03
Surgical team 3	31/10/03	7/12/03	14/11/03	7/12/03
Medical team 1	23/9/03	24/10/03	3/10/03	24/10/03
Medical team 2	10/10/03	7/11/03	24/10/03	7/11/03
Medical team 3	24/10/03	23/10/03	7/11/03	23/10/03
Medical team 2	10/11/03	7/12/03	24/11/03	7/12/03

Stage 2.

The methodology of real-time record review is described in detail in chapter 5. Case records of consecutively discharged patients were reviewed by external reviewers and staff from the units providing care. Information on adverse events and critical incidents including patient details, details of the events, the staff group responsible for the events, consequences for the patient of the event, a classification of the event in terms of stage of patient care and nature of the event, contributory factors and preventability was recorded on a specifically designed review form. Only data recorded by the external reviewer is used in this comparative study. Data was collected from 3 surgical and 3 medical firms. Results from all participating firms will be included in this comparative analysis, in contrast to previous chapters which reported only on adverse events and critical incidents in surgery.

Stage 3.

One year after the initial data collection commenced the risk management department database was searched for entries of all patients included in the study. All reports on events occurring one month before data collection commenced until the last day of data collection were retrieved. Events that took place during the index admission investigated in the record review were included for comparison.

7.3 Results

The findings from each data source will initially be presented separately followed by a section of comparison of these.

Data from Record review

288 consecutively discharged medical and surgical patients were included in the record review. Real-time record review found evidence of 42 adverse events and 40 critical incidents. Of these 16 adverse events occurred before, and were contributory to, the hospital admissions. The record review form is described in detail in chapter 5. It consists of a section for demographic information on the patient, free text description of the incident, sections for classification of the effect of the incident on the patient and hospital stay, stage of care where the incident occurred, the type of problem and section covering causation, contributory factors and possible preventative measures. For a full overview of data collected see appendix 1. The section for contributory factors was structured, giving a range of possible causes for the reviewer to choose from, thereby aiding but also guiding the reviewer. This resulted in classified data, which is easy to analyse. The section on prevention was free text and resulted in a number of unclassified comments. This allowed the reviewer to express their view freely but made analysis more difficult. An example of the information in case can be seen in box 7.5.

For comparison with incident reporting and pharmacist surveillance only events initiated during the index admission are included for further analysis.

26 (9%) patients suffered an adverse event and 40 (14%) a critical incident during the index admission of which 3 adverse events and 11 critical incidents were associated with medications. Cases detected by record review were diverse but in addition to cases related to medication errors include failure in clinical monitoring and management (17/66), technical problems with a

procedure (9/66), infection related problems (8/66) and failure to arrange adequate follow up or care at discharge (7/66).

Data from Pharmacist surveillance

The pharmacist surveillance forms included data fields for demographic information of the patients, stage of care of the incident, the staff group responsible a classification of problems and grading of severity. In addition to this it also had a section for free text explanation of the problem detected and the immediate steps taken to correct this (see box 7.2). An example of information collected from a single case can be seen in box 7.3. Most of the forms contained useful information on the type of drug error, effect on patient if any and immediate steps taken to correct a problem such as contacting the prescribing doctor to correct a dose and what action was taken.

Box 7.1 Pharmacy audit form

Date: Hospital No: Patients Name: Pharmacist:	Ward/Dispensary/ manufacturing: Consultant: Stage in care process; Preadmission Assessment/initial care Inpatient episode Discharge Post discharge	Error made by: Doctor Nurse Patient Pharmacist Other	Recommended to: Doctor Nurse Patient Other
Outcome ✕ :- Rejected Not resolved at end of survey Accepted – change of R by Dr Accepted – changed by P'cist Accepted – changed by other Accepted – change in monitoring	Problem ✕ :- Administration of drug Council/educate Monitor drug effect Need for drug therapy Provide drug product Select dosage regimen Select specific drug	Significance ✕ :- Minor Moderate Major* *toxicity/treatment failure/ ADR type B/ other	
Details of ALL Intervention (include cause, what was done to correct error) Patient outcome:			

Pharmacist surveillance led to correction of medication and prescription errors. There fore it is not surprising that pharmacist surveillance did not detect any adverse events. Pharmacists identified a total of 30 medication errors in the 288 patients. The classification of medication errors is mutually exclusive. The medication problems related to failure to prescribe regular or indicated medication (15/30) and failure to prescribe correct dose of drug (9/30). Other types of problems detected were failure to select a specific drug and failure to prescribe treatment duration and correct route of administration.

Table 7.3 Classification of all errors detected by pharmacy surveillance according to data collection form

Frequency of types of errors		
Error type	Number	Percentage
Failure to prescribe	15	50%
Incorrect dosage regimen	9	30%
Failure to monitor drug levels	1	3%
Selection of specific drug	2	7%
Incorrect route of administration	1	3%
Inappropriate duration of therapy	1	3%
Failure to act on monitoring	1	3%
Total:		100%

Of the total number of errors detected by pharmacy surveillance 2 were classed as major (e.g. patient admitted with acute coronary syndrome and not prescribed low molecular weight heparin); 9 as moderate (e.g. no reduction of dose of co-amoxiclav in patient with renal failure) and 19 as minor (e.g. failure to prescribe non-essential regular medication on admission). Examples of the

seriousness as classified by the data collection form and the types of errors detected by pharmacists can be seen box 7.2 below

Box 7.2 Classification of seriousness of errors and examples of medication errors

- **2 major** errors were detected:
 - Fragmin not prescribed for a patient admitted with acute coronary syndrome
 - Warfarin missed off TTA
- **9 errors** were of **moderate** severity, for example
 - No finishing date for potassium supplements
 - Co-prescribing fludrocortisone and frusemide (93 year old with hypotension)
 - Dose of co-amoxiclav too high for patient with poor renal function
 - Glaucoma eye drops not prescribed on admission
- **19 errors** were of **minor** severity, for example
 - Only medication acutely necessary prescribed on admission
 - wrong dose enalapril prescribed
 - Hyoscine regime incorrect

The data collected by pharmacist surveillance did not contain any information on contributory factors or causation of the error, nor did it contain information that could aid future prevention of similar problems

Critical incident reporting

In total 11 (4%) incident reports were filed on the 288 patients included in the record review. Of these 4 were clinical in nature (1.4% of admissions) and all of these were classified as critical incidents. Clinical cases reported by incidence reporting were failure of support service in a case of delay in cross-matching blood for a patient requiring emergency surgery (1/ 4), poor clinical handover of a patient from accident and emergency to ward nurses (1/4), fall with injury to patient; bruise to head requiring doctor to review the patient (1/4) and a Venflon

cannula misplaced in the brachial artery (1/4). The other 7 reports concerned falls with no injury to the patients and episodes where security staff were called to wards in relation to absconded or aggressive patients. 1/11(9%) of incident reports were submitted by a doctor, this described a clinical incident. 1/11 was completed by a security guard called to the ward to assisted with an abusive intoxicated newly admitted patient. 9/11(81%) incident reports were submitted by nurses of which 3 were clinical. Information available on the IR forms relating to clinical incidents varied from simply stating that the incident had taken place to a full description of the incident and preceding events. None of the incident reports stated useful ways of preventing the recurrence of similar events.

There is no classification of incidents suggested on the incident reporting form making analysis and amalgamation of data difficult, nor is there a request for information on contributory factors and causation of reported incidents. The incident reporting forms contain a section for the line or area manager to indicate what actions have been taken to prevent future problems. This section was completed in 2 of 4 of the clinical forms but none of the comments were on actual preventative measures taken.

Differences and Overlap between the 3 data sources

Record review found evidence of 26 adverse events and 40 critical incidents in the study cohort during the index admission of which 3 adverse events and 11 critical incidents were associated with medications. Pharmacists detected prescription/drug errors affecting 31 (10%) patients which all constituted critical

incidents. 3 of these overlapped with the 14 medication error detected by record review.

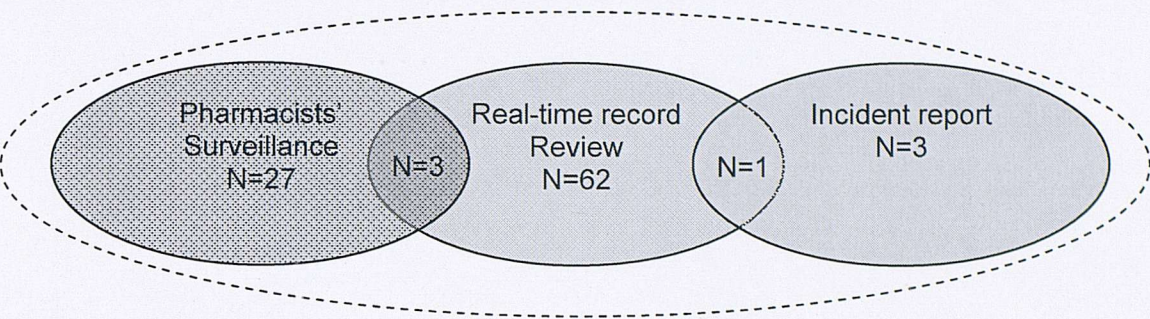
One incident report overlapped in part with one critical incident detected by record review. This was a fall with injury to patient due to failure to nurse a drunk and confused patient in his bed. None of the adverse events detected by record review were reported on an incident reporting form. The other 3 clinical incidents found by the incident reporting system were not detected by record review. In the other 3 cases it is unlikely for anything to have been recorded in the patient record (delay in cross-matching, inadequate nursing handover and misplacement of a Venflon in the brachial artery,). Table 7.4 below summarise the number of events detected by record review and incident reporting. Data from pharmacist surveillance is not included in this table as only medication errors are detected by this method.

Table 7.4 Number of events detected by different methods

Method of detection	Critical incidents and adverse events	Adverse Events	Critical incidents
Record review	66 (23%)	26 (9%)	40 (14%)
Incidence reporting	4 (1.4%)	0	4 (1.4%)

There is no data source which detect all adverse events or critical incidents and as is presented above and can be seen in graphical representation below there is some overlap between the 3 data sources but also a larger number of events found by one of the 3 methods.

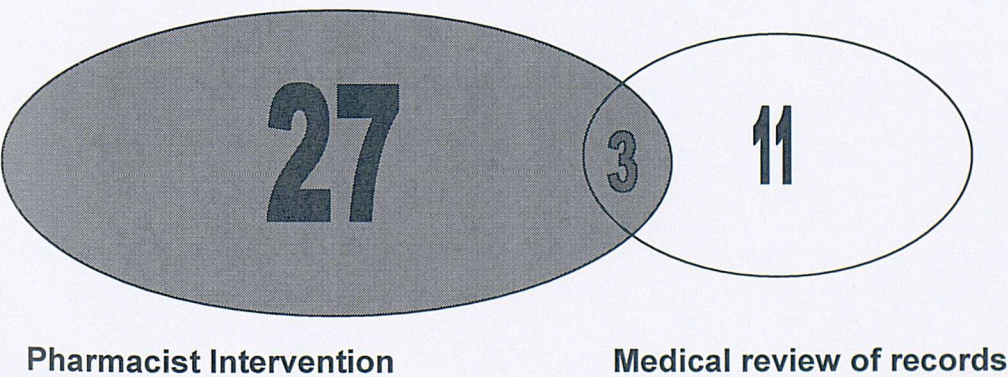
Fig 7.1 Illustration of overlap of all critical incidents and adverse events detected in the same patient cohort



Medication errors

Medication errors detected by pharmacists mainly related to failure to prescribe regular or indicated medication (15/30) and failure to prescribe correct dose of drug (9/30). Other types of problems detected were failure to select a specific drug and failure to prescribe treatment duration and correct route of administration. Medication errors detected by record review were mainly failure of the monitoring process needed in conjunction with medication use (5/14) and inappropriate prescription of several drugs leading to drug interactions (4/14). No medication errors were reported through the incidence reporting system.

Fig 7.2 Overlap of medication errors detected by pharmacy intervention and record review



Information available from each method

The amount of detailed information and the way in which this was presented varied for each of the 3 data sources. Information available from record review covers the widest range of topics and this is the only method, which seeks information on contributory factors to the occurrence of an event. The information gained from record review is more detailed than that of pharmacy review even though many of the same topics are addressed. Data available from critical incidents reports is less structured and classified than that gained from record review or pharmacy surveillance. A summary of the data field in each of 3 sources data collection forms can be seen in table 7.1.

To illustrate the amount of data available in each data field of the 2 forms a representative completed form for each of the 3 methods are presented below. Note all patient identifying material has been altered to protect the patient's identity but the information regarding the event is from actual cases.

Box 7.3 Example of data on collection forms for pharmacy surveillance

Date: 1/8/04 Hospital No: 33355544 Patients Name: Jonathan Boyd Pharmacist: Tejal Patel Ward/Dispensary/manufacturing: Ward Consultant: Higgens Stage in care process: Inpatient episode Error made by: Doctor Problem: Need for drug Recommended to: Doctor Outcome: change by Pharmacists Significance: moderate Details of ALL Intervention: This patient has a low K+ of 3.2. Not on IV fluids, no K-sparing agents or K+ replacement. Called HO on team, suggesting patient prescribed Sando K, she agreed. Sando K 2 bd prescribed for 2 days recommended K level checked then before further prescription of Sando K

Box 7.4 Example of data on collection forms for Incidence reporting

Date 4/10/2003

Patient name Oliver white

Dob 2.10.1922

Hospital Nr 555511166

Ward Haldane

Date and time of incident 4/10/2003 22.00

Location NPH

Description: blood asked for being x-matched (4 units) at 7:00pm (1900 hours). Not x-matched till 10.00pm (22.00) when patient was on the operating table needing it badly.

Injuries sustained Nil

Details of reporter

Name Dr Aster

Position SHO anaesthetics

Contact Nr Bleep

Managers follow up

Date notified of incident 13.11.03

Was location/person/equipment authorised Yes

Was the activity of the person Authorised Yes

Were safe work practices being used Yes

Manager's action taken/planned to prevent recurrence Patient suddenly dropped his haemoglobin during surgery. Technician dealing with another patient's blood who did not require surgery. Mr White did not have difficult antibodies.

Managers name and contact details Sister in Theatre

Box 7.5 Example of data on collection forms for pharmacy surveillance

Date of review 3/8/04

Reviewer ID SO

Case Number 239

Patients age 71

Sex Female

Date of admission 14/8/2004

Date Of Discharge 29/8/2004

Degree of emergency: Routine

Primary diagnosis: Open elective Cholecystectomy

Co-Morbidities GORD, Colorectal cancer

Team caring for patient: Colorectal surgery

Type of event – Adverse event

Date of AE 18/8/04

Details of contributory events: Low K⁺ in IV fluid, only 60 mmol KCL over 3 days post op. No increase in K⁺ given even though noted on 16/8 K=3.4 and down to 3.1 on 18/11.resulting in fast AF

Details in causation of adverse event: Failure to act on noted low K⁺, Failure to adequately replace K⁺ post op when NBM.

Details of injury: Fast AF + Chest pain - Digoxin for cardioversion and rate control.

Any other relevant details: Took place over weekend contribute to delay in Increasing K⁺ intake and monitoring.

How of the does this occur: Rarely (1-9%)

Describe the principle problem in the patient's care that led to the AE/CI: 1. Failure to replace fluid and electrolytes as per usual post op guidelines.

2. Failure to act on abnormal result.

How adequate were the medical records: Adequate

Describe the impact on the patient: Severe chest pain for 2 days requiring IV GTN and Morphine.

Degree of disability: No physical impairment at discharge

Effect on hospital resources: Prolonged stay

Additional procedure as result of AE: V/Q scan, Trop I, ABGs

Additional medications: Digoxin, Morphine, GTN infusion.

Stage of care: Ward care

The principle problem in ward care due to a failure in medical care.

Describe the problem: Failure to prescribe adequate K replacement and failure to act on abnormal result.

Who provided the ward care relating to the problem: 1. team PRHO

2. Ward doctor unlikely to know patient

Nature of the problem: Drugs/fluid/blood

How was the drug / fluid administered? IV

Was there an error in the prescription/preparation of drugs/iv fluids/blood? Yes too little prescribed

Was there an error or accident in administering drugs/iv fluids/blood? No

Was there a failure to monitor drug action/toxicity/fluid balance? Failure to act on monitoring results.

What was the drug? Potassium

Describe the drug's adverse effect: Not enough K given to patient NBM resulting in fast AF with cardiac ischaemia.

What was the nature of the drug-related injury/incident? Drug less effective than expected (e.g. as result of delayed treatment; dose too little)

Was the person responsible for managing the drug regimen for this patient of appropriate seniority or experience? yes

Would a doctor using reasonable medical judgement prescribe the drug, even with knowledge beforehand that this adverse effect could occur? Yes

What was the cause of the drug-related injury/incident? Right drug but wrong dose or length of treatment

Contributory factors:

Individual Factors: lack of knowledge of individual, attitude motivation problem long shift /under pressure

Work environment: Inadequate staffing at time of event, out of hours

Give details of the 3 most important contributory factors: Failure to prescribe adequate k⁺ replacement, should have been done by team before weekend. Failure by weekend PRHO to act on low K.

Preventability:

In your judgement, is there some evidence that the AE was preventable? Yes

Level of preventability: Strong evidence for preventability

Describe the manner in which this AE could have been prevented: Reinforcement of importance of electrolyte management to PRHOs.

7.4 Discussion

The 3 methods examined in this study vary in respect to the amount and detail of data collected. This study has found that real-time record review identified both adverse events (9%) and critical incidents (14%) in the care of hospitalised medical and surgical patients. Pharmacist surveillance found medication errors, all of which were critical incidents, in 10% of patients and incident reporting detected no adverse events but critical incidents in 1.4% of patients. The overlap of events found by each method was very low (3 CI detected by both record review and pharmacists surveillance and 1 CI by both record review and incident reporting).

There are also variations in the time taken to collect data for each of the methods which reflect differences in the cost of each method of data collection. Critical incident reporting depends on staff making an active decision on whether to report an incidence or not. The factors influencing this are many, and vary between individuals, but in all cases it demands a break from normal routine of working to seek out and complete an incident report. The opportunity for reporting is ongoing as opposed to the time limited nature record review and recording of data for pharmacist surveillance. The incident reporting form is relatively unstructured with no classification of events. In this study we found that only few clinical events were reported in this way and that information on which to base future changes to prevent similar events was not available.

Record review in contrast is undertaken over a limited period of time such as 3-4 weeks. During this time however, all discharged patients are reviewed and

where problems in care are identified they are all included in the data collection. This allows the incidence of adverse events and critical incidents to be calculated as the denominator is immediately available. The information recorded is extensive and detailed but to a large extent classified aiding analysis of events. Information on contributory factors and means of preventing similar events is specifically requested. In this study record review detected the most critical incidents overall. It allowed examination of all aspects of care and was the only method detecting actual adverse events. The resources needed for record review however are substantial and the information collected is not available on a routine basis.

Pharmacists are continuously reviewing inpatient's prescription charts and correcting errors. For set periods of time the interventions are recorded and collated for departmental audit. The information collected is categorised but also include the opportunity for free text comments. In this study surveillance by pharmacists detected the highest number of medication related events but all of these were classified as critical incidents. The events were well described but there was no information on contributory factors or ways of prevention. The denominator in terms of in-patient days surveyed is not immediately available making comments on the incidence for ongoing surveillance of incidents difficult.

7.5 Conclusion

Each of the method examined in this chapter have strengths and weaknesses and an appreciation of this and clear goals of what information is required is essential for selection of a data source. Pharmacist surveillance by its nature only looks at medication errors but is built on ongoing activities of pharmacists

making the cost of data collection relatively low. The information is classified in a manner that aids analysis but provides limited information on which to base preventative interventions. Record review provides a fuller picture of problems with all aspects of care but in a snapshot of time. It needs to be set up for specified time period and is relatively labour-intensive. However it provides rich data and may include information on contributory factors taking the whole system of care into consideration. Incident reporting yield limited information on problems with care because of the small number of events reported. It is however relatively low cost and has the advantage of continuously recording problems thereby having the potential to detect patterns of rarely occurring events.

Chapter 8

8. Training program for clinicians to perform Record Review

8.1 Introduction

In study 1 (chapter 5 and 6) of this thesis I tested for the first time a new methodology of local record review to be carried out by clinicians under the guidance of an external reviewer. Although this was successful as a pilot study there were discrepancies between the cases found by the reviewer and the external expert. The registrar reviewers received only very limited training in the form of a general introduction to the data collection form and definitions of AE, CI and preventability. Inevitably there were time constraints and the additional work was not welcomed. It became clear that to continue developing a methodology of local record review one would need a systematic training program to ensure maximum benefit of the data collection and also for ensuring the reliability and validity of the findings.

8.2 Review of training given to reviewers in studies of retrospective record review- literature search and summary

In order to search the literature for details of previous efforts in training of reviewers I carried out a Medline search from inception to date (May 2005) using search terms “record review”, “training”, “manual”, “adverse event” as well as hand searching all published studies of retrospective record review (RRR) for details of training of stage 2 reviewers. Due to the specialist subject of training reviewers in identification of adverse events by record review the only relevant

references found were from the national AE studies. The descriptions of training of stage 2 reviewers are summarised in table 8.1.

Table 8.1 Training in record review

Publication year	Lead author	Country	Comments on teaching
1989	Brennan	US (NY)	
1995	Wilson	Australia	All underwent a two-day training course and were provided with a training manual.
1999	Gawande	US Colorado	'trained'
2001	Vincent	UK	Each reviewer screened sets of notes under supervision until they were judged to be fully conversant with the review process'
2003	Davis	New Zealand	'specifically trained doctors'
2004	Baker	Canada	Provincial physician and nurse leaders underwent training and used a standard set of hospital charts and a training manual.

These study-teams largely devised their own teaching programmes of reviewers by learning from the experiences of previous studies (personal communication with Neale, Vincent, Wilson). Generally this was done by supervised review of standardised or anonymised case records and by using a manual describing the review process (personal communication Neale, Vincent, Wilson). No specific information on reviewer training has been published in the literature.

There are significant differences between large scale retrospective record review and smaller local projects of real-time record review by clinicians. For one the

funding and time available for local initiatives are very limited but the need for absolute reliability and consistency of the data collected is perhaps less important in a local project. Here the aim is not obtain completely reliable epidemiological data but get information which is accurate enough to be trusted locally and to provide a stimulus for and guide improvement of care. In this context a training program lasting several days may not be realistic or necessary. To get an idea of what was desirable from a methodological perspective we consulted local experts in record review. It was important to design a training programme around what was a practical and realistic for use by a busy clinician. We therefore also informally consulted both the clinical staff involved in the first study and other surgical registrars and consultants. All these were concerned that a training program should be as brief as possible taking a maximum of a clinical session (3 hours) to fit into the usual duties of a busy clinician.

8.3 Design and development of preliminary training program in record review

The reviewer training program was designed to address the main outcome measures of record review; recognition of adverse event (or critical incidents) and determination of preventability. Description, classification and identification of contributory factors of adverse events and critical incidents according to the modular review form were also regarded as potentially important. These secondary outcome measures were given less priority because of the time constraints and the anticipated challenges in achieving consistency in these aspects of review. The training programme in record review used adult learning principles by making the programme interactive and by building on the participants' background knowledge and experience as well as identifying areas

where their preconceived ideas were counterproductive to the aims of the review and focus on these.

A teaching programme lasting 3 hours was designed starting with a general introduction to record review studies and an overview of findings of epidemiological studies. A didactic session with an overview of the real-time record review process was then given. This was followed by clarification of the definitions and examples of adverse events, critical incidents and preventability. The session had both didactic elements and time for participants to work through examples in a plenary setting. This was followed by small group work on identification and classification of case summaries. Full details of the draft program can be seen in Box 8.1

Box 8.1 Draft training program

- General introduction to patient safety, epidemiology of harm and record reviews. Development of rapid record review (RR); overview of previous studies, methodologies and findings
- Overview and understanding of methodology of rapid record review Definitions and examples of AE and CI and preventability. Discussion of examples of adverse events and critical incidents.

Case review practical 1

- Practical exercise in classification and description of AE/CI including Identification of contributory factors, plenary
- Where to look for information in the notes, how information may be presented in the notes. Mainly didactic and interactive plenary

Case review practical 2

- Detailed practical exercise in interpreting clinical information uncovered including contributory factors and entering data onto the review form. Group work with feedback to individuals on specific problems with comprehension or use of the tools.
- Group feedback on issues picked up during practical and other questions brought up by delegates.

8.4 Pilot Testing: Training program tested on a group of clinicians

The training programme was tested informally with surgical registrars and experienced record reviewers. The programme was modified in the light of comments and discussions. The final draft program (box 8.1) was tested on a group of surgeons from a surgical unit wishing to carry out real-time record review to evaluate their service. This study is described in more detail in chapter 11. The training was particularly challenging as the clinicians first language was Spanish. All slides and case summaries were translated into Spanish. The

participants on the course were asked to complete review forms of case summaries before and after the training.

The training went well despite the language barrier. The clinicians were engaged in the subject and commented that many of the training cases and scenarios were recognisable from their own practice. It became clear that more time than originally anticipated was needed for discussion of cases and classification of AE/CI and preventability. The concepts and definitions were easily grasped but their interpretation in relation to individual cases and their relationship with surgical terminology of complications required further discussion. It was difficult to refer to the RTRR-MRF in the short time available for training due to its length. Participants spent much time flicking through the form to find the correct page and section.

This training course was also an opportunity for testing the efficacy of the training by asking the clinicians to review cases before and after the training. The MRF was used for this but unfortunately this was not successful. The 26 page form was far too long for the clinicians to familiarise themselves with in the short time available. Both before and after training the participants spent much of the time trying to work out which sections of the MRF to complete. Their entries within the time given were therefore meaningless as a reflection of their ability to correctly classify cases with AE and CI or to assess preventability.

8.5 Redesign of training following piloting

The experiences of piloting were invaluable and led to a number of changes to both the training programme itself and its planned evaluation. It became clear

that the definitions of AE and CI were readily accepted but that the clinicians needed the opportunity and more time than anticipated to test these on cases they had experienced themselves to deepen the learning. There was also confusion around how expected complications related to adverse events and critical incidents. These points led to a change in emphasis in the delivery of the training program, time allocated to individual topics and to the inclusion of examples of traditional “complications” to illustrate how these might relate to AE/CI.

The most significant development as a result of piloting was the design of a very brief and simple training review form (TMRF). This form was designed to contain all the main element of the MRF but without the detail. The TMRF can be seen in appendix B. This form allowed the trainees to record their findings and become familiar with the structure of the review form without the delay and confusion which resulted from using the full MRF for testing of review ability before and after training in the short amount of time available.

8.6 Evaluation of systemised training in Real-time Record Review (RTRR)

Having designed a training program it was important to assess the effect of structured training of clinicians with no previous experience of record review for adverse events and critical incidents. To achieve this aim a study was designed with the objective of evaluating the value of training in terms of AE/CI identified, classification of events, rating of preventability and contributory factors.

8.7 Methods

Design

The study was designed as assessment of case review before and after the training programme.

Setting

The training was held at the headquarters of the National Patient Safety Agency (NPSA) and advertised on the NPSA website. It was open to all clinicians and clinical risk management staff with a clinical background. It was hoped this would attract a group of 20-25 clinicians for a day seminar. The resulting interest was so great that 3 seminars were held.

Participants

Participants in the study were those attending a training day in record review for identification of AE and CI. It was mentioned in the advert and on the application form that the course would be evaluated. No participants declined to be part of this. The participants were a mix of practising clinicians and risk management staff with a background as nurses, midwives and doctors.

Assessment of training

A series of case summaries were designed containing critical incidents or adverse events. These were all based on real cases from previous record review studies or personal experiences of staff members of our unit. After construction of 6 case summaries these were reviewed independently by 2 expert reviewers (SO and GN). The findings were recorded on a short review

form designed for training and evaluation of reviews before and after training (see appendix B). Once all the reviews were completed independently the two expert reviewers met to compare classification of each event. There was full agreement on the class of event (AE/CI) and on preventability. In one case, where there was disagreement on the classification of the nature of the problem, the case summary was rewritten to eliminate ambiguity. The cases were graded as easy or complex based on the opinion of the two expert reviewers. The 6 case summaries were divided into two groups (set A and set B) of same level of difficulty, see appendix B. The participants were randomised to receive set A or B before training and the other set after training.

Outcome measures

The main outcome measures in this study were improvement in determination of AE/CI and preventability. The secondary outcome measures of success of the training were improvements in selecting the correct stage of care and nature of problem as well as the results of the course evaluation form completed by the participants.

Procedure

The format of each of the 3 training days was identical.

Pre-training assessment

Initially a brief (3min) presentation was given describing the TMRF and the definitions of CI, AE and preventability. The each participant was given a randomised set (A or B) of 3 case synopses and 3 TMRF to record their findings.

They were given 30 min to do this and asked to complete a case before moving to the next.

Training

The training program was the delivered over the next 3 hours (plus time for breaks). The full details of the training programme and the training material can be seen in appendix B.

Post-training assessment

At the end of the formal training each participant was given the opposite set of cases to that they had received in the morning. They were again given 30 minutes to complete as many reviews as they had time for. The participants were asked to work alone and not to discuss the cases during the course. All case summaries and review forms were collected and kept by the course organisers between the two tests to avoid participants gaining knowledge of cases between the two tests. At the end of the course the participants were given a course evaluation form (see appendix B) and were asked to complete this anonymously. The evaluation form contained Likert scales (1-5) for evaluation on the course material, content of training day, style of training day and relevance to practice(1=very poor, 2=poor, 3=adequate, 4=good, 5=very good). In addition to this there were free text boxes for comments on the best and worst aspects of the day and on how the training day would change they future work.

Analysis

The data on outcome measures are all non-parametric categorical data. After taking statistical advice a binominal test was performed for findings before and after training to assess significance of improvements. I tested the hypothesis that any statistically significant difference in favour of correct review on the entire group of reviews seen after but not before training was due to the training intervention. I did not use McNamer test for comparison of the ability of individual participants because of differences in the number of reviews performed by each participant performed before and after the training.

8.8 Results

Participants

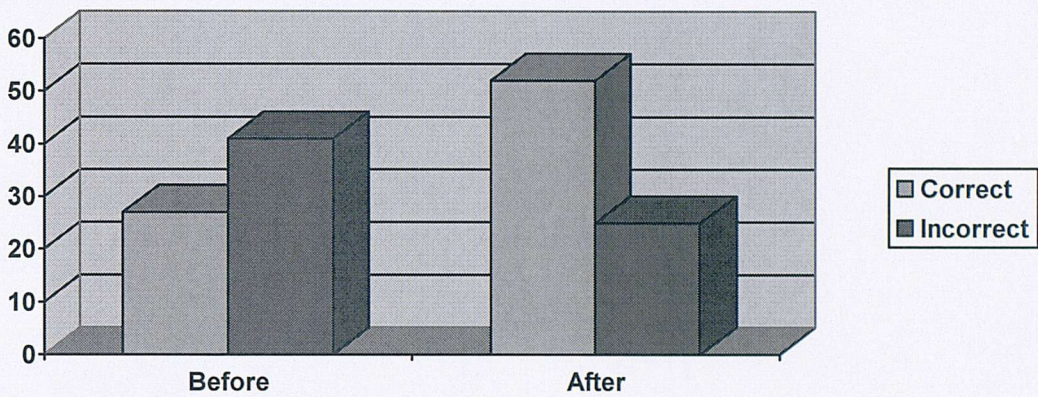
A total of 53 clinical participants attended the 3 courses. 19 on the first, 18 on the second and 13 on the third course. The maximum number of registration on each course date was set at 20. In addition to the numbers above some non-clinical observers attended but they do not form part of the data analysis. The 53 clinician participants completed a total of 145 reviews, 68 before training and 77 after. Incomplete reviews without classification of the event were excluded from the data analysis. Each participant completed between 1 and 4 reviews in total.

Adverse Event/Critical Incident determination

The review of case summaries had 3 possible outcomes. The reviewer could indicate that was an adverse event, a critical incident or that there were neither an AE nor a CI. The reviews were evaluated on the basis of whether the reviewer indicated the correct of the 3 possible categories. Before training the

participants made the correct assessment in 27/68 cases (39.7%, $p=0.114$). After training the correct assessment was made in 52/77 cases (67.5% $p=0.001$).

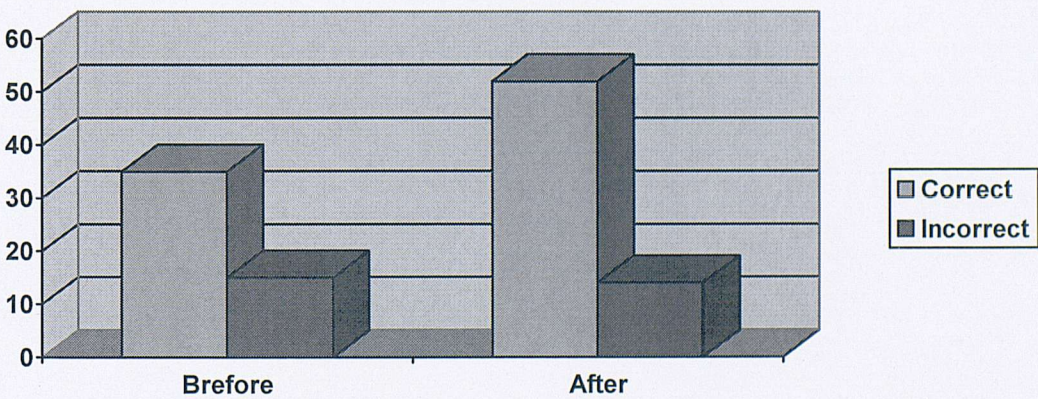
Fig 8.1 Correct classification of case as AE/CI/no problem



Preventability determination

There was a slight improvement in the ability to assess preventability for the case summaries. Before training 35/50 (70%, $p=0.007$) reviewers assessed preventability correctly, after training this was 52/66 (79%, $p<0.0001$).

Fig 8.2 Correct Preventability



Classification of stage of care and nature of problem

There was no significant improvement in the ability to correctly select stage of care and nature of problem. Stage of care was correctly indicated in 29/62 (47%, $p=0.704$) cases before training and in 38/73 (52%, $p=0.815$) after training. Although there is a small improvement this is not statistically significant and a 52% correct review rate after training is not satisfactory. The main cause of incorrect selection of the stage of care was selection of “during a procedure” instead of “early in admission” when the problem related to an incorrect CT scan result in the early phase of admission. The other main cause was selection of “during procedure” when a Venflon became infected, this occurred during ward care.

The nature of problem was correctly selected in 19/58 (33%, $p=0.012$) before training and in 32/73 (44%, $p=0.349$). The main reason for the poor performance on this question was multiple selections of problems on the review form despite instructions to only select one. Even if the correct problem was selected multiple selections were not correct use of the review form and therefore rated as an incorrect classification.

Assessment of case summaries used to evaluate training

Results were analysed for each of the cases to determine their value for training purposes. These data may then be used to develop further cases for training. For detailed results see table 8.2 below. Case C and F are excluded as these were reviewed sufficiently infrequently (Case F once and Case C 3 times). All cases were able to identify improvements in the classification of the case as

AE/CI/No problem but case D less so. Preventability was generally well assessed but case A and D had very high levels of correct assessment before training and did there for not reveal any improvement after training. These two cases were rated as easy by the 2 reviewers. Case B and E were rated as more difficult and both of these cases were able to demonstrate improvement after training with the difference being significant for case B. Classification of AE and preventability were the main outcome measures in this assessment and the main focus of the teaching. Looking at assessment of stage of care and nature of the problem the results were not surprisingly poorer. There was variability in the ability of the cases to detect improvement but overall the ability to assess this correctly at the end of the training was less than for the main outcome measures, some cases even showed a slight deterioration after training. Case D was best showing improvement in selection of stage of case and case B and E were best at showing improvement in selection of nature of problem.

Table 8.2 Correct classification of case and preventability for each case

Case and question	Nr before (%)	Nr after (%)	p-value before training	p-value after training
Case A AE/CI/No problem	Yes= 6(26%) No= 17(74%)	Yes=14(67%) No=7(33%)	0.035	0.189
Case A Stage of care	Yes=13(59%) No=9(41%)	Yes=10(48%) No=11(52%)	0.523	1.000
Case A Nature of problem	Yes=15(68%) No= 7(32%)	Yes=18(86%) No=3(14%)	0.134	0.001
Case A Preventability	Yes=17(85%) No= 3(15%)	Yes=18(90%) No= 2 (10%)	0.003	<0.001
Case B AE/CI/No problem	Yes=6(55%) No=5(45%)	Yes=12(86%) No=2(14%)	1.000	0.013
Case B Stage of care	Yes=7(78%) No=2(22%)	Yes=3(23%) No=10(77%)	0.289	0.092
Case B Nature of problem	Yes=1(14%) No=6(86%)	Yes=6(46%) No=7(54%)	0.125	1.000
Case B Preventability	Yes=1(25%) No=3(75%)	Yes=6(60%) No=4(40%)	0.625	0.754
Case D AE/CI/No problem	Yes=11(46%) No=13(45%)	Yes=16(73%) No=6(27%)	0.839	0.052
Case D Stage of care	Yes=8(33%) No=16(67%)	Yes=13(59%) No=9(41%)	0.152	0.523
Case D Nature of problem	Yes=3(14%) No=19(86%)	Yes=2(9%) No=20(91%)	0.001	P<0.001
Case D Preventability	Yes=14(67%) No=7(33%)	Yes=14(67%) No=7(33%)	0.189	0.189
Case E AE/CI/No problem	Yes=4(40%) No=6(60%)	Yes=13(93%) No=1(7%)	0.754	0.002
Case E Stage of care	Yes=6(75%) No=2(25%)	Yes=8(62%) No=5(38%)	0.289	0.581
Case E Nature of problem	Yes=0(0%) No=7(100%)	Yes=4(31%) No=9(69%)	0.016	0.267
Case E Preventability	Yes=3(60%) No=2(40%)	Yes=10(91%) No=1(9%)	1.000	0.12

Evaluation of training for professional groups and current job

The participants in the training days were asked to indicate their professional background and their current job role, whether this was primarily clinical or mainly in risk management. This allowed for evaluation of the impact of training

across professional groups and between clinicians engaged in clinical work or in risk management. The results are summarised below in tables below.

Table 8.3 Training of nurses

	Cate- gory	Proportion of correct reviews	p- value	Cate- gory	Proportion of correct reviews	p- value
Correct classification of AE/CI/No problem	Nurse before	15/37 41%	0.324	Nurse after	30/41 73%	0.004
Correct Stage of care	Nurse before	17/33 52%	1.000	Nurse after	26/41 63%	0.117
Correct nature of problem	Nurse before	12/31 39%	0.281	Nurse after	18/41 44%	0.533
Correct preventability	Nurse before	16/26 62%	0.327	Nurse after	29/38 75%	0.002

Nurses improved in their ability to undertake review after the brief period of training. Before training they indicated the correct classification of cases in 41% of cases (p=0.324); after training this had improved to 73% of reviews (p=0.004). There was also a significant improvement in this group in determining preventability. This was correct in 62% (p=0.327) of reviews before and 75% (p=0.002) of reviews after training. Nurses also improved in their ability to reach the correct classification of stage of care and nature of problem although this change did not reach conventional levels of statistical significance (P<0.05).

Table 8.4 Training of doctors

	Cate- gory	Proportion of correct reviews	p- value	Cate- gory	Proportion of correct reviews	p- value
Correct classification of AE/CI/No problem	Doctor before	8/15 53%	1.000	Doctor after	12/17 71%	0.143
Correct Stage of care	Doctor before	4/15 27%	0.118	Doctor after	4/16 25%	0.077
Correct nature of problem	Doctor before	3/14 21%	0.057	Doctor after	8/16 50%	1.000
Correct preventability	Doctor before	8/12 67%	0.388	Doctor after	13/15 87%	0.007

As can be seen in the table above doctors also improved after training in both identification of events and determining preventability. The level of correct reviews of 71% after training was not significant due to the small numbers of doctor reviews but the level is acceptable. The rate of correct preventability assessments of 87% ($p=0.007$) is significant.

In addition to doctors and nurses, midwives also attended the training course but the numbers were too few to justify separate analysis as a professional group. They are however included in the analysis of current job role the results of which are shown in table 8.5 and 8.6 below.

Table 8.5 Training of clinicians in clinical jobs

	Category	Proportion of correct reviews	p- value	Category	Proportion of correct reviews	p-value
Correct classification of AE/CI/No problem	Clinicians before	13/30 43%	0.585	Clinicians after	20/30 67%	0.099
Correct Stage of care	Clinicians before	16/28 57%	0.572	Clinicians after	13/29 45%	0.711
Correct nature of problem	Clinicians before	10/26 38%	0.327	Clinicians after	13/29 45%	0.711
Correct preventabil.	Clinicians before	18/23 78%	0.011	Clinicians after	23/27 85%	p<0.001

Delegates in clinical jobs improved in their ability to determine AE (43% vs. 67%) and preventability (78% vs. 85%).

Table 8.6 Training of clinicians in risk management jobs

	Category	Proportion of correct reviews	p-value	Category	Proportion of correct reviews	p-value
Correct classification of AE/CI/No problem	RM before	12/31 39%	0.281	RM after	27/39 69%	0.024
Correct Stage of care	RM before	11/28 39%	0.345	RM after	20/38 53%	0.871
Correct nature of problem	RM before	6/28 21%	0.004	RM after	18/38 47%	0.871
Correct preventabil.	RM before	15/24 63%	0.307	RM after	25/33 76%	0.005

Clinician in risk management jobs improvement in both AE/CI and preventability determination was statically significant. They also improved in ability to correctly identify stages of care and nature of problems but this improvement was not significant.

Course evaluation

In total 49 evaluation forms were completed. The comments were generally supportive. 89.8 % of the participants rated the course materials as good or very good (mean 4.16 (95%CI 3.99-4.33), median 4), 87.8% rated both the content and the style of the training day as good or very good (mean 4.20 (95%CI 4.02-4.39), median 4) and 85.8% of the participants rated the relevance to practice as good or very good (mean 4.35 95%CI 4.11-4.59, median 5). The

participants were asked to comment on how the training day would change their work or practice. 38/49 (77.6%) gave actual examples of changes they would make.

Box 8.2 Examples of comments on how the training will change the way the participants work

- “More methodical reviews of case notes when auditing specific issues in midwifery”
- “I will try to implement reviewing all deceased patients’ records”
- “Use the record review form and engage clinical staff in becoming reviewers in order to establish the number of AE/CI in the organisation.
- “Will use the material in training of staff in the trust”
- “Use this tool for self and peer assessment of practice within clinical setting”

8.9 Discussion

The results from the series of training days showed that at the end of training clinicians with no prior experience of the definitions of AE and CI were able to correctly classify these in 67.5% of cases and reach the correct assessment of preventability in 79% of cases. These results suggest that a reasonable degree of competence in rapid record review may be achieved within a single training session of 3 hours. Large studies of RRR have reached agreement of the presence of an AE in 75-85% of cases and on preventability in 58-80% (Vincent, 2001; Davis, 2002; Brennan, 1989; Brennan, 1991; Baker, 2004; Wilson, 1995). Although one cannot directly compare inter-rater reliability between trained

reviewers and newly trained clinicians against a gold standard review, this study shows the practicality of record review to an individual hospital and unit. There is less agreement on the type of event (No Problem/AE/CI) than on presence of an AE in large AE studies but the reviewers in this study were given 3 possible outcomes, compared with only 2 in the AE studies. Agreement on preventability has traditionally been lower than agreement on the presence of and AE in RRR studies and the results from this training exercise compare favourably (Wilson, 1995; Baker, 2004; Localio, 1996).

In assessment of stage of care and nature of the problem, training made much less difference. There was variability in the ability of the case summaries to reveal improvement after training but overall the ability to assess this correctly at the end of the training was less than for the main outcome measures. For some cases there was even a slight deterioration after training. Classification by stage of care and nature of problem has not previously been validated in terms of the degree of agreement between reviewers. Thus there is no standard for comparison. Training focused on the main outcome measures. The sub-classification of stage of care and nature of problem was introduced to the participants on the course but there was insufficient time to consider these issues in depth. This is less of a problem as the individual review forms contain narratives of the clinical problems which may be used to guide initiatives for improved care. The sub-classification of stage of care and the nature of problem may therefore carry less significance.

This study shows that it is possible to train nurses to review case summaries for the presence of AE/CI and to evaluate preventability. Many of these nurses had current jobs in risk management which may have influenced the result but these findings may never the less influence the debate on training nurses to be involved in stage 2 of the classical methodology of retrospective record review. Fewer doctors attended the training sessions and therefore it was therefore possible to demonstrate the same significance of training in this group. Both those holding clinical and risk management jobs benefited from training.

Designing and being able to test a training program in record review was a challenge. There was no detailed information on how this was achieved in previous large retrospective record review studies but personal communication with the authors of the UK study was useful as were comments from surgical colleagues and the experience gained in study 1. The development of training was greatly influenced by the conflicting pressures of needing to ensure adequate training to get meaningful results whilst making this as brief as possible. This was a constant balance which was driven towards a program that was realistic in a local clinical setting where the need for absolute reliability and consistency of the data collected is perhaps less important than the engagement and involvement of clinicians. I regard this as crucial if the data collected are to drive change. My aim was to provide data which are accurate enough to be trusted locally and to useful enough to provide a stimulus for focused improvement in care. This became the guiding principle in the development of the training.

The focus on the main outcome measures of classifying medical records as showing no problems in care, critical incidents or adverse events and on assessing preventability was deliberate as these are the only parts of the review process that have been evaluated for validity and reliability in retrospective record review studies (Wilson,1995;Baker,2004;Baker,2004;Brennan,2004). Other outcome measures are rarely discussed in detail in publication of RRR studies. The experience from running the pilot training was invaluable in designing and running the record review training days at the NPSA. It triggered the design of the short training review form which has the components of the full review form in terms of event and preventability determination with confidence scores and classification of stage of care and nature of problem but is much less detailed. Piloting showed that it was not feasible to use the full 26 page MRF for training over such a short time or for evaluation of training given the practical constraints.

8.10 Conclusion

This study shows that the principles of record review with extraction of information from clinical cases and determination of AE/CI and preventability can be successfully taught and carried out by clinicians. It is possible to achieve acceptable review performance after only very brief training designed to suit the busy schedules and conflicting pressures of practising surgeons. The results of the secondary outcome measures of sub-classification of stage of care and nature of problem were less impressive. It is not possible to know if this is a result of insufficient teaching of this, difficulties due to the structure of the review form allowing multiple selections or a general problem of achieving consistency

in this area of the review. These questions would need to be addressed separately.

Chapter 9

9. Development and testing of computerised data-entry system

9.1 Introduction

The initial success of simplified real-time record review led to the ongoing work of this thesis with refinement of the method, development and testing of a teaching programme and development of a computerised data entry programme. The clinician-reviewers in study 1 all remarked on the length of the review form and how they felt this was off-putting. Data transfer from the paper form to an SPSS database for analysis was very labour intensive and, with 102 variables, the potential for error in data entry great. For the methodology of rapid real-time record review to be transferable and useful in normal clinical settings these factors had to be addressed. The solution was development of a computerised review and data entry tool based on the modular review form used in study 1 (see appendix A). The development of this will briefly be described followed by results of usability and reliability testing.

During the development of the computerised methodology the National Patient Safety Agency (NPSA) expressed interest in the methodology. This was as a result of presentations to the NPSA both at external conferences and after invitation to present at an internal staff meeting at NPSA London headquarters. The NPSA was involved in setting up a mapping study of what and where information on adverse events and critical incidents are held in individual NHS trusts. Part of this would be record review to determine the rate of adverse

events in the trusts. A collaboration was set up using the computerised data entry. This will be described in detail in the second part of this chapter.

9.2 Development of electronic review and data entry tool

The aim of a computerised data entry system and database was to provide a user friendly review interface and eliminate the need for data transfer from paper to an electronic database. With technical advice and programming assistance a database was designed and built for this purpose. The development and testing of this was lengthy. I will in this section describe design and rationale for the platform, structure, content and standard reports of the electronic modular review form EMFR. Screen prints of the data entry screens can be seen in Appendix C.

Platform

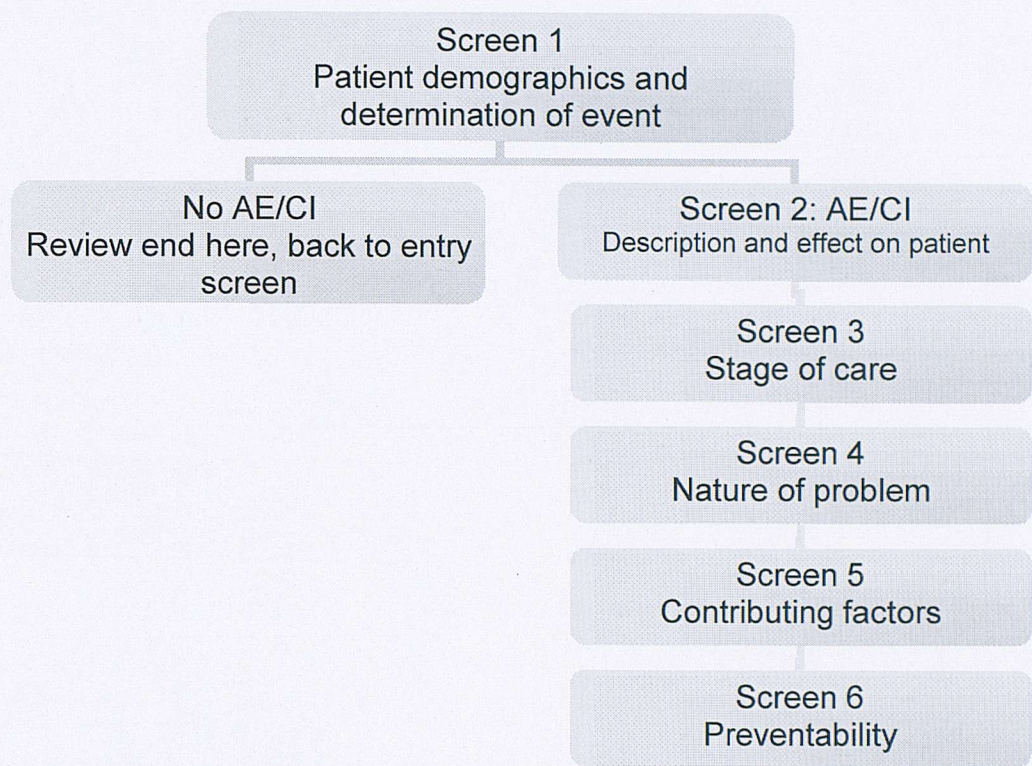
The platform of the database needed to be readily available in clinical settings to ensure it was suitable for routine use rather than just a research tool. A Microsoft Office format therefore seemed sensible. To be able to organise the data in a suitable fashion and carry out basic standard analysis Microsoft Access was chosen. This database also allows export to SPSS and other data handling programs for more sophisticated analysis.

Structure

The overall structure of the modular form was retained in the EMRF. The database is organised as a series of linked tables with individual front ends for data entry. Screen prints can be seen in appendix C. The first screen the

reviewer sees is similar to section A of the MRF in appendix A. Data on the demographics of the patient, identity of the reviewer and a determination of and adverse event (AE) or critical incident (CI) is entered. If there is no AE or CI this is indicated, the review ends here and the reviewer is taken back to the front page of the system. If there is an AE or CI the reviewer is taken to the next review screen which corresponds to the rest of section A and section B in the MRF. At the end of this the reviewer is required to select a stage of care corresponding to the 6 stages of care in the MRF and is taken to a screen corresponding to the section C of the MRF. Similarly a nature of problem is selected and the appropriate screen displayed. After this is completed the reviewer is shown a data entry screen for contributing factors and lastly a screen where the reviewer is asked to determine if there is any evidence for preventability of the event. At the end of this screen the reviewer has the opportunity to enter further AE, CI or to end the review for that patient. See Fig 9.1 for schematic structure

Fig 9.1 structure of the EMRF



Content

The overall content of the MRF was retained in the EMRF but there were a few additions and some questions were left out. The main difference in the content is a reduction of detailed questions in the sections of stage of care and nature of problem. There are a few additions in the section of demographic information of patients. Here the reviewer is asked to indicate the severity of the patients' co-morbidities as for ASA scoring and likewise the patient's state of health on admission. This was thought more useful for comparing complexity of the medical condition of patients than a simple list of co-morbidities. In addition there is also a section for indication the complexity of the surgical procedure based on the BUPA classification (Sutton, 2002). In the last section on preventability there is a list of suggested areas of change to prevent future

AE/CI from which the reviewer can choose once they have entered free text suggestions for this.

Analysis

A simple set of reports were written and included in the database to aid analysis of the data collected in individual units. These contain the number of admissions, the rate of AE, CI, the rate of selection of stage of care and nature of problems, the selected contributing factors and the rate of preventability.

9.3 Usability and reliability testing of electronic review and data entry tool

It is important after design of any data entry tool to test the usability of this. Only then do flaws in design and data handling come to light. There were many such smaller steps in the development process, which do not merit discussion here. After completion of the final draft version was it appropriate to test the use on a larger scale with actual data entry and use in a record review study. It was also essential to assess the reliability of the methodology as well as the data entry tool with review by two independent reviewers with similar levels of training, no or same prior knowledge of the cases and same amount of time and commitment to the study. I was fortunate enough to be invited to assist in the design and supervision of a mapping study supported by the NPSA of what and where information on adverse events and critical incidents are held in individual NHS trusts. Part of this would be record review to determine the rate of adverse events in the trusts. As part of the collaboration on this study, record review was carried out using the EMRF. Comments on the use of the EMRF were collected and inter-rater reliability assessed as described below.

9.4 Methods

Aim

The aim of this part of a larger NPSA backed study was firstly to assesses the usability of the EMRF and secondly the reliability of the review process by having 2 independent external reviewers assess a subset of the case records.

Design

The study was designed as a single stage retrospective record review of a random sample of 200-250 case records of admission from April 2004-April 2005.

Setting

The study was set in a large district general hospital in outer London.

Patients

The study included adult medical and surgical patients including gynaecological but excluding obstetric cases. Paediatric admissions were excluded form the study.

Training of reviewers

The main reviewer (HH) in this study was an SpR in public health with 10 years previous experience as a GP. HH was trained on one of the training dates described chapter 8. In addition to this she had access to SO to discuss cases of uncertainty during review of the first 50 cases. The second reviewer was SO, the author of this thesis.

Selection of cases for reliability assessment

A subset of the case records was double reviewed for reliability assessment of the review methodology. None of the cases in the double review had previously been discussed between HH and SO. A random sample of 10% of review negative case notes, 40% of cases with AE and 16% of cases with CI found after review by HH were reviewed by SO. SO had no knowledge of the proportion of each type of record and were blinded as to the review outcome of the records on first review.

Procedure

HH was responsible for sampling, extraction of the notes from the medical record department, liaison with the risk management of the host hospital,

9.5 Results

Reliability assessment

A total of 220 case records were reviewed by HH in this study using the EMRF. HH found a total of 40 (18%) AE of which 24 (60%) were preventable and 31 CI (14%) of which 26 (84%) were preventable.

SO reviewed 33 of the 220 case notes to assess inter-rater reliability. In these notes SO found 14 AE and 5 CI. In the same 33 case notes HH had found 12 AE and 6 CI. Both reviewers agreed there were no CI or AE in 14 case notes and in total they agreed on the presence and class of event in 27/33 case notes (82%). The kappa score for agreement on AE, CI or no event was $k=0.75$ (95%CI 0.56-0.95). Both reviewers agreed on preventability in 10 of 16 cases

identified by both (63%). They agreed on the stage of care in 14/16 cases (88%) and on classification of the nature of the problem in 12/16 cases (75%).

Table 9.1 Results of double review for reliability assessment

Reviewer 2	Reviewer 1			
	No event	CI	AE	Total
No event	14	1	0	15
CI	1	3	0	4
AE	1	2	11	14
Total	16	6	11	33

Usability assessment

The reviewer HH generally found the EMRF easy to use. She submitted a series of comments, which are summarised below. There were 2 classes of comments, firstly those relating to the structure inherited from the EMRF and secondly software issues of the inter-face. The main criticism related to the structure inherited from the MRF, mainly repetition of free text information on AE on screen 2 (description of AE), then again on screens 3 and 4 (stage of care and nature of problem) and on screen 5 contributing factors. HH also commented that the questions for pre-admission were confusing and that it was difficult to classify side effects of drugs in the medication section of section D (or screen 4 – nature of problem = medication related).

Comments on problems with the software interface were few; there was no space for entry of time taken on review as had been the case on the MRF, There was a mistake in the free text box for comments on deficiencies of notes

limiting these to 8 words. It was not possible to list items on separate rows on screen 5=contributing factors.

9.6 Discussion

The EMRF was successfully used to review 220 case records in this study. The findings of the study of and AE rate of 18% and CI rate of 14% is in the spectrum of what one would expect based on the findings of RRR studies (Vincent, 2001;Thomas, 2000;Schioler, 2001;Michel, 2004;Davis, 2002 ;Brennan, 1991;Baker, 2004;Wilson, 1995). This study was carried out in the same hospital as described in chapter 7 of comparison of different methods of identifying AE and CI. The wider NPSA study was built on the results, findings and questions raised by this study. Both the rate of AE and CI found in the present study and the rate of preventability are very similar to those found in study 2 (chapter 7) which also examined record review in both general medical and surgical patients.

It was possible to assess Inter-rater reliability in this study due to the comparability of the 2 reviewers. Reliability of the class of event in the case notes was good ($\kappa = 0.75$ (0.56-0.95)). The total numbers of cases containing AE or CI are too small to provide meaningful kappa statistic on the other outcome measures but the degree of agreement between the 2 reviewers were very good and in line with large scale studies of RRR (Wilson, 1995;Localio, 1996;Baker, 2004). There was 63% agreement on preventability in the AE and CI detected by both reviewers. This is in line with the findings of AQHCS where there was agreement on preventability in 58% of cases with AE.

None of the large scale RRR studies have published data on inter-rater reliability of their sub-classification of types of AE and there have been no studies assessing this part of the original MRF2 as developed by Woloshynowych et al (Woloshynowych, Neale, & Vincent 2003). Hence there is no external benchmark for comparison of the agreement on stage of care of 88% and on nature of problem of 75%. Both levels of agreements are however very satisfactory.

Many of the comments on usability of the review process and recording mentioned by HH are shared with the registrar reviewers' comments from study 1. After these comments and my experience of reviewing and checking others reviewers entries I feel the area of repetition in the form needs to be addressed. From my experience the best organisation of the data entry fields would be a detailed free text narrative on data entry screen 2. On the subsequent data entry screens the field for free text should be retained but placed at the bottom of the data entry screen and titled "additional comments". This will allow for further comments or reflections of the reviewer after they have progressed in the analysis of the case without seeming to repeatedly ask the same question. It will also encourage the reviewer to be explicit in the initial narrative, making easier to data mine or review the free text. The problems with the software interface are also recognised and must be addressed in any further updates of the EMRF.

9.7 Conclusion

This chapter describes the development of a computerised review interface and direct data entry system for use in record review for detection of AE and CI. This has been developed and although some minor improvements are needed, it was successfully used to review 220 case notes in an external study by a reviewer not involved in the development of this methodology or review interface. The inter-rater reliability in a small sub sample of 33 case notes was good and agreement on preventability, stage of care and nature of problem was satisfactory.

Chapter 10

10. Exploring Implementation of Real-time Record Review

10.1 Introduction

This chapter describes the final study of this thesis, implementation of focused record review and the use of a computerised review and data entry tool.

The focus of this thesis has been the development of a new method of record review to be carried out near the time of discharge from hospital, closely involving in the process clinicians caring for the patients. Previous chapters have described how the methodology of traditional retrospective record review was initially modified to fit this objective and how this was tested.

With the experience and lessons learned, I proceeded to develop a training programme for reviewers (chapter 8), computerisation of the data-collection tool with electronic data entry and reliability assessment (chapter 9) and testing of the methodology in a different hospital setting without ongoing input from the author to assess transferability (Chapter 11). This chapter draws together the learning from all these studies. Surgeons involved in the care of patients have a crucial role to play in review of records both to tap into knowledge of events not documented in the case records and to ensure ownership of the data and a willingness to change practice as a result of the findings. The challenge is to engage and train surgeons to carry out record review.

This chapter explores some practical considerations of the implication of real-time record review and falls into 4 main parts. Part 1 describes the revised methodology and use of the EMRF by external reviewer to review consecutive cases. This gives the background data on which to base both the comparisons made with selected cases and with findings by clinicians. It also provides the data presented to clinicians of the unit to assess the changes made to care delivery and structure based on data from RTRR. Part 2 consider the possibility of carrying out record review on highly selected cases and compare the learning achieved from this with that gained from reviewing consecutive unselected cases. A frequent comment encountered when presenting or teaching the methodology is concern that it will be too time consuming to assess all discharged patients over a time period without any pre-selection of cases or screening by strict criteria such as death. Surgeons are today under multiple time pressures from both clinical and administrative responsibilities. Part 3 describes the findings by surgeons using the EMRF for RTRR and compare the findings with those of the external reviewer. Part 4 describe the presentation of the results to the surgical unit and the response to the data. In addition the question the feasibility of the workload involved is addressed. Time constraints are important considerations if real-time record review is to be implemented as part of routine practice by surgeons.

10.2 Aim

The aims of this chapter were

1. Explore the implementation of the revised methodology and electronic review tool for Real-time Record Review
2. To compare data available from consecutive discharges with data gained from review of strictly selected cases
3. To explore the difference between trained clinician reviewers and external reviewer
4. To assess the feasibility and workload involved
5. To record organisational changes made based on the results of the study

10.3 Part 1 - Review of consecutive discharges by external reviewer

All consecutive cases were reviewed by an external reviewer to provide detailed information firstly as a background against which to compare other aspects of this study and secondly to ensure adequate results to drive change within the surgical firm in this study.

10.4 Methodology

Design

The design of this part of the study was a single stage review process without screening. An external reviewer reviewed all consecutive discharges. Data collection was prospective and carried out at the time of discharge. Case records were assessed for adverse events and critical incidents.

Setting

The study was set in an Inner-London teaching hospital with full radiology, intensive care and support services on site. High dependency care (HDU) patients were looked after by the surgical team in a designated HDU bay in the surgical ward.

The surgical firm participating is an academic department consisting of 1 professor, 1 reader (half-time on this site) and 3 consultant senior lecturers. Middle grades include 3 SpRs and 2 part-time clinical fellows at SpR level. Special interests are coloproctology, upper GI surgery and advanced laparoscopic surgery.

Ethics

The local ethics committee was consulted on the study but formal ethics approval was not required as the study falls under the remit of quality assurance.

Patients

100 consecutively discharged NHS patients from one general surgical team (including both elective and emergency admissions) were entered into the study. A formal calculation of sample size and power calculations were not undertaken. The sample size was based on what was deemed to be the maximum number of patients which the registrars would be willing and able to assess the case records of. Engagement in the process of evaluation of care was deemed more important than strict statistical significance in order that such work will stimulate improvements of care. Patients under the main care of another teams but who

received an operation under the team were also included. In these patients only AE/CI relating to this aspect of care were recorded. We did not include patients who had been reviewed by a member of the team but where there was no ongoing care involvement, nor did we include private patients seen by the junior members of the clinical team.

Patients were not informed of the study nor required to give consent in line with previous studies in this field.

Data collected

Data was anonymised after collection. Details of the data collected on each patient were in line with that described in development of the EMRF in chapter 9 (See Appendix C). Data collected on all patients included patient demographics, diagnosis, co-morbidities, duration of admission and presence or absence of AE/CI. In the cases where a critical incident or adverse event was detected, further information included the stage of care of the event, the nature of the event, contributing factors and possible ways of preventing similar events in the future.

Training of reviewers

The external reviewer carried out the review of consecutive cases. This reviewer is the author of this thesis and trained in record review.

Procedure

After discharge from hospital the notes were tracked and taken to the office of the team where review was undertaken using the unit computer. The review was undertaken as soon as possible after discharge. The study coordinator (SO) was responsible for tracking and movement of notes. The reviewer completed a logbook with a record the total time spent on the review process. All notes were reviewed an external reviewer (SO). Before the final analysis was performed all adverse events and critical incidents were discussed with an experienced senior reviewer and physician (Professor Graham Neale) to establish if criteria for adverse event, critical incident and preventability had been met in all cases.

Patient demographics were collected on all patients. Notes were evaluated for detection of adverse events and or critical incidents. In the cases where these had occurred in-depth analysis of the circumstances were carried out in accordance with the EMRF.

10.5 Results

As summary of the results which relates the comparative parts of this study and to driving change are presented here. Tables with all numerical results with relevant confidence intervals and additional data can be seen in appendix D.

Patient demographics

In total 104 surgical patients were included in the study. The ages ranged from 17-88, the mean and median age was 53 years. 66 patients underwent an operation. There were 66 emergency admissions and 38 elective admissions.

Demographic information was collected on all patients for the benefit of clinicians to assess their case mix but also to look for differences between patients with and without critical incidents. Full details of this can be seen in appendix D.

Adverse Events and Critical Incidents

Of 104 patients in the study 10 (10% (95%CI 5-17)) suffered an adverse event. There were a total of 12 independent adverse events. As each AE and CI presents a potential opportunity for learning results will be presented for each event rather than for each patient affected. Of the adverse events 7/12 (58% (95%CI 32%-80%)) were deemed preventable. 21 (20% (95% CI 14%-29%)) of patients experienced a critical incident in their care. In total 25 CI were identified all of which were preventable. In total 27% (95% CI 19%-36%) patients experienced problems in their care in the form of an adverse event and/or a critical incident with 10% (95% CI 5-17%) of patients suffering at least one adverse event +/- a critical incident and an additional 17% (95% CI 11%-26%) of patients only a critical incident.

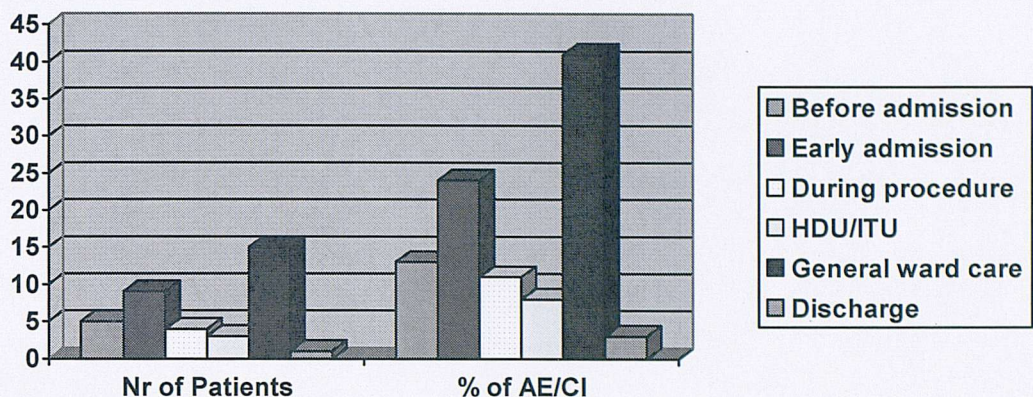
Specialty/team responsible for care at the time of adverse events

All of adverse events and 24/25 critical incidents detected occurred whilst being under the care of the surgical team.

Stage of care where care-problems occurred

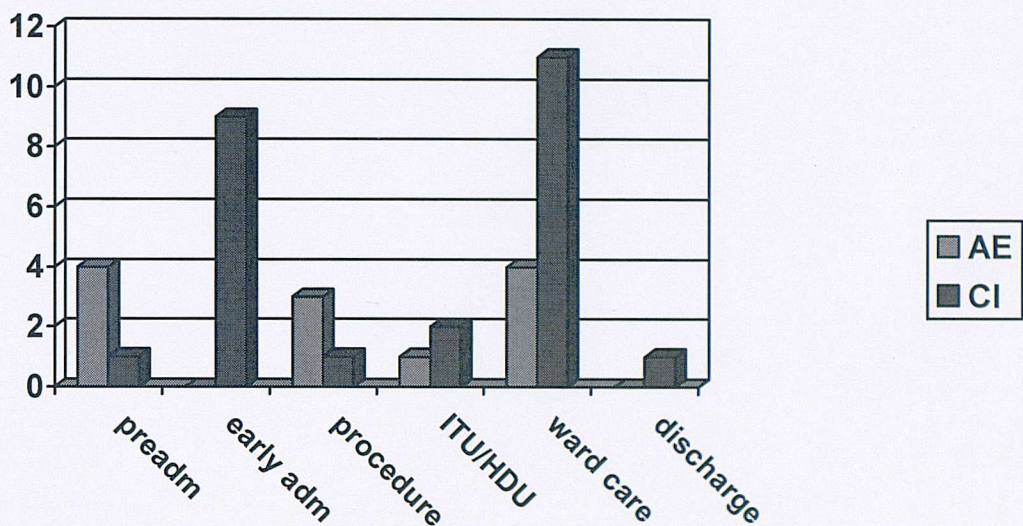
The stage of care where the care problem originated or where it most contributed to the event or incident was recorded. As can be seen in fig 10.1 the majority of problems arose from ward care and early in the admission

Fig 10.1 All care problems distributed over stages of care



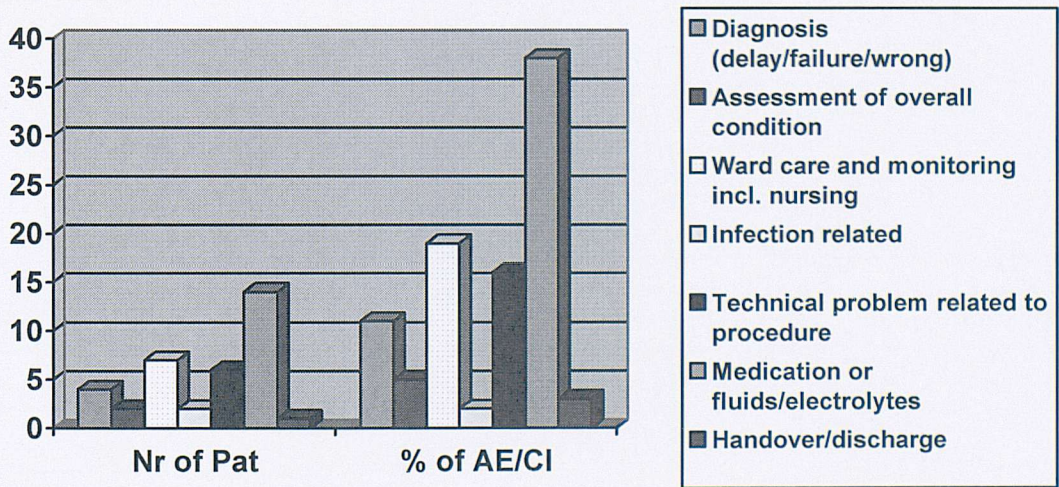
Both AE and CI are of interest as indicators of weaknesses in the care-process and CI's are potential AE's. However it was important to see if AEs and CIs followed the same distribution over stages of care. As can be seen in fig 10.2 below this was not the case. As one would expect we identified a number of AE occurring before the index admission and causing or contributing to this. These were mainly outcomes of operations at previous admissions. There was only one CI identified at the preadmission stage, which was a failure to act on an abnormal result at preadmission, but this did not lead to harm of the patient nor delay in treatment.

Fig 10.2 Distribution of AE and CI over stages of care



It is clear from these findings that the majority of problems of care are related to general ward care which include ongoing medical input and decision making, ongoing investigations and actions as results of these, nursing care and pharmaceutical therapy. Only 11% of problems were directly related to surgical procedures during the index admission. To look further into the nature of problems, which arose in the care of surgical patients events, were categorised into 7 categories as in the EMRF.

Fig 10.3 Classification of problems of care for all care problems combined

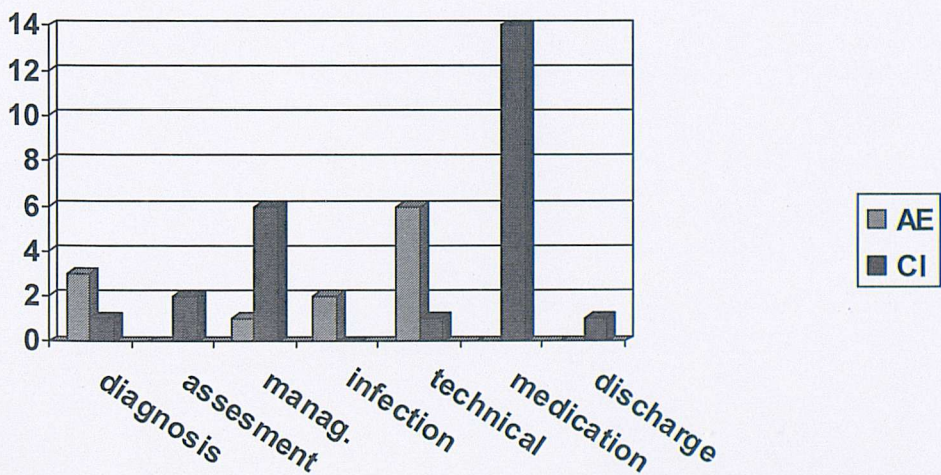


As can be seen from fig 10.3 the majority of problems arose from aspects of general ward care such as medication/fluid prescribing or monitoring, general ward care and monitoring of patients. Again it is clear that only the minority of problems traditionally attributed to surgical care stems directly from technical aspects of surgical procedures. The proportion of procedure related problems reflect both those during the index admission and those, which occurred during previous admissions but caused the index admission. Reaching the right diagnosis timely was also a problem.

As for stage of care, the nature of problems were analysed separately for AE and CI to look for different patterns.

The largest single class of problems were medication problems but in this patient group they did not lead to harm of patients. The majority of these were failure to prescribe DVT prophylaxis in high-risk patients and adequate antibiotics for both prophylaxis and treatment. Infections were hospital acquired wound and chest infections. Diagnostic problems were related to timely investigation and interpretation of results. Technical surgical problems covered a range from port site bleeding to anastomotic leak.

Fig 10.4 Categories of AE and CI



Consequences to patients and hospital resources

Consequence to patients of adverse events

The majority of adverse events had a minor impact on the patients' quality of life and were expected to resolve within one month. However 3/12 AE resulted in death or disability lasting up to a year. See table 10.1 below.

Table 10.1 Consequence to patients of adverse events

Degree of disability	Nr of Pt	% of AE
No physical impairment	1	8%
Minimal impairment for less than 1/12	3	25%
Moderate impairment for less that 1 year	5	42%
Permanent impairment	1	8%
Death	2	17%

Effects of adverse events on hospital stay

The majority of adverse events had a negative impact on hospital resources by increasing the length of the admission or leading to readmission of the patient.

Table 10.2 Effects of adverse events on hospital stay

Effect of AE	Nr of Patients	% of all AE
No effect on duration	1	8%
Increase in admission duration	7	58%
Re-admission	4	33%

Contributory factors

The reviewers was asked to indicate both by free text comments and by selecting from a previously validated grouped list which factors might have contributed to the occurrence of an AE or CI (see appendix C). The reviewer could select as many factors as were relevant. Each group had 4 to 7 items. Table 10.3 below shows the total number of times each group was indicated and the main individual factors chosen within these.

Table 10.3 Contributing factors all care problems

Factor group	Number of times implicated	Main individual factors
Patients factors	14	Patient's co-morbidities
Task factors	10	Lack of or failure to adhere to protocols
Individual factors	37	Lack of attention to detail
Team factors	26	Poor teamwork Inadequate supervision
Work environment	12	Out-of- hours
Organisational factors	9	Lack of resources Lack of senior leadership

10.6 Part 2 - Selective computerised real-time record review to examine a locally defined issue

During presentations and teaching sessions on the methodology, as part of the work of this thesis, concerns about the workload involved in doing review of all cases rather than just reviewing a small number of highly selected cases were repeatedly raised. On approaching the firm for agreement to participate in the study, senior clinicians were asked to comment on what they expected problems to be and what cases they would be particularly interested in reviewing. To be able to assess the relative work load involved and value of the information gained, information was also collected by an external reviewer on all cases as described above. This part of the chapter presents the methodology and results of the focused review by the external reviewer and feasibility and workload of the selective compared to continuous case review.

10.7 Aim

The aim of this part of the study were

1. To assess what can be gained by analysis by an external reviewer examining cases selected using locally defined issues.
2. To explore differences in number, types and patterns of AE and CI from selected review as opposed to review of consecutive cases.

10.8 Methodology

Much of the methodology of this section is identical to that described above for review of continuous cases. Only methodological points that differ from what is described above will be presented here.

Design

The review process in this study was a 2-stage process with screening by the external reviewer of all consecutive discharges for 3 highly selected criteria. Data collection was prospective at the time of discharge. Case records were assessed for adverse events and critical incidents.

Patients

After discussion with a senior clinician from the firm with particular interest in this study, it was decided to include patients who had been to ITU/HDU, had died in hospital and patients who had stayed in hospital for more than 13 days in the focused review. This part of the study included discharged patients who fulfilled any of the 3 above criteria during the period of data collection as described above

Data collected

Data collection for included patients was identical to that of patients in the continuous review.

Procedure

The procedure for included selected cases was the same as that described above. Screening was carried out by review of the discharge list generated by the clinical team, this contains a brief case summary which mentioned if that patient had received HDU/ITU care, information on discharge status and duration of stay.

10.9 Results

Patient demographics

In total 15 surgical patients were included in this part of the study. These were a subset of the 104 patients in the continuous review. 8 received HDU/ITU care some of which also stayed more than 13 days in hospital. An extra 5 patients had admissions of over 13 days as their only criterion and 2 patients died. The age ranged from 17-88, the mean and median age was 53 years.

Number of care problems detected

Only 15 of 104 cases satisfied the selective review criteria of death, HDU/ITU admission or admission longer than 13 days. These cases however, included 8 of the 12 adverse events (67%) but only 8 of 25 critical incidents (32%) identified in the review of all consecutive patients. The 8 AE were found in 6 case records and 5 were deemed preventable. 6 of 14 patients experienced a critical incident in their care. The 8 CIs were found in 6 records and all were deemed preventable. In total 10/15 patients experienced problems in their care in the form of an adverse event and/or a critical incident with 6/15 patients suffering at least one adverse event +/- a critical incident and an extra 4 only a critical incident. As can be seen from table 10.4 there was no difference in the rate of preventability between selected and unselected cases although the actual numbers are small.

Table 10.4 comparison of preventability selective vs. continuous cases

Cases	Preventable AE	Preventable CI
Review of consecutive discharges	7/12	25/25
Review of screen positive cases	5/8	8/8

Specialty/team responsible for care at the time of adverse events

All adverse events and critical incidents detected occurred whilst being under the care of the ASU team.

Patterns of events

To gauge the value of carrying out only review of highly selected cases it is important to see if the both data sets indicate similar sort of clinical problems. To elucidate this, a comparison was made for the main categorisations of events between the results of selected cases and continuous cases.

Stage of care

A comparison of the stage of care of the selected and unselected cases is shown in table 10.5

Table 10.5 Stage of Care

Stage of care	AE/CI in selected cases (% (95% CI))	of AE/CI in unselected cases (% (95% CI))
Before admission	2/16 (13% (4%-36%))	5/35 (14% (6%-29%))
Early admission	1/16 (6% (1%-28%))	8/35 (23% (12%-39%))
During procedure	2/16 (13% (4%-36%))	3/35 (9% (3%-22%))
HDU/ITU	3/16 (19% (7%-43%))	3/35 (9% (3%-22%))
General ward care	8/16 (50% (28%-72%))	15/35 (43% (29%-59%))
Discharge	0/16 (0% (0%-19%))	1/35(3% (0.5%-15%))

Selection of cases tends to lead to a higher proportion of AE/CI occurring later in the admission and naturally all of those occurring within ITU/HDU for these specific screening/selection criteria. Few of the many critical incidents initiated early in the admission were found in the highly selected screen positive cases. As expected we identified some AE, which occurred before the index admission and caused or contributed to this. These were mainly as a result of operations during previous admissions. The majority of problems in care detected in the selected cases were related to general ward care which includes ongoing medical input and decision making, ongoing investigations and actions as results of these, nursing care and pharmaceutical therapy. When comparing the stages of care of events the main difference is in the higher proportion of cases during HDU/ITU in the selected cases, as one would expect as this group is over represented by the screening criteria. A lower proportion of problems were detected in the early stages of care in the selected cases as a result of not

including the high number of critical incidents which occurred in early in the admission in the review of consecutive cases.

Nature of care problems

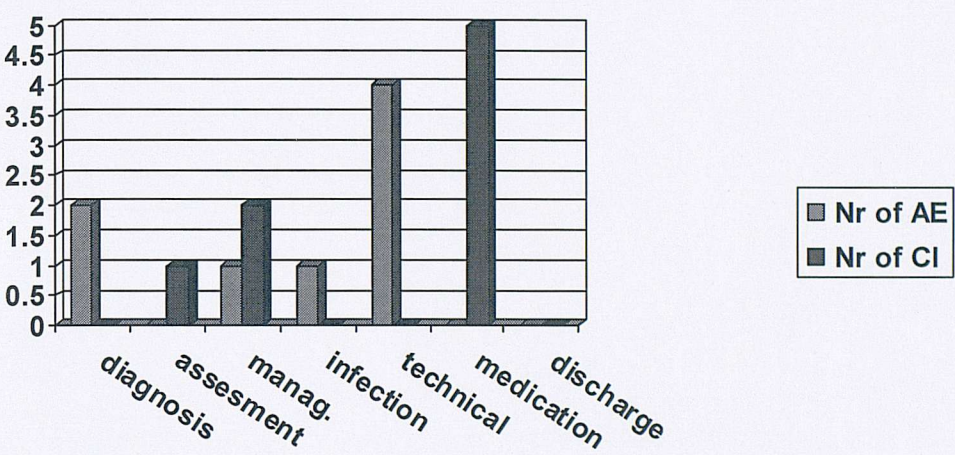
In the selected cases the majority of problems were medication/fluid prescribing or monitoring and general management and monitoring of patients, all aspects of general ward care. A significant proportion stemmed directly from surgical procedures. The proportion of procedure related problems reflect both those during the index admission and those, which occurred at previous admissions but caused the index admission. Reaching the right diagnosis timely was also a problem. The nature of the problems detected were largely similar in the two groups of cases, see table 10.6

Table 10.6 Nature of care problems

Nature of problem	AE/CI selected cases (%(95%CI))	AE/CI unselected cases (% (95% CI))
Diagnosis (delay/failure/wrong)	2/16 (13% (4%-36%))	4/37 (11% (4%-25%))
Assessment of overall condition	1/16 (6% (1%-28%))	2/37 (5% (2%-18%))
Ongoing management and monitoring incl. nursing	3/16 (19% (7%-43%))	7/37 (19% (9%-34%))
Infection related	1/16 (6% (1%-28%))	2/37 (5% (2%-18%))
Technical problem related to procedure	4/16 (25% (10%-50%))	7/37 (19% (9%-34%))
Medication or fluids/electrolytes	5/16 (31% (14%-56%))	14/37 (38% (24%-54%))
Discharge or handover arrangement	0/16 (0% (0%-19%))	1/37 (3% (0.5%-14%))

The largest single class of problems in the selected cases were medication problems, all of which were critical incidents. Infections were hospital acquired wound and chest infections. Diagnostic problems were related to timely investigation and interpretation of results.

Fig 10.5 Categories of AE and CI in selected cases



Consequence to patients of adverse events

Looking at only the adverse events one might expect that these would be more severe and have a worse impact on the patient's quality of life in the selected cases based on the screening criteria. As can be seen from table 10.7 this is indeed the case.

Table 10.7 Comparison of the impact on patients from AE in selected and unselected cases

Degree of disability	AE selected cases (%)	AE continuous cases (%)
No physical impairment	1/8(13%)	1/12 (8%)
Minimal impairment for less than 1/12	0	3/12 (25%)
Moderate impairment for less that 1 year	4/8(50%)	5/12 (42%)
Permanent impairment	1/8(13%)	1/12(8%)
Death	2/8(25%)	2/12 (17%)

The majority of adverse events had a major impact on the patients’ quality of life with 38% of AE resulted in death or permanent disability.

Effects of adverse events on Hospital stay

The majority of adverse events had a negative impact on hospital resources by increasing the length of the admission or leading to readmission of the patient.

Table 10.8 Comparison of the impact on hospital resources from AE in selected and continuous cases

Effect of AE	% of patients with AE selected cases	% of patients with AE continuous cases
No effect on duration	1/8(13%)	1/12 (8%)
Increase in admission duration	5/8(63%)	7/12 (58%)
Re-admission	2/8(25%)	4/12 (33%)

Contributory factors

As for the unselected cases the reviewer indicated which factors might have contributed to the occurrence of AE or CI. Table 10.9 below shows the total number of times each group was indicated and the main individual factors chosen within these.

Table 10.9 Contributing factors

Factor group	Number of times implicated selected	Main factors individual selected	Main individual factors continuous cases
Patients factors	11	Patient's co-morbidities	Patient's co-morbidities
Task factors	9	Difficult task	Lack of or failure to adhere to protocols
Individual factors	20	Lack of attention to detail	Lack of attention to detail
Team factors	9	Poor teamwork	Poor teamwork Inadequate supervision
Work environment	5	Out-of- hours	Out-of- hours
Organisational factors	5	Lack of resources	Lack of resources Lack of senior leadership

These factors were largely the same in both the unselected and selected cases.

Feasibility

The main motivation for reviewing only highly selected cases is to reduce the overall time spent on the review process. The external reviewer kept a log of time spent on reviewing each case. These data were used to compare the work involved in reviewing for each of the 2 methods. The total time spent on reviewing care records for the screen positive case records was 26 hours. The mean time spend on each record was 15 min (95%CI 13-17 min). The mean

time spend on reviewing cases containing AE or CI was 24 min (95%CI 20-28min)

Table 10.10 Time spent of record review

	External reviewer unselected cases time (95% CI)	External reviewer selected cases
Total time	26 hours	6 hours
Mean time all	15 min (13-17min)	26 min(19-32 min)
Mean time AE/CI	24 min (20-28 min)	30 min (20-39 min)
Mean time no event	12 (10-14 min)	20 (9-31 min)

The total time spent on reviewing records of highly selected cases was only 6 hours. The mean time spent on cases with no AE/CI was 20 min as opposed to 12 min for unselected cases.

10.10 Discussion of comparison

It is clear from this comparison that the screening criteria are good at selecting cases with adverse events. 58% of all adverse events were found in only 13% of the 104 case records. However only 35% of the critical incidents were found in this selected group. This difference in detection of critical incidents explains some of the differences in the stage of care with a smaller proportion being found early in the admission of the selected cases. The distribution of nature of problems is remarkably similar in the 2 data sets. As one would expect the seriousness of adverse events and their impact on the patients' quality of life is more severe in the selected cases as patients who died are included in the small number of patients as are patients with prolonged stay.

The review of the selected case records took only 6 hours in contrast to the total review time of 26 hours it took to review all case records. As one would expect, because of the high proportion of cases with AE/CI, the mean time spent each record was higher on the selected cases. Only the actual time spent on review is mentioned here. There is no estimation of the additional significant workload in collecting, sorting and tracking notes. From a workload point of view the additional time spent screening for these criteria would be more than offset by the reduction in time spent on review and notes handling. These particular screening criteria of admission longer than 13 days, HDU/ITU treatment during admission and/or death would be easily identifiable by clinical teams through their work lists and knowledge of patients and would as such not carry a significant workload.

10.11 Conclusion

These 3 screening criteria of prolonged admission, HDU/ITU care and/or death were effective at reducing the work load of case review and highlighted problems representative of the problems found in all of the 104 case records included in the review process. This type of review in isolation does however not give an immediate denominator and it can therefore be difficult to calculate rates of events. Although the data are limited they show that selection of cases reduces the number of AE identified by 40% and CI by two thirds. Although most AE with more serious outcome are identified in the selected series of cases the reduction of critical incidents detected may reduce the opportunity to identify systems weaknesses before they lead to significant harm.

10.12 Part 3 - Review by Surgical trainees

It was initially anticipated that the SpRs of the firm would review all cases and this was agreed with the senior clinicians. However shortly after the study started there were a series of staff changes which made this impossible. Due to the importance of involving clinicians from the firm to ensure ownership of the data, the involvement of the registrars was renegotiated and it was decided that in the very limited time available they would review a random sample of 25% of the case records included in the overall sample. It was also important to determine what the rate and type of problems detected by the registrars was in this study where they received structured training and to compare the findings to study 1 where the registrar reviewers had only a minimal instruction in record review. In this part of the chapter I will present the methodology of the registrar review and compare the results obtained by the external reviewer to those by the clinicians involved. Feasibility and work load will also be presented. Data collection with review by external reviewer and local clinicians are regarded as complementary. Differences in background, training and more importantly prior knowledge and biases of each case make it impossible to sensibly assess the correlation of results between the two groups in the form of kappa score.

10.13 Aim

The aims of this part of the study were

1. To assess what SpRs can achieve by reviewing case records for critical incidents and adverse events after systematic training and using a computerised data entry system.

2. To explore differences in number, types and patterns of AE and CI between SpRs and the external reviewer.

10.14 Methodology

Much of the methodology of this section is identical to that described above for review of consecutive cases. Only methodological points that differ from what is described above will be presented here.

Patients

A random sample of 25% of case records from the overall study were forwarded for review by the registrars shortly after discharge. Unfortunately some of these were removed for use elsewhere before they could be reviewed.

Data collected

Data collected on included patients is identical to that collected in the review of consecutive cases.

Procedure

For included selected cases this identical to that described in the overall review.

10.15 Results

The case records of 21 patients were reviewed by the SpRs. The registrars detected 4 adverse events and 9 critical incidents in the 21 case records. In the same case records the external reviewer detected 5 AE and 6 CI.

Table 10.11 Comparison of events detected by SpRs and external reviewer

	Cases assessed	Total AEs	Preventable AEs	Total CIs	Preventable CIs
SpR	21	4	3	9	8
External reviewer	21	5	4	6	6

Registrars detected all but one of the adverse events which were detected by the external reviewer. They found more critical incidents in this group of patients than the external review.

Comparison between the critical incidents and adverse events detected by external reviewer and registrars

The following section will present the differences in the adverse events and critical incidents detected by registrars and the external reviewer.

Table 10.12 Events detected and classification of stage of care

Stage of care	No of events external	No of events registrars
Before admission	1	0
Early in admission	3	6
During procedure	1	1
Post-op, ITU/HDU	2	1
General ward care	4	4
End of admission/discharge planning	0	1

Table 10.12 above show the comparison between events detected by the external reviewer and the registrars. I will here explore differences in the type of events detected by the registrars as compared with the external reviewer. The registrars did not detect adverse events occurring before the index admission, but they detected events in all other stages of care. Notably they detected 1 AE and 5 CI early in admission and 1 AE and 3 CI during ward care.

The external and registrar reviewers also found similar number of each of the nature of problems detected in these cases as seen in table 10.13

Table 10.13 Comparison of Nature of problem

	No of events external	No of events registrar
Failure to diagnose	3	2
Failure to assess overall condition	0	0
Failure in management and monitoring incl nursing	4	2
Infection related	0	0
Technical procedure related problem	1	1
Failure in give medication or fluid/ electrolytes	3	5
Other	0	2

Agreement on detection of adverse events was good. The SpR reviewer only failed to detect one of the AE detected by the external reviewer. This was a readmission of a patient with a missed diagnosis of right lower lobe pneumonia as the cause of right upper quadrant pain despite an abdominal CT scan noting a small right plural effusion and some basal changes in the base of the right lung. In contrast agreement on detection of critical incidents was poor. In total 13 different CI were detected by the SpRs and or the external reviewer. Only 2 of a potential 13 CI were described by both the external reviewer and the SpRs. The registrars detected a total of 3 CI more than the external reviewer. The SpRs detected 6 critical incidents not detected by the external reviewer and the external reviewer 5 not detected by the SpRs. The cases not detected by the SpRs were failure to prescribe glaucoma eye drops, an incident in which Cefuroxime and Metronidazole was wrongly prescribed via oral route to a patient with presumed peritonitis and therefore not given for 24 hours, a patient who seemed to have received IV 3 doses of Ciprofloxacin and Gentamicin with no indication and no mention of this in the case records and lastly a patient with abnormal observations for 24 hours without any action taken until the patient collapsed when walking to the toilet. The critical incidents not recorded by the external reviewer was failure to carry out Glasgow scoring on a patient with pancreatitis, 2 cases with failure to prescribe DVT prophylaxis, failure to decrease the dose of chlordiazipoxide for alcohol withdrawal according to protocol resulting in excessive drowsiness and case of a discharge summary for another patient filed in the patients case records.

Feasibility and willingness to participate

The surgical firm participating in this study was selected because it was linked to the academic department in which the Clinical Safety Research Unit is embedded. Despite this connection there had never been any previous formal clinical or research connection between the clinical firm and the CSRU nor had there been any measurements or initiatives related to patient safety. The 5 consultant surgeons of the clinical firm were approached to obtain permission to include their patients and junior staff in the study. All were willing to be included but only 2 were genuinely engaged in the process. The registrars of the unit were approached shortly after arriving in the unit and although all agreed to participate in the study, they were concerned about the time commitment and especially that time spent reviewing cases would detract from their potential learning time in the operating theatre.

The registrars spent a total of 6 hours reviewing the 21 case notes. The mean time spent reviewing a record was 17 min (95%CI 12-22) compared with the external reviewer who took a mean time 25 min (95%CI 17-31) to review the same records. The registrars spent a mean time of 20 min (95%CI 11-31) reviewing records with AE/CI and a mean of 14 min (95%CI 9-19) reviewing records with no care problems.

10.16 Discussion

The registrars detected nearly as many AE and more CI than the external reviewer in this study. The results presented here contrast with the findings in study 1 reported in this thesis (chapter 5 and 6) where the registrars only detected 8/19 AE and 4/19 CI. Another notable difference is that the SpRs in

this study detected care problems in all stages of care but one and similar types of problems to those detected by the external reviewer. In study 1 the care problems detected by SpRs were largely confined to problems related to technical problems with operations and wound infection and the SpRs largely missed problems with diagnosis, ongoing management and medication errors. Although the numbers here are small it would seem that there is an overall higher detection rate of AE and CI by the SpRs in this study and that these are distributed over a wider range of areas of surgical care. This is likely, at least in part, due to better and more systemised training of the registrars as compared with study 1. Although there was poor agreement on the CI detected the overall themes of care problems detected were the same for SpRs and the external reviewer, with the majority relating to medication errors, diagnosis and ongoing management and monitoring. Formal Kappa statistics on inter-rater reliability has not been performed due to the small number of cases and the differences in the information available to the two reviewers with SpRs having knowledge on unrecorded aspects of the patients care. Inter-rater reliability of the computerised data entry system has been separately evaluated and presented in chapter 9.

A major benefit of involving registrars in this study was to promote ownership of the results and belief in the data by the clinicians in the team. Having documented care problems as part of this study created a sense of responsibility for change. This was felt by particularly the SpRs as both a duty to improve patients' where possible care from an altruistic perspective but also a necessity because they felt vulnerable against potential complaints from future

patients who experienced harm from the problems they had identified unless they could prove that had been taken to improve these.

The registrars were willing to participate but were concerned about the impact in their other clinical duties. The time taken on case notes review was equivalent to the time taken by the external reviewer for the same set of records. For registrar reviewers to commit to the process it is essential that they receive strong support and encouragement by their consultants and receive clearly scheduled time in which to do this.

10.17 Part 4 - Changes made as result of surgical audit

The lead clinician of the firm in this study was interested in using the findings for improvement of the service and care provided. This part of the chapter describes how the findings were presented to the clinicians of the firm, how they were received and what action was planned as a result. Due to the time constraints of completing this thesis it was not possible to revisit the firm to record how the planned changes were implemented.

Audit meeting presentation:

The preliminary findings were presented during the monthly surgical directorate audit meeting. This meeting should be attended by all surgeons and junior doctors in the directorate. Unfortunately this is usually not the case and on the date of presentation of this study's findings only 2 of 5 of the consultants and one of the 4 registrars were present. The findings were presented in 30 minute presentation of the overall findings which included the rate of adverse events and critical incident, the stages of care affected and the nature of problems detected. The presentation was followed by a very brief discussion. The results were largely accepted by the clinicians as being a true reflection of the care delivered by the service. The only discussion of possible changes needed as a result of the data was related to improving prescription of DVT prophylaxis by pre-printing the prescription of thrombo-embolic deterrent stockings and low molecular weight heparin on the drug charts for all surgical patients. No action was taken on this during the following 3 months.

Presentation to Consultant of the unit:

Due to staff availability and a prolonged holiday season it was not possible to schedule a meeting attended by all consultants and the head of the department until 2 months after the initial presentation of the data at the audit meeting. This meeting was not attended by junior doctors or nursing staff. The consultants had all been sent a written report of the findings without details of individual cases prior to the meeting. The results were presented as before, but this time included a summary of the themes of clinical problems found and contributory factors. Like at the initial presentation, the results were accepted as a reflection of the problems on the firm without much discussion. The ensuing discussion of how to act on the results was very lively and open with several of the consultants mentioning cases of AE and CI they had experienced in the past few weeks. The presentation was followed by a lengthy discussion on what changes should be implemented as a result of these findings. It was decided that one of the senior consultants should meet with the authors of the study to draw up a list of initiatives to be discussed at a later meeting.

Plans for change

A meeting with a senior consultant, a registrar representative and the author of this thesis was held to discuss possible changes of the delivery and structure and care in the firm. Most of the problems which occurred outside of the operating theatre could be traced back to missed opportunities of stopping the chain of events putting patients at risk during ward rounds, preadmission and discharge phase of care. Many problems seemed to have arisen from lack of

structure of the clinical team on the ward and uncertainty about assigned responsibility for each patient.

After analysing all the problems from the record review as well as relying on undocumented information of current problems, four main areas of change were identified.

These were;

1. Greater structure of the clinical team with clearly assigned responsibility for individual patients and tasks.
2. Checking of the pre-assessment process with use of checklists and cross checking by review of cases by registrars.
3. Changes to the discharge process and increased discharge information to GP's and in the notes.
4. Increased structure of inpatient care with changes to post-take and general ward rounds, existing plans for changes to HDU care and the departmental business meeting on Monday morning.

The final document with details of the accepted plan for change can be seen in appendix E.

These changes were presumed to address the contributing factors to the adverse events and critical incidents detected outside of the operating theatre.

These were particularly poor team work, lack of attention to detail, failure to follow protocols and lack of leadership and ward based supervision of junior staff. Other changes were also discussed but rejected due to logistical constraints or failure to reach agreement between the consultants.

Chapter 11

11. The wider impact of Real-Time Record Review

11.1 Introduction

The central aim of this thesis is to develop a method of record review which can be carried out locally involving clinicians to identify adverse events and critical incidents in patient care. Previous chapters have described how the methodology was developed, tested and refined. This chapter describes how both the methodology it self and the work of the thesis in general has had an impact outside the immediate research group. The first section will describe the impact and wider use of the methodology itself where as the second section will look at the capacity which has been built as a result of the work conducted for this thesis.

11.2 Wider use of real-time record review

The crucial test of this methodology is to determine if it can be used without ongoing support from the author of this thesis and to assess if the methodology is transferable to other healthcare settings. A small study was set up to formally test this. The Clinical safety Research Unit was contacted by a surgeon, Dr Pardo from Complejo Hospitalario De Ciudad Real, who was interested in evaluating the safety of his hospital's general surgical service. After initial talks collaboration was established on a study using the methodology of real-time record review.

11.3 Method

Design

The review process in this study was a single stage process without screening. Nurses and surgeons together reviewed all consecutive discharges. Data collection was prospective at the time of discharge. Case records were assessed for adverse events and critical incidents.

Setting

The study was set in the general surgical service of a large district general hospital in the Ciudad Real, Castile-La-Mancha, Spain. The service provided all aspects of general abdominal, breast and endocrine surgery and surgical staff consisted of 13 fully trained specialists and 1 higher surgical trainee at registrar level. The data collection took place during a moderately busy period during the summer.

Ethics

The risk management department and the head of the surgical service approved the study. In line with other such studies patient consent was not required. Information on all adverse events was shared with the head of the local risk management departments so that action could be taken where needed.

Patients

At Complejo Hospitalario the surgical unit take over care from the medical teams once a decision to operate has been made. Therefore very few patients were admitted to the surgical service without having an operation performed.

The local clinicians decided to include 110 consecutively operated patients in this study. A formal calculation of sample size and power calculations were not undertaken. The sample size was decided locally as the maximum number of patients which the clinicians would be able to assess the case records of. Engagement in the process of evaluation of care was deemed more important than strict statistical significance in order that such work will stimulate improvements of care. All patients were over the age of 16.

Data collected

The data was collected using a Spanish translation of the second stage review form used in study 1 of this thesis (see appendix A and F). All cases were reviewed and data on patient demographics collected for all patients. The reviewer then made an assessment of the presence or absence of adverse events and critical incidents. In cases where a critical incident or adverse event were detected, further information was collected including the stage of care of the event, the nature of the event, contributing factors and possible ways of preventing similar events in the future.

Training of reviewers

The reviewers were trained during two 3-hour sessions lasting 2 1/2 hours partly in English and partly with real-time translation by Dr Pardo. All teaching materials and review tools were translated into Spanish. The teaching program was a precursor to that developed and tested in chapter 8. Additional time was spent on training to compensate for the language barrier.

Procedure

The author of this thesis visited the hospital for 2 days to assist with the set up of the study and to teach the reviewers. Medical and nursing notes were filed and kept separately; the nursing notes were therefore reviewed by nurse reviewers and the medical notes by surgeons at the same time. Any identified or suspected adverse events were discussed between the nurse and surgeon reviewer of the case. After the site visit and training, the local clinicians decided to only look for adverse events and not include critical incidents in the data collection to reduce the workload for reviewers.

11.4 Results

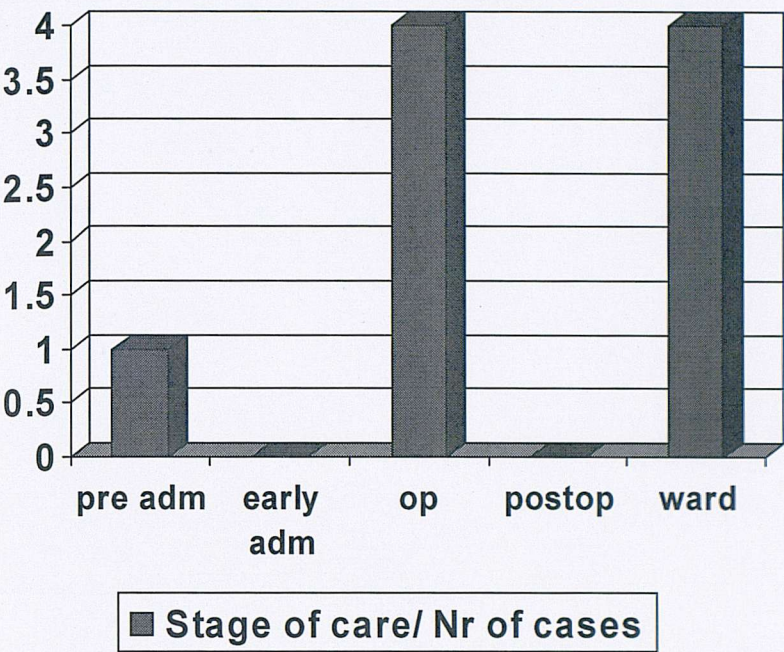
Although data was collected on demographics this will not be presented here as the aim of this section is to look at the feasibility and impact of the methodology in a separate healthcare setting.

Clinical findings

The reviewers found 9 adverse events in 110 consecutive patients. The rate of adverse events was 8% (95% CI 4%-15%).

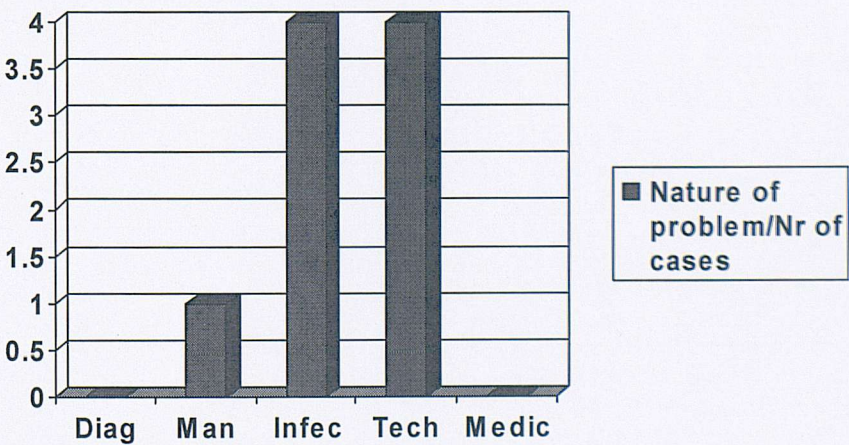
Examples of adverse events detected included bile leak following laparoscopic cholecystectomy and wound infections after elective surgery. The adverse events predominately occurred during operative procedures and during ward care.

Fig. 11.1 Stages of care of adverse events



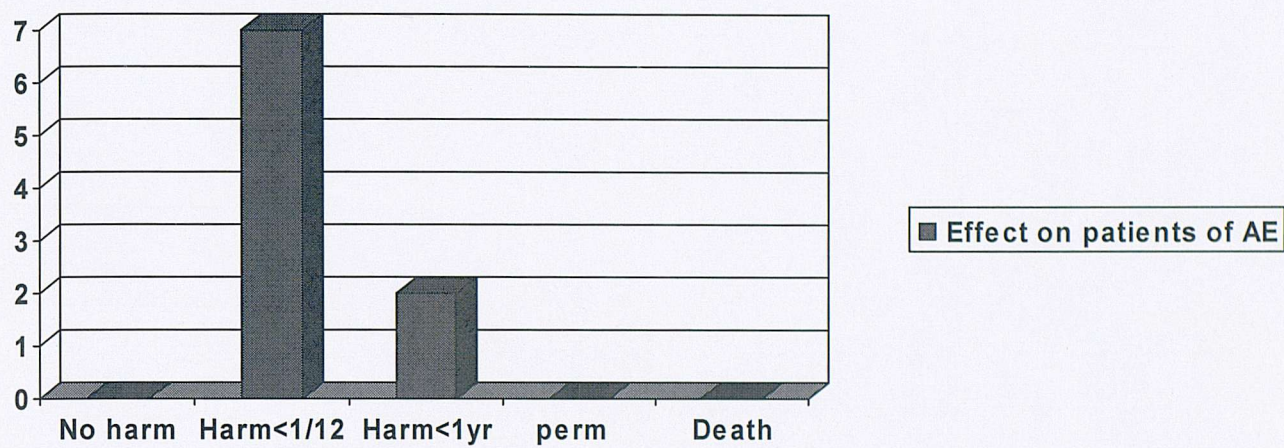
The types of problems were mainly technical or related to infection. All the infections identified were surgical site infections some of which required readmission and re-operation. See fig 11.2

Fig 11.2 Nature of problems of adverse events



None of the patients suffering adverse events died, but 7 patients suffered disability lasting up to one month and 2 impairment or disability lasting between one and six months.

Fig 11.3 Harm to patients from AE



Of the 9 patients who suffered an AE, 2 needed readmission and 7 had their admission prolonged.

Impact of study

Following initial scepticism particularly from the older surgeons, the clinicians of the service became interested in participating in the study and amongst the younger surgeons of the unit there was a genuine belief that it was important for surgeons to engage in patient safety. The younger surgeons, who acted as reviewers in the study, all recognised the potential for error in their work and many remarked on how examples of the AE included in the review training sessions had recently happened to them individually or within the service in general. The findings of the study were discussed in a general meeting of the unit attended by all staff. In particular the high rate of infections received a large amount of attention. It was decided that action was required and a plan was

made to try and reduce the rate of surgical site infections in collaboration with the infection control department. This resulted in the surgical department promoting hand-hygiene and the introduction of alcohol hand cleaning gel in all patient rooms and compulsory use of this on all ward rounds before and after seeing each patient. The hospital where the data was collected was due to be replaced by a new building at a separate site. Any further outcome and action arising from the study are to be discussed once the move has been completed.

Even six months after the completion of the data collection, the attitude to patient safety remains changed in the unit. In the words of Dr Pardo:

“Without any doubt the people involved in the study has changed their point of view related to patient safety. Risk management related to surgical complications, communication with patients and relatives, technical errors is now one of the common topics in our daily sessions. We now talk in an open way in most of the cases.”

Comment

This study shows that it is possible for clinicians to carry out this type of assessment of care independently and that the results are both trusted locally and can lead to action. The data collection was completed on 110 patients. Although the rate of 8% is lower than one might expect from UK and international data, the reviewers were clearly able to identify errors in their own practice. The reviewers found mainly problems with wound infections and technical problems during procedures but no problems of diagnosis and only

few problems with ongoing monitoring and management. This may reflect the true profile of adverse events at this site although it is different to that found at the 2 UK sites. The patient population was different with all of patients undergoing an operation, HDU post operative care was delivered by intensivists on a separate unit, surgical care was consultant led with consultants being resident on-call 24 hours/day and with a daily consultant ward round of all inpatients. It is also possible that despite training, the reviewers, like the clinician reviewers of study 1, did not focus on problems not directly related to operations.

There is however little doubt of the wider effect this study has had on the clinicians of this service. The involvement of both surgeons and nurses from the service ensured involvement and engagement in a patient safety initiative not previously seen in this service. Patient safety and risk management as topics were given a direct relevance to surgeons. The most important outcome was the changes made to hand-hygiene practices as a direct result of this study. During the site visit to set up the study I was invited to attend a ward round where I remarked on the fact that no member of staff cleaned or washed their hands in between patients even when examining wounds. When it was mentioned that this would not take place in the UK due to our problem with MRSA, it was shrugged off by the surgeons as they did not perceive their hand-hygiene practice as having an impact on patients. After the study this view was clearly reversed and action was taken. This is a powerful example on how data collected and owned by the surgeons are more likely to lead to change than advice and directives from outside the unit.

11.5 Wider impact of the work of this thesis

The methodology has been shared with and adapted in various ways in NHS trusts in the UK as a result of the training days and presentations at conferences such as the 9th European Forum on Quality Improvement in Healthcare 2004, ISQUA conference 2005, NPSA Patient Safety 2004 and 2006 and Risk 2005. Representatives from more than 10 acute care trusts have received additional material and advice in setting up period record review in their service. Some have been interested in periodic continuous review, other in using the review form and training materials to conduct reviews of deaths or other highly selected cases and some doctors have been interested in using the methodology for self assessment of their complications to understand the caused of these and for use in peer appraisal.

As a result of the work conducted in this thesis I gained a deep understanding of the methodology of both retrospective record review studies and the practicalities of organising and managing record review studies. The training program did not only reach clinicians from many different NHS trusts, it also helped me to further develop my teaching ability. These perhaps softer outcomes of this thesis have allowed me share this new-built capacity in a number of concrete ways. In addition to playing a central role in designing and co-supervising the NPSA backed study mentioned in chapter 9, I have also made significant contributions to two projects which will be described below.

Pilot study to determine the rate of adverse events in Scottish hospitals

I was invited give an introduction to record review, train reviewers of the study and later to act as technical advisor to an initial pilot study to assess the rate of adverse events in Scotland. The pilot is conducted at Aberdeen Royal Infirmary and led by Dr David Williams and Dr Brian Cuthbertson. The study was designed prior to my involvement. My role in the study has been to provide formal training of nurse and doctor reviewers, act as final expert reviewer in difficult cases, provided additional validation of all adverse events detected and to ensure the methodology is sound. In addition to this I have supplied all review and training materials as well as the database for analysis and will be carrying out this analysis. The review is close to completion and will be followed by publication.

World Health Organisation – World Alliance for Patient Safety

Dr Ross Wilson lead clinician from the Quality of Australian Healthcare Study invited me to co-chair and deliver a 5 day regional WHO workshop for 9 countries from the Middle East and Africa. The aim of the workshop was to teach and enable delegates from 9 developing countries to set up and conduct studies using retrospective record review to determine the scale of harm arising from health care. The workshop was organised by and held in the Eastern Mediterranean Regional Office of the WHO and was supported by the World Alliance for Patient Safety and WHO Geneva. My responsibility was to deliver an overview of record review methodology, support development of project management teams and to train delegates who would act as reviewers. This project is ongoing as is my involvement and will be followed up by 2 further

workshops to support the ongoing studies and to supply assistance with interpretation of results including action planning. In addition to my involvement on the workshops, I have also redesigned the review tools and manual used in the original QAHCS for use in this context and will be acting as technical advisor providing technical advice to individual countries as needed during their studies. The results of the individual studies will be shared with the supervision group who will be publishing both the methodology and the aggregated findings. This larger study will have implications beyond the participating countries as this is the first time studies to determine the rate of adverse events have been carried out in developing countries. The findings will influence the focus of patient safety in developing countries and capacity has been built in the participating countries to support further studies in their region.

11.6 Conclusion

The work of this thesis has had a number of outlets both in terms of direct use of the methodology and training programme developed but also in terms of the capacity build for patient safety and record review study. Further work of record review in developing countries is planned. The next challenge will be to build on the experience of involving clinicians and looking at cases in real-time in larger scale studies as this will be of particular use in record-poor settings.

Chapter 12

12. Discussion and conclusion

12.1 Introduction

Surgery has a strong tradition of professional self-assessment stemming back to the work of Codman in the late 19th century. In the UK this has developed into the current practice of auditing specific elements of care and outcome. There has been a growing general agreement that there is a high frequency of error in medicine and the need to study the frequency and causes of these to reduce avoidable harm to patients. This has largely been born out of developments in other industries and is slowly beginning to take root in surgery. Despite this recognition and acceptance of error it has been difficult to engage individual clinicians in measurement and analysis of their own practice.

Chapter 2 illustrates how there are different methods for identifying adverse events and critical incidents in hospital care. All have their own benefits and weaknesses in terms of cost, work involved and spectrum of events identified. Incident reporting systems are relatively low cost to maintain once instigated but information on details of contributory factors and preceding events, important for understanding of problems and future prevention, is often lacking in such systems. National surgical mortality reviews such as NCEPOD and SASM have succeeded in engaging the surgical profession in review of deaths and has led to changes in working practices. The limitation of these audits is that they only look at patients who have died and predominantly after surgery. In the case of NCEPOD not all deaths are included in the audit and the local learning from the

audit is not assured. Local morbidity and mortality meetings have the potential for detailed discussion of adverse outcomes. Often however these review only a fraction of adverse events with an emphasis on serious rare cases rather than the common minor events that are the main source of patient harm. Prospective observation for identification of adverse events has the advantage of being able to integrate several data sources such as staff interview, observation of care delivery, case notes, staff meetings and ward rounds. But this is costly, labour intensive and suffers logistical difficulties.

Record review has been used as an epidemiological tool for estimating the incidence of adverse events in several countries. There has however been strong criticism of the traditional methodology of retrospective record review and despite repeated efforts to improve the reliability this remains as only fair for most studies. Retrospective record review has also suffered limitations of relying solely on information recorded in the patient records and has been relatively costly to do at a large scale. There have however been recent interesting developments to improve the methodology by moving away from a reliance solely on the medical record as the source of information to involving clinical staff in detection of adverse events with improvements in the reliability as a result.

These findings led to the development of the present method of detecting adverse events and also critical incidents. The requirement of this method was that it should build on the surgical tradition of peer assessment and audit and should therefore include surgeons in the data collection. Record review was

identified as a validated research methodology for detection of adverse event. Furthermore some of its weaknesses could be addressed by involving clinicians and by refinement of the review process.

12.2 Summary of Findings

The traditional method of retrospective record review was adapted from a research methodology of retrospective audit to use by clinicians in real time. This method was tested and the results are described in detail in chapter 5. This study collected a large amount of data on a total of 134 patients. Clinicians, both doctors and nurses worked successfully together to review the records of patients they had cared for. The rate of adverse events was 14% of which 64% were preventable. A critical incident was detected in the care of 15% of patients, 96% of which were preventable. The majority of both AE and CI related to non-operative aspects of surgical care. The data collected was presented to both the staff involved and to the Hospital staff in general at a Grand Round attended by more than 150 members of staff. However it did highlight some weaknesses in the methodology which required further work. These were mainly issues concerning the need for systematic training clinician reviewers, the feasibility of participation of clinical staff with multiple other duties and simplification of the review, data entry and analysis process. In addition it was not possible to assess reliability in terms of inter-rater reliability in this initial study because of the differences in time available between registrars and the expert and the limited training provided to the registrars. Discrepancies between the findings of the two types of reviewers did however highlight the need for a formal reliability assessment of further developments of the methodology.

Chapter 7 look at 3 different methods of detection of adverse events and critical incidents to evaluate if real-time record review can identify adverse events and critical incidents not highlighted by existing systems. Each of the methods examined have strengths and weaknesses. Record review provided a fuller picture of problems across all aspects of care but in a snapshot of time. The data were however rich and include information on contributory factors taking the whole system of care into consideration in contrast to incident reporting and ongoing pharmacist surveillance of medication errors.

The need for training was addressed in chapter 8 by the development of a training programme for clinicians to carry out real-time record review. This training program was evaluated and it was found that the principles of record review with extraction of information from clinical cases and determination of AE/CI and preventability can be successfully taught to and carried out by clinicians. It is possible to achieve acceptable review performance after only very brief training designed to suit the busy schedules and conflicting pressures of practicing surgeons.

Chapter 9 describe the development of a computerised review interface and direct data entry system for use in record review for detection of AE and CI with the aim of improving safety in surgery. Although the need for some minor improvements was identified, it was successfully used to review 220 case records in a study by an independent reviewer not involved in the development of this methodology or review interface. The inter-rater reliability in a small sub

sample of case notes was good for case classification and agreement on preventability, stage of care and nature of problem was satisfactory.

Chapter 10 brought together the improvements made to the methodology of real-time record review and tested these in a clinical setting with involvement of surgeons. In addition to this it addressed the issue of carrying out review of a very select group of cases and the feasibility of clinician involvement in real time record review.

12.3 Development of the methodology

The main focus of this thesis is the development of a methodology for detection of both adverse events and critical incidents. There are a number of new developments in real-time record review as developed in this thesis.

Involving local clinicians in review of care

Firstly review is carried out near or at the time of discharge by the clinicians from the team caring for the patient possibly supported by an external reviewer which could be from within the safety and quality or risk-management unit of the hospital. Involving clinicians in all or part of the review allows for information not recorded in the case record to form part of the review. It also engages the clinicians in a patient safety initiative and provides them with ownership of the data and greatly enhances the possibility of further engagement in safety improvement.

Widening the scope – Inclusion of critical incidents/potential for harm

A further advance made in this thesis is the identification of critical incidents, which did not result in actual harm to patients but where there was potential to do so, as part of record review. By including critical incidents in the review clinicians can address a wider range of problems in their practice than if they concentrated solely on AE. CI and AE may share the same characteristic or they have different profiles such as seen in the study described in chapter 10. Critical incidents per definition all have the potential to cause harm and addressing these as well as actual harm raises the possibility for proactive rather than simply reactive change.

Focus on collecting data on which to base improvements

This methodology also goes further than traditional record review in analysis of detected AE/CI by systematically classify the stage of care, nature of problem and factor contributing to AE and CI. This part of the thesis builds on the work started by Woloshynowych et al. When the Modular review form for this work was adapted the focus was on simplifying the form where possible and to exclude data which was unlikely to be useful locally for making change. In addition to this new data fields were added with particular relevance to surgery such as the BUPA classification of complexity of surgery and ASA scoring of the patient. Data was specifically collected on the seniority and supervision of staff involved in AE and CI as was data on the type of day and type of operating list on which procedures were carried out.

Electronic review interface

The methodology of real-time record review was designed with a view to creating a method which could become part of the usual audit and self assessment of surgeons and be carried out periodically. It became clear after the initial study that a paper based review form with the need for extensive data transfer was a hindrance to regular use because of the workload involved and the potential for data loss and transcription errors. This led to the development of a computerised review tool and data entry system to simplify the review process and aid analysis. This system has been successfully used to carry out review, record and analyse the findings of over 325 records. The interface was generally well received. There are however some problems with the interface which would need to be resolved before it is suitable for wide distribution. In addition to the technical problems described in chapter 9, it would be beneficial to revert to a 6 point scale for healthcare causation and preventability to follow the already validated scales used in RRR. A restructuring of the free text fields would also be useful to ensure both an adequate narrative describing the case and the problem detected as well as avoiding the impression of needless repetition of information. It would also make any data mining of free text narratives easier to have this collected in one part of the database. These and other possible developments of the EMRF are unfortunately outside the scope and funding of this thesis but would be warranted if there were a desire for this method to be used widely.

Training in record review

A major output from this thesis other than the methodology and EMRF for RTRR is the training program developed for clinicians in record review. The evaluation of training showed that at the end of training clinicians with no prior experience of the definitions of AE and CI were able to correctly classify these in 67.5% of cases and reach the correct assessment of preventability in 79% of cases. These results from complete novices in this field after only 3 hours of training are very encouraging and compare well with the findings of large studies of RRR where reviewers have typically been trained over a longer period of time or on 1 or 2 week residential courses. In these studies reviewers have reached agreement of the presence of an AE in 75-85% of cases and on preventability in 58-80%.

12.4 Discussion of methodological issues

Screening and selection of cases

The screening approach undertaken in the initial study mirrored that of traditional record review and its purpose was to select cases with a high likelihood of AE or CI for full review by a doctor. This type of screening was found to be very sensitive to AE and somewhat less so to CI. This approach selected about 40% of the total number of cases for clinician review. It was found in study 1 that the time spent on screening case records without AE or CI was equivalent to the time it took SpRs to review these and as such the screening process was not cost effective. Traditional screening however has the benefit of involving several members of the clinical team in the review process thereby making it a multi disciplinary team effort and also gaining information of

unrecorded care problems from the screeners. Screening for critical incidents has not previously been assessed for the screening criteria used in study 1 (chapters 5-6) which were developed to identify adverse events and not critical incidents. This method does not screen specifically for critical incidents and it can be seen from chapter 10 that when screening criteria are further tightened the number of critical incidents that are detected are reduced. Critical incidents are in this thesis seen not so much as a main outcome measure but as an additional learning opportunity for the clinical team on which data should be collected in records reviewed for adverse events. The absolute validity and reliability for detection of critical incidents by RTRR is lower than that for adverse events as seen by the results of this thesis.

The time commitment needed for carrying out review of unscreened cases has been raised as a potential problem. This led to the investigation of the amount of data a unit could get from carrying out review of only a very limited number of cases in chapter 10. It is clear from this comparison that the limited screening criteria of death, ITU/HDU care and prolonged stay of 14 days or more were good at selecting cases with adverse events in this study. In only 14% of the cases from the unselected review were 67% of all adverse events, however only 32% of the critical incidents were found in this selected group. The distributions of nature of problems of the AE and CI identified were remarkably similar in the 2 data sets. The review of the selected cases took only 6 hours in contrast to the total review time of 26 hours for review of the unselected cases. The main problem with highly selected record review is that it is not possible to determine the rate of either AE or CI. This makes it difficult to track

improvements over time. Another potential problem of highly selected review is the smaller proportion of critical incidents which may lead to an incomplete picture of the safety and quality problems of the service.

Clinician and external reviewers

Both the study described in chapter 5 and that in chapter 10 explore the different findings of external reviewers and clinicians from the teams involved in the care of patients included in the review. In the first study the clinician reviewers found about half of the adverse events and one third of the critical incidents which were detected by the external reviewer. The SpRs did not detect additional AE or CI. Furthermore the type of problems they described were largely technical problems and what might be seen as traditional “surgical complications” such as post operative bleeding and post operative infections. These clinicians had received only limited training in the review process which may have accounted for at least some of this disparity. Interesting in the later study where the SpR reviewers had received formal training, they detected nearly as many AE and more CI than the external reviewer. Another notable difference is that the SpR reviewers in the later study detected care problems in all categories of “stage of care” and “nature of problem” where these were detected by the external reviewer. Although there was poor agreement on the individual CI detected, the overall themes of care problems were the same for SpRs and the external reviewer with the majority relating to medication errors, diagnosis and ongoing management and monitoring. Although the number of cases is small, it seems that with appropriate training the detection rate of AE and CI and the findings of the SpR reviewers are comparable to those of the

external reviewer. It is unfortunate that only a small number of reviews were carried out by registrar reviewers in the later study due to logistical influences outside the investigators control. With training and motivation clinician reviewers can detect and describe a range of care problems to shed light on current safety problems in a surgical team.

The inter rater-reliability of the EMRF was assessed in Chapter 9 by 2 independent fully trained external reviewers so that record review was assessed without influence of differing background knowledge of the cases. The overall inter-rater reliability of determination of AE and CI was found to be good to excellent where as the inter-rater reliability of preventability was moderate. These findings compare well with published reliability rates of larger series of retrospective record review using traditional review tools.

Training in record review

The evaluation of training showed that clinicians were able to correctly classify 67.5% of cases summaries and reach the correct assessment of preventability in 79% of cases summaries. Although one cannot directly compare review of case summaries and actual full length care records there are parallels to the findings of reliability assessment of record review. In traditional record review, reviewers have reached agreement of the presence of an AE in 75-85% of cases and on preventability in 58-80%. Although one cannot directly compare inter-rater reliability between trained reviewers and newly trained clinicians against a gold standard review, the results after the training study are good. The agreement on the type of event (No Problem/AE/CI) in the case of record

review taught in the context of this thesis, is more complicated as there are 3 possible options (CI, AE or No problem in care) compared with traditional RRR where there only 2 possible outcomes (AE or no AE). Agreement on preventability has traditionally been lower in RRR studies and the results from this training exercise compare very favourably with these.

A very interesting finding from evaluation of the training programme was that nurses provided effective and accurate review of case summaries for the presence of AE/CI and to evaluate preventability. Many of these nurses had current jobs in risk management which may have influenced this result. This finding may never the less open the possibility for training nurses to carry out record review perhaps as independent reviewers from within hospitals where RTRR is carried out by clinicians.

The development of training was greatly influenced by the conflicting pressures of needing to ensure adequate training to get meaningful results whilst making this as brief as possible. There was a constant friction between the need for a program which was realistic in a local clinical setting and the need for reliability and consistency of the data. The aim was to provide data which is accurate enough to be trusted locally and to provide a stimulus for improvement of care. There are no claims that this is the best possible training course in record review but it has been shown to be effective and is of a short enough duration to be compatible with attendance by busy clinicians.

Limitation of real-time record review

The limitations of this methodology lie in the difficulty in engaging practicing surgeons in carrying out this type of audit as assessment of safety of care. Training and supervision of surgeon reviewers will affect the validity and reliability of the results. If this type of work is seen as an unwanted additional workload then the reviewers are likely to be less thorough in their reviews of case record and likely to miss important facts. If reviewers are not trained sufficiently they are more likely to be influenced by their own biases and impression of the standard of care or wrong interpretations of the key definitions in the review methodology.

12.5 Implementation of real-time record review

One would expect frontline healthcare workers to be able to identify and respond to failures and errors in provision of healthcare. This principle lies behind the hypothesis of this thesis and the results of the studies in chapter 5, 10 and 11 supports this hypothesis. The next natural step in improvement of patient safety is the ability of clinicians and the wider healthcare organisation to use this information to create change. A traditional barrier to change as a result of casually observed failures have been pointed out by Edmondson and Tucker (Tucker 2003). The culture of healthcare which encourages healthcare professionals to take personal responsibility for standards of care also encourages the healthcare professionals to solve problems in care delivery as they occur with the common result that these failures are “patched on the spot” but without alteration of the underlying processes that led to the failure. RTRR provides the opportunity to address more than the immediate cause of care

problems a chance to address the underlying process to prevent similar problems in the future.

To maximised improvement of care, cooperation between frontline clinicians, doctor- and nurse-managers and the wider organisation must be in place (Tucker 2003). Barriers to change can be found at different stages of the healthcare system at the level of the patient, the individual healthcare professional, the healthcare team, the healthcare organisation or the wider political environment. Although not all of these levels are important to all change-initiatives, it is important to keep this perspective in mind. Evidence has shown that a combination of interventions addressing specific barriers to change is more effective than simple interventions (Grimshaw 2002). This is partly to overcome some of the cultural barriers to change which exists within the NHS part of which is a strong resistance to what is perceived as external pressure for change and separate subcultures amongst clinician's and managers (Davies 2000). Strong support of patient safety improvement from clinical and managerial leaders improves the likely success of any changes made as a result of RTRR. Clinicians led initiatives are more likely to succeed on the ground but to have wider success managerial support is needed to tackle the underlying process that lead to these. Where the clinical culture has traditionally focused on the responsibility towards the patients in their immediate care, management culture is focused on corporate responsibility both to all patients of the organisation but also for organisational government and budgets (Davies 2000). As RTRR identifies AE and hereby also some of the financial implications in terms of prolonged admissions and readmissions and well as

potential liability for claims for preventable adverse events, it provides information which may satisfy both clinical and managerial culture in order to stimulate organisational change.

Engagement needs to be driven from the top of the institution or department undertaking RTRR. A real engagement of consultants, rather than just passive acceptance, is essential to motivate their juniors to embrace the review process. The experience from the units participating in this thesis is that provided the reviewers are supported, they will soon see the value of the review process and appreciate the learning they receive from this.

The difference in time needed to carry out review of unselected cases over a period of time such as one month compared to review of highly selected cases such as death, prolonged stays or other criteria aimed at addressing a local problem is an important question in terms of local implementation of this type of review. This significant time difference means that review of selected cases can be fitted into the usual busy work schedule without specific of time allocation for this over a period of time where as review of continuous cases would take up half a session per day over the same period. It may be that well staffed or less busy units would be able to carry out unselected review where as units working to or beyond capacity could still benefit from this type of review but would at least initially be forced to look at a smaller number of cases. The choice of approach may also be made depending on the aim of the review exercise. One unit may have a particular problem with HDU care and may therefore wish concentrate of patients coming through this type of care. Other units may feel

they have more general problems which are perhaps harder to define and would therefore benefit further from reviewing all cases over a period of time. There is a place for both approaches but the constraints and limitations of each should be appreciated.

Implementation of traditional screening for 15 criteria for wider use of RTRR is likely to prove difficult due to the need for involving additional nursing or junior doctor staff. Its benefit is likely to be outweighed in the current UK context of a RTRR in a surgical service where case records are removed early from the ward for coding to ensure payment by results and where nursing is commonly understaffed often dependent on agency workers. Junior doctors' availability for screening is limited by shift work and falling numbers of SHOs as a result of the reforms of medical postgraduate education. In this reality it is very difficult ensure prompt detailed screening of records for the 15 screening criteria used in this type of screening. The delay introduced by screening before review is very likely to result in the notes not being available in a large number of cases.

The question remains if this type of review should be carried out under external supervision with independent review of cases by an external reviewer. The answer to this will depend on the purpose and circumstances of the review. Record review for use within the department assessed need not have an independent assessment of the quality of the review provided the reviewers are adequately trained. One would expect integrity of the reviewers and that these would not deliberately hide or distort events. If the unit is concerned with the reliability of the results then all or a sub-sample of the cases could be reviewed

independently by 2 clinicians. This type of review by clinicians is not intended to provide a comparison between units or teams. If the data is to be used outside the clinical team where it is collected then an independent double review is needed on at least a sub-sample to ensure the reliability of the data.

Ownership of data has proven an important factor in provoking change on both chapter 10 where the problems with the organisation of the clinical team was appreciated by some consultants but denied by others and in chapter 11 where an external assessor's comments on poor hand-hygiene were dismissed until local data collection highlighted the problem. In both cases ownership of data highlighting an organisational problem and the resulting clinical issues led to the clinicians feeling they owned the problem. Adult learning theories consider that people need to experience problems first hand before they are motivated to change (Grol 1997, Grol 2003). Having experience the problem changes are most effectively implemented if clinicians themselves reflect upon and discuss solutions based on evidence. Interventions based on individual obstacles experienced locally seem to be more effective than interventions that are not, this was one of the main conclusions of Grol's major review of transfer of evidence into practice published in the Lancet in 2003. These theories support the likely benefit of the approach of RTRR and the value of engaging clinicians assessing and improving patient safety.

A key point of involving surgeons in this type of review is to promote ownership of the results and belief in the data by the clinicians. In the studies in this thesis it was found that once clinicians had documented care problems as part of the

review, it created a sense of responsibility for change. This was felt by particularly the SpRs as both a duty to improve patients care where possible but also a necessity as they felt that they would be vulnerable in the case of future complaints from patients experiencing harm from recognised problems unless they could prove that action had been taken to improve the systems of care. For these reasons it is imperative to involve clinicians in the review of if not all cases then at least in some to create ownership of and trust in the data.

12.6 Implications for further research

Further validity and reliability assessment of clinician review

Review by SpRs of all included case records was part of the original protocol and agreement with the surgical unit participating in the study described in chapter 10. Unplanned staffing changes at both Consultant and SpR level however meant that this was not possible. Further research is warranted to explore further if proper training in record review will improve the reliability. This can be done by fully trained clinician led real-time review of cases with blinded independent experienced external double review for full validation of clinicians findings and to further explore differences in number and types of events detected from the medial records and those identified from clinicians with additional insight in unrecorded aspects of the case. Such study should ideally also included all or at least a proportion of the case records undergoing double review by clinicians to look at inter-rater reliability at clinician review level although some variability may be expected here as a result of varying degrees of knowledge of unrecorded care.

Further development of the electronic review form

The changes previously mentioned to the EMRF should be instigated, namely changes to the free text fields on the second screen (description of AE/CI) and re-introduction of the 6-point confidence scale of healthcare causation and preventability. The current reports should be developed to be easier to carry out and interpret with clearer labelling of categories and findings. Following these changes the form should be revalidated in its new form.

Changes to classification of care problems

Further changes may be in the future be carried out looking into a clearer classification of the “nature of problems” as the current classification contains a mix of immediate failures and final outcomes of AE and CI and it has not been possible to get good agreement on classification on nature of problem. This classification has however been extensively assessed by Woloshynowych and colleagues in the past and any redesign would require thorough re-evaluation.

Development of a manual in Real-time record review

If this methodology is to be used extensively by independent units wishing to carry out self assessment of adverse events and critical incidents in their care then a formal detailed manual should be produced. This should contain details of the methodology of real-time record review and should ideally go along with the training course.

12.7 Discussion of implications of real-time record review and thesis

Implications for clinical practice

Changes planned or made as a result of RTRR have been described in chapter 10 and 11. Chapter 11 highlights the importance of clinicians' trust in and ownership of the data to drive change. Changes to hand hygiene practices were made only after completion of the review and not as a result of comments on the problem by an outside safety expert. This is a powerful example of how data collected and owned by the surgeons is more likely to lead to change than advice and directives from outside the unit. The concluding part of chapter 10 describes how the findings of RTRR in the unit led to a, previously absent, willingness to examine and change the team organisation. In addition to this it was also planned to adopt proven safety practices such as check-listing and cross-checking which have been developed in other industries. Again in this unit it seemed that change was driven by a trust in the results of RTRR as a true picture of the problems of the unit which had not previously been appreciated by all of the consultants in the unit. It becomes very difficult not to act on what is perceived as valid and reliable data. What these changes are and how they should be implemented is up to the individual unit or hospital instigating RTRR and should be based on their findings and local systems. RTRR merely serves as a mirror to reveal problems and provide actual data on these.

Wider implications for methodology developed

I will continue to work towards the wider use of the methodology of real-time record review used as part of a portfolio of audits and safety initiatives undertaken in surgical units. This will be done through publication of this work (one paper under review and a second paper is under preparation), through

continued presentation of the methodology at both scientific and educational meetings and through ongoing contact and support to NHS trusts already or interested in using this methodology. In addition lobbying has already resulted in meetings with representatives of the UK Department of Health, the General Medical Council and the Healthcare Commission. For the wider use of this methodology the most likely successful avenue is gradual spread of the methodology through direct contact with interested organisations as already started as a result of the training dates mentioned in chapter 8 and feedback from presentations at meetings. It is intended that RTRR can be carried out periodically in units to survey and describe current safety problems. This will require strong and active leadership by the consultants in charge of the units and higher surgical trainees should carry out the review of case records. Using SpRs as reviewers has the advantage of these usually spending only one year or less in the unit and therefore may see problems with “fresher eyes” than staff who have been in the unit for a long time. The exposure to this kind of patient safety initiative during training could also make future generations of consultant surgeons more focused on patient safety and potential problems in the systems of care in their own practice.

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Appendix A

A.1 Real-time Record Review Modular Review Form – RTRR MRF

CONFIDENTIAL

MODULAR REVIEW FORM (MRF2)

for

Retrospective Case Record Review

Directions:

1. Complete stage A in full
2. Complete stage B in full
3. Complete the relevant subsection(s) in Stage C (as identified in A7)
4. Complete the relevant subsection(s) in Stage D (as identified in Stage C)
5. Complete stage E in full
6. "AE" means adverse event
7. Please print or write responses or notes legibly
8. Please return this form to the team leader on completion
9. A manual is available with definitions

Stage A PATIENT INFORMATION AND BACKGROUND TO ADVERSE/ CRITICAL EVENT

A1 REVIEWER INFORMATION

Date of Review:

d	d	m	m	y	y

Reviewer ID Number:

--	--	--

Time Commenced Review:

--	--	--

Case Number:

--	--	--	--

Time Review Finished:

--	--	--

(use 24 hour clock)

A2 PATIENT INFORMATION

Patient's age:

--	--	--

Sex: M/F

--

Pregnancy: Yes/No

--

Date of Admission:

--	--	--	--	--	--

Date of Discharge:

--	--	--	--	--	--

or Date of Death

d d m m y y

Degree of emergency at time of admission

☐ 1 Critical (life at risk)☐ 3 Semi-urgent☐ 2 Urgent (emergency)☐ 4 Routine (non-urgent / waiting list)

A3 NATURE OF ILLNESS

Primary diagnosis

Prognosis from the primary illness? To answer tick relevant **Yes** or **No** responses to 3A, 3B and 3C**3A** Complete recovery back to patient's normal health ☐ **Yes** ☐ **No**If **yes**, then complete recovery is:

- | | |
|--------------------------|----------------------------|
| ☐ | 1 Probable |
| ☐ | 2 More likely than not |
| ☐ | 3 Possible (20-50% chance) |
| ☐ | 4 Unlikely |

3B Recovery with residual disability ☐ **Yes** ☐ **No**If **yes**, then recovery is:

- | | |
|--------------------------|-----------------------|
| ☐ | 1 Non-progressive |
| ☐ | 2 Slowly progressive |
| ☐ | 3 Rapidly progressive |

3C Terminal illness☐ **Yes** ☐ **No**If **yes**, the prognosis is:

- | | |
|--------------------------|--------------------------------|
| ☐ | 1 Likely to die this admission |
| ☐ | 2 Likely to die within 3 month |
| ☐ | 3 Expected to survive >3 month |

A4 CO-MORBIDITIES

Please tick all of the following co-morbidities that apply to this patient or

--

No co-morbidities
Not known

Cardio-vascular

- | | |
|--------------------------|--------------------------------------|
| ☐ | Coronary artery disease |
| ☐ | Peripheral vascular disease |
| ☐ | Cardiac insufficiency or dysrhythmia |
| ☐ | Hypertension |

Respiratory

- | | |
|--------------------------|--|
| ☐ | Asthma |
| ☐ | COPD (chronic obstructive pulmonary disease) |
| ☐ | Other serious lung problem (e.g. <i>severe tuberculous scarring, pneumonectomy</i>) (specify) _____ |

Gastro-intestinal

- | | |
|--------------------------|--|
| ☐ | Chronic or recurrent dyspepsia |
| ☐ | Inflammatory bowel disease Crohn's / colitis |
| ☐ | Chronic liver disorder |

Endocrine

- | | |
|--------------------------|--|
| ☐ | Diabetes |
| ☐ | Endocrine disorder (e.g. <i>thyroid, adrenal</i>) (specify) _____ |

Neurological

- | | |
|--------------------------|---|
| ☐ | Epilepsy |
| ☐ | Stroke |
| ☐ | Parkinson's |
| ☐ | Dementia |
| ☐ | Other serious neurological disorders (e.g. <i>MS, MND</i>) (specify) _____ |

Renal

- | | |
|--------------------------|-----------------------|
| ☐ | Chronic renal disease |
|--------------------------|-----------------------|

Haematological

- | | |
|--------------------------|-----------------------|
| ☐ | Anaemia |
| ☐ | Leukaemia |
| ☐ | Lymphoma |
| ☐ | Other (specify) _____ |

Existing cancer

- | | |
|--------------------------|---------------|
| ☐ | Specify _____ |
|--------------------------|---------------|

Bone/joint disorders

- | | |
|--------------------------|-----------------------------|
| ☐ | Osteoporosis |
| ☐ | Severe rheumatoid arthritis |
| ☐ | Severe osteoarthritis |

Disability

- | | |
|--------------------------|-----------------------|
| ☐ | Wheel chair bound |
| ☐ | Blind |
| ☐ | Deaf |
| ☐ | Learning difficulty |
| ☐ | Other (specify) _____ |

Psychiatric

- | | |
|--------------------------|-----------------------|
| ☐ | Schizophrenia |
| ☐ | Affective disorder |
| ☐ | Other (specify) _____ |

Psychosocial

- | | |
|--------------------------|-----------------------|
| ☐ | Alcoholism |
| ☐ | Drug abuse |
| ☐ | Smoker |
| ☐ | Homeless |
| ☐ | Other (specify) _____ |

Infection

- | | |
|--------------------------|--|
| ☐ | AIDS |
| ☐ | Chronic infection (e.g. <i>Hep C, MRSA</i>) (specify) _____ |

Trauma

- | | |
|--------------------------|-------------------------------------|
| ☐ | Multiple Traumas (e.g. <i>RTA</i>) |
|--------------------------|-------------------------------------|

Nutritional status

- | | |
|--------------------------|-----------------------|
| ☐ | Obese |
| ☐ | Cachetic |
| ☐ | Other (specify) _____ |

Other co-morbidity

- | | |
|--------------------------|---------------|
| ☐ | Specify _____ |
|--------------------------|---------------|

Allergies

- | | |
|--------------------------|---------------|
| ☐ | Specify _____ |
|--------------------------|---------------|

A5 SPECIALTY CARING FOR PATIENT

Indicate with a tick (✓) under which specialty the patient was admitted.
Indicate with a cross (x) which specialty was responsible for the patient when the AE/CI occurred.

GENERAL

☐ 0 uncertain

☐ 1 Accident & Emergency (A&E)

☐ 2 General Intensive Care

SURGEY

☐ 3 Anaesthesiology

☐ 4 Cardiac Surgery

☐ 5 Colon/Rectal Surgery

☐ 6 General Surgery

☐ 7 Gynaecology

☐ 8 Neurosurgery

☐ 9 Upper GI/ lap surgery

☐ 10 Orthopaedic Surgery

☐ 11 Paediatric Surgery

☐ 12 Plastic Surgery

☐ 13 Thoracic Surgery

☐ 14 Vascular Surgery

☐ 15 Urological Surgery

☐ 16 ENT Surgery

☐ 17 Eye Surgery

☐ 18 Other (specify) _____

MEDICINE

☐ 19 Cardiology (incl. CCU)

☐ 20 Dermatology

☐ 21 Endocrinology

☐ 22 Family Practice

☐ 23 Gastroenterology

☐ 24 Geriatrics (care of the elderly)

☐ 25 Haematology

☐ 26 Immunology and Allergy

☐ 27 Infectious Disease

☐ 28 Internal Medicine (not otherwise classified)

☐ 29 Medical Oncology

☐ 30 Medical Ophthalmology

☐ 31 Neonatology

☐ 32 Nephrology

☐ 33 Neurology

☐ 34 Pathology

☐ 35 Paediatrics

☐ 36 Physical Medicine

☐ 37 Psychiatry

☐ 38 Pulmonary Disease

☐ 39 Radiation Therapy

☐ 40 Radiology

☐ 41 Rehabilitation Unit

☐ 42 Rheumatology

☐ 43 Other (specify) _____

OTHER

☐ 44 Dentistry/Oral Surgery

☐ 45 Dietary

☐ 46 Hospital Physical Plant

☐ 47 Midwifery

☐ 48 Nursing

☐ 49 Osteopathy

☐ 50 Pharmacy

☐ 51 Physical or Occupational Therapy

☐ 52 Podiatry

☐ 53 Support Services (e.g. transportation)

☐ 54 Other (specify) _____

A6 IDENTIFYING MAIN FEATURES OF THE ADVERSE EVENT OR CRITICAL INCIDENT

An adverse event has to fulfil all **three** criteria:

a) an **unintended injury or complication**,

b) **temporary or permanent disability and/or increased length of stay or death**

c) **caused by health care management**

a) INJURY or COMPLICATION

Was there a patient injury or complication?

☐ Yes ☐ No

b) DISABILITY / EXTENDED STAY

Did the injury or complication result in disability at the time of discharge and/or a prolonged hospital stay (or re-admission or out-patient treatment) or death?

1 Disability at discharge

2 Prolonged/subsequent stay or treatment

3 Death

☐ Yes ☐ No

☐ Yes ☐ No

☐ Yes ☐ No

c) CAUSE OF INJURY OR COMPLICATION

This question relates to circumstances that led to the injury such as a procedure or treatment that caused the injury or whether there was some omission in management or ordinary standard of care. One way to help understand this question is to consider whether the injury or complication would have occurred if the procedure had not been carried out. For example where a patient suffered a wound infection following surgery there is strong evidence that healthcare management is responsible (the wound infection would not have occurred without the surgery). Where the patient may have been predisposed to wound infections then the confidence score for will be reduced.

Was the patient's injury/complication caused by

☐ 1 health care management

☐ 2 health care management interacting with disease process

☐ 3 solely by disease process

A6 (cont.)

After consideration of the clinical details of the patient's management, *irrespective of preventability*, **what level of confidence do you have that the HEALTH CARE MANAGEMENT caused the injury?**

- ☐ 1 Virtually no evidence for management causation/system failure.
Injury entirely due to patient's pathology (no AE: then STOP)
- ☐ 2 Slight to modest evidence for management causation
- ☐ 3 Management causation not likely; less than 50-50 but close call
- ☐ 4 Management causation more likely than not, more than 50-50 but close call
- ☐ 5 Moderate/strong evidence for management causation
- ☐ 6 Virtually certain evidence for management causation

If no adverse event was identified please proceed to answer the following questions:

A **critical incident** need not lead to harm to the patient

Definition: 1. An undesirable event in the patient management, which could have lead to harm to the patient.. 2.An event during the patient management which did lead to harm of the patient but which resulted in no delay in or disability at time of discharge.

During the care of this patient did an undesirable event in the patient management occur which could have lead to harm to the patient?

- ☐ YES
☐ NO

Did an event occur during the patient management, which did lead to harm of the patient but which did not result in delay in or disability at time of discharge?

- ☐ YES
☐ NO

If the answer to both these two questions is no the review is now completed.

If an adverse event or a critical incident has been identified please complete remaining sections and continue Review

If more than one AE/CI is identified, please complete a separate form for each

A7 ADVERSE EVENT/CRITICAL INCIDENT SUMMARY

Date of adverse event

--	--	--	--	--	--

Describe AE/CI in context of overall illness

d d m m y y

Give details of the pre-admission assessment / waiting period relevant to AE/CI _____

Give details of contributory events leading up to the AE/CI _____

Give details of any key action/inaction that played a significant part in the causation of the AE/CI _____

Give details of the injury or complication caused by the AE/CI _____

Give any other details relevant to the AE/CI (e.g. time of event if known) _____

With this clinical scenario indicate, if possible, how often this sort of injury or complication may occur?

☐ 1 very rarely (<1%)☐ 3 occasionally (10-24%)☐ 2 rarely (1-9%)☐ 4 frequently (> 25%)Describe the principal problem in the patient's care that led to the AE/CI (e.g. was it a diagnostic error, technical mishap, failure to monitor, etc.)

A7 (cont.)

Identify any other problems (major lapses in care) related to this AE/CI and when these occurred in relation to the principal problem

1. _____
2. _____
3. _____

Specify the period(s) during which the principal problem in care occurred. Tick as many as apply to the principal problem. This will identify which sub-section in Stage C you will need to complete.

- ☐ **C0.** Care prior to admission to hospital (includes care and diagnosis by GP, care given in outpatients department and during previous admissions)
- ☐ **C1.** Care on admission to a ward (includes pre-operative assessment and assessment in A&E department and emergency care before full assessment)
- ☐ **C2.** Care during a procedure (including surgery and anaesthesia)
- ☐ **C3.** Post-operative care or post-procedure/High dependency or ITU care
- ☐ **C4.** General ward care (after operation; or after full assessment and commencement of medical care)
- ☐ **C5.** End of admission assessment and discharge care

Was there an error in handling the AE/CI?

☐ Yes ☐ No ☐ Not clear

If so, give details _____

A8 ADEQUACY OF RECORDS FOR JUDGEMENT OF AE/CI

How adequate were the records in providing information to enable judgements of AE?

- ☐ 1 Medical records were adequate to make a reasonable judgement
- ☐ 2 Some deficiencies in the records (specify) _____
- ☐ 3 Major deficiencies (specify) _____
- ☐ 4 Severe deficiencies, impossible to make judgements about AE (specify) _____

Stage B: THE INJURY AND ITS EFFECTS

B1 DISABILITY CAUSED BY ADVERSE EVENT

Describe the impact of the adverse event on the patient (e.g. increased pain and suffering for x days; delayed recovery from primary illness; patient not given adequate care and support; contributed to or caused death)

Please use your judgement to assess the degree of disability (tick the relevant number)
Physical impairment

- ☐ 0 No physical impairment or disability (still an AE if hospital stay was prolonged, CI if not)
- ☐ 1 Minimal impairment and/or recovery in one month
- ☐ 2 Moderate impairment, recovery in one to six months
- ☐ 3 Moderate impairment, recovery in six months to a year
- ☐ 4 Permanent impairment
- ☐ 5 Permanent nursing or institutional care required
- ☐ 6 Death (specify what was the contribution of AE to the death)
- ☐ 6.1 Death unrelated to AE

☐ 6.2 Minimal contribution from AE

☐ 6.3 Moderate contribution from AE

☐ 6.4 Death entirely due to AE
- ☐ 7 Cannot reasonably judge

B2 THE EFFECT OF THE ADVERSE EVENT ON HOSPITAL RESOURCES

Was a portion of, or the entire hospitalisation, due to the AE (including transfer to another hospital where known)

- ☐ 1 No increase in hospital days
- ☐ 2 Portion of hospital stay
- ☐ 3 Re-admission (entire subsequent hospital stay)

B1 EFFECT ON PATIENT CAUSED BY CRITICAL INCIDENT

Describe the impact of the adverse event on the patient (e.g. increased pain and suffering for x days; delayed recovery from primary illness; patient not given adequate care and support)

B3 ADDITIONAL TREATMENT AS A RESULT OF THE AE/CI

What additional *procedures* (medical or surgical procedures, including any unnecessary investigations) were performed as a result of the AE/CI?

What additional *medications* (including intravenous fluids and blood transfusion) were administered as a result of the AE/CI?

What additional *treatment* (e.g. physiotherapy, counselling) was given as a result of the AE/CI?

Stage C: PERIOD OF HOSPITALISATION DURING WHICH ADVERSE EVENT OCCURRED

Complete: Section(s) relevant to the adverse event (see A7) AND Section C6

C0 ADVERSE EVENT OR CRITICAL INCIDENT RELATED TO CARE PRIOR TO ADMISSION (Includes care or referral from GP, outpatients care and preceding hospital admissions)

When did the principal problem occur?

- ☐ 1. in primary care
- ☐ 2. during outpatient care or investigation
- ☐ 3. during previous hospital admission
- ☐ 4. problems with referral process

Who provided the initial care?
in outpatient

- ☐ 1. House officer/SHO
- ☐ 2. Registrar
- ☐ 3. Consultant
- ☐ 4. Other

Previous admission

- ☐ 1. House officer/SHO
- ☐ 2. Registrar
- ☐ 3. Consultant
- ☐ 4. Other

What was the nature of the principal problem in this phase of care (indicate as many as apply)

- ☐ 1 Failure to diagnose primary condition correctly → D1
- ☐ 2 Overall assessment → D2
(e.g. Failure to perform a satisfactory assessment of patient's overall condition including appropriate tests; No evidence of focussed assessment such as of cardio-respiratory system)
- ☐ 3 Management/monitoring incl. Nursing/Ancillary care → D3
(e.g. Failure to act upon results of tests or findings; Failure to set up adequate monitoring; Failure to provide prophylactic care (e.g. physiotherapy); Failure to provide high-dependency/ ITU care)
- ☐ 4 Infection-related → D4
- ☐ 5 Technical problem related to a procedure → D5
(including inappropriate/unnecessary procedures, e.g. urinary catheterisation)
- ☐ 6 Failure to give correct medication/maintain correct hydration / electrolytes / blood (including failure to provide prophylactic medication e.g. anti-coagulants/antibiotics) → D6
- ☐ 7 Resuscitation → D7
- ☐ 8 Other (e.g. falls; specify) _____

Were there any other problems during this period/section of care not covered by the above?

☐ Yes ☐ No

If so, specify _____

C1 ADVERSE EVENT OR CRITICAL INCIDENT RELATED TO CARE ON ADMISSION WARD (Including pre-op assessment)

When did the principal problem occur?

- ☐ 1. in A&E (accident & emergency department) before admission to the ward
☐ 2. during the pre-admission booking/pre-assessment clinic
☐ 3. during the initial ward assessment (up to first working diagnosis and initial treatment)
☐ 4. during the pre-operative assessment

Who provided the initial care?
in A&E

- ☐ 1. Casualty officer
☐ 2. A&E registrar/Staff grade
☐ 3. A&E consultant
☐ 4. Other (specify) _____

On the ward

- ☐ 1. House officer/SHO
☐ 2. Registrar
☐ 3. Consultant
☐ 4. Other (anaesthetist for pre-op assessment) _____

For patients requiring surgery, who was responsible for the pre-op assessment?

- ☐ 1. House officer in booking clinic
☐ 2. House officer on ward
☐ 3. Nurse specialist in booking/pre-assessment clinic
☐ 4. Anaesthetist
☐ 5. Other (specify) _____

What was the nature of the principal problem in this phase of care (indicate as many as apply)

In A & E or On Ward

- ☐ 1 Failure to diagnose primary condition correctly → D1
☐ 2 Overall assessment → D2
(e.g. Failure to perform a satisfactory assessment of patient's overall condition including appropriate tests; No evidence of focussed assessment such as of cardio-respiratory system)
☐ 3 Management/monitoring incl. Nursing/Ancillary care → D3
(e.g. Failure to act upon results of tests or findings; Failure to set up adequate monitoring; Failure to provide prophylactic care (e.g. physiotherapy); Failure to provide high-dependency/ ITU care)
☐ 4 Infection-related → D4
☐ 5 Technical problem related to a procedure → D5
(including inappropriate/unnecessary procedures, e.g. urinary catheterisation)
☐ 6 Failure to give correct medication/maintain correct hydration / electrolytes / blood (including failure to provide prophylactic medication e.g. anti-coagulants/antibiotics) → D6
☐ 7 Resuscitation → D7
☐ 8 Other (e.g. falls; specify) _____

Were there any other problems during this period/section of care not covered by the above?

☐ Yes ☐ No

If so, specify _____

C2 PROCEDURE RELATED PRINCIPAL PROBLEM (including surgical operations, anaesthesia, manipulation of fractures, invasive medical/endoscopic/radiological procedures)

To which procedure was the AE related?

☐ 1 Administration of anaesthetic
(specify type; e.g. inhalation, local, epidural) _____

- ☐ 2 Surgical operation
☐ 3 Manipulation of fracture
☐ 4 Endoscopic procedure
☐ 5 Needle biopsy
☐ 6 Vascular catheterisation
☐ 7 Interventional radiology
☐ 8 Other specialist procedure (specify) _____

- ☐ 9 Gaining IV access
☐ 10 Setting up CVP line
☐ 11 Catheterising bladder
☐ 12 Draining fluid from body cavity
☐ 13 Thoracic drain for pneumothorax
☐ 14 Lumbar puncture
☐ 15 Administering drugs other than orally
☐ 16 Siting a naso-gastric (or naso-enteric) tube
☐ 17 Other ward-based procedure (specify) _____

When was the procedure (or the administration of anaesthesia) carried out?

Date _____ Time of start _____

Specify patient's medical condition that required the procedure if different from the primary diagnosis indicated in A3 _____

Was the procedure

- ☐ 1 Emergency
☐ 2 Semi-emergency

- ☐ 3 Elective
☐ 4 Not clear

Who undertook the procedure or anaesthesia?

- ☐ 1. Consultant or fully trained operator
☐ 2. Supervised trainee
☐ 3. Unsupervised trainee
☐ 4. Other (specify) _____
☐ 5. Not clear

What was the nature of the principal problem underlying the AE

- | | |
|--|------|
| ☐ 1 Diagnosis | → D1 |
| ☐ 2 Overall assessment (incl. Pre-op assessment) | → D2 |
| ☐ 3 Management/monitoring (incl. Nursing/Ancillary care) | → D3 |
| ☐ 4 Infection-related related to a procedure | → D4 |
| ☐ 5 Technical problem related to a procedure
(e.g. Intubation; Equipment failure; Monitoring during procedure) | → D5 |
| ☐ 6 Drugs/ Fluids (incl. anaesthetic agent) / Blood | → D6 |
| ☐ 7 Resuscitation | → D7 |
| ☐ 8 Other (specify) _____ | |

Were there any other problems during this period/section of care not covered by the above?

☐ Yes ☐ No

If so, specify _____

C3 PRINCIPAL PROBLEM DURING IMMEDIATE POST-PROCEDURAL CARE, HIGH DEPENDENCY CARE or ITU CARE

When did the principal problem occur?

- ☐ 1. during the immediate post-procedural care (i.e. whilst in the recovery area)
☐ 2. during high dependency care
☐ 3. during care in the intensive care unit

Describe the principal problem: _____

What is the nature of the principal problem?

- | | | |
|----------------------------|---|------|
| ☐ 1 | Diagnosis | → D1 |
| ☐ 2 | Overall assessment | → D2 |
| ☐ 3 | Management/monitoring (incl. Nursing/Ancillary care)
(e.g. Failure to monitor adequately; Failure to treat appropriately;
Failure to ensure condition stable before handover) | → D3 |
| ☐ 4 | Infection-related | → D4 |
| ☐ 5 | Technical problem related to a procedure | → D5 |
| ☐ 6 | Drugs (including anaesthetic agent) / Fluids / Blood | → D6 |
| ☐ 7 | Resuscitation | → D7 |
| ☐ 8 | Other (specify) _____ | |

Were there any other problems during this period/section of care not covered by the above?

☐ Yes ☐ No

If so, specify _____

C4 PRINCIPAL PROBLEM RELATED TO WARD CARE (Including errors in clinical management)

If the principal problem was in ward care, was it due to (Tick all that apply)

- ☐ 1 a failure in medical care (i.e. care by ward doctors)
- ☐ 2 a failure in nursing care
- ☐ 3 a failure in care from professions allied to medicine:
- ☐ 3.1 Physiotherapy
- ☐ 3.2 Dietician/nutritionist
- ☐ 3.3 Pharmacist
- ☐ 3.4 Chiropody
- ☐ 3.5 Social worker
- ☐ 3.6 Other (specify) _____

Describe the principal problem: _____

Who provided the episode of ward care related to the principal problem?

- ☐ 1 Ward doctor (house officer or SHO status) who 'knew' the patient
- ☐ 2 Ward doctor *unlikely* to 'know' patient (on-call HO/SHO)
- ☐ 3 Ward doctors under guidance of specialist registrar
- ☐ 4 Trained specialists (specialist registrar/consultant)
- ☐ 5 Senior nurse
- ☐ 6 Junior nurse
- ☐ 7 Agency nurse
- ☐ 8 Other allied professional (specify) _____
- ☐ 9 Other (specify) _____
- ☐ 10 Cannot determine from record

What was the nature of the principal problem? (tick the appropriate number(s))

- ☐ 1 Diagnosis → D1
- ☐ 2 Overall assessment → D2
- ☐ 3 Medical management/monitoring (incl. Nursing/Ancillary care) → D3
- ☐ 4 Infection-related → D4
- ☐ 5 Technical problem related to a procedure → D5
- ☐ 6 Drugs/ Fluids / Blood → D6
- ☐ 7 Resuscitation after collapse → D7
- ☐ 8 Other (specify) _____

Were there any other problems during this period/section of care not covered by the above?

☐ Yes ☐ No

If so, specify _____

C5 FAILURE TO ASSESS ADEQUATELY AT THE TIME OF DISCHARGE

Which doctor was directly responsible for assessing the patient before discharge?

- ☐ 1. House-officer/SHO
☐ 2. Registrar
☐ 3. Consultant
☐ 4. Other (specify) _____

What is the nature of the principal problem?

- | | | |
|----------------------------|--|------|
| ☐ 1 | Diagnosis | → D1 |
| ☐ 2 | Overall assessment | → D2 |
| ☐ 3 | Medical Management/monitoring/ Nursing care
(e.g. Clinical condition not under good control; Patient not well enough to be discharged, e.g. mobilised; Failure to teach patient about their condition; Failure to communicate adequately with services in community care, including GP) | → D3 |
| ☐ 4 | Infection-related | → D4 |
| ☐ 5 | Technical problem related to a procedure | → D5 |
| ☐ 6 | Drug problem/ Fluids e.g. Medications not appropriate) / Blood | → D6 |
| ☐ 7 | Resuscitation | → D7 |
| ☐ 8 | Other (specify) _____ | |

Were there any other problems during this period/section of care not covered by the above?

☐ Yes ☐ No

If so, specify _____

C6 NATURE OF THE PRINCIPAL PROBLEM

From your responses to all sections completed above indicate which section(s) in D are to be completed

- ☐ D1
☐ D2
☐ D3
☐ D4
☐ D5
☐ D6
☐ D7

Stage D: PRINCIPAL PROBLEMS IN THE PROCESS OF CARE

Go to the relevant sections in Stage D as identified in Stage C (C6)

D1 ADVERSE EVENT OR CRITICAL INCIDENTS RELATED TO DIAGNOSTIC OR ASSESSMENT ERROR

Was the AE/CI the result of diagnostic error?

☐ Yes ☐ No

If yes, give details _____

Was the AE/CI the result of a delay in diagnosis?

☐ Yes ☐ No

If yes, what was the length of delay? _____

Was the person responsible for the diagnostic assessment (at which there was unacceptable error or delay) of appropriate seniority or experience?

☐ Yes ☐ No

If no, explain _____

Factors contributing to the diagnostic error (tick as many as apply).

- ☐ 1 Failure to take an adequate history and/or to perform a satisfactory physical examination.
- ☐ 2 Failure **or** delay to employ indicated test.
- ☐ 3 Test was incorrectly performed
- ☐ 4 Test was incorrectly reported
- ☐ 5 Failure **or** delay to receive report
- ☐ 6 Failure **or** delay to act upon results of tests or findings.
- ☐ 7 Failure to draw sensible/reasonable conclusions or make a differential diagnosis
- ☐ 8 Failure **or** delay to get expert opinion from:
 - ☐ 8.1 more senior member of team
 - ☐ 8.2 specialist clinical team
 - ☐ 8.3 non-clinical specialist (e.g. radiologist) (specify) _____
- ☐ 9 Expert opinion incorrect
- ☐ 10 Other (specify) _____

Did other factors contribute to AE/CI?

- ☐ 1 Led to inappropriate or inadequate treatment
- ☐ 2 Risk:benefit ratio of treatment was not assessed/appreciated
- ☐ 3 Patient's degree of vulnerability was not recognised
- ☐ 4 Other (specify) _____

Were there any other problems related to diagnostic assessment?

☐ Yes ☐ No

If yes, give details _____

D2 ADVERSE EVENT/ CRITICAL INCIDENT FROM FAILURE TO APPRECIATE PATIENT'S OVERALL CONDITION

Was the person responsible for the care of this patient of appropriate seniority or experience?

☐ Yes ☐ No

If no, explain (e.g. lack of appropriate supervision) _____

In what respect was overall assessment inadequate?

- ☐ 1 Failure to take a full clinical history
- ☐ 2 Failure to examine carefully
- ☐ 3 Failure to take account of co-morbidity
- ☐ 4 Failure to monitor adequately
- ☐ 5 Failure to record
- ☐ 6 Failure to communicate to the rest of the team (clinical and multi-disciplinary)
- ☐ 7 Other (specify) _____

How did this contribute to AE/CI?

- ☐ 1 Patient's degree of vulnerability was not recognised
- ☐ 2 Risk:benefit ratio of treatment was not assessed/appreciated
- ☐ 3 Led to inappropriate or inadequate treatment
- ☐ 4 Other (specify) _____

Were there any other problems related to assessment or management of the patient's overall condition?

☐ Yes ☐ No

If yes, give details _____

D3 AE/CI ARISING FROM A FAILURE IN CLINICAL MONITORING / MANAGEMENT
(incl. discharge arrangements, nursing/ancillary services)

Indicate if the patient was:

- ☐ 1 Post operative (including postmanipulation of fracture)
- ☐ 2 Undergoing medical (non-surgical) treatment
- ☐ 3 Undergoing rehabilitation
- ☐ 4 Other (specify) _____

Was the AE/CI the result of problems in the monitoring / observation of this patient?

☐ Yes ☐ No

If yes, give details _____

Was the AE/CI the result of failure in overall management (acting on observations) of the patient?

☐ Yes ☐ No

If yes, what was the problem in management? _____

Was the AE/CI the result of failure to ensure condition stable before handover to other areas?

☐ Yes ☐ No

If yes, give details _____

Was the person responsible for the care of this patient of appropriate seniority or experience?

☐ Yes ☐ No

If no, explain _____

Was the inadequate monitoring/management related to failure to recognise:

- ☐ 1 Abnormal vital signs (including neurological status)
- ☐ 2 Problems with fluids/electrolytes including renal function
- ☐ 3 Side-effects of medication
- ☐ 4 Cardio-pulmonary dysfunction
- ☐ 5 Damage to skin and pressure areas
- ☐ 6 Adequate mobilisation
- ☐ 7 Infection
- ☐ 8 Poor progress in healing (e.g. checking gut function after abdominal operation; care of wounds/canula sites)
- ☐ 9 Changes to the patient's general condition (e.g. patient develops a medical condition, e.g. CHF)
- ☐ 10 Other (specify) _____

Continue overleaf

D3. (Cont.)

In what respects was clinical management unsatisfactory?

- ☐ 1 Failure to take note of 'routine' observations e.g. TPR charts, neurological assessment, fluid balance (check if charts completed)
- ☐ 2 Delay in noting lab/test results
- ☐ 3 Not aware of significance of lab/test results
- ☐ 4 Failure to act appropriately on lab/test results
- ☐ 5 Poor note-keeping
- ☐ 6 Inadequate handover
- ☐ 7 Lack of liaison with other staff
- ☐ 8 Inadequate 'out-of-hours' cover/working practice
- ☐ 9 Guideline/ protocol failure (either not available or not followed)
(specify) _____
- ☐ 10 Apparent failure to recognise deterioration
- ☐ 11 Deterioration recognised but additional care not provided (specify, e.g. was high dependency care indicated) _____
- ☐ 12 Failure to recruit help
 - ☐ 12.1 Medical
 - ☐ 12.2 Nursing
 - ☐ 12.3 Ancillary (specify) _____
- ☐ 13 Other (specify) _____

Was there a failure in discharge procedure?

☐ Yes ☐ No

If yes, indicate which of the following apply to this patient regarding and give details

- ☐ 1 Failure to educate the patient including use of protocols (e.g. for asthma, diabetes, post MI)

- ☐ 2 Failure to show evidence that discharge status was appropriate to home conditions (e.g. careplan)

- ☐ 3 Failure to liaise adequately with community carers (e.g. GP, district nurse, social worker)

- ☐ 4 Other (specify) _____

What other factors interacted with failure in monitoring/management, handover or discharge to cause to the AE/CI?

- ☐ 1 Condition not treated or not treated adequately
- ☐ 2 Patient's degree of vulnerability was not recognised
- ☐ 3 Risk:benefit ratio of treatment was not assessed/appreciated
- ☐ 4 Other (specify) _____

Were there any other problems related to monitoring/management including handover and discharge?

☐ Yes ☐ No

If yes, give details _____

D4 ADVERSE EVENT OR CRITICAL INCIDENT IN RELATION TO FAILURE TO PREVENT/CONTROL/MANAGE INFECTION

What was the site of infection/infection related to?

- ☐ 1 Surgical wound
- ☐ 2 Internal invasive procedure
- ☐ 3 Urinary tract
- ☐ 4 Respiratory tract
- ☐ 5 Blood
- ☐ 6 Other (specify) _____

What was the nature of the infection?

- ☐ 1. Contaminated wound
- ☐ 2. Side-effect of drugs (specify type):
 - ☐ a. Antibiotic-induced C. difficile
 - ☐ b. yeast infection
 - ☐ c. Immuno-suppressive drugs
 - ☐ d. Other (specify) _____
- ☐ 3. Cross-infection (specify type):
 - ☐ a. MRSA (describe) _____
 - ☐ b. Salmonella
 - ☐ c. Other (specify) _____
- ☐ 4. Foreign body (specify type):
 - ☐ a. Urinary catheter
 - ☐ b. Venflon or intravenous catheter
 - ☐ c. Swab
 - ☐ d. Drainage tube
 - ☐ e. Shunt
 - ☐ f. Other (specify) _____
- ☐ 5. Stasis (specify type):
 - ☐ a. Respiratory depression
 - ☐ b. Urinary retention
 - ☐ c. Other (specify) _____
- ☐ 6. Other type of infection (specify) _____

Was the person responsible for the prevention/control/management of infection of appropriate seniority or experience?

☐ Yes ☐ No

If no, explain _____

What were the errors in managing the AE/CI due to infection? Give details.

- ☐ 1 Failure to drain pus or remove necrotic material _____
- ☐ 2 Failure to give appropriate antibiotics (including overuse) _____
- ☐ 3 Failure to give appropriate physiotherapy (e.g. chest) _____
- ☐ 4 Failure to maintain care of catheters/canulas/drains/wounds _____
- ☐ 5 Other (specify) _____

How did this contribute to AE/CI?

- ☐ 1 Failure to minimise risk in a vulnerable patient
- ☐ 2 Risk:benefit ratio of treatment was not assessed/appreciated
- ☐ 3 Led to inappropriate treatment
- ☐ 4 Other (specify) _____

D4. (Cont.)**Were there any other problems related to the management of infection?**☐ **Yes** ☐ **No**

If yes, give details _____

D5 ADVERSE EVENTS DIRECTLY RELATED TO A PROBLEM WITH AN OPERATION OR PROCEDURE**Was the procedure**

- ☐ 1 ward-based
☐ 2 in operating theatre suite
☐ 3 elsewhere (e.g. radiology; specify) _____

Do you consider the procedure was performed by a person of appropriate seniority?

☐ Yes ☐ No

If no, give reasons _____

Choose one of the following that best describes the nature of the adverse event (give details where possible)

☐ 1 Avoidable delay in undertaking procedure (specify) _____

☐ 2 Inappropriate procedure – specify alternative _____

☐ 3 Inadequate assessment/treatment/preparation before procedure (specify) _____

4 Anaesthetic incident

☐ 4.1 Intubation (specify) _____

☐ 4.2 Anaesthetic agent _____

☐ 4.3 Equipment failure _____

☐ 4.4 Monitoring during procedure (e.g. oxygenation, CO₂, airway pressure) _____

☐ 4.5 Other (specify) _____

5 Operation/procedure accident

☐ 5.1 Difficulty in defining anatomy (specify) _____

☐ 5.2 Inadvertent organ damage (specify) _____

☐ 5.3 Bleeding (specify, e.g. from slipped ligature; from vascular puncture) _____

☐ 5.4 Perforation. (specify nature) _____

☐ 5.5 Anastomotic breakdown (specify contributory factors) _____

☐ 5.6 Wound problem (e.g. dehiscence). (specify) _____

☐ 5.7 Siting prosthesis _____

☐ 5.8 Equipment failure (e.g. inappropriate use, misuse, failed; specify) _____

☐ 5.9 Other (specify) _____

☐ 6 Inadequate monitoring during procedure (specify) _____

7 Infection-related

☐ 7.1 Wound (including trip-related cellulitis) _____

☐ 7.2 Internal infection (e.g. abscess, specify) _____

☐ 7.3 Other (e.g. cholangitis, specify) _____

☐ 8 Other, including inefficacious result (specify) _____

Continue overleaf

D5. (Cont.)

Did other factors contribute to the procedure-related AE? ☐ Yes ☐ No

If yes, specify

- ☐ 1 Patient's degree of vulnerability was not recognised
- ☐ 2 Risk:benefit ratio of treatment was not assessed/appreciated
- ☐ 3 Led to inappropriate or inadequate treatment
- ☐ 4 Other (specify) _____

Were there any other problems related to the management of a procedure? ☐ Yes ☐ No

If yes, give details _____

D6 ADVERSE EVENTO CRITICAL INCIDENTS RELATED TO PRESCRIBING, ADMINISTRATION OR MONITORING OF DRUGS OR FLUIDS (including BLOOD)

How was the drug / fluid administered?

- | | | |
|---|--|--|
| ☐ 1 Intravenous | ☐ 4 orally | ☐ 7 topical |
| ☐ 2 Intra-muscular | ☐ 5 sublingual | ☐ 8 rectal |
| ☐ 3 Subcutaneous | ☐ 6 intrathecal | ☐ 9 Other (specify) _____ |

Was there an error in the prescription/preparation of drugs/iv fluids/blood? ☐ Yes ☐ No

If so, specify _____

Was there an error or accident in administering drugs/iv fluids/blood?
(e.g. too high dose, incorrect site, haematoma, delay in acting on prescription) ☐ Yes ☐ No

If so, specify _____

Was there a failure to monitor drug action/toxicity/fluid balance? ☐ Yes ☐ No

If so, specify _____

What was the drug?

- | | | |
|---|--|--|
| ☐ 1 antibiotic | ☐ 7 sedative or hypnotic | ☐ 13 potassium |
| ☐ 2 antineoplastic | ☐ 8 peptic ulcer medication | ☐ 14 NSAID |
| ☐ 3 anti-seizure | ☐ 9 antihypertension | ☐ 15 Narcotic (e.g. morphine/pethidine) |
| ☐ 4 anti-diabetes | ☐ 10 antidepressant | ☐ 16 Diuretics |
| ☐ 5 cardiovascular | ☐ 11 antipsychotic | ☐ 17 Other (specify) _____ |
| ☐ 6 antiasthmatic | ☐ 12 anticoagulant | _____ |

Name of drug: _____

Describe the drug's adverse effect: _____

What was the nature of the drug-related injury/incident?

- | |
|---|
| ☐ 1 Drug less effective than expected (e.g. as result of delayed treatment; dose too little) |
| ☐ 2 Side-effect of drug |
| ☐ 3 Effect of high dose for this patient in this circumstance |
| ☐ 4 Idiosyncratic (allergic) re-action |
| ☐ 5 Drug-drug interaction |
| ☐ 6 Other (specify) _____ |

Was the person responsible for managing the drug regimen for this patient of appropriate seniority or experience? ☐ Yes ☐ No

If no, explain _____

Would a doctor using reasonable medical judgement prescribe the drug, even with knowledge beforehand that this adverse effect could occur? ☐ Yes ☐ No

Continue overleaf

D6. (cont.)

What was the cause of the drug-related injury/incident?

- ☐ 1 No underlying cause (other than patient's response)
- ☐ 2 Delay in prescribing (specify) _____
- ☐ 3 Delay in administering (after prescribing) _____
- ☐ 4 Wrong drug prescribed (specify) _____
- ☐ 5 Right drug but wrong dose or length of treatment _____
- ☐ 6 Right drug but wrong route (specify) _____
- ☐ 7 Error in administration (describe) _____
- ☐ 8 Inadequate monitoring (describe) _____
- ☐ 9 Other (specify) _____

Did other factors contribute to the drug-related AE/CI?

- ☐ 1 Patient's degree of vulnerability was not recognised
- ☐ 2 Risk:benefit ratio of treatment was not assessed/appreciated
- ☐ 3 Led to inappropriate treatment
- ☐ 4 Other (specify) _____

Were there any other problems related to the management of fluids or blood?

☐ Yes ☐ No

If so, specify _____

Stage E: CAUSATIVE / CONTRIBUTORY FACTORS and PREVENTABILITY OF AE

E1 CAUSATIVE FACTORS

The occurrence of an adverse event or critical incident, and the actions or omissions of those involved, may be influenced by many contributory factors. Many of these could only be assessed satisfactorily by interviewing the staff involved in the care of the patient. Please indicate, where possible, likely causative factors. Mark unlikely factors with **U**, possible factors with **1, 2** or **3**.

Please rate each of the following factors according to its importance, as you see it, in the occurrence of this particular adverse event.

Unlikely to
be relevant

Possibly
relevant

Somewhat
important

Very
important

U

1

2

3

1. Patient characteristics

- 1.1 Patient was not able to understand/communicate with clinical/nursing team
(e.g. deaf, stroke, language difficulties in absence of interpreter or cultural differences)
- 1.2 Personality or social factors
- 1.3 Was co-morbidity an important contributory factor?
- 1.4 Other patient characteristics (specify) _____

U	1	2	3
☐	☐	☐	☐
☐	☐	☐	☐
☐	☐	☐	☐
☐	☐	☐	☐

2. Task factors

- 2.1 New, untested or difficult task or procedure
- 2.2 Evidence of lack of guidelines/protocols or their use
- 2.3 Test results unavailable, difficult to interpret or inaccurate
- 2.4 Poor task design/structure
- 2.5 Other task factors (specify) _____

U	1	2	3
☐	☐	☐	☐
☐	☐	☐	☐
☐	☐	☐	☐
☐	☐	☐	☐
☐	☐	☐	☐

3. Individual factors

- 3.1 Staff working outside their expertise
- 3.2 Lack of knowledge of individuals
- 3.3 Lack of skill of individuals
- 3.4 Attitude/motivation problem
- 3.5 Long shift/under pressure
- 3.6 Other individual staff factors (specify) _____

U	1	2	3
☐	☐	☐	☐
☐	☐	☐	☐
☐	☐	☐	☐
☐	☐	☐	☐
☐	☐	☐	☐
☐	☐	☐	☐

4. Team factors

- 4.1 Poor teamwork
- 4.2 Inadequate supervision
- 4.3 Poor verbal communication
- 4.4 Inadequate handover
- 4.5 Poor written communication (e.g. defects in notes)
- 4.6 Other team factors (specify) _____

U	1	2	3
☐	☐	☐	☐
☐	☐	☐	☐
☐	☐	☐	☐
☐	☐	☐	☐
☐	☐	☐	☐
☐	☐	☐	☐

5. Work environment

- 5.1 Defective or unavailable equipment
- 5.2 Problems with provision or scheduling of services (e.g. theatre list, lab tests, x-rays)
- 5.3 Inadequate functioning of hospital support services
(e.g. pharmacy, blood bank or housekeeping)
- 5.4 Inadequate staffing at the time of the AE
- 5.5 Out of hours (time of day/day of week) factors
- 5.6 Other work environmental factors (specify) _____

U	1	2	3
☐	☐	☐	☐
☐	☐	☐	☐
☐	☐	☐	☐
☐	☐	☐	☐
☐	☐	☐	☐
☐	☐	☐	☐

6. Organisational/Management factors

- 6.1 Lack of essential resources (e.g. ITU beds)
- 6.2 Poor co-ordination of overall services
- 6.3 Inadequate senior leadership
- 6.4 Other organisational/management factors (specify) _____

U	1	2	3
☐	☐	☐	☐
☐	☐	☐	☐
☐	☐	☐	☐
☐	☐	☐	☐

E2 Give details on the 3 MOST IMPORTANT contributory factors to this AE

1. _____

2. _____

3. _____

E3 ASSESS THE PREVENTABILITY OF THE ADVERSE EVENT

In your judgement, is there some evidence that the AE was preventable? ☐ Yes ☐ No

Rate on a 6 point scale the strength of evidence for preventability.

- ☐ 1 Virtually no evidence for preventability
- ☐ 2 Slight to modest evidence for preventability
- ☐ 3 Preventability not quite likely; less than 50-50 but close call
- ☐ 4 Preventability more likely than not; more than 50-50 but close call
- ☐ 5 Strong evidence for preventability
- ☐ 6 Virtually certain evidence for preventability

If you ticked 2 - 6, answer the following questions:

Describe briefly the manner in which the AE could have been prevented. _____

Can you identify any reason(s) for the failure to prevent this AE _____

A9 EXPERTISE OF REVIEWER

Was the reviewer's judgements limited or hampered by lack of subspecialty knowledge?

☐ Yes

☐ No

Mark **Yes** if you think a specialist's review is necessary and indicate which specialty or discipline (e.g. pharmacy) listing as many as necessary:

Describe the judgement, which is limited or hampered by lack of subspecialty knowledge, and the clinical question you would pose to a specialist

Describe the resolution of the question(s) posed following consultation with a specialist

Specialist's ID number:

Appendix B

Appendix B Material relating to training in record review

B.1 Program for training day in record review

Training day program

9.45-10.00 Registration

10.00-10.15

- Welcome and introduction

10.15-10.45

- General introduction to patient safety, epidemiology of harm and record reviews. Development of rapid record review (RR); overview of previous studies, methodologies and findings by Prof Vincent

10.45-11.15

Case review practical 1

- Review of case synopses for identification, classification and preventability of adverse events.

11.15- 11.35

- Overview and understanding of methodology of rapid record review
Definitions and examples of AE and CI and preventability. Discussion of examples of adverse events and critical incidents.

11.35-11.50 Break 15 min

11.50-13.10

- The long review form MRF2, what information is sought for RR 10 min
- Practical exercise in classification and description of AE/CI including Identification of contributory factors 35 min
- Potential outcome data and use of data from rapid RR. Where to look for information in the notes, how information may be presented in the notes. (By Dr Neale 30 min)

13.10-13.55 Lunch

13.55 – 14.45

Case review practical 2

- Detailed practical exercise in interpreting clinical information uncovered including contributory factors and AE/CI/preventability and entering data on review form. Group work with feedback to individuals on specific problems with comprehension or use of tools. Ongoing during exercise
- Group feedback on issues picked up during practical and other questions brought up by delegates. 10 min

14.45 – 14.55 Break 10 min

14.55-15.25

Case review practical 3

- Individual analysis of cases

15.25 -15.45

- How to implement RR locally. Our results and tips on implementing RR in practice, computerised RR.

15.45- 16.00 Questions and Close

16.00 – 17.00 optional extra time for discussion

The course organisers are available to take further questions and discuss how RR can be implemented locally.

Accompanying brief manual with slides, review forms, cases analysed and copy of expert findings will be available at end of course.

B.2 Assessment cases

Study ID A

67 years old male business man

Index admission: Admitted 06.01.04 Discharged 14.01.04
Under care of general medical team on take

Presented at A&E with left chest pain and a little short of breath – symptoms developed over a period of 2 days after returning from Hong Kong by air. Stuffy nose during flight. Occasional cough (smokes 5-10 a day). No past medical history.

Examination

OE Somewhat overweight and in some discomfort
T 37.2 P100 R 20
CVS BP 170/90 HS 1 and 2 normal. No ankle oedema.
RS Doesn't seem able to take a completely full breath. Catches on left side.
Dull to percussion left base.
Soft breath sounds. No rub heard.
Abdo: n.a.d.

Investigation

Hb 13.8 WCC 10.2 (neutros 75%) Platelets 342
Urea, electrolytes, LFTs normal
CXR shows shadowing at left base. ? some fluid.

Diagnosis ?PE ?chest infection

Request for CT chest: Sudden onset of SOB Limited physical signs ?PE ?Chest infection

Verbal report – evidence of pneumonic consolidation L base

Initial treatment

Oral antibiotics and kept in over the weekend

Team contacted afternoon of 09.01.04 because consultant radiologist written report state evidence of pulmonary embolism. This is subsequently confirmed by V/Q scan on 10.01.2004

Summary of rest of admission: During rest of admission treated according to PE protocol with LMW heparin and warfarinisation.

Background: Verbal and preliminary CT report by year 1 Radiology registrar on a Friday evening. Scan formally reported by consultant radiologist on Monday afternoon. Change of report telephoned to requesting doctor same day.

Study ID B

Mr RJ aged 55

Primary diagnosis: Peritonitis following perforation of colon at colonoscopy.
Laparotomy with colonic resection, wash out and primary anastomosis.

Date of admission 2/8/2004

Date of discharge 12/8/2004

History on admission.

Underwent elective day-case colonoscopy on 1/8/2004 for surveillance because of family history of colorectal cancer. Was very anxious about the procedure before this. Had abdominal pain in recovery. Was given hyosin/ buscopan and discharged by the nurse without being seen by the doctor. Was told that the investigation was normal.

Same evening abdominal pain worse, called GP but told that abdominal pain is normal for the first 24 after colonoscopy and to see his own doctor next morning if not better. Next morning he was feeling worse with fever and unable to move due to pain. Wife called ambulance and Mr Jacklin was taken to A&E.

Past medical history: Nil of note

Family History: Farther and brother had colorectal cancer by the age of 60.

Drug history: No regular medication. No known allergies

Social: Works as an accountant, smokes 20/day, drinks 18 units/week. Lives with his wife.

Examination on admission.

Respiratory: Normal

Cardiovascular: Hr 100, BP 140/85. All else normal.

Abdomen: Peritonism

Bloods WBC 16, Hb 12 Na 135, K 4, Urea 6 Creat 85.

Erect chest xray: Free air under left hemi-diaphragm

Summary of next 24 hours

Taken to theatre for laparotomy, Purulent peritonitis and perforation of descending colon just below splenic flexure. On table wash out and resection of affected area with primary anastomosis. Loop ileostomy formed to protect the anastomosis.

Post op on HDU over night then returned to ward.

Summary of rest of stay.

Prolonged ileus for 4 days before passing wind though ileostomy. After that took a further 4 days for Mr Jacklin to learn to manage his ileostomy and be ready for discharge. It is planned for Mr Jacklin to have the ileostomy reversed after 6 months if all is well.

Review of notes from colonoscopy.

The colonoscopy was listed as performed by Dr Fernandez a gastro-enterologist registrar and the consultant Dr Roberts. The note states that very high doses of midazolam and morphine were used as the procedure was poorly tolerated by the patient but at no time was the patients respiration suppressed. Normal examination of rectum and ascending colon. Unable to enter the transverse colon and the procedure abandoned.

Background:

You know that the registrar who performed the colonoscopy is regarded as good but still very inexperienced. She was on call the night before as one of her colleagues was off sick. The consultant in charge of this list often goes to his office down the corridor during the list to do paper work and only returns intermittently.

Study ID C

Mr. RS 52 year old man. Admitted 23/6/2004 Discharged 24/6/2004

Diagnosis: Right inguinal hernia

Admitted on day of op, saw the SHO pre op who took consent and marked patient (Correct side marked with black arrow on right thigh/ hip)

Operation note:

Surgeon: Consultant surgeon B

Operation: RIH

Incision: Mistakenly made 6 cm skin incision in left groin though skin and subcutaneous fat. Deep closure with 3.0 vicryl. 3.0 Prolene subcuticular to skin.

Patient re-draped. Incision: 6 cm right groin.

Procedure uneventful.

Post op instructions: Patient to be seen by surgical team on return to ward.

Ward entry 23/6/2004. Surgeon B: Patient seen post op. Mistaken left sided incision explained to patient. Apology made and explanation of procedures to prevent this given. Patient seems happy with explanation at this stage.

Patient discharged 24/6 to GP nurse follow up for removal of sutures.

Background

- Last patient on the surgeon's list. Mr. RS did not require a shave as he had shaved himself.
- Surgeon B made a skin incision on the left side – then stopped.
- Checked under the drapes, and found an arrow on the right thigh. Checked the consent that confirmed the wrong side.
- Closed the skin incision, re-draped, performed the operation on the correct side
- Surgeon B had been on call the night before and had been awake from 3:00am and was operating in hospital from 4:00am to 5:00am
- No bed is available for a consultant surgeon on call, so surgeon B had then driven home, had one hour's sleep and then showered and changed to drive back to hospital to start his theatre list at 8:00am the next day.

- The theatre list was a waiting list initiative, so surgeon A had not previously met any of the patients. The SHO had seen and consented them that morning.
- Another theatre list with similar operations had to be cancelled as the other surgeon C was unwell.
- Surgeon B was asked to squeeze another patient on his list to help out. There was thus time pressure on surgeon B to complete the last operation as theatre staff wanted to add on an extra patient
- At the start of the operation surgeon B was distracted by the ensuing discussion of whether to agree to add on another patient.
- After draping, the arrow was not visible under the drapes.

Study ID D

RA 84y old female

Admitted 17.4.2003 Discharged 24.4.2003 Under the care of Care of Elderly team.

Known anaemia . Recently short of breath
Hb 7.0 MCV 87 WCC 5.2 (neutro 43%) Platelets 125
On iron and folic acid but Hb not improved.
Admitted from clinic for blood transfusion

Co-morbidity: Frail elderly patient with peripheral vascular and coronary heart disease

Examination

Pale
CVS BP150/90 HS normal Short systolic murmur
RS clear
Abdo: n.a.d.

Treatment

2 units packed cells

Progress

Delay in getting more blood. Drip kept going over weekend.
Patient uncomfortable and had developed swelling of ankles
Further blood available but not given because forearm red swollen and painful.
Diagnosis: cellulitis
Treatment Cannula out
Elevate arm
Augmentin

Back ground: IV access difficult, nurse attempted to site venflon but PRHO was called as this failed. Short staffed on ward over weekend with some shifts filled by agency staff and others left unfilled.

Study ID E

Mr Johnson aged 68

Admission 2/3/2005 Discharge 12/3/2005

Elective admission for open radical gastrectomy as treatment for gastric cancer.

Co-morbidities: Smoker, COPD, Hypertension,

Medication: inhalers, Anti-hypertensives, Statin, Allergies not recorded in the notes.

Pre-op stay and surgery unremarkable (Op note: Presumes curative resection, macroscopically normal lymph nodes.)

First 24 hours post op in HDU on humidified oxygen and receiving chest physiotherapy and salbutamol nebulisers. Doing well sat O₂ 94-96% on 28%. Post op epidural for pain relief.

Transferred to surgical ward on a Friday.

Seen by doctors on Saturday am. Ward round entry: Sat 94%, O₂ on nasal specs, Apyrexial. Wound fine. Pain well controlled, epidural to come out.

Over weekend no further notes by doctors. Nursing note that patient has not been seen by physio. No nebulisers prescribed on drug chart.

Monday am ward-round: Pyrexial 38.5 for 12 hours, O₂sat 91%, RR24, No note on coughing or sputum. Seen on ward round by doctors. Tender upper abdomen, wound fine. Presumed chest infection. CXR requested, physio requested again. Put on oxygen (not humidified).

Monday early evening reviewed with chest x-ray by on call doctor. Pyrexia 39, RR 28 O₂sat 89%, drowsy and confused. CXR reveal left lower lobe collapse and right lower lobe consolidation with small pleural effusion. Blood gases: pO₂ 7.8 pCO₂ 6.8.

Patient treated for pneumonia with antibiotic, humidified O₂ and physiotherapy.

Patient made a slow recovery and discharged at day 10.

Note

You know that the surgical ward has problems with nursing handovers and that nursing leadership there is currently weak. There is no set format for medical hand over. The junior doctor on the team caring for Mr Johnson is known to be sloppy, he is often late and is not well liked by his colleagues.

Study ID F

JA female aged 27

Admitted as emergency from OP clinic 7.5.2003 Discharged 14.5.2003
Under care of consultant gastroenterologist

Known Crohns disease for 3 years. Treated with various drugs - prednisolone, salazopyrine and most recently azathioprine (for 8 weeks. Started in OPD by consultant). Last seen in clinic a month ago no blood results in notes from this clinic, no clinic letter in notes. Hand written entry: Improving. Plan: continue and review in 4/52.

Less abdominal pain but still intermittent diarrhoea. Sore mouth.

Now tired and lethargic. Unable to work. Occasional palpitations

Examination

Pale and ill-looking. Aphthous ulceration buccal mucosa. Bruising on arms where she says she knocked against furniture.

BP 110/70 Heart sounds I and II normal

Lungs clear

Abdomen. Generally a little tender – especially right iliac fossa.

Cranial nerves and reflexes normal

Investigation

Hb 7.1 WCC 1.2 Platelets 50,000

Bill 22 Albumin 30 ALT 57 AP 140 Prothombin time 18 secs

Na 130 K 3.5 Urea 3.0 Creat 67

Diagnosis

Pancytopenia secondary to treatment with azathioprine

Treatment

Stop Azathioprine. Blood transfusion.

B.3 Training Modular review form – TMRF

Review Form for Critical Incidents and Adverse Events



Role of Reviewers

Aim to identify adverse events and critical incidents from case record review in 'real time'

1. **An adverse event** must satisfy 3 criteria. It is:

- An unintended injury or complication
- Causing disability (persisting at time of discharge); death; prolongation of hospital stay; re-admission to hospital or need for treatment after discharge
- And is caused by health care management

It may or may not be related to a critical incident. For example a post-operative wound infection leading to prolonged hospital stay **is** an adverse event (it was unintended and not caused by the disease. You will be asked to assess to what extent the adverse event was due to health care management and to what extent you consider it preventable

2. **A critical incident** need not lead to harm. It may be described as an undesirable event in the management of the patient that could have caused harm (or actually did cause harm but enough to satisfy the criteria of an adverse event).

3. **Preventability** If reasonable steps to prevent this occurrence can be identified or if harm would not have arisen if standard levels of care had been used

Read each patient record carefully noting if you find any **adverse events** or **critical incidents** (aspects of health care management that give cause for concern)

For each adverse event/ critical incident please complete a separate form

Section A

Patient study ID _____

Reviewer ID _____

Date _____

Time commenced review _____

Time review finished _____

Date of admission _____

Date of discharge _____

Speciality at discharge _____

Age _____

Specialty responsible for care leading to event _____

Primary diagnosis _____

Primary procedure _____

Comorbidities _____

Did the patient suffer an adverse event?

☐ YES

☐ NO

Did a critical incident occur in the management of this patient?

☐ YES

☐ NO

If you did not identify an adverse event or critical incident **stop here**. If you think that there probably was a problem but this cannot be adequately characterised because the evidence is too scanty please continue and fill in what you can (see last question)

Briefly describe critical incident or adverse event identified _____

Level of confidence that health care management caused the AE (tick)

- ☐ Injury due entirely to disease process
- ☐ Management causation low (<50% causation)
- ☐ Management causation contributed (>50% to AE)
- ☐ Virtually certain evidence for management causation

Section B

Describe the impact of the adverse event on the patient (e.g. increased pain and suffering for x days; delayed recovery from primary illness; patient not given adequate care and support; contributed to or caused death)

Section C

When did the management problem leading to AE/CI occur

- ☐ Before admission (GP, Out-patient clinic, previous admission)
- ☐ Early in admission (A&E, admission ward, pre-op assessment)
- ☐ During a procedure (including surgery and anaesthesia)
- ☐ Post-operative/procedural care; ITU and HDU
- ☐ General ward care
- ☐ End of admission assessment and discharge planning

Please give details relating to the stage of care

Section D

What was the nature of the problem in care

- ☐ Failure to diagnose correctly/promptly
- ☐ Failure to assess patient's overall condition adequately (including co-morbidities)
- ☐ Technical problem related to procedure
- ☐ Hospital-acquired infection
- ☐ Problem in management/monitoring incl. nursing and other professional care
- ☐ Failure to give correct/monitor the effect of medication/maintain correct hydration/electrolytes
- ☐ Resuscitation
- ☐ Other (specify)

Please give further details relating to the nature of the problem in care

E1 CAUSATIVE FACTORS

The occurrence of an adverse event or critical incident, and the actions or omissions of those involved, may be influenced by many contributory factors. Many of these could only be assessed satisfactorily by having personal knowledge of the case or by interviewing the staff involved in the care of the patient. **Please indicate, where possible, likely causative factors. Mark any factors you think may be important.**

1. Patient characteristics

- 1.1 Patient was not able to understand/communicate with clinical/nursing team
(e.g. deaf, stroke, language difficulties in absence of interpreter or cultural differences)
- 1.2 Personality or social factors
- 1.3 Was co-morbidity an important contributory factor?
- 1.4 Other patient characteristics (specify) _____

2. Task factors

- 2.1 New, untested task or procedure
- 2.2 Evidence of lack of guidelines/protocols or their use
- 2.3 Test results unavailable, difficult to interpret or inaccurate
- 2.4 Poor task design/structure
- 2.5 Other task factors (specify) _____

3. Individual factors

- 3.1 Staff working outside their expertise
- 3.2 Lack of knowledge of individuals
- 3.3 Lack of skill of individuals
- 3.4 Attitude/motivation problem
- 3.5 Long shift/under pressure
- 3.6 Other individual staff factors (specify) _____

4. Team factors

- 4.1 Poor teamwork
- 4.2 Inadequate supervision
- 4.3 Poor verbal communication
- 4.4 Inadequate handover
- 4.5 Poor written communication (e.g. defects in notes)
- 4.6 Other team factors (specify) _____

5. Work environment

- 5.1 Defective or unavailable equipment
- 5.2 Problems with provision or scheduling of services (e.g. theatre list, lab tests, x-rays)
- 5.3 Inadequate functioning of hospital support services
(e.g. pharmacy, blood bank or housekeeping)
- 5.4 Inadequate staffing at the time of the AE
- 5.5 Out of hours (time of day/day of week) factors
- 5.6 Other work environmental factors (specify) _____

6. Organisational/Management factors

- 6.1 Lack of essential resources (e.g. ITU beds)
- 6.2 Poor co-ordination of overall services
- 6.3 Inadequate senior leadership
- 6.4 Other organisational/management factors (specify) _____

Describe any issues that you think underlay the AE/CI

Please describe in detail up to 3 contributory events

Preventability

Do you judge the AE/CI as preventable?

Yes
No

How strong is the evidence

Virtually no evidence for preventability
Modest evidence for preventability (< 50%)
Reasonably strong evidence for preventability (>50%)
Virtually certain evidence for preventability

If preventable, describe briefly how -

Can you identify any reason for failure to prevent?

Expertise

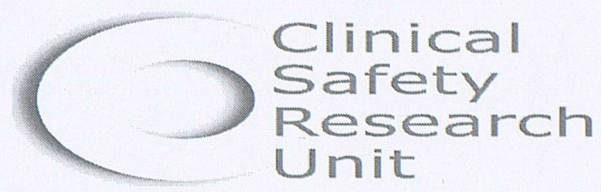
Was your judgement limited by lack of subspecialty knowledge?

Not at all
Perhaps a little
Somewhat affected
Yes limited by lack of specialty knowledge

Describe _____

B.4 Training day evaluation

Training day in record review for identification of adverse events



Course Evaluation Questionnaire

Please rate the quality of:

	Very High 5	High 4	Adequate 3	Low 2	Very Low 1
Course Materials					
Content of training day	5	4	3	2	1
Style of training day	5	4	3	2	1
Relevance to practice	5	4	3	2	1

Do you feel that the aims and objectives of the training day were clear and if so were they met ?

PLEASE LIST THREE THINGS YOU LIKED BEST ABOUT THE TRAINING DAY

PLEASE LIST THREE THINGS YOU LIKED LEAST ABOUT THE TRAINING DAY

WHAT CHANGES WILL YOU MAKE TO THE WAY YOU WORK AS A RESULT OF THIS TRAINING DAY

Appendix C

C.1 Electronic Modular Review Form – EMRF

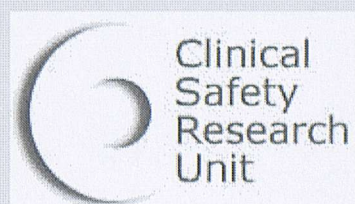
Modular Review Form

Unit Name:

Add Patient

Administration

Exit



Patient Details

Record No Study ID 0 Age 0 Sex Admission date Discharge date

Mode of admission

State of health at admission

Diagnosis

Specialty caring for patient Other

Co-morbidities (may be more than one)

Severity of co-morbidities

Cardiovascular
Respiratory
Gastro-intestinal
Endocrine / Metabolic
Neurological
Other

Primary procedure / operation

Complexity of primary procedure

Adequacy of medical records

Medical records deficiencies

Observer

Adverse Event

An adverse event is an unintended patient injury leading to a prolonged inpatient stay, disability at discharge or death caused by health care

Critical Episode

A critical episode is an undesirable event in the management of the patient that could have led to harm or did so but did fulfil the criteria of an

No Event

Adverse Event (AE) Details

Description

Date of AE

Specialty caring for patient during AE

Please indicate impact on patient of AE

Estimate increased length of stay (days)

Level of confidence that health
care management caused the AE**Describe AE in context of overall illness (free script)**

Details of pre-admission assessment / waiting period relevant to AE

Details of contributory events

Details of and key action / inaction that played significant part in causation

Details of injury caused

Any other details relevant to AE

When did the management problem leading to the AE occur

[Continue](#)

To what extent is your judgement hampered by lack of knowledge

Critical Episode (CE) Details

Was the episode of substandard care

Date of CE Specialty caring for patient during CE

Describe CE in context of overall illness (free script)

Details of pre-admission assessment / waiting period relevant to CE

Details of contributory events

Details of and key action / inaction that played significant part in causation

Details of injury caused

Any other details relevant to CE

When did the management problem leading to the CE occur

Continue

To what extent is your judgement hampered by lack of knowledge

Table C1

Periods of Care

Pre-admission

In what phase of pre-hospital care

	▼	Other	
----------------------	---	-------	----------------------

Who was responsible at the interface

	▼	Other	
----------------------	---	-------	----------------------

Who was responsible for directing service

	▼	Other	
----------------------	---	-------	----------------------

What was the nature of the problem in care

	▼
----------------------	---

Other	
-------	----------------------

Continue

Table C2

Periods of Care

During admission process

In what phase of admission

Who was responsible at the interface

Did you find evidence of appropriate supervision

What was the nature of the problem in care

Other

Continue

Table C3

Periods of Care

Procedure-related

To which procedure was AE / CE related

When was it carried out

Was the procedure

Who undertook procedure

Other

What was the nature of the problem in care

Other

Continue

Table C4

Periods of Care

Post-procedural care, HDC or ITU

When did the principal problem occur

Who was managing the patient

What was the nature of the problem in care

Other

Continue

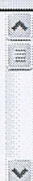
Table C5

Periods of Care

General ward care

Nature of problem (may be more than one)

Failure in medical care
Failure in nursing care
Failure in professional care allied to medicine
Physio
Dietician
Pharmacist



Other

Describe details of the problem in care

Who was responsible

Other

What was the nature of the problem in care

Other

Continue

Periods of Care

Discharge & discharge arrangements

Is there good evidence of assessment at the time of discharge? ☐ Yes

Who appears to have been taking responsibility?



Is there lack of good written communication to?

 Other

If communication substandard what were the inadequacies?



Other

What was the nature of the problem in care



Other

Continue

Table D1

Nature of the AE / CE

Related to diagnostic or assessment error

Give brief details of diagnostic error or delay (free script)

Who was taking responsibility?

 Other

Is there evidence that the responsible person was likely to have insufficient experience / knowledge?

☐ Yes

Factors contributing to diagnostic / assessment error (may be > 1)

Failure in history taking	v v v v v
Failure in physical examination	
Failure or delay to employ appropriate test/investigation	
Test incorrectly performed	
Test incorrectly reported	
Failure / delay in receiving report	v

Other

Continue

Table D2

Nature of the AE / CE

Failure to evaluate overall condition

Who appears to have taken hands-on responsibility for assessing this patient?

In what respect was overall assessment inadequate

Other

How did this contribute to AE / CE

Other

*Did you indentify any other problems related to assessment /
management of overall condition (Y / N and free script)*

☐ Yes

Continue

Table D3

Nature of the AE / CE

Failure in clinical monitoring/management

Was the monitoring problem in or during

Nature of the problem (free script)

Was the principal problem

Other

Was the inadequate monitoring / assessment related to failure to recognise

Other

In what respect was the management unsatisfactory

Other

Continue

Table D4

Nature of the AE / CE

Related to prevent/control/manage infection

To what was the site of infection related?

Other

Describe the nature of the infection (free script)

Classify the nature of the infection

Other

Errors in management

Continue

Table D5

Nature of the AE / CE

Related to problem with operation/procedure

Where was the procedure undertaken?

Other

Who undertook the procedure

Describe technical problem in detail (free script)

Classify the nature of the AE / CE

Other

Other problem related to procedure (including inefficacious result)

Continue

Table D6

Nature of the AE / CE

*Related to prescribing / administering /
monitoring drugs or fluids (including blood)*

How was drug / fluid administered

Other

Was there an error in prescribing / preparation of drugs/iv, fluids/blood? ☐ Yes

Specify

Was there an error/accident in administration

Other

Was there a failure to monitor drug action / toxicity / fluid balance ☐ Yes

What sort of drug / fluid

Name of drug / fluid

Give details of the nature of the adverse effect (free script)

Nature of drug-related injury/incident

Other

Causation

Other

Who was responsible

Other

How severe was drug-related error / incident (see www.nccmerp.org)

Continue

Table D7

Nature of the AE / CE

Problem with handover / discharge arrangements

Date of handover Time of handover Day of the week

Clarity of written instructions / information

Adequacy of subsequent case record

Inadequacy of discharge letter (select all that apply)

Principal diagnosis
Complicating factors
Treatment at time of discharge
Advice on subsequent treatment and monitoring
Details of information given to patient/relatives/district nurse
Prognosed follow-up

Where there any other problems related to handover or discharge? ☐ Yes

If Yes, please give details

Continue

Contributory Factors

Describe up to 3 events or factors contributing to this patient's adverse event / critical episode

Select as many of the following contributory factors that you can identify as having had an influence on this patient's adverse event/critical episode

1. Patient Characteristics

Unable to understand/communicate with clinician/nursing team
 Personality or social factors
 Patients co-morbidity was an important contributory factor?
 Other patient characteristics

2. Task Factors

New, untested or difficult task or procedure
 Evidence of lack of guidelines/protocols or their use
 Test results unavailable, difficult to interpret or inaccurate
 Poor task design/structure
 Other task factors

3. Individual Factors

Staff working outside their expertise
 Lack of knowledge of individuals
 Lack of skill of individuals
 Lack of general attention to detail and thoroughness
 Attitude/motivation problem
 Long shift/under pressure
 Other individual staff factors

4. Team Factors

Poor teamwork
 Inadequate supervision
 Poor verbal communication
 Inadequate handover
 Poor written communication (e.g. defects in notes)
 Other team factors

5. Work Environment

Defective or unavailable equipment
 Problems with provision or scheduling of services
 Inadequate functioning of hospital support services
 Inadequate staffing at the time of the AE
 Out of hours (time of day/day of week) factors
 Other work environmental factors

6. Organisational / Management Factors

Lack of essential resources (e.g. ITU beds)
 Poor co-ordination of overall services
 Inadequate senior leadership
 Lack of availability of ambulatory investigation and follow up arrangements
 Other organisational/management factors

Continue

Preventability

Do you judge the AE as preventable? ☒ Yes

How strong is the evidence for preventability?

If preventable, describe briefly how

Can you identify any reason for the failure to prevent?

Which of these measures may help prevent similar events occurring in the future
(select as many as you think apply by scrolling down)

**Further
Adverse Events**

**Further Critical
Episodes**

Finish

Appendix D

D.1 Additional data from Chapter 10

Results

1. Patient demographics

In total 104 surgical patients were included in the study. The age ranged from 17-88, the mean and median age was 53 years. 66 patients underwent an operation. There were 66 emergency admissions and 38 elective admissions. Demographic information was collected on all patients for the benefit of clinicians to asses their case mix but also to look for differences between patients with and without critical incidents.

Table D.1 State of health on admission

Category	Frequency	Percent
Missing data	2	1.9
Fit and well	12	11.5
Mild systemic illness	37	35.6
Moderate systemic illness	48	46.2
Severe possible life threatening illness	5	4.8
Total	104	100.0

Table D.2 Severity of co-morbidities

	Frequency	Percent
Missing data	6	5.8
healthy	39	37.5
mild systemic illness	38	36.5
moderate systemic illness	21	20.2
Total	104	100.0

Fig D.1 Distribution of patients according to admission category

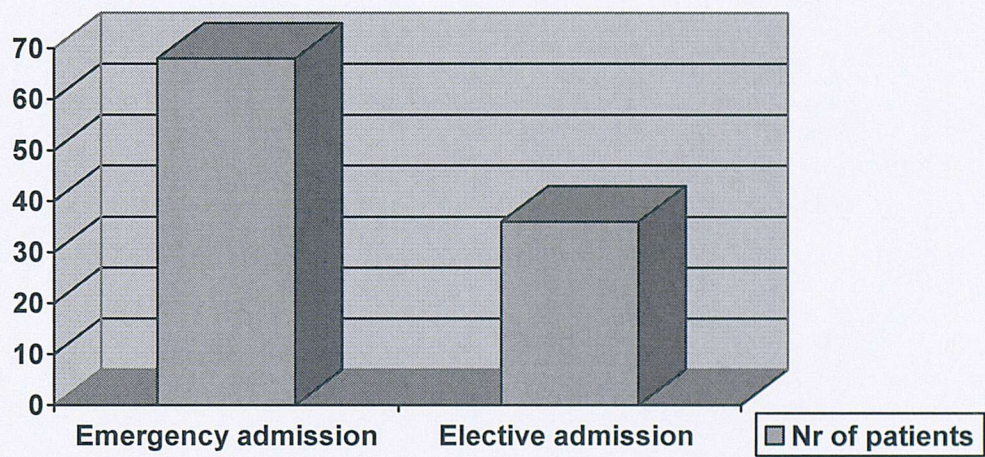


Table D.3 Complexity of operations

	Frequency	Percent
No operation	38	36.5
Minor	1	1.0
Intermediate	33	31.7
Major	21	20.2
Major plus	9	8.7
Major complex	2	1.9
Total	104	100.0

Table D.4 Stage of care consecutive case review all AE/CI combined

Stage of care	Nr of Patients (n= 37)	% of AE/CI (95% CI)
Before admission	5	13% (6-28)
Early admission	9	24% (14-40)
During procedure	4	11% (4-25)
HDU/ITU	3	8% (3-21)
General ward care	15	41% (26-57)
Discharge	1	3% (0.5-14)

Table D.5 Stage of care AE consecutive case review

	Pre- admission	Early admission	Procedure	ITU/HDU	Ward care	Discharge
AE	4	0	3	1	4	0
CI	1	9	1	2	11	1

Table D.6 Nature of problem consecutive case review all AE/CI

Nature of problem	Nr of Pat (n= 36 missing data)	% of AE/CI (95% CI)
Diagnosis (delay/failure/wrong)	4	11% (4-25)
Assessment of overall condition	2	6% (2-18)
Ward care and monitoring incl. nursing	7	19% (10-35)
Infection related	2	6% (2-18)
Technical problem related to procedure	6	16% (8-32)
Medication or fluids/electrolytes	14	38% (25-55)
Handover/discharge	1	3 (0.5-14)

Table D.6 Nature of problem consecutive case review

	diagnosis	assessment	Manage- ment	infection	technical	medication	Dis- charge
AE	3	0	1	2	6	0	0
CI	1	2	6	0	1	14	1

Admission category and influence of AE/CI

There were 7 (11%) AE and 14 CI (21%) in the 66 emergency admissions compared with 5 AE (13%) and 9 CI (24%) in the 38 elective admissions. There

was no higher incidence of AE in emergency admissions as seen in some parts of the literature. Likewise there was no difference between the rate of AE depending on the severity of co-morbidities or state of health on admission, see table 9.13 and 9.14 below.

Table D.7 Rate of AE and CI depending on severity of co-morbidities

	Nr of AE (% of patients in category)	Nr of CI (% of patients in category)
Healthy	2(5%)	9(23%)
Mild systemic illness	6 (16%)	9 (24%)
Moderate systemic illness	3 (14%)	8(38%)

Table D.8 Rate of AE and CI depending on the state of health on admission

Category	Frequency	Percent
Fit and well	0	3(25%)
Mild systemic illness	4(10%)	8(21%)
Moderate systemic illness	8(17%)	12(25%)
Severe possible life threatening illness	0	3(60%)

Appendix E

E.1 Accepted plan for changes based on result of RTRR

Proposal for Change to organisation of care at Surgical Unit X

Following the recent record review study and presentation of results to the consultants of this unit the authors of these recommendations were assigned responsibility of devising changes to delivery of inpatient care by the Surgical Unit X to address some of the problems highlighted by record review.

Most of the problems which occurred outside of the operating theatre could be traced back to missed opportunities of stopping the chain of events putting patients at risk during ward rounds, preadmission and discharge phase of care. Many problems seemed to have arisen from lack of structure of the clinical team on the ward and uncertainty about assigned responsibility for each patient.

After analysing all the problems from the record review as well as relying on undocumented information of current problems 4 main areas of change were identified.

These were;

5. Greater structure of the clinical team with clearly assigned responsibility for individual patients and tasks.
6. Checking of the pre-assessment process with use of checklist and review of cases by registrars
7. Changes to the discharge process and increased discharge information to GP's and in the notes
8. Increased structure of inpatient care with changes to post take and general ward rounds, existing plans for changes to HDU care and the departmental business meeting on Monday morning.

This document list the suggested changes in some detail as a introduction to a discussion of these by the clinical team, before agreeing on a final plan of change and implementation.

1. Structure of the clinical team:

We suggest that the clinical team is structured more tightly to ensure clear lines of responsibility but also clearly set out routes of advice taking on all levels. Recognising that there is great variability in the number of SHOs and PRHOs it is suggested that each be assigned a primary responsibility to a consultant but that there may be some fluidity at this level. Each registrar should be assigned one or two consultants for whom they would primarily work. This will have implications for the responsibility of inpatients care, theatre lists, ward rounds, advice taking and seeking and organisation of the Monday business meeting.

Registrar 1 would work for Consultant1/Consultant2

Registrar 2 would work for Consultant 3

Registrar 3 would work for Consultant 4

Registrar 4 would work for Upper GI consultant/new Upper GI post

Once the team expand to cover the additional Upper GI consultant with an additional registrar, this post will remain primarily with this post and will cross cover in the absence of registrar 4

In the absence of any registrar another registrar will be assigned their responsibility for inpatient care for the duration of absence. Actual sessions such as clinics and theatre lists will be reduced or dividend amongst the registrars present as most practical.

2. Checking of the pre-admission assessment

The current pre-admission assessment will remain the primary responsibility of one PRHO per clinic. Any significant problems detected during the clinic should be discussed with the registrar assigned to the consultant of the list the patient is booked for at the time. After the end of the clinic it is the responsibility of the PRHO to complete a check list for each patient with a brief summary of the patient and reason for procedure, results of essential staging or pre-op investigations, DVT prophylaxis and routine anaesthetic investigations. The PRHO will present these to an assigned registrar. Each checklist will then be signed by both the registrar and the PRHO. Any abnormal or missing results requiring action will be highlighted. It is the checking registrars responsibility to direct the initial action of the PRHO and the PRHO must thereafter contact the registrar assigned to the consultant due to operate on the patient(or their allocated deputy in the case of absence)for further action and advice. A check list system is already being piloted on the upper GI patients. It is likely that separate check lists need to be prepared for upper and lower GI surgery.

3. Changes to the discharge process and increased discharge information to GP's and in the notes.

Each patient should have an entry in the notes stating that they are fit for discharge and what the follow up plan is. This need not interfere with the nurse discharge process but they should be required to state this in the medical progress notes as well as in the nursing documentation. More importantly all patients should have a dictated discharge summary. It will be the responsibility of the registrar of the consultant in charge of the patients care to dictate these. Cancer patients discharge letters should be dictated by their consultant although this may be delegated to

the registrar if they wish. It is acknowledged that the infrastructure to ensure this is not currently in place.

4. Increased structure of inpatient care

Mirroring the structure of the clinical team, changes should be made to the way the inpatient care is delivered. These changes are likely to benefit the training of registrars as well as the care of patients.

In principal the registrar is responsible for ward rounds and general inpatient care of his/her consultant's patients. The more junior members of the sub-team (when present) are also responsible for ensuring planned care is delivered. Although specific tasks may be delegated to other team members the responsibility of ensuring care is delivered and results acted on remain with the sub-team members. This has some implications for the conduction of routine activities.

Post take ward round (PTWR) and morning business ward rounds

The only consultant ward round in the morning (7.30-9) should be the PTWR. Other consultant WR should take place at other times. The consultants can naturally attend the ward and see pre-op patients during this time but the team should not be interrupted in the business or PTWR. On 'take' days the team and on call consultant will first see all emergency admissions, this will allow presentation by the night team before they go home and planning of urgent care of sick patients. The team will then after first see HDU and then the remaining patients. As a principle the registrar assigned to the consultant (or allocated deputy during absences) should see and make decision on the relevant patients. Where support is needed this may be offered by more senior members of the team as appropriate without taking over the ward round of that patient. A new discipline for conduct during ward round will be taught and implemented if agreed.

1. Only the Registrar taking the ward round speaks unless a question has been asked.
2. The patients will be asked of their symptoms
3. The accompanying nurse will be asked for any changes or other concern
4. The patient will be examined as appropriate for their condition
5. All obs/drug charts and results will be reviewed.
6. A management plan will be made
7. The registrar will summarise the case and abstract what needs to be documented in the notes

Departmental business meeting on Monday mornings

The registrars responsible to each patient will present the case at the Monday morning meeting. A proforma for each patient needs to be completed and filed in the notes by the SHO/PRHO responsible for each patients. For each patient the following must be addressed; diagnosis&procedure, current problems and management plan. The notes of any patients with problems or long admissions should be present at the meeting.

The responsibility of inpatient care of all consultants' patients will be assigned, at least at a registrar level, and provision for cross cover made in cases of absence even when this is only for a day. Responsibility for checking of preadmission assessment will be assigned weekly. Attendance for all lists and clinics will be checked as per usual practice. It is the responsibility of the most senior registrar present to ensure a proforma weekly timetable for the unit is completed and distributed to all members of the team and posted and displayed on the ward and the ASU and ward offices after the end of the business meeting.

Appendix F

F.1 Extract of Spanish translation of Real-time Record Review Modular Review Form

CONFIDENCIAL

PROTOCOLO MODULAR (MRF2)

para

Revisión Retrospectiva de Historias Clínicas

Pasos a realizar:

1. Complete la parte A completamente
2. Complete la parte B completamente
3. Complete las secciones relevantes en la parte C (tal como han sido identificadas en A7)
4. Complete las secciones relevantes en la parte D (tal como han sido identificadas en C)
5. Complete la parte E completamente
6. "IA" significa incidente adverso
7. "IC" significa incidente critico

Parte A INFORMACION DEL PACIENTE. ANTECEDENTES DE IA/IC

A1 INFORMACION DEL REVISOR

Fecha de la revisión

d d m m y y

Número de ID del revisor:

Hora de inicio de la revisión

Caso Número

Hora de final de la revisión

(use 24 hour clock)

A2 INFORMACION DEL PACIENTE

Edad

Sexo

Embarazo S/N

Fecha de Ingreso

Grado de urgencia al ingreso

1 Critico vida en peligro

3 Semi-urgente

2 Urgente

4 Programada

Fecha de Alta o muerte

d d m m y y

A3 TIPO DE PATOLOGIA

Diagnóstico primario

Intervención realizada

ASA:

A4 CO-MORBILIDAD

No comorbilidad

Desconocido

Cardio-vascular

Enfermedad coronaria

Enf. Periférica vascular

Insuficiencia cardíaca o arritmia

Hipertension

Respiratorio

Asma

EPOC

Otro problema pulmonar (ej *tuberculosis severa*) (especificar)

Gastro-intestinal

Dispepsia

EII: Crohn / colitis ulcerosa

Hepatopatía crónica

Endocrino

Diabetes

Alteraciones endocrinas(e.g. *tiroides, suprarrenal*) (especificar)

Neurológica

Epilepsia

ACVA

Parkinson

Demencia

Otras alteraciones neurológicas (e.g. *EM MND*) (specify)

Renal

Insuficiencia renal crónica

Hematologico

Anemia

Leucemia

Linfoma

Otra (specify)

Cancer

Especificar

Enf de la articulación

Osteoporosis

Artritis reumatoide severa

Osteoartritis

Incapacidad

Silla de ruedas

Ceguera

Sordera

Problemas de aprendizaje

Otra(specify)

Psiquiátrico

Esquizofrenia

Trastorno afectivo

Otra(specify)

Psicosocial

Alcoholismo

Abuso de drogas

Fumador

Mendigo

Otra (specify)

Infection

SIDA

Infección crónica (e.g. *Hep C, MRSA*) (specify)

Trauma

Trauma Multiple

Estado nutricional

Obeso

Caquéctico

Otro(specify)

Otra co-morbilidad

Specify

Alergias

Specify

A5 ESPECIALIDAD A CARGO DEL PACIENTE

Indique con una cruz (x) que especialidad era responsable del paciente cuando sucedió el IA/IC

GENERAL

☐ 0 desconoc.

☐ 1 Urgencias

☐ 2 Cuidados Intensivos

S
U
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G
E
R
Y

- ☐ 3 Anestesia
- ☐ 4 Cirugía Cardíaca
- ☐ 5 Coloproctología
- ☐ 6 Cirugía General
- ☐ 7 Ginecología
- ☐ 8 Neurocirugía

- ☐ 9 Cirugía Gastrointestinal
- ☐ 10 Traumatología
- ☐ 11 Cirugía Pediátrica
- ☐ 12 Cirugía Plástica
- ☐ 13 Cirugía Torácica
- ☐ 14 Cirugía Vascular

- ☐ 15 Urología
- ☐ 16 ORL
- ☐ 17 Oftalmología
- ☐ 18 Otra _____

M
E
D
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E

- ☐ 19 Cardiology (incl. CCU)
- ☐ 20 Dermatology
- ☐ 21 Endocrinology
- ☐ 22 Family Practice
- ☐ 23 Gastroenterology
- ☐ 24 Geriatrics (care of the elderly)
- ☐ 25 Haematology
- ☐ 26 Immunology and Allergy
- ☐ 27 Infectious Disease

- ☐ 28 Internal Medicine (not otherwise classified)
- ☐ 29 Medical Oncology
- ☐ 30 Medical Ophthalmology
- ☐ 31 Neonatology
- ☐ 32 Nephrology
- ☐ 33 Neurology
- ☐ 34 Pathology
- ☐ 35 Paediatrics

- ☐ 36 Physical Medicine
- ☐ 37 Psychiatry
- ☐ 38 Pulmonary Disease
- ☐ 39 Radiation Therapy
- ☐ 40 Radiology
- ☐ 41 Rehabilitation Unit
- ☐ 42 Rheumatology
- ☐ 43 Other (specify) _____

O
T
H
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R

- ☐ 44 Maxilofacial
- ☐ 45 Nutrición
- ☐ 46 Fisicos
- ☐ 47 Matronas

- ☐ 48 Enfermería
- ☐ 49 Osteopatía
- ☐ 50 Farmacia
- ☐ 51 Fisioterapia
- Occupational Therapy

- ☐ 52
- ☐ 53 Servicios de apoyo (ej ambulancia)
- ☐ 54 Otra _____

A6 IDENTIQUE LAS CARACTERISTICAS PRINCIPALES DEL IA O IC

Un incidente adverso debe cumplir los tres criterios

- a) **lesión no intencionada o complicación**
- b) **Incapacidad temporal o permanente y/o incremento de la estancia o muerte**
- c) **causado por los cuidados médicos o de enfermería**

1) **LESION O COMPLICACION** Se produjo una lesión al paciente o complicación ☐ Si ☐ No

2) **INCAPACIDAD / INCR. ESTANCIA** Produjo la lesión o complicación incapacidad al alta o aumento de la estancia, o reingreso o requirió tratamiento extrahospitalario u originó la muerte?

- 1 Incapacidad al alta ☐ Si ☐ No
- 2 Incremento de la estancia o tratamiento ☐ Si ☐ No
- 3 Muerte ☐ Si ☐ No

3) **CAUSAS DE LA LESION O COMPLICACION**

Esta parte esta relacionada con las circunstancias que originaron la lesion, tales como el procedimiento o tratamiento que originó la lesión o si se produjo una omisión en el tratamiento estándar del paciente. Una de las formas de entender esta parte es considerar si la lesion o la complicación se hubiese originado si el procedimiento no hubiese tenido lugar. Por ejemplo cuando un paciente sufre una infección de una herida tras la cirugía existe una fuerte evidencia de que el manejo del paciente es responsable (la infección de la herida no se hubiese producido sin cirugía). Si el paciente hubiese estado prdispuesto a la infección de la herida el grado de confianza el el origen de la misma se reducirá

La lesion/complicación al paciente fueoriginada por:

- ☐ 1 Cuidados medicos
- ☐ 2 Cuidados medicos interaccionando con su patología
- ☐ 3 Solo por su patología

Si no se ha apreciado la presencia de un incidente adverso rellene por favor los siguientes apartados

Un **incidente crítico** no necesita originar daño al paciente

Definición: 1. Un evento no deseado en el cuidado del paciente que podría haberle originado daño.
2. Un evento durante el cuidado del paciente que le originó daño pero que no provocó retraso del alta ni incapacidad en el momento de la misma.

Durante el cuidado de este paciente se produjo un evento no deseado que le podría haber originado daño?

☐	SI
☐	NO

Durante el cuidado del paciente se produjo un evento que le originó un daño pero que no produjo un retraso en el alta ni incapacidad en el momento de la misma?

☐	YES
☐	NO

Si la respuesta a las dos preguntas es NO, la revisión se puede considerar terminada

Si se ha identificado un IA/IC por favour rellene el resto de las secciones y continúe con el protocolo

Si se ha identificado mas de un IA/IC deberá rellenar un protocolo por cada uno de ellos

A7 RESUMEN DEL IA/IC

Fecha del incidente adverso

d d m m y y

Describe el IA/IC en el contexto de la enfermedad

Describe detalles sobre el estudio antes del ingreso que puedas ser relevantes para el IA/IC

Describe detalles de eventos que hayan podido contribuir al IA/IA

Describe detalles de acciones/no acciones clave que hayan podido tener un papel importante en la causa del IA/IC

De detalles de la lesión o complicación causada por el IA/IC

De otros detalles que puedan ser de interés para el IA/IC (por ejemplo momento del incidente si es conocido)

Una vez descrita la situación, con que frecuencia puede ocurrir este tipo de lesión o complicación?

☐ 1 muy rara (<1%)

☐ 3 ocasionalmente (10-24%)

☐ 2 rara (1-9%)

☐ 4 frecuentemente (> 25%)

Describe el principal problema en el cuidado del paciente que originó el IA/IC(gfué un error diagnóstico, error técnico, no monitorización del paciente...etc)

A7 (cont.)

Identifique otros problemas en el cuidado medico relacionados con el IA/IC y cuando sucedieron en relación con el problema principal

- 1. _____
- 2. _____
- 3. _____

Especifique el/los periodo(s) durante el cual se originó el principal problema de cuidado. Marque tantos como se puedan aplicar al problema principal TEsto identificará que subsección de la parte C hace falta completar

- ☐ C0. Cuidado antes del ingreso (incluye cuidado proporcionado en AP, consultas externas o durante ingresos previos)
- ☐ C1. Cuidado durante el ingreso en una planta (lo que incluye estudio preoperatorio, estudio en Urgencias antes del diagnóstico definitivo)
- ☐ C2. Cuidado durante un procedimiento (incluyendo cirugía y anestesia)
- ☐ C3. Cuidados post-operatorios o tras el procedimiento o cuidado en la UCI
- ☐ C4. Cuidados generales de la planta (tras la intervención o tras el estudio completo o al iniciar el tratamiento médico)
- ☐ C5. Al final del ingreso al dar los cuidados al alta

Se produjo un mal manejo del IA/IC? ☐ Si ☐ No ☐ No esta claro

Si es así proporcione los detalles _____

A8 CALIDAD DE LAS HISTORIAS CLINICAS PARA LA EVALUACION DEL IA/IC

Como eran de adecuadas las historias clínicas a la hora de proporcionar información para ealuar la presencia de IA/IC?

- ☐ 1 Las historias clínicas eran adecuadas para realizar un buen juicio del caso
- ☐ 2 Existían carencias en la historia (especificar) _____
- ☐ 3 Existían carencias importantes (especificar) _____
- ☐ 4 Existían carencias severas que hacían imposible la evaluación de IA/IC (especificar) _____

Stage B: LA LESION Y SUS EFECTOS

B1 INCAPACIDAD ORIGINADA POR EL INCIDENTE ADVERSO

Describe el impacto del incidente adverso en el paciente (p.ej. incremento del dolor durante x días; retraso en la recuperación de la enfermedad principal, paciente al que no se le ha proporcionado cuidado adecuado lo que ha contribuido a su muerte)

Por favor evalúe el que a su juicio puede ser el grado de incapacidad (marque el número adecuado)

- ☐ 0 No incapacidad física (sigue siendo un IA si se prolonga la estancia, un IC si no se prolonga)
- ☐ 1 Mínima incapacidad y/o recuperación en un mes
- ☐ 2 Incapacidad leve, recuperación en 1 a 6 meses
- ☐ 3 Incapacidad moderada, recuperación en 6 meses a 1 año
- ☐ 4 Incapacidad permanente
- ☐ 5 Muerte (especifique cual fué la contribución del IA al fallecimiento)
- ☐ 5.1 Contribución minima del IA

☐ 5.2 Contribución moderada del IA

☐ 5.3 El fallecimiento fué debido al IA

☐ 5.4
- ☐ 6 No se puede juzgar de forma razonable

B2 EFECTO DEL IA EN LOS RECURSOS DEL HOSPITAL

Fué toda la hospitalización, o solo parte de ella debida al IA? Incluyendo el traslado a otro centro?

- ☐ 1 No incremento de los días de ingreso
- ☐ 2 Parte de los días de ingreso
- ☐ 3 Reingreso (todo el ingreso)

B1 EFECTO EN EN PACIENTE CAUSADO POR EL IC

Describe el impacto en el paciente del Incidente Crítico (p.ej. incremento del dolor durante x días; retraso en la recuperación de la enfermedad principal, paciente al que no se le ha proporcionado cuidado adecuado lo que ha contribuido a su muerte)

B3 TRATAMIENTO ADICCIONAL COMO CONSECUENCIA DEL IA/IC

Qué procedimienttos adicionales (médico o quirúrgico, incluyendo pruebas innecesarias) se realizaron como resultado del IA/IC?

Qué medicación adicional (incluyendo fluidos IV y transfusions de sangere) fueron administrados como consecuencia del IA/IC?

Qué tratamiento adicional (p.ej. fisioterapia,) fué proporcionado como resultado del IC/IA?

Stage C: PERIODO HOSPITALARIO EN EL QUE SUCEDE EL EFECTO ADVERSO

Complete: Secciones relevantes al efecto adverso (ver A7) Y Sección C6

C0 EFECTO ADVERSO O INCIDENTE CRÍTICO PREVIO A LA ADMISIÓN (Incluido los cuidados del médico cabecera, cuidados del paciente extrahospitalario previo a la admisión)

¿Cuándo sucedió el problema principal?

- ☐ 1. en atención primaria
- ☐ 2. durante el estudio y/o atención en consultas externas
- ☐ 3. previa a la admisión hospitalaria
- ☐ 4. problemas al remitir al enfermo

¿Quién proporciona los cuidados iniciales al paciente ambulatorio?

- ☐ 1. Médico de cabecera
- ☐ 2. Residente
- ☐ 3. Adjunto
- ☐ 4. Otros

Previo a la admisión

- ☐ 1. Médico de cabecera
- ☐ 2. Residente
- ☐ 3. Adjunto
- ☐ 4. Otros

¿Cuál es la naturaleza del principal problema en esta fase del cuidado(indica todas las posibles)

- ☐ 1 Diagnóstico incorrecto de la enfermedad primaria

→ D1
- ☐ 2 Valoración general

→ D2

(e.j. Fallo en la realización de una correcta valoración de la condición global del paciente incluido los exámenes apropiados; No evidencia de una valoración precisa como por ejemplo del sistema cardio-respiratorio.)
- ☐ 3 Manejo/monitorización incluido el cuidado de enfermería/auxiliares

→ D3

(e.j. Fallo en el manejo de los resultados de pbas complementarias; fallo en la correcta monitorización; No proporcionar cuidados profilácticos (e.j. fisioterapia); No proporcionar cuidados intensivos.)
- ☐ 4 Infección.

→ D4
- ☐ 5 Problemas técnicos relacionados con el procedimiento

→ D5

(incluidos procedimientos innecesarios/ inapropiados, e.j. catéter urinario)
- ☐ 6 No dar la medicación correcta/ mantener la hidratación/electrolitos/sangre

→ D6

(no administrar medicación profiláctica; e.j. antibióticos, anticoagulantes)
- ☐ 7 Resucitación

→ D7
- ☐ 8 Otros (e.j. caídas; específica)

Hubo cualquier otro problema durante este periodo/sección del proceso no mencionado arriba

☐ Si ☐ No

Si es así especifica

C1 EFECTO ADVERSO O INCIDENTE CRÍTICO RELACIONADO CON LA SALA DE ADMISIÓN (Incluida la valoración preoperatoria).

¿Cuándo ocurrió el problema principal?

- ☐ 1. en el servicio de urgencias antes de la admisión en planta
- ☐ 2. durante el periodo de admisión.
- ☐ 3. durante la valoración inicial en planta (diagnóstico y tratamiento inicial)
- ☐ 4. durante la valoración preoperatoria

¿Quién proporcionó el cuidado inicial?

En urgencias

En la planta

- ☐ 1. Administrativo de urgencias

☐ 2. Residente/Adjunto de urgencias

☐ 3. Consultant de urgencias.

☐ 4. Otros (especifica) _____
- ☐ 1. Adjunto

☐ 2. Residente

☐ 3. Consultant

☐ 4. Otros (anestesista del preoperatorio)

Para los pacientes intervenidos, ¿quién fue responsable de la valoración pre-operatoria?

- ☐ 1. House officer in booking clinic
- ☐ 2. Adjunto en la planta
- ☐ 3. Enfermera
- ☐ 4. Anestesista
- ☐ 5. Otros (especifica) _____

¿Cuál fue el principal problema en esta fase del tratamiento (indica tantos como correspondan)

En urgencias o en planta

- ☐ 1 Diagnóstico incorrecto de la enfermedad primaria

→ D1
- ☐ 2 Valoración general

→ D2

(e.j. Fallo en la realización de una correcta valoración de la condición global del paciente incluido los exámenes apropiados; No evidencia de una valoración precisa como por ejemplo del sistema cardio-respiratorio.)
- ☐ 3 Manejo/monitorización incluido el cuidado de enfermería/auxiliares

→ D3

(e.j. Fallo en el manejo de los resultados de pbas complementarias; fallo en la correcta monitorización; No proporcionar cuidados profilácticos (e.j. fisioterapia); No proporcionar cuidados intensivos.)
- ☐ 4 Infección.

→ D4
- ☐ 5 Problemas técnicos relacionados con el procedimiento

→ D5

(incluidos procedimientos innecesarios/ inapropiados, e.j. catéter urinario)
- ☐ 6 No dar la medicación correcta/ mantener la hidratación/electrolitos/sangre

→ D6

(no administrar medicación profiláctica; e.j. antibióticos, anticoagulantes)
- ☐ 7 Resucitación

→ D7
- ☐ 8 Otros (e.j. caídas; especifica) _____

Hubo cualquier otro problema durante este periodo/sección del proceso no mencionado arriba

☐ Si ☐ No

Si es así especifica _____

C2 PROCEDIMIENTO RELACIONADO CON EL PROBLEMA PRINCIPAL (incluido intervención quirúrgica, anestesia, manipulación de fracturas, procedimientos invasivos endoscópicos/radiológicos/médicos)

¿Con qué procedimiento está relacionado el EA?

- | | |
|--|---|
| ☐ 1 Administración del anestésico
(específica; e.j. inhalación, local, epidural) | ☐ 9 Canalización de vías |
| ☐ 2 Intervención quirúrgica | ☐ 10 Setting up CVP line |
| ☐ 3 Manipulación de fracturas | ☐ 11 Cateterización vesical |
| ☐ 4 Procedimientos endoscópicos | ☐ 12 Drenaje de líquido intraabdominal |
| ☐ 5 Biopsia con aguja | ☐ 13 Drenaje torácico por neumotórax |
| ☐ 6 Cateterización vascular | ☐ 14 Punción lumbar |
| ☐ 7 Radiología intervencionista | ☐ 15 Administración de drogas no orales |
| ☐ 8 Otros procedimientos (específica) | ☐ 16 Colocación de sonda nasogástrica |
| | ☐ 17 Otros procedimientos en planta (específica) |

¿Cuándo se realizó el procedimiento (o la anestesia) ? Día normal ___ Noche o fin de semana ___

Especifica la condición médica del paciente que requirió el procedimiento si fuese diferente del diagnóstico primario indicado en A3 _____

Fue el procedimiento

- | | |
|--|--------------------------------------|
| ☐ 1 Urgencia | ☐ 3 Electivo |
| ☐ 2 Semi-urgencia | ☐ 4 Not claro |

¿Quién realizó el procedimiento o la anestesia?

- ☐ 1. Adjunto
- ☐ 2. Residente supervisado
- ☐ 3. Residente no supervisado
- ☐ 4. Otros (específica) _____
- ☐ 5. No claro

¿Cuál fue la naturaleza del problema principal subyacente al EA?

- | | |
|--|------|
| ☐ 1 Diagnóstico | → D1 |
| ☐ 2 Evaluación general (incl. evaluación preoperatoria) | → D2 |
| ☐ 3 Manejo/monitorización (incl. cuidados de enfermería/auxiliares) | → D3 |
| ☐ 4 Infección relacionada con el procedimiento | → D4 |
| ☐ 5 Problemas técnicos relacionados con el procedimiento
(e.g. Intubación; Fallo del equipo; Fallo de monitorización durante el procedimiento) | → D5 |
| ☐ 6 Drogas (incl. anestésicos) /Líquidos / Sangre | → D6 |
| ☐ 7 Resucitación | → D7 |
| ☐ 8 Otros(específica) _____ | |

Hubo cualquier otro problema durante este periodo/sección del proceso no mencionado arriba

☐ Si ☐ No

Si es así especifica _____

C3 PROBLEMA PRINCIPAL DURANTE EL POSTOPERATORIO INMEDIATO, REANIMACIÓN, CUIDADOS INTENSIVOS.

¿Cuándo ocurre el problema principal?

- ☐ 1. en el post-operatorio inmediato
- ☐ 2. en reanimación
- ☐ 3. en UCI

Describe el problema principal: _____

¿Cuál es la naturaleza del problema principal?

- ☐ 1 Diagnóstico

→ D1
- ☐ 2 Evaluación general

→ D2
- ☐ 3 Manejo/monitorización (incl. cuidados de enfermería/auxiliares)

→ D3
- (e.g. Incorrecta monitorización; Tratamiento inapropiado;

No asegurar la estabilidad del paciente antes del alta)
- ☐ 4 Infección

→ D4
- ☐ 5 Problemas técnicos relacionados con el procedimiento

→ D5
- ☐ 6 Drogas (incl. anestésicos) /Líquidos / Sangre

→ D6
- ☐ 7 Resucitación

→ D7
- ☐ 8 Otros(especifica)_____

Hubo cualquier otro problema durante este periodo/sección del proceso no mencionado arriba

☐ Si ☐ No

Si es así especifica _____

C4 PROBLEMA PRINCIPAL RELACIONADO CON LOS CUIDADOS EN PLANTA (Incluidos errores en el manejo clínico)

Si el problema principal fue en los cuidados en planta, a que se debió (Tick all that apply)

- ☐ 1 fallo en el cuidado médico (i.e. médico de planta)
- ☐ 2 fallo en el cuidado de enfermería
- 3 fallo de otros especialistas:
- ☐ 3.1 Fisioterapia
- ☐ 3.2 Nutricionista
- ☐ 3.3 Farmacólogo
- ☐ 3.4 Podólogo
- ☐ 3.5 Trabajador social
- ☐ 3.6 Otros(especifica) _____

Describe el problema principal: _____

¿Quién realizó la acción relacionada con el problema principal?

- ☐ 1 Cirujano
- ☐ 2 Otro especialista (especifica) _____
- ☐ 3 Residente
- ☐ 4 Enfermera
- ☐ 5 Estudiante de enfermería
- ☐ 6 Auxiliar
- ☐ 8 Otros (especifica) _____
- ☐ 9 No se puede determinar con los datos de la historia

¿Cuál es la naturaleza del problema principal?

- ☐ 1 Diagnóstico → D1
- ☐ 2 Evaluación general → D2
- ☐ 3 Manejo médico/monitorización (incl. cuidados de enfermería/auxiliares) → D3
- ☐ 4 Infección → D4
- ☐ 5 Problemas técnicos relacionados con el procedimiento → D5
- ☐ 6 Drogas (incl. anestésicos) /Líquidos / Sangre → D6
- ☐ 7 Resucitación → D7
- ☐ 8 Otros(especifica) _____

Hubo cualquier otro problema durante este periodo/ sección del proceso
no mencionado arriba ☐ Si ☐ No
Si es así especifica _____

C5 FALLO EN LA CORRECTA VALORACIÓN DEL PACIENTE EN EL MOMENTO DEL ALTA.

¿Qué médico fue el responsable directo de informar al paciente antes del alta?

- ☐ 1. Residente
- ☐ 2. Adjunto
- ☐ 3. Otros (especifica) _____

¿Cuál es la naturaleza del problema principal?

- ☐ 1 Diagnóstico

→ D1
- ☐ 2 Evaluación general

→ D2
- ☐ 3 Manejo medico/monitorización/cuidados de enfermería

→ D3
- (e.g. Estado clínico no controlado; Paciente dado de alta en malas condiciones;

No se enseña al paciente lo suficiente sobre su nueva situación; Insuficiente informacion

Sobre los cuidados que requiere de forma ambulatoria
- ☐ 4 Infección

→ D4
- ☐ 5 Problemas técnicos relacionados con el procedimiento

→ D5
- ☐ 6 Drogas /Líquidos e.j. medicación incorrecta / Sangre

→ D6
- ☐ 7 Resucitación

→ D7
- ☐ 8 Otros(especifica) _____

Hubo cualquier otro problema durante este periodo/sección del proceso no mencionado arriba

☐ Si ☐ No

Si es así especifica _____

Stage D: PROBLEMAS PRINCIPALES EN EL PROCESO ASISTENCIAL

Ir a las secciones relevantes en la tabla D identificadas en la tabla C (C6)

D1 EFECTO ADVERSO O INCIDENTE CRÍTICO RELACIONADO CON UN ERROR EN EL DIAGNÓSTICO O EN LA VALORACIÓN.

¿Fue el EA/IC resultado de un error en el diagnóstico? ☐ Sí ☐ No

En caso afirmativo dar detalles _____

¿Fue el EA/IC resultado de un retraso en el diagnóstico? ☐ Sí ☐ No

Si afirmativo, ¿cuanto tiempo de retraso? _____

¿Tenía la persona responsables de la evaluación diagnóstica la suficiente experiencia ☐ Sí ☐ No

Si negativo, explicar _____

Factores que contribuyen al error diagnóstico (marca todas las posibles).

- ☐ 1 Fallo al realizar la historia clínica y/o realizar un correcto examen físico
- ☐ 2 Fallo o **retraso** al solicitar las pruebas indicadas
- ☐ 3 Pruebas realizadas de forma incorrecta
- ☐ 4 Pruebas informadas de forma incorrecta
- ☐ 5 Fallo o **retraso** al recibir el informe
- ☐ 6 Fallo o retraso para actuar con los resultados de las pruebas
- ☐ 7 Fallo en las conclusiones o error en el diagnóstico diferencial
- ☐ 8 Fallo o **retraso** en solicitar la opinión experta de:
 - ☐ 8.1 miembros del servicio
 - ☐ 8.2 especialistas clínicos
 - ☐ 8.3 especialistas no clínicos (e.g. radiólogos) (especifica) _____
- ☐ 9 Opinión del experto incorrecta
- ☐ 10 Otros (especifica) _____

¿Hubo algún otro problema relacionado con la valoración diagnóstica? ☐ Yes ☐ No

En caso afirmativo dar detalles _____

D2 EFECTO ADVERSO/INCIDENTE CRÍTICO DERIVADO DE UNA INADECUADA VALORACIÓN DEL ESTADO GENERAL DEL PACIENTE

¿Tenía la persona responsable del cuidado del paciente la suficiente experiencia?

☐ Sí ☐ No

En caso negativo, explicar (ej. Falta resupervisión) _____

¿En qué aspecto fue inadecuada la valoración general del paciente?

- ☐ 1 Historia clínica incompleta
- ☐ 2 Examen físico insuficiente
- ☐ 3 No se tuvo en cuenta la co-morbilidad
- ☐ 4 Inadecuada monitorización
- ☐ 5 No se recoge la información en la historia clínica.
- ☐ 6 No se comunica la información al resto del equipo (clínico y multidisciplinario)
- ☐ 7 Otros (especificar) _____

¿De qué forme contribuyó al EA/IC?

- ☐ 1 El grado de vulnerabilidad del paciente no fue reconocido
- ☐ 2 El riesgo/beneficio del tratamiento no fue valorado
- ☐ 3 Llevó a un tratamiento inapropiado o inadecuado
- ☐ 4 Otros (especificar) _____

¿Hubo algún otro problema relacionado con la valoración o manejo del estado general del paciente?

☐ Sí ☐ No

En caso afirmativo, dar detalles _____

D3 EA/IC DEBIDO A UN ERROR EN LA MONITORIZACIÓN O EL MANEJO CLÍNICO.
(incluido planificación del alta, servicio de enfermería)

Indique la situación del paciente:

- ☐ 1 Post operatorio
- ☐ 2 En proceso de tratamiento medico (no quirúrgico)
- ☐ 3 En proceso de rehabilitación
- ☐ 4 Otros, especificar _____

¿Fue el EA/IC resultado de problemas en la monitorización / observación del paciente?

☐ Sí ☐ No

En caso afirmativo, dar detalles _____

¿Fue el EA/IC resultado de un error en el manejo general (observación) del paciente?

☐ Sí ☐ No

Si afirmativo, ¿cuál fue el problema? _____

¿Fue el EA/IC resultado de una inadecuada estabilización del paciente antes del traslado a otras áreas?

☐ Sí ☐ No

Si afirmativo, dar detalles _____

¿Tenía la persona responsable del cuidado del paciente la suficiente experiencia?

☐ Sí ☐ No

En caso negativo, explicar _____

La inadecuada monitorización/manejo estuvo relacionada con fallo para reconocer:

- ☐ 1 Signos vitales anormales (incluido el estado neurológico)
- ☐ 2 Problemas con los líquidos/electrolitos incluida la función renal
- ☐ 3 Efectos secundarios de la medicación
- ☐ 4 Alteraciones cardiopulmonares
- ☐ 5 Lesiones cutáneas o úlceras de decúbito
- ☐ 6 Adecuada movilización
- ☐ 7 Infección
- ☐ 8 Evolución lenta de la cicatrización (e.g. valorar función intestinal antes de la operación; cuidado de las heridas y de las vías)
- ☐ 9 Cambios en el estado general del paciente
- ☐ 10 Otros, especificar _____

Continue overleaf

D3. (Cont.)

En qué aspecto fue insatisfactorio el manejo clínico del paciente?

- ☐ 1 Error en la anotación de la observaciones rutinarias como por ejemplo . gráficas de constantes, valoración neurológica, medición de balance hidroelectrolítico.
- ☐ 2 Retraso en la anotación de los resultados de analisis o test de laboratorio.
- ☐ 3 Subestimar los resultados de dichos análisis/test de laboratorio.
- ☐ 4 Fallo en la interpretación apropiada de dichos análisis de laboratorio.
- ☐ 5 Desorden, poco cuidado al guardar notas, informes.
- ☐ 6 Poca o mala información en el pase de guardia.
- ☐ 7 Carecer de contacto o cooperación con otro adjunto.
- ☐ 8 Exceso de horas de trabajo.
- ☐ 9 Fallo en el cumplimiento de guías clínicas y protocolos de actuación.
(especificalos) _____
- ☐ 10 Fallo al reconocer el deterioro del paciente.
- ☐ 11 Reconocimiento del deterioro del paciente, pero ausencia de cuidados necesarios para intentar paliarlos (especificalos) _____
- ☐ 12 Fallo al pedir ayuda
- ☐ 12.1 Medico
- ☐ 12.2 Enfermera
- ☐ 12.3 Auxiliar. (especificalos) _____
- ☐ 13 Otros (especifica cuales) _____

Estaba el fallo en relación con el procedimiento del alta?

☐ Si ☐ No

Si es así, indica en cual de los siguientes aspectos y describe los detalles.

- ☐ 1 Fallo al explicar al paciente las recomendaciones a seguir, incluyendo manejo de protocolos con medicamentos (ej. Asma , diabetes. I) _____
- ☐ 2 Alta inapropiada en relación con las condiciones sociales del enfermo (ej anciano intervenido quirúrgicamente , que no tiene apoyo familiar y vive solo en su casa) _____
- ☐ 3 Fallo en la coordinación/cooperación de los cuidados sanitarios extrahospitalarios. _____
- ☐ 4 Otros (especificalos) _____

Qué otros factores han podido interaccionar con los fallos en el control/monitorización de constantes del paciente , cambio de turno de guardia o proceso de alta clínica?

- ☐ 1 Factores no tratados o tratados de forma inadecuada
- ☐ 2 El grado de vulnerabilidad del paciente no ha sido reconocido (pacientes con importante comorbilidad)
- ☐ 3 Mala evaluación del cociente riesgo-beneficio del tratamiento efectuado.
- ☐ 4 Otros (especificalos) _____

Donde existen otros problemas en relación con el control clinico/monitorización de constantes del paciente, incluidos cambios de turno/proceso de alta?

☐ Si ☐ No

Si es así, da detalles _____

D4 EFECTO ADVERSO/INCIDENTE CRÍTICO RELACIONADO CON UN FALLO EN LA PREVENCIÓN/CONTROL/MANEJO DE LA INFECCIÓN.

¿Cuál fue el lugar de la infección/ relación con algún procedimiento?

- ☐ 1 Herida quirúrgica
- ☐ 2 Procedimientos invasivos
- ☐ 3 Tracto urinario
- ☐ 4 Aparato respiratorio
- ☐ 5 Sangre
- ☐ 6 Otros, especificar _____

¿Cuál fue la naturaleza de la infección?

- ☐ 1. Herida contaminada
- ☐ 2. Efecto secundarios a drogas (especificar):
 - ☐ a. C. difficile inducido por antibióticos
 - ☐ b. Infección por hongos
 - ☐ c. Drogas inmunosupresoras
 - ☐ d. Otros (especificar) _____
- ☐ 3. Infección cruzada (especificar)
 - ☐ a. SAMR (describe) _____
 - ☐ b. Salmonella
 - ☐ c. Otros, (especificar) _____
- ☐ 4. Cuerpo extraño (especificar):
 - ☐ a. Catéter urinario
 - ☐ b. Catéter intravenoso
 - ☐ c. Compresa
 - ☐ d. Tubo de drenaje
 - ☐ e. Shunt
 - ☐ f. Otros (especificar) _____
- ☐ 5. Stasis (especificar):
 - ☐ a. Depresión respiratoria
 - ☐ b. Retención urinaria
 - ☐ c. Otros (especificar) _____
- ☐ 6. Otro tipo de Infección (especificar) _____

¿Tenía la persona responsable de de la prevención/control/manejo de la infección la experiencia suficiente?

☐ Sí ☐ No

En caso negativo, explicar _____

¿Fueron los errores en el manejo del EA/IC origen de la infección? Dar detalles

- ☐ 1 No se drena un absceso o se desbrida material necrótico _____
- ☐ 2 No se prescriben los antibióticos apropiados _____
- ☐ 3 No se aplica la fisioterapia adecuada (e.j respiratoria) _____
- ☐ 4 Inadecudo cuidado de catéteres/cánulas/drenajes/heridas _____
- ☐ 5 Otros (especificar) _____

¿De qué forma esto contribuyó al EA/IC?

- ☐ 1 Fallo a la hora de minimizar riesgos en un paciente vulnerable
- ☐ 2 El riesgo/beneficio del tratamiento no fue valorado
- ☐ 3 Llevó a un tratamiento inapropiado o inadecuado
- ☐ 4 Otros (especificar) _____

Continued overleaf

D4. (Cont.)

¿Hubo algún otro problema con el manejo de la Infección?

☐ Sí ☐ No

En caso afirmativo, dar detalles _____

D5 EFECTO ADVERSO DIRECTAMENTE RELACIONADO CON LA INTERVENCIÓN-PROCEDIMIENTO.

El procedimiento o la intervención fue

- ☐ 1 en la planta
☐ 2 en el quirófano
☐ 3 otro lugar (e.g. radiología, especificar) _____

¿Consideras que el procedimiento fue realizado por una persona con Experiencia suficiente?

☐ Sí ☐ No

En caso negativo, dar razones _____

Elige la que mejor describa la naturaleza del efecto adverso (dar detalles si fuese posible)

☐ **1** Retraso del procedimiento evitable (especificar) _____

☐ **2** Procedimiento inadecuado, especificar alternativa _____

☐ **3** Inadecuada valoración/tratamiento/preparación previo al procedimiento (especificar) _____

4 Incidente anestésico

☐ 4.1 Intubación (especificar) _____

☐ 4.2 Agente anestésico _____

☐ 4.3 Fallo del equipo _____

☐ 4.4 Fallo durante la monitorización (e.j. oxigenación, CO₂, presión aérea) _____

☐ 4.5 Otros (especificar) _____

5 Incidente durante la intervención/procedimiento

☐ 5.1 Dificultad para reconocer la anatomía (especificar) _____

☐ 5.2 Lesión visceral inadvertida (especificar) _____

☐ 5.3 Hemorragia (especificar, e.j. ligadura floja; punción vascular) _____

☐ 5.4 Perforación (especificar origen) _____

☐ 5.5 Dehiscencia anastomótica (especificar factores contribuyentes) _____

☐ 5.6 Problemas de la herida (e.j. dehiscencia). (especificar) _____

☐ 5.7 Siting prosthesis _____

☐ 5.8 Fallo del equipo/instrumental (e.g. uso inapropiado, fallo; especifica) _____

☐ 5.9 Otros (especificar) _____

☐ **6** Inadecuada monitorización durante el procedimiento _____

7 Relacionado con la infección

☐ 7.1 Herida (celulitis) _____

☐ 7.2 Infección interna (e.g. absceso, especifica) _____

☐ 7.3 Otros (e.g. colangitis, especifica) _____

☐ **8** Otros, incluidos resultado insatisfactorio (especificar) _____

Continue overleaf

D5. (Cont.)

¿Hubo algún otro problema relacionado con el manejo del procedimiento? ☐ Sí ☐ No

En caso afirmativo, dar razones _____

D6 ACONTECIMIENTOS ADVERSOS/INCIDENTES CRÍTICOS EN RELACIÓN CON LA PRESCRIPCIÓN, ADMINISTRACIÓN O MONITORIZACIÓN DE FÁRMACOS O FLUIDOS (INCLUIDA TRASFUSIÓN SANGUÍNEA)

Como fueron administrados dichos fármacos/fluidos?

- | | | |
|---|---------------------------------------|--|
| ☐ 1 Intravenosa | ☐ 4 oral | ☐ 7 topica |
| ☐ 2 Intra-muscular | ☐ 5 sublingual | ☐ 8 rectal |
| ☐ 3 Subcutanea | ☐ 6 intratecal | ☐ 9 Otros (cuales?) _____ |

Existió algún error en la prescripción o preparativos de dichos fármacos/fluidos/sangre?

☐ Si ☐ No

Si es así, descríbelos _____

Existió algún error o accidente durante la administración de dichos fármacos/fluidos/sangre? (ej. Dosis incorrecta, vía de administración, retraso en la administración...)

☐ Si ☐ No

Si es así, descríbelos _____

Existió algún error al controlar la acción /toxicidad/efectos adversos de los fármacos /fluidos administrados?

☐ Si ☐ No

Si es así descríbelos _____

Qué fármaco era?

- | | | |
|---|--|---|
| ☐ 1 antibióticos | ☐ 7 sedantes o hipnóticos | ☐ 13 potasio |
| ☐ 2 antineoplásicos | ☐ 8 antiulcerosos | ☐ 14 NSAID |
| ☐ 3 antiepilépticos | ☐ 9 antihipertensivos | ☐ 15 Narcóticos (ej. Cl morfina) |
| ☐ 4 antidiabéticos | ☐ 10 antidepresivos | ☐ 16 Diuréticos |
| ☐ 5 cardiovasculares | ☐ 11 antipsicóticos | ☐ 17 Otros (cuales) _____ |
| ☐ 6 antiasmáticos | ☐ 12 anticoagulantes | |

Nombre del fármaco: _____

Describe los efectos adversos del fármaco: _____

Dé que tipo fue la naturaleza del incidente relacionado con el fármaco?

- ☐ 1 Fármaco menos efectivo de lo esperado (ej. Como resultado del retraso del inicio del tratamiento, dosis demasiado pequeña)
- ☐ 2 Efecto derivado del fármaco administrado
- ☐ 3 Efecto secundario a dosis elevada, para el paciente y situación en concreto.
- ☐ 4 Reacción alérgica
- ☐ 5 Interacción con otros fármacos
- ☐ 6 Otros (cuales) _____

Estaba capacitada o tenía la suficiente experiencia la persona responsable del control del régimen terapéutico del paciente?

☐ Si ☐ No

Si no fue así, explícalo _____

Prescribió de forma correcta el fármaco el médico, conociendo de antemano qué estos efectos adversos podían ocurrir?

☐ Si ☐ No

Continue overleaf

D6. (cont.)

Cual crees que fue la causa en relación con el incidente?

- ☐
- 1 No existe una causa mencionable (otras que la que son responsabilidad del paciente)
-
- ☐
- 2 Retraso en la prescripción del fármaco (especificalo)
-
- _____
-
- ☐
- 3 Retraso en la administración del fármaco (tras ser prescrito) _____
-
- ☐
- 4 Error en la prescripción del fármaco (especifica)
-
- _____
-
- ☐
- 5 Fármaco adecuado, pero error en la dosis o duración del tto _____
-
- ☐
- 6 Vía de administración inadecuada (describela)
-
- _____
-
- ☐
- 7 Error en la administración
-
- (describe) _____
-
- ☐
- 8 Inacuado control tras la administración del fármaco(describe)
-
- _____
-
- ☐
- 9 Otros (especificalo)
-
- _____

Existieron otros problemas relacionados con el manejo de sangre o fluidos? ☐ Si ☐ No

Si es así , descríbelo

Fase E: FACTORES CAUSANTES / DESENCADENANTES DE AE/CI , POTENCIALMENTE EVITABLES.

E1 FACTORES CAUSANTES

Las acciones realizadas u omitidas en relación con los accidentes adversos o incidentes críticos pueden estar influenciadas por factores desencadenante.Muchos de ´setos se podrían evitar con la intervención del personal relacionado con los cuidados del paciente.Indica, por favor, los posibles factores causantes.Marca con **U** factores que no sean desencadenantes y los posibles factores desencadenantes con 1, 2 ó 3 (en función de su importancia en la aparición de dicho AE/CI).

U (factores no desencadenantes) **1** (posible) **2**(bastante) **3** (factor desencadenante muy importante)

1. Características del paciente

- 1.1 El paciente no pudo entender/comunicarse con el equipo médico /enfermería.
(ej diferencias culturales, problemas de idioma).
- 1.2 Personalidad/Factores sociales del paciente
- 1.3 Fue la comorbilidad un factor importante?
- 1.4 Otras (describelas)_____

U	1	2	3
☐	☐	☐	☐
☐	☐	☐	☐
☐	☐	☐	☐
☐	☐	☐	☐

2. Factores reelacionados con la actividad diaria

- 2.1 Procedimiento nuevo, no realizado antes o difícil.
- 2.2 Errores en el uso guias clínicas o protocolos.
- 2.3 Resultados de pruebas mal valorados o de difícil interpretación.
- 2.4 Mala programación de las actividades
- 2.5 Otros (describelos) _____

U	1	2	3
☐	☐	☐	☐
☐	☐	☐	☐
☐	☐	☐	☐
☐	☐	☐	☐
☐	☐	☐	☐

3. Factores individuales

- 3.1 Personal trabajando fuera de su campo de experiencia habitual.
- 3.2 Falta de conocimientos individual
- 3.3 Falta de habilidad individual
- 3.4 Problemas de actitud o motivación.
- 3.5 Trabajar bajo presión o jornada excesiva
- 3.6 Otros factores individuales(especifica)) _____

U	1	2	3
☐	☐	☐	☐
☐	☐	☐	☐
☐	☐	☐	☐
☐	☐	☐	☐
☐	☐	☐	☐
☐	☐	☐	☐

5. Ambiente de trabajo

- 5.1 Equipo defectuoso o no disponible
- 5.2 Problemas con las citaciones de los servicios (lista de quirófano, Rx)
- 5.3 Funcionamiento inadecuado de servicios centrales
(e.g. farmacia, banco de sangre)
- 5.4 Falta de personal en el momento de IA
- 5.5 Fuera de horario (hora del día/día de la semana)
- 5.6 Otros factores del ambiente (especificar)_____

U	1	2	3
☐	☐	☐	☐
☐	☐	☐	☐
☐	☐	☐	☐
☐	☐	☐	☐
☐	☐	☐	☐

6. Factores de Gestión y Organización

- 6.1 Falta de recursos esenciales (Camas de UCI)
- 6.2 Pobre coordinación entre servicios
- 6.3 Liderazgo senior inadecuado
- 6.4 Otros factores de Gestión y Organización (especificar)_____

U	1	2	3
☐	☐	☐	☐
☐	☐	☐	☐
☐	☐	☐	☐
☐	☐	☐	☐

E2 De detalles de los 3 factores contribuyentes mas importantes

1.

2.

3.

E3 ANALIZAR LA PREVISIBILIDAD DEL INCIDENTE ADVERSO

A su juicio,existe evidencia de que el IA fuera previsible?

☐ Si

☐ No

Marque del 1 al 6 la como era la evidencia existente para esa previsibilidad

- ☐

1 Ninguna evidencia de previsibilidad
- ☐

2 Leve a moderada evidencia de previsibilidad
- ☐

3 No muy previsible, menos del 50-50 pero cerca
- ☐

4 Mas probable que fuera previsible, mas del 50-50 aunque cerca
- ☐

5 Importante evidencia de previsibilidad
- ☐

6 Virtualmente evidencia completa de previsibilidad

Si ha marcado 2 - 6, conteste a las siguientes preguntas:

Describa brevemente la forma en la que el IA se pudo haber prevenido

Puede identificar las razones por las que no se pudo prevenir el IA?