

The investigation and analysis of critical incidents and adverse events in healthcare

M Woloshynowych, S Rogers, S Taylor-Adams
and C Vincent



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**Health Technology Assessment
NHS R&D HTA Programme**





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The investigation and analysis of critical incidents and adverse events in healthcare

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Abstract

The investigation and analysis of critical incidents and adverse events in healthcare

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Objectives: To carry out a review of published and unpublished work on the analysis on methods of accident investigation in high-risk industries, and of critical incidents in healthcare. To develop and pilot guidelines for the analysis of critical incidents in healthcare for the hospital sector, mental health and primary care.

Data sources: Literature already available in the Clinical Risk Unit, University College London. Work by known experts in the field of accident investigation and analysis. Electronic databases including PsycINFO and MEDLINE. Websites for accident investigation reports.

Review methods: Twelve techniques from other high-risk industries were reviewed in detail using criteria developed for the purpose. This review provided a conceptual framework for the healthcare review and appraisal process, as well as providing a critical assessment of the industry techniques. Rigorous searching and screening identified 138 papers for formal appraisal and a further 114 were designated as providing potentially useful background information. A formal appraisal instrument was designed, piloted and modified until acceptable reliability was achieved. From the 138 papers, six techniques were identified as representing clearly definable approaches to incident investigation and analysis. All relevant papers were reviewed for each of the six techniques: Australian Incident Monitoring System, the Critical Incident Technique, Significant Event Auditing, Root Cause Analysis, Organisational Accident Causation Model and Comparison with Standards approach.

Results: All healthcare techniques had the potential of being applied in any specialty or discipline related to healthcare. While a few studies looked solely at death as an outcome, most used a variety of outcomes

including near misses. Most techniques used interviewing and primary document review to investigate incidents. All techniques included papers that identified clinical issues and some attempt to assess underlying errors, causes and contributory factors. However the extent and sophistication of the various attempts varied widely. Only a third of papers referred to an established model of accident causation. In most studies examined there was little or no information on the training of investigators, how the data was extracted or any information on quality assurance for data collection and analysis. There was some variation in the level of expertise and training required but to undertake the investigation to an acceptable depth all required some expertise. In most papers there was little or no discussion of implementation of any changes as a result of the investigations. A quarter of publications gave some description of the implementation of changes, though few addressed evaluation of changes.

Conclusions: The reviews demonstrate that, while much valuable work has been accomplished, there is considerable potential for further development of techniques, the utilisation of a wider range of techniques and a need for validation and evaluation of existing methods which would make incident investigation more versatile and use limited resources more effectively. Further exploration of techniques used in high-risk industries, with interviews and observation of actual investigations should prove valuable. Existing healthcare techniques would benefit from formal evaluation of their outcomes and effectiveness. Studies should examine depth of investigation and analysis, adequacy and feasibility of recommendations and cost effectiveness. Examining implementation of recommendations is a key issue.



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Glossary and list of abbreviations

Technical terms and abbreviations are used throughout this report. The meaning is usually clear from the context, but a glossary is provided for the non-specialist reader. In some cases, usage differs in the literature, but the term has a constant meaning throughout this review.

Glossary

Accident An unplanned event or sequence that results in undesirable consequences. An incident with specific safety consequences or impacts.

Analysis The use of methods and techniques of arranging facts to (a) assist in deciding what additional facts are needed, (b) establish consistency, validity and logic, (c) establish sufficient and necessary events for causes and (d) guide and support inferences and judgements.

Cause An event, situation or condition which results or could result directly or indirectly in an accident or incident.

Consequence The cumulative, undesirable result of an incident, usually measured in health/safety effects, environmental impacts, loss of property and business interruption costs.

Critical incident An unplanned event or series of events and circumstances that may result in an undesirable consequence.

Failure mode and effects analysis A hazard identification technique in which all known failure modes of components or features of a system are considered in turn and undesired outcomes noted.

Fault tree A method for representing the logical combinations of various system states that lead to a particular outcome.

Fault tree analysis Estimation of the hazardous incident (top event) frequency from a logical model of the failure mechanisms of a system.

HAZOP Hazard and operability study: a systematic qualitative technique to identify and evaluate process hazards and potential operating problems using a series of

guidewords to examine deviations from normal process conditions.

Human error Any human action (or lack thereof) that exceeds some limit of acceptability where the limits of human performance are defined by the system. Includes actions by designers, operators and managers that may contribute to or result in an accident.

Human factors A discipline concerned with designing machines, operations and work environments so that they match human capabilities, limitations and needs.

Investigation A detailed systematic search to uncover facts and determine the truth of the factors (who, what, where, when, why and how) of accidents.

Incident investigation The management process by which underlying causes of undesirable events are uncovered and steps are taken to prevent similar occurrences.

Incident investigation team A group of qualified people who examine an incident in a manner that is timely, objective, systematic and technically sound to determine that factual information pertaining to the event is documented, probable causes are ascertained and complete technical understanding of such an event is achieved.

Risk A measure of economic loss or human injury in terms of both the incident likelihood and the magnitude of the injury.

Root causes A prime reason why an incident occurred. Root causes are often related to deficiencies in management systems.

continued

Glossary continued

Task analysis An analytical process for determining the specific behaviours required of the human components in a human-machine system. It involves determining the detailed performance required of people and equipment and the effects of environmental

conditions, malfunctions and other unexpected events on both.

Witness A person who has information related, directly or indirectly, to the accident or incident.

List of abbreviations

A&E	accident and emergency department	ISA	intelligent safety assistant
AAM	accident anatomy method	JCAHO	Joint Commission on Accreditation of Healthcare Organisations
AEB	accident evolution and barrier function model	MES	multi-linear event sequencing
AIMS	Australian Incident Monitoring System	MORT	management oversight and risk tree
ALARM	Association of Litigation and Risk Managers	MRI	magnetic resonance imaging
APSF	Australian Patient Safety Foundation	MRSA	methicillin-resistant <i>Staphylococcus aureus</i>
BA	barrier analysis	MRWPPM	Mersey Region Working Party on Perinatal Mortality
CCDM	cause consequence diagram method	NPSA	National Patient Safety Agency
CIT	critical incident technique	OACM	organisational accident causation model
CDP	care delivery problem	OWAM	organisation with a memory
CMP	care management problem	PCA	patient-controlled anaesthesia
CRU	Clinical Risk Unit	PEM	psychological error mechanisms
CWS	comparison with standards	PIF	performance-influencing factors
EEM	external error modes	QAHCS	Quality in Australian Health Care Study
FMEA	failure modes and effects analysis	RCA	root cause analysis
GFT	general failure types	SEA	significant event auditing
GOC	generic occurrence classification	STEP	sequentially timed events plotting
HAZOP	hazard and operability study	TA	task analysis
HTA	hierarchical task analysis	THR	total hip replacement
IAEA	International Atomic Energy Agency	TOR	technical operations review
ICU	intensive care unit	WSA	work safety analysis
IDA	influence diagram approach		

All abbreviations that have been used in this report are listed here unless the abbreviation is well known (e.g. NHS), or it has been used only once, or it is a non-standard abbreviation used only in figures/tables/appendices in which case the abbreviation is defined in the figure legend or at the end of the table.



Executive summary

In other high-risk industries, learning from accidents and near misses is a long-established practice, in fact it is a cornerstone of safety analysis and improvement. In contrast, learning within healthcare has often been fragmentary and uncertain. In the last 10 years, however, sufficient work has accumulated within healthcare to warrant a review of methods of investigation and analysis, supplemented by a parallel overview of methods of investigation and analysis in other settings.

Objectives of the review

The objectives of the review were:

- to carry out a review of published and unpublished work on the analysis of methods of accident investigation in high-risk industries and to provide a sound conceptual and practical foundation for the review of healthcare methods
- to carry out a review of published and unpublished work on the analysis of critical incidents in healthcare
- to develop guidelines for the analysis of critical incidents in healthcare for the hospital sector, mental health and primary care
- to pilot the three sets of guidelines.

Review of techniques of accident analysis in high-risk industries

The diversity of techniques used in other industries greatly impressed us, as did the clarity with which they were presented and the power and conceptual development of some of the methods. A search of relevant databases, websites and specialist literature yielded 19 accident investigation and analysis techniques. Of these, 12 were selected and reviewed in detail. All had some strong points, although the approaches varied in comprehensiveness, theoretical adequacy, use of resources and the extent to which they were used and accepted. Some techniques stood out as being of particular value. For instance, MORT (Management Oversight and Risk Tree), if carried out completely, is an extremely comprehensive technique examining an accident from several

perspectives using a toolbox of techniques. Many of these techniques provide useful methods of solving specific accident investigation or analysis problems. For example, barrier analysis is an exceptionally quick and useful approach to identifying where and how to implement specific types of defences and barriers within an organisation.

Review of studies of healthcare approaches

Initial searches on electronic and other databases identified 1950 potentially relevant papers. After screening of abstracts, 562 papers were obtained for further review. After further screening, 138 papers were identified for formal appraisal and a further 114 were designated as providing potentially useful background information.

A formal appraisal instrument was designed, piloted and modified until acceptable reliability was achieved. From the 138 papers, six techniques were identified as representing clearly definable approaches to incident investigation and analysis. We excluded from formal appraisal those techniques which had been used in less than five peer-reviewed published studies. All relevant papers, to a maximum of ten, were reviewed for each of the six techniques: Australian Incident Monitoring System (AIMS), the Critical Incident Technique, Significant Event Auditing (SEA), Root Cause Analysis (RCA), Organisational Accident Causation Model (OACM) and Comparison with Standards approach.

All techniques had the potential to be applied in any specialty or discipline related to healthcare. Although a few studies looked solely at death as an outcome, most used a variety of outcomes including near misses. Most techniques used interviewing and primary document review to investigate incidents. All techniques included papers which identified clinical issues and some attempt to assess underlying errors, causes and contributory factors. However, the extent and sophistication of the various attempts varied widely. Only one-third of papers referred to an established model of accident causation. In most

studies examined there was little or no information on the training of investigators, how the data were extracted or any information on quality assurance for data collection and analysis. There was some variation in the level of expertise and training required, but to undertake the investigation to an acceptable depth all required some expertise. In most papers there was little or no discussion of implementation of any changes as a result of the investigations. One-quarter of publications gave some description of the implementation of changes, although few addressed evaluation of changes.

The development and piloting of a guide for the investigation and analysis of critical incidents and adverse events in healthcare

The review of methods of accident investigation in high-risk industries showed that there are a number of potentially useful techniques that could be used in healthcare. Review of techniques used in healthcare revealed two of particular interest and potential, RCA and OACM, but there were also methodological developments in other approaches that might be transferable (e.g. group-based approaches in SEA, taxonomies from the monitoring studies, links to implementation in audit and peer review approaches). Our learning from these techniques underpins the guide that appears in this publication. For three specialities, acute care, mental health and primary care, a research group was set up to test and pilot a draft version of the guide. Changes were then made following their experiences, comments and discussions. The resulting guide is included in Chapter 6 of the report, with case examples in the corresponding appendix.

The future of incident investigation in healthcare

The principal recommendations were as follows.

Defining the technique and providing manuals and guidelines

Manuals and descriptions of the methods of investigation and analysis need to be developed. Researchers need to provide much more detail on the purpose of the technique, its context of use and the process of investigation.

Resources and the need for training

High-risk industries recognise that accident investigation is a specialist and complex task, which requires substantial investment in training dedicated accident investigators. Healthcare professionals engaged in investigations also need adequate training and experience. Local teams need sufficient time to enable them to produce a thorough report with serious attention to implementing changes.

Implementation of changes

Both researchers and investigation teams need to give more attention to recommendations for change and implementation of changes. Research studies cannot always consider the whole cycle of investigation, analysis, implementation and evaluation, but as the techniques develop more attention should be given to linking findings directly to future prevention.

Integration of techniques

The range of effective approaches available in high-risk industries suggests that investigators of clinical incidents should think in terms of a 'toolbox' of approaches, where specific techniques would be used for different purposes and at different stages of an investigation.

Conclusion

Our reviews demonstrate that, while much valuable work has been accomplished, there is considerable potential for further development of techniques, the utilisation of a wider range of techniques and a need for validation and evaluation of existing methods, which would make incident investigation more versatile and use limited resources more effectively.

Future research

Further exploration of techniques used in high-risk industries, with interviews and observation of actual investigations, should prove valuable. Existing healthcare techniques would benefit from formal evaluation of their outcomes and effectiveness. Studies should examine depth of investigation and analysis, adequacy and feasibility of recommendations and cost-effectiveness. Examining implementation of recommendations is a key issue.

Chapter I

Risk management, patient safety and the investigation of clinical incidents

Clinicians have always reflected on the reasons for successful or adverse outcomes, but these reflections have generally been private or shared only with close colleagues. Furthermore, the reasons for success and failure have usually been couched in personal terms, in that the clinician's individual ability and character have been seen as the major determinants of the quality of diagnosis and treatment. When medicine was simpler and often in the hands of one individual this may have been a reasonable view. Now it is complex, reliant on high technology and team based. A huge range of factors determine the quality of care and, correspondingly, the occurrence of adverse outcomes. The analysis of adverse outcomes and critical incidents therefore needs to be more sophisticated and to move beyond simplistic conceptions of human error, fault and blame.

In other high-risk industries, learning from accidents and near misses is a long-established practice, in fact a cornerstone of safety analysis and improvement. Accident investigation has acquired a high priority and many of these industries have invested heavily in the development of proactive and reactive safety assessment tools. Aviation accidents, for instance, are exhaustively investigated and the lessons learnt are disseminated widely, with important changes made mandatory by the regulatory authorities. In contrast, learning within healthcare is fragmentary, uncertain and usually confined to individuals or teams.¹ In the past 10 years, however, sufficient work has accumulated within healthcare to warrant a review of methods of investigation and analysis, supplemented by a parallel overview of methods of investigation and analysis in non-healthcare settings.

The aims of the current project, set out fully below, are to review methods of incident investigation and analysis both within and outside healthcare. The results of these reviews provide the foundations for the development of guidelines for incident investigation and analysis in healthcare. This introductory chapter provides the context for the study and the report. We review

the development of formal quality and safety initiatives in the NHS, particularly the development of risk management and incident reporting. We discuss the way in which incidents and adverse outcomes are studied in healthcare, contrasting this with the approach taken in high-risk industries. After a brief overview of these developments, we outline the objectives of the present review and the structure of this report. Guidelines for the investigation and analysis of clinical incidents, developed from this work, are presented in the final chapter. For the purposes of this document, high-risk review refers to a review of methods used by industries other than healthcare such as the aviation, nuclear and petrochemical industries. In contrast, healthcare review refers to a review of methods used by healthcare organisations only.

Quality and safety in the British NHS

For most of the 54 years of the existence of the NHS in Britain, the quest for improved quality has been a fragmented affair. In the early days it rested on the notion of improving health facilities, supplying well-trained staff and enabling them to deliver a service which was presumed to be inherently of a generally high standard. In the 1960s and 1970s, quality improvement initiatives, such as medical audit, were largely uniprofessional activities and, even then, were by no means comprehensive. There were few examples of where they contributed to corporate quality strategies within individual health organisations.²

The late 1980s and early 1990s saw a major change of emphasis. Medical and later clinical audit became a requirement for hospital doctors working in the NHS. The concept of clinical effectiveness gained widespread acceptance within the health professions and stimulated activity in producing guidelines and protocols to improve clinical decision-making.³ The repeated observation that the benefits of research were slow to become part of routine practice⁴ yielded to an

evidence-based medicine movement,⁵ with its origins in North America. It rapidly became international in its application.

Despite these developments, there was still no unifying concept or system to drive progress comprehensively until the advent of clinical governance in 1998. The United Kingdom 1999 Health Act introduced, for the first time, a statutory duty on NHS Trusts and Primary Care Trusts to assure and improve the quality of healthcare that they deliver, which in practice means implementing clinical governance. Clinical governance is defined as⁶

“A framework through which NHS organisations are accountable for continuously improving the quality of their services and safeguarding high standards of care by creating an environment in which excellence in clinical care will flourish.”

Clinical governance is, in effect, an endorsement of the ideas of whole system quality improvement which have been increasingly influential in healthcare in the UK and elsewhere.⁷ National guidance on clinical governance explicitly states that systems for managing risk and adverse events should form a central component of arrangements for clinical governance in NHS organisations.⁶

Risk management in NHS trusts

Until the late 1980s, no NHS organisations had a formal risk management function, although many had some of the components or apparatus of risk management in place. For example, most had some form of accident reporting, many had health and safety committees and advisors and most had people responsible for managing complaints and litigation. However, these components were rarely connected, or made to work together, and there was little ownership at a corporate level by senior managers and clinicians. The essentials of risk management – linked processes for identifying, analysing and then controlling risk – were definitely not in place. However, in 1995 the introduction of national standards for risk management made it a national requirement that NHS Trusts should have such systems in place.⁸

In research undertaken in 1998, Walshe and Dineen⁹ demonstrated that most NHS trusts had moved at least some way towards developing systems for risk management and that some had made rapid progress in establishing risk management as part of their organisation. At that

time almost all NHS trusts had a named member of the board who took responsibility for clinical risk management and some form of senior group or committee tasked with leading on clinical risk management. Most NHS trusts also had a nominated individual who took day-to-day responsibility for clinical risk management across the trust – a clinical risk manager. However, this role was almost always combined with other roles and responsibilities.

In 1998, almost all trusts had some form of system for clinical incident reporting in place. Of those trusts, over three-quarters indicated that their clinical incident reporting systems were being used across all clinical directorates or service areas, with the remainder using incident reporting in some areas only (such as obstetrics or anaesthetics). There was, however, little consensus about what sort of clinical incidents should be reported and the numbers of incidents being reported varied widely. Most trusts reported that the numbers of clinical incidents being reported were rising, usually attributing the rise to an increased awareness among clinicians of the need to report clinical incidents, and a greater willingness to do so, rather than to any underlying change in the quality of care.⁹

Trusts captured a substantial set of information about each clinical incident, including details of patients and staff involved, where and when it happened, what the incident was, and often what action had been taken following the incident. All trusts said that someone, usually the clinical risk manager, was responsible for reviewing every incident report. The great majority of trusts had a system for filtering out the few most serious and urgent incidents and subjecting them to some form of senior clinical and managerial review. However, few trusts followed any established method of investigation, relying primarily on clinical experience and commonsense approaches.

From risk management to patient safety

Clinical risk management was initially developed as a means of controlling medical negligence litigation. In 1975, the total cost of claims to the NHS was around £1 million, but by 1996 claims for clinical negligence cost the NHS about £200 million. Costs were predicted to reach £500 million per annum within a few years,¹⁰ with obstetric claims representing over half of the financial burden. Early risk management strategies

were dominated by attempts to reform the legal system and stem the rising costs of compensation. Gradually, however, the need to systematically examine the underlying clinical problems became apparent, together with the need to care for injured patients rather than simply treating them as potential litigants.¹¹

The costs of clinical negligence litigation to the NHS do not, by themselves, explain the growing recognition of the need for clinical risk management. In the NHS, the rise of risk management is part of a wider and growing interest in quality management and improvement, reflected in a succession of government and professional initiatives¹² aimed at ensuring that healthcare organisations have robust and effective systems for assuring the quality of care they provide. There has also, in the last decade, been a much greater recognition of the costs and consequences of adverse events, highlighted by this growing attention to the quality of healthcare, and this in itself has promoted the development of risk management. In addition, a series of high-profile system failures, in which major lapses in the quality of care have resulted in serious injuries to patients, have done much to raise public and professional awareness about the risks of healthcare and the need to explore actively ways of protecting patients and making healthcare safer.¹³

Several important new initiatives in the last 5 years underline the increasing attention paid to patient safety. In the USA, organisations such as the National Patient Safety Foundation are pioneering a much more sophisticated approach to patient safety, drawing on research and practice from a number of different industries. The recent report of the Institute of Medicine on 'Building a safer healthcare system'¹⁴ starkly set out the scale of harm of patients and an ambitious and radical agenda for change, which attracted Presidential backing in the USA. In Australia, the results of the Quality in Australian Health Care Study (QAHCS)¹⁵ were initially marred by political interference, setting back the implementation programme that was to follow. However, major initiatives are now underway at both a federal and national level. In Britain, the Department of Health commissioned a major report on 'An organisation with a memory',¹ a report covering similar ground to the Institute of Medicine report, but in a British context. The *BMJ* devoted an entire issue to the subject of medical error¹⁶ in a determined effort to move the subject to the mainstream of academic and clinical enquiry. The launch of the National Patient Safety Agency

(www.npsa.nhs.uk) in 2001 in the UK brought an additional focus on safety, particularly on the recording and learning from serious clinical incidents. Further examples could be given of initiatives in Canada, several countries in Europe and Asia of an increasing interest in research on patient safety and practical approaches to the management of risk. Finally, in 2001, the WHO passed a resolution to establish a worldwide patient safety programme.¹⁷

Adverse events in healthcare

Iatrogenic effects of drugs and other treatments have been recorded in many studies, although not always labelled as such.¹⁸ However, it is only comparatively recently that the overall scale of injury to patients has become apparent. These broad aggregate studies of adverse events (unintended injury to patients) have been a powerful driver of patient safety. The Harvard Medical Practice Study (HMPS)¹⁹ found that adverse events, occasions on which patients are unintentionally harmed by treatment, occurred in almost 4% of admissions in New York State. For 70% of patients the resulting disability was slight or short-lived, but in 7% it was permanent and 14% of patients died in part as a result of their treatment. Serious harm therefore came to approximately 1% of patients admitted to hospital. Similar findings have been reported from studies carried out in Colorado and Utah in 1992.²⁰ The QAHCS revealed that 16.6% of admissions resulted in an adverse event, of which half were considered preventable.¹⁵ A British pilot study of 1014 patient records suggested that 10.8% of patients admitted to British hospitals may suffer adverse events.²¹ With 8.5 million admissions to English hospitals each year, this could mean that there are as many as 850,000 adverse events per annum.

The overall financial impact of adverse events in terms of resources and reduced efficiency is unknown, but it is clearly vastly greater than the immediate costs of litigation. An operation with an adverse outcome, for instance, may lead to at least one further operation, a longer stay in hospital, additional outpatient appointments and so on. In Australia, adverse events were estimated to account for 8% of all hospital bed-days.¹⁵ In Britain, each adverse event led to an additional 8 days in hospital, suggesting a total cost to the NHS of £2 billion per annum in extra bed-days, over half of which is preventable.²¹ In addition, adverse events involve substantial costs in the form

of long-term care, disability payments and other benefits, which are likely to far outweigh the costs of individual hospitals. Adverse events also involve a huge personal cost to the people involved, both patients and staff. Many patients suffer increased pain, disability and psychological trauma, often compounded by a protracted, adversarial legal process. Staff may experience shame, guilt and depression after making a mistake, with litigation and complaints imposing an additional burden.¹¹

As yet epidemiological studies have been primarily hospital based. The available evidence in primary care, scattered though it is, suggests that safety issues will be as important in this context as in hospital settings.²² Mental health is a largely unexplored area in the patient safety literature but some recent findings (for instance, many patients who commit suicide have been in recent contact with mental health services, who may have failed to recognise the severity of their depression¹) suggest that systematic investigation of adverse outcomes is much needed.

The investigation and analysis of clinical incidents in healthcare

Adverse outcomes, and sometimes near misses, are often reviewed in morbidity and mortality meetings. Usually, however, several incidents are reviewed during a meeting, with little opportunity to review a case in detail. Often only the immediate and most obvious departures from good practice can be identified. Such meetings are usually confined to a single department, so it can be difficult to resolve more general issues such as inter-departmental conflicts or wider problems of hospital policy. The advent of clinical risk management as a hospital-wide activity offers the chance for detached investigation of a selection of serious or potentially serious incidents. Few risk managers or clinicians carry out such investigations, unless involved in major enquiries, but there is enormous potential for organisational learning.¹ Investigations that are conducted often focus excessively on the actions or omissions of individual clinicians, and seldom examine the background to such events. The fundamental causes of adverse events usually lie in a variety of systemic features operating at the level of the task, the team, the work environment and the wider organisational context.²³

The literature on the analysis of critical incidents and adverse events in healthcare is diverse and poorly integrated. There are studies of single and

multiple incidents in many hospital specialities, in primary care and in mental health, but little work on the development of the method either conceptually or practically. In primary care, for instance, there are studies of prescribing, referrals, deaths, complaints and medical negligence.^{24–27} Within hospitals, studies have been carried out in intensive care,²⁸ anaesthesia^{29,30} and paediatrics.³¹ Many of these studies refer to the original paper on critical incidents³² and to previous studies using the technique. Few, however, have made any attempt to develop the method, consider its validity or provide guidelines for other researchers or clinicians. Some studies do nevertheless provide useful information on the process of enquiry. For instance, Berlin and colleagues,²⁴ although not primarily concerned with the development of methods, describe the actual procedures used in their audit of deaths.

There are, however, a range of well-established frameworks in which the investigation and analysis of critical incidents play some part. For example, analysis of critical incidents occurs to a greater or lesser extent in confidential enquiries into maternal or postoperative deaths, significant event auditing, reviews of complaints and malpractice cases and in some quality assurance approaches.³³ A few investigators have begun to use human factors methods (used to investigate accidents in fields such as the aviation, nuclear and chemical industries) in healthcare settings.^{34–36} However, very few of the wide range of human factors methods have yet been explored in depth.

Understanding adverse events

Human error is routinely blamed for disasters in the air, on the railways, in complex surgery and in healthcare generally. However, quick judgements and routine assignment of blame obscure a more complex truth. The identification of an obvious departure from good practice is usually only the very first step of an investigation. While a particular action or omission may be the immediate cause of an incident, closer analysis usually reveals a series of events and departures from safe practice, each influenced by the working environment and the wider organisational context. Although this more complex picture is gaining acceptance in healthcare,²³ it is seldom put into practice in the investigation of actual incidents.

Analyses of accidents in high-risk industries have led to a much broader understanding of accident causation, with less focus on the individual who

makes an error and more on pre-existing organisational factors that provide the conditions in which errors occur.³⁴ This 'human factors' approach, as it is called, is a hybrid discipline which focuses on the human component within complex socio-technical systems. The assessment of accidents in large-scale systems has acquired a high profile in industry, after such disasters as the King's Cross Underground fire in London, the Chernobyl nuclear power plant explosion and the Piper Alpha oil disaster in the North Sea. Reason's model³⁷ was originally developed for use in these complex industrial systems and has now been adapted for use in medical settings.^{35,38,39}

Leape¹⁸ has argued that, if we are to understand adverse events in healthcare, more attention must be given to psychological and human factors research on the nature, mechanisms and causes of error, particularly the fact that liability to error is strongly affected by the context and conditions of work. Critical incident and organisational analyses of individual cases have illustrated the complexity of the chain of events that may lead to an adverse outcome.^{36,37} The root causes of an adverse event may lie in a variety of interlocking factors such as the use of locums, communication and supervision problems, excessive workload and training deficiencies. Some fundamental features of a unit, such as poor communication within a team, may be implicated in a wide variety of adverse clinical events.¹¹

There is a considerable relevant literature on accident analysis in fields such as the aviation, nuclear and chemical industries, which can provide conceptual underpinning for the human factors approaches recommended by Leape and others (see Chapter 3). The formal investigation and analysis of adverse events and accidents in industry have become a well-established practice. Accident and safety researchers have developed a variety of 'human factors' methods both to investigate and to analyse accidents. Accident investigation in industry is grounded in theories of accident causation. Various theories have been put forward, such as domino cascade, chain reaction and multicausality theories.^{40,41} Waring⁴² outlined a generic accident investigation process which focuses on establishing the facts of the adverse event (e.g. who, what, when), analysing the causes and making recommendations to prevent recurrence. A variety of data collection techniques exist (e.g. interviewing relevant personnel, observation, simulation techniques, hierarchical task analysis, fault and event trees, record review). Formal approaches to analysis include human

error analysis, human reliability assessment and human reliability management systems.⁴³ In addition, a number of comprehensive human error taxonomies have been produced to categorise error.⁴⁴

Healthcare and other high-risk industries

The aviation, nuclear power, chemical and petroleum industries are also complex, hazardous activities carried out in large organisations by, for the most part, dedicated and highly trained people. The parallels with healthcare are obvious and it would be surprising if we could not learn from them and in fact many useful ideas and practices have transferred from aviation to medicine, such as simulation and team training in anaesthesia and other specialties.

In addition to similarities there are many differences between industry and healthcare. First, healthcare consists of an extraordinarily diverse set of activities. Healthcare encompasses the complexities of medicine; the mostly routine, but sometimes highly unpredictable and hazardous world of surgery; the much more personalised specialty of primary care, where patients may have relationships with their doctors over many years; the treatment of acute psychosis, requiring rapid response and considerable tolerance of bizarre behaviour; and numerous other specialties, some highly organised, such as the administration of blood products, while others are necessarily unpredictable, such as the rapid, constantly changing environment of emergency medicine. Second, we could consider the range of environments and associated responsibilities: hospital medicine, care in the community, care in general practice surgeries, patients who monitor and treat their own condition and care given in people's homes. Even with the most cursory glance at the diversity of healthcare, the parallels with the comparatively predictable high-hazard industries, with usually a limited set of activities, begins to break down.

Third, high-risk industry work is, ideally, routine. Where possible, any emergency or departure from usual practice is to be avoided. Healthcare is, in large part, also routine but in certain areas healthcare staff face very high levels of uncertainty. For example, the patient's disease may be masked and so can be very difficult to diagnose, the results of investigations are not necessarily clear cut or the treatment is complicated by multiple co-

morbidities or by atypical reactions. Here, a tolerance for uncertainty on the part of healthcare staff, and indeed the patient, is vital. Hence, the nature of the work is very different from most industrial settings.

A related issue, highlighted by Reason,⁴⁵ is that pilots and nuclear power plant operators spend most of their time performing routine control and monitoring activities. For the most part the aircraft or the plant runs itself, and the pilot or operator is simply checking and watching. Pilots do, of course, take over manual control and need to be highly skilled, but actual 'hands on' work is a relatively small part of their work. In contrast, much of healthcare work is very 'hands on' and, in consequence, much more liable to error. The most routine tasks, putting up intravenous infusions or lines to deliver medication, all require skill and carry an element of risk. Finally, and most obviously, passengers in trains and planes are generally in reasonable health. Many patients are very young, very old, very sick or very disturbed, and in different ways vulnerable to even small problems in their care.

In addition to the actual activities of healthcare differing from those of other industries, its organisation and management are also very different in some respects. Gaba⁴⁶ has argued that these contrasts are illuminating and have implications for safety. First, most high-risk industries are very centralised with a clear control structure. In contrast, healthcare, even national systems such as in the UK, is fragmented or decentralised. In countries with more mixed systems, such as the USA, making changes across the entire system is enormously difficult. Gaba explains how the dominance of the individual physician as the locus of control, while necessary at a clinical level, permits a variability in practice that can be detrimental to safety. If nurses, for instance, are constantly responding to different practices of senior physicians, unnecessary variability and potential for error are introduced. In other organisations, a much greater degree of skill and standardisation is achieved by devoting much more time to training and preparation for the job. Despite the intensive training of medical schools, a young doctor will still arrive on a new ward and be expected to pick up local procedures informally – sometimes with disastrous consequences. Finally, Gaba points out that healthcare is comparatively unregulated compared with other industries. In the UK, there is in fact a plethora of regulatory bodies, each with responsibility for some aspect of education,

training or clinical practice. There are undoubtedly too many organisations, consuming too much management time. Despite these efforts to regulate the system, there is still very little effect on day-to-day clinical practice. Thus, although there are undoubtedly many similarities between healthcare and other high-risk industries, some differences are also apparent. While this does not mean that techniques used outside healthcare cannot transfer to health settings, they may in practice have to be modified and may not prove useful in all healthcare settings.

Objectives of the review

Approaches to incident investigation and analysis in healthcare appear, even from this brief overview, to be comparatively undeveloped in relation to those in other high-risk industries. This project aims to assess available methods in both healthcare and other industries with the intention of developing valid and practical guidelines to assist in learning from clinical incidents in the acute sector, primary care and mental health. Specific objectives are as follows:

1. to carry out a review of published and unpublished work on the analysis of methods of accident investigation in high-risk industries and to provide a sound conceptual and practical foundation for the review of healthcare methods
2. to carry out a review of published and unpublished work on the analysis of critical incidents in healthcare
3. to develop guidelines for the analysis of critical incidents in healthcare for the hospital sector, mental health and primary care
4. to pilot the three sets of guidelines.

We framed our approach to the analysis of clinical incidents and adverse events by drawing on methods of accident analysis outside healthcare. This material contributed to the development of criteria for the assessment of incident analysis in healthcare and to the development of guidelines in healthcare settings (see Chapter 6).

An outline of the report

This section summarises the approach taken in each of the remaining chapters of the report to assist the reader in discerning the themes and structure of the full report. We have endeavoured to keep the chapters to a reasonable length,

summarising the main findings and making use of appendices to supplement and support the arguments advanced.

Chapter 2 Methodology for review of accident investigation in high-risk industries

This chapter discusses methodologies for reviewing methods of accident investigation outside healthcare, taking as its starting point the earlier review of available methods by Benner.⁴⁷ A brief overview of the approach to analysis and investigation outside healthcare is provided along with a summary of the evaluation approach used by Benner and the developments of our own evaluations for the present study.

Chapter 3 Review of methods of investigation and analysis in high-risk industries

This chapter provides an overview of accident investigation in high-risk industries setting out the aims of such investigations and an overview of their methods. Twelve specific techniques are described and an assessment is made of their particular strengths, limitations, range of application and relevance to healthcare.

Chapter 4 Methods used in the conduct of the healthcare review

The nature and purpose of our review of healthcare techniques is outlined. Methods of search and initial screening are described, followed by the development of a formal appraisal process and the procedures of the review.

Chapter 5 Review of healthcare methods for the investigation and analysis of critical incidents

This chapter provides the results of the initial search strategy, the subsequent screening of papers and further selection according to defined criteria. Six core techniques are identified for detailed evaluation and comparison:

- Australian Incident Monitoring System (AIMS)
- critical incident technique (CIT)

- significant event auditing (SEA)
- root cause analysis (RCA)
- organisational accident causation models (OACM)
- comparison with standards (CWS)

A short, descriptive summary of each technique is provided, based on papers providing the fullest description of the method in question. A sample of key studies are then reviewed and formally appraised, leading to a formal evaluation and comparison of the different methods with due regard to differences in purpose and context of application.

Chapter 6 A guide for the investigation and analysis of critical incidents and adverse events in healthcare

The development and piloting of the guidelines developed during this project are outlined. A guideline for use in the acute sector, mental health or primary care is presented, which acts as a core process for any investigation. Additional techniques (reviewed in Chapter 3) which are particularly applicable to healthcare are discussed and suggestions made as to how they can be used alongside the core process.

Chapter 7 Overview and conclusions

This chapter draws together the conclusions of the reviews of incident and accident investigation within and outside healthcare. We compare the strengths and weaknesses of different approaches and make some general comments about the research and practice in healthcare in contrast to other high-risk domains. The importance of understanding the context of a particular method is highlighted, as a strict comparative evaluation of methods makes little sense when the context and purpose of the methods differs widely. However, some methods show particular strengths and should provide the foundation for the next generation of methods, which it is hoped will draw on a much wider range of research and practical experience than has hitherto been the case.

Chapter 2

Methodology for review of accident investigation in high-risk industries

This chapter sets out the methods for the review of accident and incident investigation in high-risk industries. We begin with an overview of the nature and purpose of investigations, followed by a discussion of the way in which this review contributed to our assessment of healthcare techniques. We then describe the search and assessment process of the review of high-risk techniques.

Purpose of the review of approaches in high-risk industries

Our original proposal stated that the primary purpose of our review of methods of accident investigation in high-risk industries was to focus our approach on the analysis of clinical incidents and adverse events. The review of high-risk accident investigation techniques has certainly served this purpose and, in addition, gave us food for thought on how healthcare techniques might develop in the future. The diversity of techniques used in other industries has greatly impressed us, as have the power and conceptual development of some of the methods.

The high-risk industries review assisted our development of the health review in the following ways:

- developing a comprehensive checklist of methods of data collection
- developing an appreciation of the range of theoretical perspectives
- developing an approach to assessment of the techniques
- gaining an understanding of the importance of examining a particular technique in relation to the context in which it is applied
- gaining an understanding of the range of formal tools and methods of investigation, analysis and error reduction.

The primary purpose of the present project was, of course, to review approaches used in healthcare, but these were fewer in number and therefore it was important to look at other industries to ensure

that we learnt lessons from other domains. We did not attempt to review and evaluate all the approaches used in other high-risk industries, which would have been a major undertaking and require a separate research project. Because of the richness of this material, however, we did review a larger number of papers and a larger number of techniques than we originally expected. Although all of this material helped us to formulate our aims and approach to healthcare review, only some of the high-risk industry approaches are described in detail here. The selected techniques are those that we considered to be of particular relevance to healthcare and, in accordance with the terms of our healthcare review, are restricted to reactive postaccident approaches.

Search strategy

Accident investigation methodologies in high-risk industries are generally more clearly defined as specific methodologies and techniques than those in healthcare. Manuals and descriptions of the methods of investigation and analysis are available, in addition to reports of actual investigations. Because of the availability of such descriptions, we have been able to review the techniques themselves, rather than having to extract them from case reports and descriptions of actual investigations. Descriptions of approaches taken in healthcare are, for the most part, embedded in particular studies. The approach taken may be briefly described in the methods section of a journal article, but is seldom separately described in another document and thus generally inaccessible.

The acquisition of information relating to non-healthcare accident investigation and analysis techniques was facilitated via a number of search strategies. In addition to identifying specific techniques, we collected any generally useful material on how accident investigation is undertaken in industry and on the data collection methodologies employed. This search strategy aimed to collect the most relevant and best-documented information on a variety of accident

methodologies. The main search strategies applied were as follows:

1. Review of all literature already available in the Clinical Risk Unit, University College London. A variety of texts and research reports were identified and included in the data set to be incorporated into the overview of accident investigation and analysis techniques and the general process of accident investigation in industry.
2. Search and familiarisation of work by known experts in the field of accident investigation and analysis (Reason, Wilpert and Hale). These provided a useful resource on the process of accident investigation and analysis in industry in addition to directing the researcher to references outlining specific techniques.
3. Formal search of PsycINFO and MEDLINE. This is described in more detail below.
4. A web-based search (narrow keyword search specification). Examination of Health and Safety Executive, maritime, rail, nuclear, chemical and aviation websites to identify accident investigation and analysis techniques used by these industries or general information on such techniques. Overall, very little information was gained from this approach.
5. A brief review of public enquiry accident investigation reports. The Civil Aviation Authority website in particular provided a number of web-based accident reports. However, examination of these documents showed that the focus of these reports centred on findings and outcome, rather than the process of investigation and the tools used to analyse the incidents. Consequently, very little useful information was obtained from these reports.
6. Once relevant articles had been identified, references in those papers were also screened for possible inclusion. This approach enabled the researcher to identify other technique references especially from specialist sources, e.g. the International Atomic Energy Agency (IAEA).

Electronic database searches

The PsycINFO database (1967–March 2001) was searched for articles written in English using a series of search terms related to accident investigation and risk management, drawing on terms used in initial searches and examination of work by known experts. Details of hits for each search term are given in Appendix 1. Papers dealing with personal and domestic accidents and road accidents were excluded. Sixteen papers were identified for inclusion.

A further literature search was undertaken on MEDLINE (1975–2001). Free text terms were used and the search was limited to articles written in English using some of the more successful search terms employed in the PsycINFO search. We also included some technique specific search terms as we wanted to discover whether any non-health accident investigation and analysis methods were being used in the healthcare sector. Details of the number of hits obtained for each search term are given in Appendix 2. Fifty-two references were selected for inclusion.

Overview of initial screening strategy

The literature review provided a list of available references of potential relevance to the project. Each reference comprised the title, author, source, publisher, ISSN, publication year and, when available, the abstract. These data were reviewed to determine which references would be collected from the library for full review and possible inclusion in the final accident investigation and analysis overview of non-health techniques.

We selected the following industries as sharing some common characteristics with healthcare in that they are all complex systems, there are potentially serious consequences from accidents, they involve multiple dynamic processes and involve some degree of uncertainty in decision-making:

- nuclear
- chemical/petrochemical
- transport (rail, air, aerospace or sea, but not road).

The next step was a preliminary exploration of the number and range of techniques in use. The researcher identified, where available, the three or four of the key accident investigation and analysis techniques most used in each of the above industries or domains. These techniques, 19 in all, were used to direct the next stage of the search strategy, which was to narrow the publications to a core list for detailed review. In addition to technique descriptions and discussion papers, we also included any papers of general relevance to accident investigation, such as discussions or studies of human error or performance issues in this context. This selection produced 104 papers, 52 from MEDLINE, 16 from PsycINFO and 36 from other sources, mostly from already established personal libraries and contacts.

(Almost all papers from the original MEDLINE and PsycINFO searches were included.) All of these papers were reviewed in detail and 19 separate techniques were identified. Of these, seven were primarily proactive approaches and thus did not fit the purpose of our healthcare review or, as in the case of the CIT, were already included in the healthcare review. The remaining 12 techniques were included in the formal review. The techniques excluded at this stage were:

- ISA (intelligent safety assistant)⁴⁸
- MES (multi-linear event sequencing)^{49,50}
- TOR (technical operations review)^{51,52}
- HAZOP (hazard and operability study)^{53–56}
- CIT (critical incident technique)^{32,53,57–59}
- AEB (accident evolution and barrier function model)⁶⁰
- WSA (work safety analysis).^{52,61}

A brief description and references for these excluded techniques are included in Appendix 3 and a flow chart to show the literature screening is given in Appendix 4.

Final screening and selection of articles

The purpose of the high-risk review was to provide an overview of the techniques themselves rather than, as in the healthcare review, to examine instances of their application. As we have pointed out above, this is feasible in the high-risk area as techniques are clearly described in their own right with manuals, technical documents and the like. The next stage of selection was simply to identify those articles or documents that best described the technique in question.

Four key selection criteria were applied to collected or summarised references to determine whether the full reference would be obtained and reviewed for inclusion in the final overview of non-healthcare accident investigation and analysis techniques. The following selection rationale was applied:

1. The technique must be used or have been developed as a tool to investigate and/or analyse accidents in industry.
2. The accident and analysis tool was in the public domain. Proprietary tools and techniques, without full documentation available, were excluded.
3. Multiple referencing – where possible more than one reference outlining a particular

accident investigation and analysis tool would be required, so that techniques could be fully reviewed and summarised.

4. A small selection of references which discussed how accidents are generally investigated and analysed in industry were also collated. This was to allow the preparation of a general introduction to the subject of accident investigation and analysis in high-risk industries.

Assessment process

The process of appraisal was split into three main stages:

- summarising the key features of the techniques
- development of summary tables
- assessment of individual techniques.

Summarising the key features of the techniques

As each document was obtained it was categorised as either a general source of information on accident investigation or an accident investigation and analysis technique. Through this distinction two broad groups of documents emerged:

1. Accident process data file – information was collated on how other industries conduct accident investigation and analyses. This information was used to prepare an introduction to Chapter 3. An overview of the general features of the process of accident investigation is presented there to assist the reader in understanding the review that follows.
2. An accident investigation and analysis techniques data file – this document collated in summary form all information relevant to a particular accident investigation and analysis technique. For each technique we were able to build a repository of information from a variety of source references:
 - (a) technique title
 - (b) historical development
 - (c) theoretical basis
 - (d) known strengths of technique
 - (e) known limitations of technique
 - (f) key references.

Development of accident investigation and analysis technique summary tables

Each technique was then subjected to a preliminary assessment by one of the investigators (STA) who is well versed in methods used outside

healthcare. The primary purpose of this assessment was not, however, to provide a formal evaluation of high-risk industry techniques, but to pilot a method of assessment and evaluation for later use in the health review. Although we did not expect that we could use the same assessment instrument, the experience of selecting appropriate criteria and carrying out a preliminary assessment was of great value in developing an approach to assessing the health techniques.

The review of 12 non-health accident investigation and analysis techniques resulted in the development of a comprehensive but long document, which would not have been easily assimilated by the reader. Key information was therefore abstracted from this data set to provide the reader with the main features or elements of each technique. The decisions underpinning the type of data abstracted were based on information and criteria provided by Benner,⁴⁷ Kirwan^{62,63} and the researcher's own experience. Benner evaluated accident models and techniques used in a variety of industries within the USA, whereas Kirwan evaluated human error identification techniques used in industry. Two main summary tables were generated for each technique and collated information on the following criteria.

Summary of individual techniques (Tables 1–12)

- an overview of the accident technique
- when technique would be used
- outputs such as recommendations provided as a result of the investigation and analysis
- positives of the technique
- negatives of the technique
- main references.

Comparison of techniques on key criteria (Table 13)

- technique available to public or proprietary
- primary method (standalone technique) or secondary method (provides special input to supplement another method)
- industry origin
- whether transferable to other industries
- applicability to investigation/analysis of serious incidents and near misses
- need for expert to facilitate investigation and analysis using technique

- need for training in technique
- whether the investigation and analysis methodology encourages all parties (internal or external to an organisation) to participate.

These two sets of tables provided a concise overview of the important features of each accident investigation and analysis technique.

Assessment of techniques

Each technique was then assessed against a pre-defined set of evaluative criteria by the human factors researcher (ST-A). These criteria were based on those used by Benner⁴⁷ with some additional material from Kirwan.^{62,63} Both papers provided a useful discussion of the nature and purpose of assessment criteria, which helped generate the final list of criteria used in the preparation of the summary technique tables. A summary of Benner's findings and the criteria he developed is given in Appendix 5.

In total, eight evaluation criteria were used, which were selected on the basis that:

- they were clearly pertinent to the value and utility of an accident investigation and analysis technique and
- the technique summaries could provide reliable and accurate information on the majority of these criteria.

To facilitate direct technique comparison we used a simple three-point scaling technique (similar to that outlined in the Benner paper). This enabled the researcher to sum individual criteria scores for each technique to provide an overall indication of the value and utility of each technique. The information gained from this evaluation along with previous experience was used to determine which techniques would be most usefully applied and adapted for use in a healthcare context. *Box 1* shows the criteria and accompanying definitions and scaling applied to each technique, where 0 = low, 1 = moderate and 2 = high, except for the resources criteria, which were scored 0 = high resources, 1 = moderate resources and 2 = low resources. Results of the application of these criteria to individual techniques are shown in *Table 14*.

BOX 1 Assessment criteria and definitions

Comprehensive – is defined by the following three criteria:

1. accuracy of identifying significant errors (i.e. those which have the most impact on risk)
 2. breadth of coverage of the technique in dealing with all forms of error
 3. ability to identify all possible errors given the task and task environment.
- Low comprehensiveness (0) = fails to satisfy any comprehensive criteria or only one.
 Moderate comprehensiveness (1) = satisfies at least two of the above criteria.
 High comprehensiveness (2) = satisfies all three of the above criteria.

Consistent – degree to which different assessors utilise the methodology in the same way and thus is more likely to yield consistency of results, versus an open-ended methodology, in which the results are likely to be highly assessor dependent.

- Low consistency (0) = relatively open-ended method.
 Moderate consistency (1) = assessor has flexibility within a detailed framework.
 High consistency (2) = tool is highly structured and therefore likely to lead different assessors to same result.

Theoretical validity (model based) – whether the approach is based on an accident model or theory of human behaviour/performance.

- Low theoretical validity (0) = just a classification system.
 Moderate theoretical validity (1) = technique makes reference to a model.
 High theoretical validity (2) = tool is the embodiment of model.

Theoretical validity – whether the technique simply assesses external error modes (EEM) – what happened; whether it also identifies psychological error mechanisms (PEM) – how it happened; and performance-influencing factors (PIF) – why it happened.

- Low theoretical validity (0) = either does not consider EEM, PIF or PEM or only one of these components.
 Moderate theoretical validity (1) = considers two of the above three components.
 High theoretical validity (2) = considers EEM, PEM and PIF.

Error reduction (usefulness) – the degree to which the technique can generate error reduction mechanisms.

- Low usefulness (0) = technique has little concern for error reduction.
 Moderate usefulness (1) = technique is capable of error reduction.
 High usefulness (2) = error reduction is a primary focus of approach.

Resources (usage) – likely resource usage in actually applying technique, in terms of assessor or experiment time.

Resources were rated either as low, moderate or high depending on the judged extent of time each technique would take to apply.

- High resources (0) = technique takes less than 1 day to apply.
 Moderate resources (1) = technique takes between 1 day and 1 week to apply.
 Low resources (2) = technique takes more than 1 week to apply.

Auditable documentation – the degree to which the technique lends itself to auditable documentation

- Low documentability (0) = utilisation of technique is difficult to document.
 Moderate documentability (1) = technique provides sufficient documentation to be repeatable.
 High documentability (2) = all assumptions are recorded and documentation is useful for future system operations.

Independence – methodology must produce blameless outputs. Do the investigation and analysis methodology identify the full scope of the accident, including role of management and employees in a way that explains the effects and interdependence of these roles without blame?

- Low independence (0) = no independence.
 Moderate independence (1) = some independence.
 High independence (2) = fully independent.

Acceptability (usage) – usage of technique to date in accident investigations and analyses.

- Low acceptability (0) = appears that technique has been developed, but only used as a prototype.
 Moderate acceptability (1) = technique has been used in a small number of accident investigations/analyses.
 High acceptability (2) = technique has received extensive usage in accident investigations/analyses.

Chapter 3

Review of methods of investigation and analysis in high-risk industries

Introduction to industrial accident investigation and analysis

The high-risk industries discussed in the previous chapter (nuclear, chemical, transport) have some similarities to healthcare in that they involve complex, multiple procedures, a degree of uncertainty in decision-making and risk to those involved. The processes of such industries are, however, much more precise, structured and established than those in healthcare and it is therefore generally easier to define a state of normal and routine operation. The corollary is that it is also easier to identify deviations from normal system operation and to discern the links between these deviations and some subsequent accident or incident.

Accidents in high-risk industries can then be viewed as the result of unplanned deviations in system operation,⁴⁸ which, if not corrected, may trigger a process which will ultimately lead to an accident.⁶⁴ In such safety critical systems, analysis of serious incidents is normally focused on finding all the causes of system failure for which practical, remedial actions can be derived. The ultimate purpose of an accident investigation is always to prevent similar occurrences and thus improve the safety of operations. Questions of who is responsible and how blame, if any, should be apportioned are secondary to these basic questions. All this occurs, ideally, in a culture in which a degree of human fallibility is accepted and blame is reserved for clear cases of negligence, recklessness or criminality.

In the last few decades, some powerful investigation and analysis methods have been developed for analysing serious accidents in technologically complex safety critical systems. However, it is important to note that in many of these high-risk/high-consequence industries, such as aerospace, the emphasis on postaccident corrective measures has shifted to the assurance of safe functioning prior to commissioning of the safety critical system.⁶⁴ For instance, some early

precommissioning risk analysis techniques such as sneak circuit analysis^{65,66} and hazard and operability studies HAZOPs⁶⁷ examine the system hardware to ensure it is safe before it goes into operation. Operational readiness of a complex, safety critical operation needs a perfect synergy between equipment, humans, procedures and management functions. The scope of risk assessment, control and accident analysis has been broadened in industry to encompass the safety management system of the entire operation. Nevertheless, although these proactive forward-looking processes have grown in importance, accident investigation continues to serve a vital function within the overall safety programme.

In summary, accident investigation techniques in high-risk industries have three main aims:

- organising investigation material once the evidence has been collected
- describing causation and developing hypothesis for further examination by experts
- guiding the development and assessment of proposed corrective actions.

The investigation process

Investigation has historically been one of the tasks most difficult to teach because good investigators often have difficulty describing what they do. However, in recent years all high-risk industries have developed extensive accident investigation training programmes for their employees. Initial courses usually require at least 7 days of dedicated study, often followed by more advanced and specific training courses at regular intervals thereafter. These organisations recognise that accident investigation is a specialist and complex task, which requires substantial investment in training dedicated accident investigators.

There are some core objectives for all accident investigations. Investigators first need to know what facts to seek. Relevant information is often readily available once its value is recognised. Second, they need to introduce and be familiar

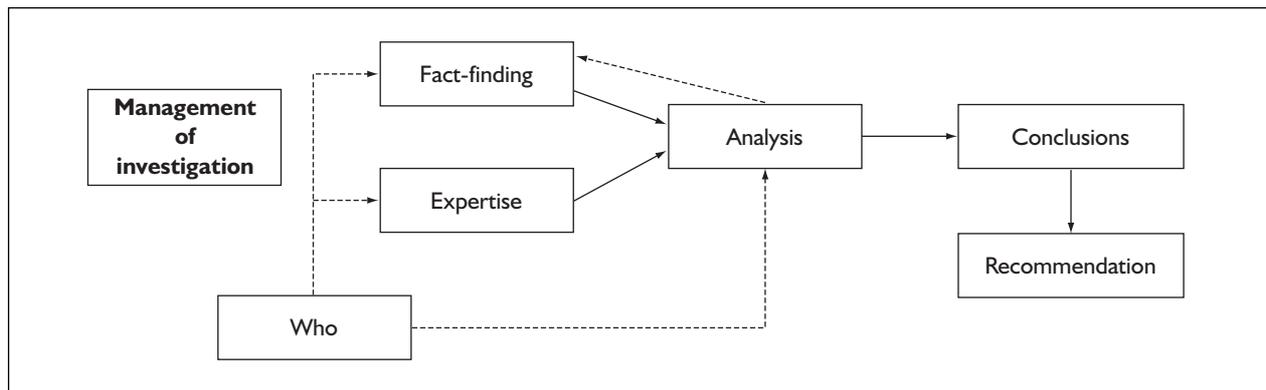


FIGURE 1 A triad of competencies used in accident investigation

with all relevant perspectives. In particular, they need to expand the perspective of local technical experts to ensure that human factors and cognitive issues are adequately addressed. Third, they must ensure that the investigation and analysis generates useable, practical conclusions and recommendations, including systemic causal factors. Finally, the results must be arranged in an orderly, coherent format.

The basic investigative process or method focuses on a triad of competencies: fact-finding, expertise and analysis (see *Figure 1*).

Fact-finding and data gathering are an essential prerequisite for successful accident investigation and analysis. Therefore, it is vital that accident investigators are well versed in the various competencies necessary to achieve this objective. The team must include people with knowledge of the technical aspects of the domain in question, or they must at least be available to guide the investigators. Investigators must also be competent in a number of analytical and investigative methods. They must, for instance, be able to undertake witness interviews or guide witness statements, observe and make meaningful assessments of the accident site, produce photographic or video evidence and collate plant schematics, training manuals and maintenance logs. There is good evidence to suggest that the cost of training investigators is quickly repaid in lowering costs for any given depth or quality of investigation if they are well trained in fact-finding skills. The essential features of accident investigation are summarised in *Box 2*.

Assembling a team and planning the investigation

The scene of an accident is often chaotic. It is therefore important that the accident investigation

BOX 2 Essential features of incident investigation

1. Preplanning: the investigation and communication procedure should be established and in place.
2. The prompt establishment of the investigation team should be organised:
 - (a) It is essential to capture all information before it evaporates.
 - (b) The team should be multidisciplinary and should include representatives from outside the area in which the incident occurred. Therefore, other personnel from within the organisation but who were not directly involved in the incident could be used, as well as external experts and advisors.
3. Investigation includes:
 - (a) The preservation and collection of physical evidence.
 - (b) Prompt interviews of eyewitnesses and other appropriate personnel.
 - (c) Determining the causes of a systematic approach to focus in on the causal factors. An example of one of the many approaches is summarised below:
 - (i) Establish the chronology of events.
 - (ii) List conditions that deviated from normal practice.
 - (iii) Jointly list all hypotheses that could account for incident occurrence.
 - (iv) Test hypotheses that could account for incident occurrence.
 - (v) List in order of likelihood.
 - (d) List statement of underlying or root causes, contributing causes, or other significant factors.
 - (e) Recommendations: actions needed to prevent reoccurrence include (i) responsibility and (ii) timing.
 - (f) Communication to other appropriate groups.
4. Follow-up to ensure closure.

follows a planned and methodical process. The first step is to assemble an appropriate team. The size and membership of the team, and the authority responsible, typically depend on the scale of the accident and the extent of the loss of life, injuries and economic losses. All staff must be notified that an accident has occurred and will be

BOX 3 Advantages and potential problems of the use of boards of investigators**Advantages:**

- Range of competencies and skills, including managerial, scientific, technical, professional and investigative specialities.
- Offer independence and diversity of views and experience.
- Improve judgmental processes and technical solutions, counteract biases and avoid traps that individuals might miss.
- Initiate safety promotion effects on members and their peers.

Potential problems:

- Some members may lack experience in investigation and analysis.
- Can be cumbersome and slow.
- Interpersonal factors may complicate the work.

investigated. Plans for the investigation must be communicated throughout the organisation and the necessary equipment and resources for the investigation made available.

For a major or moderately severe accident, a board of three to five persons will be appointed. The chairman of the board will be a person with considerable management experience and there will be at least one trained investigator with the other members providing specific technical or expert knowledge. To maintain the necessary objectivity, the board needs to operate independently from the normal operations at the scene of the accident, although it will obviously rely on the contributions and cooperation of staff from the sites in question. It is vital that the members of the board are freed from their normal workload as far as possible to enable them to devote their full attention to the investigation. An in-depth investigation typically involves 50–150 workdays. The membership of a board is augmented by appointment of as many advisors as appropriate (e.g. solicitors, doctors, scientists, engineers or other experts). Boards have many advantages over individual investigators, but also some potential disadvantages (summarised in *Box 3*).

Accident investigators must be trained in fact-finding, a skill which improves with experience and practice. Organisations should train a small number of individuals in accident investigation so that these people are able regularly to investigate, maintain and develop their skills. Accident investigators will frequently spend a large proportion of their time, up to half of the investigation phase, interviewing victims and witnesses and obtaining statements. Data gathering in the form of failure recognition, collating photographic evidence and managerial practice forms the other half of investigation phase.

Analysis of incoming information should be started early, as delays can be expensive and result

in lost information and incomplete analyses. There are many analytical accident investigation and analysis techniques available to the investigator, some of which are discussed in this report. Analysis (formal or informal, conscious or unconscious) underlies any investigation and analysis will be strongly influenced by the quality of the initial investigation and the fact-finding process. A good investigator will use an array of analytical techniques. In particular, the event and causal factors charting technique offers a useful approach to reconstructing an accident. However, the analytical techniques of management oversight and risk tree (MORT), change analysis and barrier analysis provide useful approaches to accident analysis.

The accident report should fully cover and explain the technical elements of the causal sequence(s) of the occurrence. The report should also describe the management systems, which should have, or could have, prevented the occurrence, for example, the safety or hazard analysis system and the quality assurance programme for safety. Recommendations must be produced to meet the preventative purposes of the investigation, namely:

- lower accident rates and probabilities
- reassurance to the public
- minimisation of the effect of an accident on routine operations and enhancement of overall performance.

A board may lack the time, information or competence to evaluate financial, operational and policy impacts of recommendations. It is therefore wise to suggest a further phase in which the plan can be developed, costed and implemented. A major shortcoming of many accident reports is the failure to extend recommendations beyond the behaviour and shortcomings of individuals to the wider systems which allowed the problems to occur. Ultimately the value of investigations will depend on a top management's injunction to 'tell

it the way it is'. This depends on the ability of senior management to take a mature approach and recognise that systemic factors, for which they have some responsibility, are implicated in many accidents. They also need to provide a clear direction for the investigation. A directive to take a broad systemic approach is much more likely, in the long run, to lead to safer operations than a directive that requires the identification of individuals for disciplinary action.

Findings from the review

Tables 1–12 summarise the essential features of the 12 accident investigation and analysis techniques reviewed during this project. Table 13 outlines some of the important factors of each accident investigation and analysis techniques reviewed. Table 14 provides an evaluation of the non-health accident investigation and analysis techniques. Those techniques with a higher total value can be assumed to be generally the better accident investigation and analysis techniques.

Summary and implications for healthcare

Formal evaluation of all 12 accident investigation and analysis techniques against a set of predefined evaluative criteria enabled us to identify the most useful, comprehensive and fully functional techniques. On the basis of this assessment, the techniques can be grouped into three categories:

1. those with high or mostly high scores on all criteria, such as MORT, RCA and wheel of misfortune
2. those with some (at least 2) high scores and mostly moderate scores on evaluation criteria, such as fault trees, tripod-BETA, events and causal charting, object-Z and barrier analysis (BA)
3. those which scored mostly moderate or low scores on the evaluation criteria, such as the influence diagram approach (IDA), accident anatomy method (AAM), change analysis and sequentially timed events plotting (STEP).

Based on this evaluation, it can be seen that MORT, RCA, wheel of misfortune and fault trees are the preferred accident investigation and analysis techniques.

MORT, if carried out completely, is certainly the most comprehensive and most complete

technique. A MORT investigation and analysis, however, is probably the most time-resource methodology identified during this review. It is not clear, therefore, whether it is currently suitable for use in the NHS. Only where substantial resources are available, such as in a major enquiry or perhaps a Healthcare Commission investigation, might such a technique be fully implemented. Furthermore, investigators need to be fully trained in the MORT assessments and analyses, which again is resource intensive. MORT includes some techniques, such as barrier and change analysis, which in this evaluation have not performed particularly well as stand-alone techniques. This is hardly surprising as they have been developed to undertake key components of the accident analysis process. If MORT did not include these component techniques, it may not have performed so well overall.

RCA, like MORT, performed particularly well as an accident investigation and analysis technique. Once again this result could be based on the fact that it is composed of a variety of smaller, more specific techniques which are helpful at different stages of the investigation and analysis process. Fault trees and flow diagrams are very useful in the early stages of investigation, when an incident is plotted as a chronological event, but task analysis (TA), failure modes and effects analysis (FMEA) and change analysis are more appropriate at the analysis stage of the investigation, when one needs to understand why problems have occurred.

The wheel of misfortune is a recent accident investigation and analysis technique, which has received minimal explanation and review in the literature. On paper, it appears to be a complete approach to accident investigation and analysis. It also seems simple and quick to understand and perform, yet based on accepted models of human performance. It would be useful to apply this methodology formally to the medical domain to see how it copes with investigating and analysing medical accidents.

Techniques in the second group, such as Object-Z and BA, are less suited to comprehensive accident investigation and analysis, but this does not mean they are without value. The reason why these techniques scored lower is partly due to the fact that they are geared to a specific purpose and do not have the sophisticated and comprehensive approach of some of the more highly evaluated techniques. Many of these techniques provide useful methods of solving specific accident

TABLE 1 Summary of individual techniques: Tripod-BETA

	Technique
Overview of Tripod-BETA	Tripod-BETA focuses on identifying and dealing with general failure types (GFT), the situational and organisational factors that contribute to unsafe acts and accidents. Tripod-BETA assumes that an accident occurs when hazards come into contact with targets (people, assets and environment) as a consequence of defensive failure. When investigating an incident, the process starts by exploring the losses incurred during the incident and works back to determine what defences failed and what the original hazard was and why a failure occurred. All factors contributing to each defence failure are identified and described in sequence. Not only are the trigger events identified, i.e. the last defence to fail, but also the defences that are rendered ineffective beforehand. In addition, fault trees are created that illustrate the sequence of threats or causes that could give rise to a hazard. Consequently, Tripod-BETA analysis provides information on what happened during an incident and why, enabling recommendations to be made to avoid a further incident
When would the technique be used?	Tripod-BETA would essentially be used for conducting petrochemical incident analysis in parallel with the investigation, which is supported by a software tool
Outputs, e.g. are recommendations provided as a result of the investigation and analysis?	Yes
Positives of technique	<ul style="list-style-type: none"> • Provides a structured investigation. • Software forces completeness of action recommendations by flagging tree elements that have not been verified or contain incomplete information, e.g. every active failure must have a remedial action attached to it. • Efficient as only need one trained Tripod-BETA analyst
Negatives of technique	<ul style="list-style-type: none"> • Developed for Shell, therefore usefulness to other industries uncertain. • Lacks validation and formal evaluation
References	Reason, 1997 ⁴⁵ Ferry, 1981 ⁵⁰ Doran and Van der Graaf, 1996 ⁶⁸

TABLE 2 Summary of individual techniques: influence diagram approach (IDA)

	Technique
Overview of IDA	The IDA approach is able to model qualitatively the influences on adverse outcomes existing at the organisational level. It can also quantitatively generate measures of the influence of technical, human and organisational factors on the risks posed by a particular hazardous technology. IDA charts the influences on a particular failure mode on four levels: influencing factor level, PIF level, implementation level and policy level. IDA is performed in stages. First, an influence diagram is developed identifying the factors involved at each level and their respective influence on the failure mode in question. The next step involves quantifying the elements of the influence diagram. An assessment is made for each element to determine if it has a positive or negative influence on the failure by determining its bad:good influence ratio. Then a calculation is made about the influence of the element or elements upstream. This is based on the influence of each element and the weight, or importance, attached to each element
When would the technique be used?	IDA can be used to investigate any incident and provide a qualitative and quantitative assessment. IDA can also be used as a prospective risk assessment tool
Outputs, e.g. are recommendations provided as a result of the investigation and analysis?	Recommendations can be provided if the IDA group have specifically generated them. However, as IDA provides information on PIF and organisational failures, then it is generally fairly easy to generate a list of recommendations
Positives of technique	<ul style="list-style-type: none"> • IDA is capable of yielding qualitative and quantitative risk estimates that are based on sound theoretical principles and state of the art knowledge of engineering techniques. • IDA can be used as a prospective risk assessment tool as well as a reactive accident investigation methodology
Negatives of technique	<ul style="list-style-type: none"> • This approach can be laborious for the assessment team. • The reliability and validity of the quantification process has not been rigorously tested
References	Reason, 1997 ⁴⁵ Kirwan and Ainsworth, 1992 ⁵³ Kirwan and colleagues, 1988 ⁶⁹

TABLE 3 Summary of individual techniques: sequentially timed events plotting (STEP)

	Technique
Overview of STEP	The STEP accident investigation technique aims to reconstruct the harm process by charting the events contributing to the accident (what happened, when and where). Central to STEP is the idea that accidents occur when there is deviation from the normal sequence of events to an unstable mode of operation because of actors (human beings or objects). The accident process begins when an event occurs to disrupt the balance of the process and ends in harm or loss that can be linked directly through successive events to the first undesired change that disrupted the planned process. In a STEP investigation a worksheet is developed documenting all events occurring in the accident process. These events are interconnected with arrows showing the relationship between events. Safety problems are identified in terms of causal links between preventable events that propagate the accident, or in terms of missing links to preventative events
When would the technique be used?	STEP provides an excellent process for modelling and mapping the event sequence of any incident, but best used with less complex types of incidents
Outputs, e.g. are recommendations provided as a result of the investigation and analysis?	Recommendations produced are dependent on the STEP analysis and the team of investigators' level of expertise and involvement in the field
Positives of technique	<ul style="list-style-type: none"> • Worksheet process simplifies investigation and analysis. • Simple accident investigation and analysis method
Negatives of technique	<ul style="list-style-type: none"> • Time and resource intensive. • Has not been tested rigorously. • Can become overly complex with a complicated accident sequence. • Limited information in the public domain to discuss this technique in detail. • A lot of information about what happened, but little on why an event occurred
References	Koorneek and Hale, 1997 ⁴⁸ Hendrick and Benner, 1987 ⁶⁴

investigation or analysis problems. For example, BA is an exceptionally quick and useful approach for identifying where and how to implement specific types of defences and barriers within an organisation. Events and causal charting is particularly useful at diagrammatically depicting the chronology of the event and will give some indication of the causes, but it is best used with other more evaluation-specific techniques such as barrier analysis and change analysis. Fault trees are helpful in identifying where faults in the system are likely, but need to be integrated with RCA techniques such as FMEA analysis, or BA to identify solutions to the problems identified. These specific techniques may well be useful in a healthcare environment as part of a broader package of techniques. Such a multi-technique approach would make accident investigation more versatile and use limited resources more effectively.

Techniques in the third grouping, such as STEP and change analysis, are not necessarily poor techniques, but tend either not to be well explained in the literature or to be based on experience rather than models of human behaviour. Some of these techniques may score poorly on theoretical validity or comprehensiveness,

but score very well on error reduction. As all accident investigation and analysis techniques ultimately aim to prevent future similar accidents, this criterion should perhaps be weighted more highly in the evaluation process. Alternatively, healthcare could look at the error reduction modules of these techniques and use them as specific techniques in much the same way as RCA.

The techniques summarised in this review show the broad range of accident investigation and analysis techniques available to the modern accident investigator. Results would seem to suggest that accident investigators must have a 'toolbox' of approaches available to them, which should be utilised dependent on the type of accident scenario and the particular stage of the accident investigation. Many of the techniques available within RCA and MORT should feature in this 'toolbox' approach, along with added specialist approaches such as the wheel of misfortune or the Clinical Risk Unit/Association of Litigation and Risk Managers (CRU/ALARM) protocol. If such a 'toolbox' of approaches is to be used in the healthcare sector, it is important that significant information is provided to the accident investigator on when these techniques should be

TABLE 4 Summary of individual techniques: management oversight risk tree (MORT)

	Technique
Overview of MORT	<p>MORT was initially developed for the investigation of occupational incidents at Department of Energy sites in the USA. However, the technique is also intended to support safety audits and to solve management problems. The MORT diagram is the key to the investigation process and is based on fault tree analysis. The aim of MORT is to determine what happened during an accident and why using a toolbox of techniques for accident investigation. The basic MORT diagram consists of four elements. The first defines the overall objective and the second the people or objects of value that are vulnerable to an unwanted energy flow. The third element in an incident sequence is the failure or lack of barriers and controls that are designed to keep the potentially harmful energy away from the vulnerable people or objects. The fourth element in the analysis of an incident is the precursor events. Application of the MORT technique is based on a generic tree structure laid out vertically. This tree should be viewed as a checklist. Its structure is fairly complex and it is intended to be used as a reference or standard when investigating an incident. The tree is based on historical case studies and on research performed by human factors specialists. A manual has been developed to help investigators use the generic tree. MORT is a complex technique and so a technique called Mini-MORT has been developed, which is concerned with the preparation of oral and written reports related to a full MORT analysis. MORT is a tool which should be used to review and order evidence brought in from the site. MORT has been applied to the analysis of many incidents and a variety of training courses are available to improve the investigators skill in performing a MORT analysis</p>
When would the technique be used?	<p>MORT could be used to investigate and analyse any incident; however, owing to its complexity, comprehensiveness and the resources needed to run a MORT investigation, it is suggested that MORT only be used for serious event analysis</p>
Outputs, e.g. are recommendations provided as a result of the investigation and analysis?	<p>MORT enables the user to derive recommendations to be presented to management for improved control of safety critical process from those tree events which have been evaluated as less than adequate or which lack sound assessment</p>
Positives of technique	<ul style="list-style-type: none"> • Goal oriented – emphasises safety role in building high performance and congruity with good management methods. • Comprehensive – covers all aspects of safety. • Systematic – integrates, organises and structures safety into function-defined relationships and measurements. • Simple – there are many pieces, but none intellectually difficult. • Flexible – assimilates new ideas and concepts. • Innovative – uses new technology and concepts to describe ways to gain acceptance of innovations. • Humanistic – attempts to cope with the complex human attributes of the people who operate the system, expose their problems and guide the services they need for effective satisfying work. • Practical – easy to use. • Effective – with each application of MORT investigation and analysis improves
Negatives of technique	<ul style="list-style-type: none"> • Potential for misuse – emphasis on management responsibility takes understanding, patience, determination and maturity. Blaming someone else is easier and more comfortable, but less productive. • Training – users undertaking a MORT investigation and analysis will need significant training before they are proficient MORT assessors. • Resource Intensive – a MORT investigation and analysis will need significant resources, time and people to implement a successful MORT investigation and analysis
References	<p>Johnson, 1980⁷⁰ Johnson, 1975⁷¹ Koorneek and Hale, 1997⁴⁸</p>

used, along with worked medical examples. It would be useful to categorise when each accident investigation and analysis tool could be used in medical accident analysis, for example, causal charting, flow diagrams or hierarchical task analysis (HTA) should be used at an early stage in the investigation where a chronology of the event is needed. Once a chronology of the event has been established, the investigators will want to understand how and why the incident occurred. At that point, tools such as fault trees, failure modes and effects analysis and the wheel of misfortune will be particularly helpful. Finally, analysis will

focus on what can we do to prevent this problem in the future and here techniques such as change analysis and BA are particularly useful.

In summary, healthcare can learn much from other industries regarding accident investigation and analysis. It is hoped that this review provides the start in this learning process; however, to ensure continued growth in this field, it will be necessary to begin applying these techniques in the health field, provide training and support to accident investigators and to build an accepted 'toolbox' of approaches.

TABLE 5 Summary of individual techniques: change analysis

Technique	
Overview of change analysis	<p>Change analysis compares the accident situation with a similar but accident-free situation. However, the basic assumption is that change generally signals trouble. Change analysis is characterised by six investigative steps:</p> <ol style="list-style-type: none"> 1. Look at the mishap situation. 2. Consider a similar, but mishap-free situation. 3. Compare the two situations. 4. Set down all differences between situations. 5. Analyse differences for effect on producing the mishap. 6. Integrate the differences into mishap-causal factors. <p>The practical application of these basic ideas has been incorporated into a change analysis matrix. On the left hand column of the matrix 25 potential influencing factors are listed and these are examined against the changes. Change analysis generally works best with the aid of a facilitator. Change analysis is frequently incorporated into root cause analysis investigations</p>
When would the technique be used?	Change analysis would be used when causes of inappropriate actions are obscure, when change is suspected or when one does not know where to start
Outputs, e.g. are recommendations provided as a result of the investigation and analysis?	Recommendations will be provided using change analysis if the investigating team take their analysis far enough. It is up to the organisation to ensure that recommendations are implemented and monitored
Positives of technique	<ul style="list-style-type: none"> • The more remote or difficult the causes, the more likely it is that a rundown of the matrix will offer some clues. • Useful when the accident is obscure and a quick answer is required. • A systematic and rational process allowing for an organised approach and reduces oversights. • A useful tool when investigating both simple or complex accidents. • Investigators' proficiency increases usefulness of approach
Negatives of technique	<ul style="list-style-type: none"> • Change analysis usually produces more questions than answers. • Trends and the corresponding changes may be overlooked. • There is a danger of incorrectly defining the change
References	Johnson, 1976 ⁷² Ferry, 1981 ⁵⁰ Kepner and Tregoe, 1976 ⁷³

TABLE 6 Summary of individual techniques: barrier analysis (BA)

Technique	
Overview of BA	BA focuses on establishing what barriers should have been in place to prevent a particular accident or what barriers could be installed to increase safety. BA can be used either on its own or in conjunction with another technique such as MORT or RCA. In a MORT accident investigation, BA is used to determine what happened and why it happened. BA defines an accident as an unaccounted flow of harmful energy or exposure to an environmental condition that results in adverse consequences. BA first determines the energy sources involved, the barriers that should have been present, the barriers that failed and how and the sequence of events and barrier failures leading up to the accident. The last phase of this process is best performed via MORT or fault trees. BA has strong links with MORT, RCA and FMEA. Ideally, it needs techniques such as structured interviews to gather the information and task decomposition to structure the collected data
When would the technique be used?	BA can be used either on its own or as part of a MORT analysis to determine which barriers failed to prevent an undesired energy flow. BA can also be used prospectively to analyse qualitatively whether sufficient barriers exist to ensure adequate safety or whether superfluous barriers are in place. Therefore, it is used to identify physical and administrative barriers and to review them for effectiveness, i.e. to determine the 'whys' of incidents
Outputs, e.g. are recommendations provided as a result of the investigation and analysis?	Basic recommendations can be produced. However, this is best achieved when BA is integrated within a MORT assessment or a HTA and FMEA
Positives of technique	<ul style="list-style-type: none"> • Gives an unbiased description of what happened, including information on physical barrier failures and administrative control failures, and identifies the absence of barriers that with hindsight would have helped. • Helps identify probable causal factors
Negatives of technique	<ul style="list-style-type: none"> • Its predictive analysis for future systems assumes more compliance with administrative barriers than actually tend to occur. • There is a danger of not recognising all failed barriers. • It is possible to overlook the effect of the rate and frequency of energy applied to the barrier
Reference	Trost and Nertney, 1985 ⁷⁴

TABLE 7 Summary of individual techniques: events and causal charting

Technique	
Overview of events and causal charting	The events and causal factor charting sequence can be used either as a stand-alone accident investigation tool or as an integral tool to the MORT or RCA process. The technique seeks to depict graphically the mishap from the beginning to the end. Charting shows the relationship of individual events in a mishap sequence and the related causal factors and conditions impinging on these events
When would the technique be used?	It serves as an aid to developing the evidence, in detecting causal factors and in determining the need for in-depth analysis
Outputs, e.g. are recommendations provided as a result of the investigation and analysis?	Recommendations can be provided. However, this is entirely dependent on the remit of the investigating team
Positives of technique	<ul style="list-style-type: none"> • Charting illustrates the role of multiple causes involved in a mishap by bringing them into sequences. • It visualises the sequence of events in time and the interactions and relationships of conditions and events. • Charting aids communication, interpretation and summarisation of the mishap. • When used in conjunction with MORT diagrams, causal events charting has the advantage of allowing verification and further analysis of deficiencies identified in the MORT process. • Causal events charting plays an important role in discovering cause-effect relationships without specifically apportioning blame, although responsibility will be allocated later. • Can provide a basis for recommended action when it is part of a report, and allows the recommendations to be evaluated in light of revealed events and causal factors
Negatives of technique	<ul style="list-style-type: none"> • The success of events and causal factor charting is entirely dependent on the skill and expertise of the investigator. • This technique has not been formally evaluated. • Charting can overtly simplify the sequence of events and therefore the complexity of the situation is lost, which can make recommendations somewhat flawed. • More advanced methods of charting have superseded this approach, e.g. MES
References	Ferry, 1981 ⁵⁰ Buys and Clark, 1978 ⁷⁵ Warren, 2001 ⁷⁶

TABLE 8 Summary of individual techniques: fault trees

	Technique
Overview of fault trees	Fault trees help determine the causes of an incident. They are tree-like diagrams, which show how hardware faults and human errors combine to cause system failures. They present the relationships between potential causes of accidents. Sensitivity analysis can be applied to the trees to ascertain the relative importance of each contributor to the accident. Fault tree analysis involves defining one undesirable event at the top of the tree and deciding what causes it either alone or in combination with other events. 'AND' and 'OR' gates are then used to denote the relationship between an event and those immediately below it and joined to it via the gate. When the fault tree is to be quantified, boolean algebra is used to reduce the elements contributing to the event. This also identifies those factors alone that lead directly to the accident. Complex fault trees will need to be incorporated into computer software, so as to cope with the mathematical complexity
When would the technique be used?	Fault trees are a major method of analysing risk in systems. Fault trees have different applications depending on the objective of the analysis. In a systems analysis, they can be used to assess the impact of operator error on safety, reliability and systems availability whereas in a human error analysis they can be used to analyse the conditions, factors and psychological mechanisms that combine and result in operator error
Outputs, e.g. are recommendations provided as a result of the investigation and analysis?	Yes
Positives of technique	<ul style="list-style-type: none"> • Fault trees can help identify aspects of tasks and errors that are critical to the system, and to differentiate these from the errors, which are of less consequence. • They provide a useful graphical representation of error sequences, understood by engineers and safety personnel. • As a qualitative tool it has the ability to break down an incident into root causes, thus allowing preventative measures on these basic causes to reduce the likelihood of reoccurrence
Negatives of technique	<ul style="list-style-type: none"> • Fault trees can be difficult to construct and care is needed to ensure that the logic is correct. • Can be overly complicated and unwieldy. • Some training in probability theory and the use of boolean algebra is needed to undertake quantitative analysis
References	Kirwan and Ainsworth, 1992 ⁵³ Center for Chemical Process Safety of the American Institute of Chemical Engineers, 1992 ⁵²

TABLE 9 Summary of individual techniques: root cause analysis (RCA)

Technique	
Overview of RCA	RCA finds the fundamental causes and associated action that, if corrected, will prevent reoccurrence of an adverse event. Most events will have multiple causes and for RCA to be effective a comprehensive range of factors must be considered. The analysis of root causes provides the insights needed to develop effective error reduction strategies. There are two approaches to RCA. One is very unstructured and is reliant on the experience and knowledge of the investigator. The second approach is to provide a toolbox for investigators, including MORT, TA, BA, change analysis, cause and effect charting and Tripod. This second approach standardises the reports and increases the number of root causes and error reduction strategies. RCA considers what happened, how it happened and why it happened in sequence. The stages in the process are to define and study the problem, identify contributing factors, determine proximate causes and identify root causes. Most often the technique is used reactively in healthcare to probe the reason for a bad outcome, whereas in other industries it is used most frequently as a prospective risk assessment tool. RCA incorporates more than 40 specific accident investigation and analysis tools, which can be used by the investigator to investigate incidents in a concise and effective manner
When would the technique be used?	RCA techniques would be used when accident investigators wish to answer the following questions: <ul style="list-style-type: none"> • WHAT happened? • HOW did it happen? • WHY did it happen?
Outputs, e.g. are recommendations provided as a result of the investigation and analysis?	Once the investigators have answers to the above questions, they should then use this information to derive corrective action recommendations, to be used to shape future behaviour and ensure that effectiveness is monitored
Positives of technique	<ul style="list-style-type: none"> • RCA focuses in on how to improve systems rather than at an individual level. • It helps identify system weak points. • RCA utilises a variety of techniques to investigate and analyse error. • It is a complete methodology
Negatives of technique	<ul style="list-style-type: none"> • Accident investigators must be fully trained in a variety of techniques. • It is time consuming. • RCA is overly complicated and does not guarantee a complete answer. • RCA is expensive
References	Lucas, 1997 ⁷⁷ Joint Commission on Accreditation of Healthcare Organisations, 2000 ⁷⁸

TABLE 10 Summary of individual techniques: Object-Z

Technique	
Overview of Object-Z	Object-Z is based on TA with the incorporation of operator function model (to model complex operator behaviour in engineered systems). Object-Z is a software tool that possesses temporal operators, which can model accident reports. Information is grouped into classes, so that relevant operation schemata can be grouped with a particular state schema for a more structured and readable specification. Classes, which are defined, are supervisors, tasks and plans
When would the technique be used?	To investigate and analyse any complex socio-technical incident. The technique is, however, still in the design phase
Outputs, e.g. are recommendations provided as a result of the investigation and analysis?	Yes
Positives of technique	<ul style="list-style-type: none"> • The use of Object-Z's formal notation in association with traditional analysis can improve the quality of accident reports. • Encapsulation allows different aspects to be modelled separately, whilst composition implies that classes can be built up from smaller classes. Therefore, large models can be built up from component parts. • State-of-the-art accident investigation and analysis technique, which utilises most advanced human factors techniques (i.e. human error classifications, HTA and software languages)
Negatives of technique	<ul style="list-style-type: none"> • It lacks empirical validation. • The representation of concurrency is explained minimally. • It is extremely complicated to understand, therefore an accident investigator would need significant training to use this system competently
References	Botting and Johnson, 1998 ⁷⁹ Hollnagel, 1993 ⁸² Telford and Johnson, 1996 ⁸¹ Johnson, 1997 ⁸⁰ Mitchell, 1987 ⁸³

TABLE II Summary of individual techniques: wheel of misfortune

	Technique
Overview of the wheel of misfortune	The wheel of misfortune outlines a revised theoretical model and associated classification system for use in guiding the accident investigation process. The basic structure of the proposed model is based on a concentric sphere (rather than the linear model proposed by Reason), with the innermost sphere representing the actions of the front-line personnel, the middle sphere representing local precipitating conditions and the outermost sphere representing the global conditions generated by organisations. The model is based on a series of accepted taxonomies, e.g. Rasmussen's internal failure malfunction taxonomy, ⁸⁴ the simplified decision ladder model of human information processing, which basically describes skill, rule and knowledge-based behaviour and the cognitive triad outlines the context of factors that contributed to the error being made. The wheel of misfortune taxonomy has been used to summarise the outcomes of accident investigations within the aviation and maritime industries. It therefore offers a technique by which complex incidents can be both investigated and analysed based on a model of accident causation which has supported error taxonomies
When would the technique be used?	The wheel of misfortune can be used for any complex socio-technical incident. Although the model provides some information on how to investigate the incident, it is probably best used in the analysis phase of the investigation, when one wants to understand WHAT occurred and WHY and HOW it occurred at an individual and systems level
Outputs, e.g. are recommendations provided as a result of the investigation and analysis?	The provision of outputs is unclear from current documentation
Positives of technique	<ul style="list-style-type: none"> • It is a heuristic model and the concentric spheres within spheres representation is possibly a better approximation of the reality of accident causation than linear sequences. • Focuses on the 'health of the system' rather than defences, i.e. it focuses on the over-arching consideration of whether the organisation was cognisant or aware of a specific hazard. • An alternative to Reason's 'Swiss cheese' metaphor for system failure⁸⁵ has been presented. • The wheel of misfortune is also a practical accident investigation tool, which directs the attention of the investigator to specific questions within the three layers of concern. • It is a comprehensive and perceptive approach
Negatives of technique	<ul style="list-style-type: none"> • The practical accident investigation tool is explained in too little detail to be useful to an accident investigator. • The technique has not been rigorously evaluated. It would be useful to compare this model with Reason's 'Swiss cheese' model to determine when each model might be used more appropriately. • It has been developed extensively within the realm of aviation and maritime accidents, therefore extrapolation to other industries is largely unknown
References	O'Hare, 2000 ⁸⁶ O'Hare and colleagues, 1994 ⁸⁷

TABLE 12 Summary of individual techniques: accident anatomy method (AAM)

	Technique
Overview of AAM	The AAM was developed at the Risø National Laboratory in Denmark and it uses the cause consequence diagram method (CCDM) to address the three of the general incident anatomy. It is a technique which was developed for both process-related incidents and occupational incidents. The basic assumption underpinning AAM is that any incident is the result of multiple causation and its prime objective was to provide a method for recording and analysing accident cases in such a way that the results can be used directly for risk reduction. The AAM is adapted directly from MORT. However, whereas MORT is considered a deductive technique, AAM is considered to be both inductive and deductive
When would the technique be used?	The technique can be used when considering design improvements or where the specific focus is the generation of risk reduction strategies
Outputs, e.g. are recommendations provided as a result of the investigation and analysis?	Yes
Positives of technique	<ul style="list-style-type: none"> • AAM is considered a more flexible tool for organising information from a complex event than MORT, because it is considered a deductive and inductive technique. • AAM has been continually developed and refined since its conception in the 1970s. • A Danish incident database has been developed around AAM. • The technique was specifically developed with the objective of improving risk reduction strategies. • AAM is best applied for improving design
Negatives of technique	<ul style="list-style-type: none"> • Construction of the generic AAM tree can be time consuming, e.g. more than 110 hours for a simple accident scenario. • AAM may be difficult to transfer to healthcare-type environments, where only one organisation uses this approach, as they may not have enough similar type incidents to analyse in this generic way. • This tool is less useful for analysing complex accident scenarios
References	Bruun and colleagues, 1979 ⁸⁸ Center for Chemical Process Safety of the American Institute of Chemical Engineers, 1992 ⁵²

TABLE 13 Summary of important factors for each technique

Technique	A	B	C	D	E	F	G	H
Tripod-BETA	Public	Primary	Petrochemical (Shell)	Potentially – not been tested	Both (resource intensive for near misses)	One trained expert needed	Yes (med)	Yes
IDA	Public	Primary	Unknown	Yes	Both (resource intensive for near misses)	Yes	Yes (low)	Yes
STEP	Public	Primary	Transport	Potentially – not been tested	Both (resource intensive for near misses)	Safety professional with investigation expertise needed	Yes (low)	No
MORT	Public	Secondary	Nuclear	Yes (aviation, healthcare, mining, etc.)	Both (resource intensive for near misses)	Expert user is needed as part of the investigation team	Yes (high)	Yes
Change analysis	Public	Secondary	Aviation	Yes	Both, but better for near misses and less severe incidents	Safety professional with investigation expertise needed	Yes (low)	No
BA	Public	Secondary	Nuclear	Yes (petrochemical)	Both	Safety professional with investigation expertise needed	Yes (low)	Yes
Events and causal factor charting	Public	Secondary	Unknown	Yes	Both	Safety professional with investigation expertise needed	Low	Yes
Fault trees	Public	Primary	Nuclear and chemical/process	Yes	Both, better for more complicated incidents	Expert user is needed as part of investigation team	Yes (high)	Yes
RCA	Public	Secondary	Variety	Yes	Both	Safety professional with investigation expertise needed	Yes (med)	Yes
Object-Z	Public	Primary	Human performance/error	Yes – but not been formally tested	Both	Expert (as evolving technique)	High	Yes
Wheel of misfortune	Public	Primary	Aviation, shipping and human performance	Yes – but not been formally tested	Both	Expert (as evolving technique)	Medium	Yes
AAM	Public	Primary	Chemical process	Yes	Both	Expert user is needed as part of the investigation team	High	Yes

A, Technique available to public or proprietary.
 B, Primary (stand-alone technique) or secondary (provides special input to supplement another method) method.
 C, Industry origin.
 D, Transferable to other industries?
 E, Applicability to investigation/analysis of serious incidents and near misses.
 F, Need for expert to facilitate investigation and analysis using technique.
 G, Need for training in technique (low, < 1 week's training; medium = > 1 week's training; high, > 2 weeks' training).
 H, Does the investigation and analysis methodology encourage all parties (internal or external to an organisation) to participate in the investigation?

TABLE 14 Evaluation of non-health accident investigation and analysis techniques

Evaluation criteria	Technique											
	Tripod-BETA	BA	IDA	STEP	MORT	Change analysis	Fault trees	RCA	Events and causal factor charting	Object-Z	Wheel of misfortune	AAM
Comprehensive	2	0	1	0	2	1	2	2	1	2	2	1
Consistent (accuracy)	NBT	NBT	NBT	NBT	NBT	NBT	NBT	NBT	NBT	NBT	NBT	NBT
Theoretically valid:												
(i) Model-based	2	0	1	1	2	0	1	2	0	1	2	0
(ii) EEM/PEM/PIF	1	0	1	1	2	1	1	2	1	1	2	1
Resources (usage)	1	1	1	2	2	1	1	2	1	2	2	1
Auditable documentation	1	1	1	1	2	1	2	2	2	1	2	1
Independence	2	1	1	1	2	1	2	2	1	1	2	1
Acceptability (usage)	1	2	1	1	2	1	2	1	2	0	0	2
Error reduction	1	2	0	1	2	0	1	2	1	2	2	1
NBT, not been tested.												

Chapter 4

Methods used in the conduct of the healthcare review

In this chapter, we set out the methods of the healthcare review. For a standard systematic review this would be a relatively straightforward process following a standard pattern. Review of methods used for the investigation of incidents in healthcare presents some challenges. In the sections that follow we describe some of the key principles of systematic review methodology and describe how we have adapted approaches to the purpose of the current review. We also provide background to the procedure by which techniques identified in the healthcare review were assessed, explaining similarities and differences with the equivalent activity conducted with respect to the techniques identified in the industrial, chemical and transport domains.

Overview of systematic review methodology

The importance of reviews as a guide to researchers, practitioners and policy makers is widely recognised. The volume of new information that might need to be considered continues to increase rapidly so that it has become impossible for individuals to keep updating knowledge on the basis of primary research. Reviews can also help identify areas where there are gaps in knowledge, such that further research is required. Conventional reviews can be an unreliable source of information⁸⁹ and, as a response to this, formal methods have been developed in which the identification of primary material, its appraisal and synthesis are explicit, reproducible and comprehensive.⁹⁰ Systematic reviews were originally applied almost exclusively to questions of effectiveness of healthcare interventions, and so to randomised trials. Increasingly, the approach has been adapted to the appraisal and synthesis of results of non-experimental designs and increasingly to qualitative research.^{91,92} Although there will be differences in the approaches, all are characterised by adherence to key principles. First, there will need to be a clear description of the kinds of studies which will be admissible, with inclusion and exclusion criteria predefined. Second, there will need to be an explicit and

comprehensive search strategy covering relevant information sources followed by an unbiased assessment of eligibility. Third, there will be a reproducible process for the abstraction of information from individual studies and an unbiased assessment against preset criteria. Finally, there will be summaries of the primary research reviewed and a synthesis of the overall findings of the review.⁹⁰

Relevance to the current review

This review is characterised by a focus on investigative methods, rather than outcomes of interventions, and draws on materials from different published media and across a range of study designs, featuring both qualitative and quantitative outcomes. Some guidance is available for appraising the quality of qualitative research methods (e.g. by Popay and colleagues⁹³ and Giacomini and Cook⁹⁴) as and also more traditional quantitative designs.⁹⁰ In the first part of the health review, we followed general principles of systematic review methodology. However, we then proceeded to synthesise materials on methods and the findings of appraisals into descriptions of techniques and their application, moving on to conduct assessments of the performance characteristics of each of the techniques. For such tasks we drew on a different group of supporting documents. For example, Laurant and colleagues⁹⁵ provide a model for appraising the detail of interventions, Fahlbruch and Wilpert⁹⁶ provide guidance on assessing theoretical adequacy of accident investigations and Benner⁴⁷ and Kirwan^{62,63} have evaluated models and techniques for investigating accidents in various settings. The origins of our assessment process are described in detail in Chapter 2.

Rationale for the sequence of activities

There are a variety of institutionalised quality assurance systems in healthcare, in which the investigation and analysis of critical incidents play

a part. The activity is central to confidential enquiries, to significant event auditing and in investigations of complaints and malpractice claims.^{24,97-101} Recent high-profile public enquiries into adverse outcomes of medical practice (e.g. Mohammed and colleagues¹⁰²) and some of the activities of the Healthcare Commission (www.healthcare-commission.org.uk) might also be added to this group. In a preliminary screen, we found many published studies of single and multiple incidents in hospital specialities, in primary care and in mental health and rather less work on the development of method either conceptually or practically.

The literature on accident investigation and analysis in healthcare remains diverse and poorly integrated. In particular, there has been no effort to map and appraise different approaches to the investigation and analysis of clinical incidents, a gap that this review aims to close. A particular aim of the healthcare review is to identify and assess techniques used to investigate and analyse clinical incidents in that setting. It soon became clear that such incident investigations took place within a range of different quality assurance or research frameworks, and that there were no established taxonomies for the techniques applied to investigating individual incidents. This required us to adopt a staged approach to the identification and review of the relevant literature, which involved the following steps:

1. a search of the MEDLINE database (1981–2001) for relevant materials, using a high-sensitivity search algorithm
2. a screening process to identify descriptive articles and commentaries on the application of investigative techniques and studies featuring the investigation and analysis of incidents in healthcare
3. a further iteration, reading the literature in order to identify and generate a list of techniques
4. appraisal of a selection of papers featuring the application of key techniques in healthcare settings
5. synthesis of narrative reviews of each technique based on descriptive articles and appraised papers and
6. assessment of the techniques against criteria as listed in *Table 35*, which include validity, reliability, acceptability and utility.

The methods and procedures adopted throughout this sequence of activities are described in detail in the text that follows.

Identification of relevant literature

Accident investigation methodologies outside healthcare are generally clearly defined and manuals and descriptions of the methods are available, in addition to reports of actual investigations. In addition, there are a number of standard texts which synthesise information on methodologies and their performance in different settings. Information on the application of methods in healthcare is qualitatively and quantitatively different. In healthcare there are authoritative texts for some [e.g. Joint Commission on Accreditation of Healthcare Organisations (JCAHO)⁷⁸], but by no means all approaches to the investigation of incidents. Furthermore, there has been relatively little reflection on the performance of different approaches under alternative conditions of use. In order to help address these deficiencies we searched for descriptive materials and commentaries on techniques and, in addition, searched for published studies featuring the investigation and analysis of incidents in healthcare settings. Appraisals of such published studies then served to expand our knowledge base on the ways in which techniques have been applied in healthcare and provided additional information to support assessments of validity, reliability, acceptability and utility. The need to access descriptive articles and relevant published studies informed our search procedure.

Search strategy adopted for the review

Our intention was to devise a literature search strategy which would identify a representative sample of peer-reviewed publications featuring the investigation and analysis of clinical incidents in healthcare and any additional publications which describe or discuss the methods and techniques used. Classical systematic review methodology would require exhaustive searches of electronic databases, supplemented with handsearches, citation searches and communication with colleagues. Our approach was to conduct an initial systematic search of electronic databases followed by targeted searches of alternative sources for materials providing further detail on the investigative techniques identified. These alternative sources ultimately included government documents, websites, books and new papers identified in bibliographies and through personal contacts.

The electronic search strategy that we used appears in Appendix 6. This was developed to identify relevant papers in MEDLINE (1981–2001), using thesaurus and text terms. The search strategy is a modification of the classical search strategy for systematic reviews based on crossing of concepts.

We identified three concepts which we expected to appear in publications likely to be of interest for this review:

- Concept A: mention of relevant methods of enquiry, investigation or analysis.
- Concept B: mention of errors, omissions, mistakes or iatrogenesis.
- Concept C: mention of incidents or adverse events in clinical care.

We found a search directed towards identifying publications featuring all three concepts (Concept A + B + C) to be of high specificity, but poor sensitivity. Following experimentation with alternative models, we elected to search for publications featuring (Concept A + B) OR (Concept B + C) OR (Concept A + C), which improved the sensitivity considerably despite generating a fairly large volume of citations for screening.

Inclusion and exclusion criteria

The review was designed to focus on techniques for the investigation of clinical incidents or near misses in healthcare. Our aim was to identify two groups of papers: (a) studies describing the investigation and analysis of one or more clinical incidents or near misses in a healthcare setting and (b) other publications which focus on describing, evaluating and/or discussing method, but without the formal investigation of cases.

We specified in advance that we would exclude investigations involving the use of comparison groups or controls. Therefore, we excluded all epidemiological studies (prospective or case-control designs). We also excluded studies designed to assess the reliability of diagnostic tests, which typically featured replication of tests or comparisons with gold standards. Finally, autopsy studies were excluded on the grounds that they are designed principally to assess diagnostic accuracy, rather than to investigate the causes of error.

We also specified that investigations should be carried out retrospectively. Completion of forms or

interviews documenting details after an incident or near miss had occurred was regarded as retrospective, even if this occurred within minutes or hours of the event, but prospective techniques to assess errors such as simulation experiments, or to assess potential errors such as continuous quality improvement or other system redesign approaches were excluded.

There were no country restrictions, but for practical reasons we were only able to consider publications in the English language. By considering only studies in the English language means that we will have missed any that were only published in journals that do not provide English abstracts. We acknowledge that they may be some studies that might have contributed to one of the techniques we identified or even a whole range of studies that might have identified a separate technique.

Screening of citations and identification of relevant literature

Two investigators (SR and MW) examined all titles identified by the electronic search together with their abstracts when available, then screened hard copies of candidate papers to identify those meeting inclusion criteria.

Citations were classified as (i) probable admissible study; (ii) probable admissible descriptive paper; (iii) possible interest; or (iv) no interest. Typically citations were tackled in batches of 100–200 at a time, and then followed by a meeting to resolve any disagreements. Inter-rater reliability for ‘probable study or paper’ versus ‘possible or no interest’ was monitored using the kappa statistic, and stabilised at $\kappa = 0.29$ – 0.45 following the training period.

Hard copies of publications allocated to groups (i), (ii) and (iii) were then obtained. The same investigators subsequently assessed the content of these materials against a screening checklist. This specified that **either** the paper describes or discusses an investigation method or technique **or** it was a peer-reviewed study with all of the following characteristics:

1. The paper featured one or more clinical incident or near misses.
2. The incident was one in which a patient suffered, or could have suffered, harm.

3. The incident occurred in a healthcare setting.
4. A retrospective enquiry into the incident took place.
5. The enquiry included an investigation into error or suboptimal care.

The inter-rater reliabilities for this stage ranged from $\kappa = 0.19$ to 0.55. This exercise was continued in duplicate, not only to improve precision but also because the process was considered to be an important preparatory exercise for the investigators who needed to appreciate the range and nature of the relevant literature.

The number of citations generated from the MEDLINE search was 1950, and 562 hard copies were obtained and screened. Amongst these, we identified 147 publications which featured the investigation and analysis of clinical incidents or near misses in healthcare settings and a further 96 publications which described or discussed an investigative method or technique (see Appendix 7).

Development of a glossary and classification of techniques

The papers were examined a second time in order to identify terms in the title, abstract or methods sections that indicated particular approaches or techniques. We also checked our collection of descriptive papers for methods and techniques that did not feature in the investigative studies.

Candidate terms were free listed and then organised into a glossary. The principal headings identified through this process were:

1. critical incident monitoring
2. CIT
3. SEA
4. RCA
5. CRU/ALARM protocol
6. confidential inquiry
7. occurrence screening
8. regulatory agency report
9. claims or complaints analysis
10. human factors method
11. systems analysis
12. active and latent failures approach
13. analysis of incident reports
14. organisational factors approach
15. Haddon's matrix
16. Winnipeg model
17. Failure modes and effects analysis
18. BA.

On closer reading of selected papers, it became clear that many techniques listed in the original glossary were closely related and might be considered as a single 'family'. Others were represented by no more than one or two examples and, although of interest, did not justify exhaustive consideration in the context of the review. For these reasons, we then went on to collapse the list into a more manageable grouping of techniques, which would provide the framework for selecting papers for appraisal and for the synthesis and assessment of techniques in the latter part of the review.

Although we recognised that a collapsed classification risked over-simplification and excluded consideration of approaches where 'technique' was ill defined (e.g. the majority of claims and complaints analyses, published findings from regulatory agencies and many case reports), we elected to focus on the following list as an accessible starting point for assessing the range of techniques applied to the investigation of clinical incidents in healthcare:

1. classificatory reporting (e.g. AIMS)
2. CIT
3. SEA
4. RCA
5. human factors and organisational models
6. comparison with standards approach (e.g. confidential enquiries)

Development and piloting of the appraisal process

An appraisal form was designed to assist with the systematic documentation of key features of studies featuring the investigation of critical incidents in health care. This was a substantive exercise as little consideration has been given to the design features of studies investigating clinical incidents in the past, and certainly we know of no previous attempts to appraise the quality of such studies.

The development of the appraisal instrument was informed by the following:

1. available literature and experience in developing and using appraisal tools in other projects
2. materials on investigative approaches emerging in the review of techniques for the investigation of incidents outside healthcare

3. serial appraisals of studies of investigations within healthcare, with iterative modifications of the instrument over the period of about 6 months
4. further modifications of the instrument following preliminary attempts to code, organise and present appraised data.

The final version of the appraisal form is included in Appendix 8 and consists of the following sections.

- Section A, 'Details of the appraised publication', seeks background information about the paper (i.e. country or continent in which the study/report took place, specialty, level of care) and brief outcome information on the critical incident or 'near miss' including the number of events and a summary description.
- Section B, 'Conduct of the investigation(s)', focuses on 'who' is conducting the investigation, their professional background and investigation experience and whether the authors refer to an established accident investigation technique and the framework within which investigation took place.
- Section C, 'Data collection and causal analysis', is divided into three subsections: (1) interviews and self-reports, (2) primary document review and (3) physical/logistic assessment. Each section has similar questions on the source of data, methods of data extraction/techniques used, interval between incident and investigation, time taken to extract the information, methods used for data critique and two items on quality assurance regarding data collection and data critique.
- Section D, 'Presentation and interpretation of data', focuses on how the data are presented in the results and discussion sections. Specifically, questions include how the outcomes of the investigation are formulated, whether these outcomes relate to any underlying model of accident causation, whether recommendations are made and if the level of such recommendations relate to formulation of outcomes and whether there is any intention of implementation of changes as a result of the investigation of the critical incident featured in the paper.

Two investigators (MW and SR) participated in the appraisal process. Data abstraction was conducted independently and disagreements in interpretation emerging were resolved by discussion. All papers appraised using earlier versions of the appraisal form were reappraised on items changed during the development process.

Rationale for selection of exemplar studies featured in the review

After 50 papers had been appraised, we reviewed the process for the remaining papers eligible for appraisal. The majority of studies identified through the screening process fell within the 'classificatory reporting/AIMS' group or the 'comparisons with standards' group and, amongst the 50, the number of papers appraised by technique was roughly proportional to the numbers in the background sample.

As it was not feasible to appraise all papers within the time frame of the study, we switched to a purposive sampling strategy at this point, specifying that we would appraise ten studies for each technique, or the total number of papers available, whichever was greater. For techniques with large numbers of papers available, we aimed to target a range of specialities across the publication years searched and for techniques with smaller numbers of publications, we sought actively to identify further studies by contacts with experts in the field, in an attempt to meet the target of ten papers. Ultimately, the numbers of study papers appraised and presented in this report correspond to ten each for classificatory reporting/AIMS and RCA, comparisons with standards, nine for CIT, seven for human factors and organisational models (i.e. OACM) and six for significant event auditing.

Our priority in this report, however, is less to explore the conduct of individual studies, patterns with specialities, study designs or publication dates than to provide a coherent assessment of the techniques used for the investigation of clinical incidents and near misses in healthcare. The subsequent stages of the review process therefore focus on synthesising the available information from descriptive papers and appraised studies, with the aim of addressing this objective.

Data management and analysis

With the exception of occasional items, the appraisal instrument took the form of a precoded data abstraction sheet. In this section of the review, the unit of study was the investigative technique rather than any single publication. Once the data items had been agreed, codes were entered directly on to SPSS for range and consistency checks, then analysed.

In this report, we restrict our analyses to counts and frequency distributions, selecting key variables relevant to the following:

1. country setting and speciality of appraised papers
2. source and number of incidents studied
3. the severity of the injuries and the amount of intervention required
4. the characteristics of the individual(s) carrying out the investigation
5. the types of data collection methods used
6. the individuals who were interviewed or who were submitting reports
7. the format of the questionnaire, report or interview
8. the methods used to assure quality when recording and critiquing interviews
9. the methods used to assure quality when collecting data and analysing reports
10. the methods used to assure quality when abstracting and critiquing documents
11. the methods used to assure quality when collecting and analysing data from site visits or physical examinations
12. the level and nature of formulation of the findings on causes
13. the coherence of recommendations and the evidence for implementation.

These data are presented for all of the papers appraised and stratified by the relevant technique. This presentation is intended to support informal comparisons between techniques. No formal or statistical comparisons were made on account of the complexity of the data which are presented.

Assessment of techniques for the investigation of critical incidents in healthcare

We used an approach modelled on that used for the assessment of techniques for high-risk industries outside healthcare (see Chapter 2). A comprehensive document was produced for each technique based on the descriptive publications and the appraised papers. Key information was abstracted to provide the reader with the main features of each technique using a common standard framework, which included:

1. an overview of the technique as typically applied
2. a description of the usual conditions of use
3. a description of the likely formulation and quality of outputs
4. positive points associated with the technique
5. negative points associated with the technique.

Each technique was then assessed against the predefined set of criteria introduced in the review of methods in high-risk industries. The technique was assessed against each of the following criteria:

1. whether different assessors are likely to utilise the methodology in the same way and expected to be consistent in the conclusions they draw
2. whether the approach is based on an accident model or model of human behaviour which offers theoretical validity
3. whether the technique simply assesses or identifies what happened, how it happened and why it happened
4. whether the approach is intuitively linked to the generation of error-reduction strategies
5. whether resource use is likely to be minimal, modest or substantial
6. whether the approach is likely to be auditable in its documentation
7. whether the approach produces balanced and fair outputs – without a focus on only the individual or only the system
8. whether the approach has been widely used and acceptable to participants
9. whether the approach can be expected to be comprehensive in its ability to identify significant errors
10. the extent to which the technique is applicable to other specialties.

Two researchers (MW and ST-A) conducted this assessment and then agreed on the final interpretation. The method was adapted from the work of Benner⁴⁷ and Kirwan^{62,63} for the purpose of the review and still requires independent validation. Furthermore, the information available for the assessment of methods within healthcare was qualitatively and quantitatively different to that available for methods outside healthcare. It was nevertheless our impression that the approach was useful for the assessment of techniques within healthcare and that the investigators were reasonably consistent in the assessments for the majority of items and techniques.

Chapter 5

Review of healthcare methods for the investigation and analysis of critical incidents

This chapter presents the review of methods of the investigation and analysis of critical incidents in healthcare. First, a number of relevant study types, such as occurrence screening, confidential enquiries and the analyses of claims, are described. This framework of describing such study types may be more familiar for clinicians and other readers and so is included for completeness. Next, a summary of the six core investigation techniques is presented. This is followed by the results of the appraisal of key papers on the investigation and analysis of critical incidents for each technique. The assessment of each technique, based on the appraised publications and supporting literature, is included. The criteria of this assessment are based on those compiled for the techniques used in high-risk industries described in Chapter 3. This is followed by a commentary on the strengths and limitations of the techniques and finally a summary and interim conclusions.

Description of study types

In this section we describe a number of relevant study types, namely occurrence screening, confidential enquiries, analyses of claims, analyses of reports to regulatory agencies, incident monitoring studies, incidence studies, incident recall studies, case series and case studies.

Occurrence screening

Occurrence screening is a technique in which medical records are reviewed to identify poor-quality care. It is based on two main principles: first that it is far more practicable to specify and describe what does not constitute good-quality care than to specify what does and second that to focus on poor-quality care is a good way to bring about improvements in overall standards. The process involves screening of a sample of medical records using predefined criteria such as death, increased hospital stay and unplanned transfer to an operating theatre or intensive care unit (ICU). One or more physicians then evaluate the cases in more detail, confirm the existence of an adverse outcome and elaborate on its nature. In most

studies, this stage of the process included an assessment of whether care was suboptimal and, in a few, attempts were made to assess what went wrong, and why, either using a checklist to abstract clues directly from the notes or by consultation with an expert group. Where occurrence screening is continuous, the approach may be linked with more formal approaches to the investigation of incidents, such as RCA,¹⁰³ providing a clever hybrid of performance monitoring and in-depth investigation of individual cases.

Confidential enquiries

National confidential enquiries are conducted into maternal deaths, perinatal deaths and deaths after surgery in the UK, and have been adopted by other commonwealth and non-commonwealth countries. The same model has also been adopted for sub-national level enquiries into other adverse outcomes, including asthma, community-acquired pneumonia and suicides. The deaths are typically identified through certification of death, supplemented by other reporting, or case finding initiatives. Data collection typically includes acquisition of medical notes and autopsy reports, may be supplemented with questionnaire-based enquiries to healthcare providers and especially, but not exclusively, in less developed countries might include interviews with healthcare providers and relatives. These materials are then assembled for appraisal by reviewers and with final decisions on the quality of care in individual cases taken by an expert panel. For some aspects of care, standards and criteria are available in advance but, by and large, judgements on whether care is adequate or suboptimal are made against the expectations of the peer-review group. The focus of confidential enquiries has tended to be on whether care was suboptimal, and in what way, although often insights are also provided into why care was suboptimal.

Analysis of claims

Closed claims are cases of injuries to patients where physicians have been found to be negligent in the quality of care they have delivered as judged against the performance of colleagues. Claims represent a small proportion of adverse

events, but adverse events nevertheless for which documentation is available and of which most doctors would like to be spared. Typically, a closed claim file includes copies of the medical record, narrative statements of staff involved, expert and peer reviews and reports of both the clinician and the legal outcome. The yield of information on the causes of adverse events has varied between studies. For example, in an analysis of a series of claims for adverse respiratory events in anaesthesia, the investigators found that the 'distinguishing feature in this group of claims was the reviewer's inability to identify a specific mechanism of injury'.¹⁰⁴ However, in two other series of claims for covering perinatal injury and/or maternal death, the investigators concluded that avoidable human error featured very prominently in the series.^{105,106} Clearly, the quality of the information available will have important implications for the conclusions drawn and limits the yield of useful information from complaints and claims, which await investigation.

Analysis of reports to regulatory agencies

A number of regulatory agents require the submission of reports for incidents occurring in particular areas of care, or in associated with drugs or medical devices. As with claims, the information yield from the analysis of such reports will depend critically on the quality and content of the material submitted. Reports can provide information not only on what happened, but also how and why.^{107,108} Historically, there has been more of an emphasis on pharmacodynamics where drugs are concerned and on design features where medical devices are concerned, but there are examples of publications where the human factors involved in generating adverse outcomes have also been given attention. Where the regulatory agency is less focused on drugs and technology, there may be even greater scope for learning on both the underlying and the direct causes of incident reports.¹⁰⁹

Analysis of in-house incident reports

Many institutions require staff to submit reports when incidents occur. Typically these cover a range of incidents, including accidents involving staff, problems with plant and environment and health and safety issues. There may be no particular emphasis given to the documentation of incidents where patients are injured or might have been injured. Also, it is generally accepted that this source of data will be unrepresentative of injuries to patients and probably of poor quality. Like all studies of this kind, the learning will

depend on the quality of the materials available. There are nevertheless a few studies where attempts have been made to review such reports and these are included for completeness.

Incident monitoring studies

Incident monitoring studies are directed towards collecting relatively small amounts of information on large numbers of incidents, and so providing an indication of incident types and trends. Most studies are either direct outputs of AIMS, or else studies from other sites, using the same methodology. AIMS uses a standardised form which requests basic information on the incident and who was involved, a narrative description, then the informants' view on underlying causes and opportunities for avoiding the same in the future. The submission of reports is voluntary, if enthusiastically encouraged. The information is ultimately submitted to a central databank and has generated huge numbers of studies on a wide range of topics. These have featured the full range of incidents occurring in a particular healthcare setting, particular kinds of adverse outcomes, particular pieces of equipment or particular contributory causes. AIMS is now supported by a comprehensive classificatory framework covering adverse events, types of errors and underlying causes and has developed computerised search facilities to help draw together reports with common characteristics. The main source of weakness in the overall approach is likely to be the ultimate dependency on the recollections of single individuals, who have observed, but not formally investigated, care management problems.

Incidence studies

On first inspection, this group looks similar to the incident monitoring studies. However, they often feature voluntary incident reporting as a component of study design. This activity is usually complemented with other approaches for detecting incidents in a particular cohort of patients, or a particular series of activities, over a specified duration of time. Notes review, participant or non-participant observation in ward activities is common. The investigation of cause varies tremendously from study to study. In some this is a reflective process as in the incident monitoring,¹¹⁰ but might include informal interviews with healthcare staff,¹¹¹ or more formalised approaches for the investigation of clinical incidents.¹¹² The advantage of this kind of study is that the frequency of adverse events is meaningful, and combined with more careful investigation of cause, provides the opportunity for breadth and depth in incident investigation.

Incident recall studies

The approach used in these studies has limitations, but the design may be of particular historical significance. This approach was common amongst the earliest investigations into incidents in healthcare as it allowed investigators to accumulate large numbers of incidents for analysis quickly, from which they could begin to generate taxonomies of adverse outcomes and direct and underlying causes.¹¹³ The same approach has been used to open up new settings, such as primary care.^{25,114} Investigators cite the CIT as the investigative method, although the approach described by Flanagan³² was based on prospective collection of incidents. Analysis of 'memorable' incidents inevitably has implications for informant memory and recall bias, placing limitations on the validity of the material collected.

Case series

This is a heterogeneous group characterised by case-by-case investigation and common outcomes or themes. Clearly, any of the approaches described may provide the basis for the compilation of a case series. The grouping is rather reserved for cases compiled in the context of other *ad hoc* studies or investigations. A number of studies of surgical complications fall into this group and are modelled on the confidential enquiry approach. Other case series are generated in the context of other systems such as sentinel event reporting or SEA.

Case studies

These are published because of the value of the lessons learned, but more often to support a discussion of an investigative method or theory of accident causation.

Incident investigation and analysis techniques in healthcare

Tables 15–20 summarise the essential features of the six core incident investigation and analysis techniques reviewed. Further information on each technique can be found in Appendix 9.

Descriptive data from appraised publications

Data relating to every appraised paper are included in Appendix 10. These tables provide material on key items from the appraisal form and are subdivided into each core technique.

The amount of data missing or 'not clear' from appraised papers was fairly high despite selecting papers where the technique was most clearly described. We were careful, where possible, to record data evident in the publications and avoided making assumptions.

Tables 21–33 summarise the data from the appraisal forms, giving a comparison of the core techniques. Data are presented section by section as in the appraisal form (see Appendix 8). Figures in parentheses in these tables indicate the number of papers for that category, when > 1.

Section A – 'Details of the appraised publication'

As outlined in Chapter 4, p. 33, Section A of the appraisal form seeks background information about the paper being appraised. Table 21 gives details of the country or continent in which the study took place and the specialty – subdivided into the three areas for which we have produced investigation guidelines: acute care, mental health and primary care. According to the appraised publications, all but the AIMS technique were conducted in the UK and acute care and primary care is featured in most of the techniques. Psychiatry is featured in papers related to AIMS and the OACM only.

Table 22 lists the various sources of critical incidents featured in the publications and the median and range of incidents featured for each technique. The complete list of numbers of incidents featured in the publications is given in Appendix 10. Apart from AIMS, the different techniques use a variety of sources of critical incidents and all techniques are informed of incidents from voluntary reporting systems.

Table 23 gives details of the severity of critical incidents featured, both injury suffered and treatment required. The term 'some injury' includes cases where the extent of injury is unknown and the following phrases taken from the papers to describe outcome where they did not fit our classifications: 'mild, moderate and severe effects', 'minor transient change', 'major physiological change', 'cardiac arrest', 'actual harm', 'life-threatening injury', 'foetal distress and low Apgar' and 'clinical deterioration'. Details of severity of outcome for each appraised publication are included in Appendix 10. The comparison with standards methods only looked at death as an outcome whereas all other techniques used a variety of outcomes including near misses.

TABLE 15 Summary of individual techniques: Australian incident monitoring system (AIMS)

Technique	
Overview of AIMS	<p>AIMS is intended to provide a national mechanism for reporting problems arising from health management for collecting, classifying and analysing data. AIMS is run by the Australian Patient Safety Foundation (APSF; www.apsf.net.au) and was introduced in 1996 as a tool for any incident or potential incident in healthcare to be reported, using a single standard form. Specialty-based pages on these forms have been developed for anaesthesia, intensive care, emergency medicine, surgery, pathology and general practice.</p> <p>The AIMS report forms consist of two components: part A, a confidential incident report form; and part B, an anonymous incident monitoring section. In Part A incident information is collected at local level and is then coded using the APSF software. The coding of the information provides the means for understanding the underlying causes of the incident and for analysing the contributing factors. Part B is sent to the APSF after all identifying information has been removed. This anonymous data are then entered into an aggregated database that allows all health units to receive comparative information linking their performance with other 'like' organisations. The de-identified data support the aggregation of low-frequency events at international level and are therefore very effective for identifying and coordinating system-based strategies to detect, manage and prevent problems better.</p>
When would the technique be used?	AIMS is used for any actual or potential incident or accident in healthcare
Outputs, e.g. are recommendations provided as a result of the investigation and analysis?	<p>AIMS uses a classification system of software specifically designed for 'things that go wrong' in healthcare. The software elicits the key features of the incident, places the event in context and records the contributing factors, both system-based errors and human errors.</p> <p>Some of the contributing factors that are recorded are:</p> <ul style="list-style-type: none"> • management decisions • infrastructure, working conditions • communications, records • staff quantity and quality • supervision and tasking • equipment availability and/or suitability • policies, protocols and pathways
Positives of technique	<ul style="list-style-type: none"> • The system ensures confidentiality and anonymity and therefore staff are more likely to report the incident (there is some legal protection). • Identification of common factors, trends from aggregated data. • Such identification can assist to justify changes or proposals that require funding. • National and international system allows comparative data analysis
Negatives of technique	<ul style="list-style-type: none"> • Data depend on those included in the forms and cannot be investigated further if not already done so at local level. • The level of information is dependent on the amount of detail provided by the person reporting the incident. • Only one type of data is collected and analysed – secondary documentation – giving no opportunity to check accuracy
References	<p>Morris and Morris, 2000¹¹⁵ Steven and colleagues, 1999¹¹⁶ Sinclair and colleagues, 1999¹¹⁷ Chen and colleagues, 1998¹¹⁸ Vinen, 2000¹¹⁹</p>

TABLE 16 Summary of individual techniques: critical incident technique (CIT)

Technique	
Overview of CIT	<p>The CIT was first described by Flanagan,³² who described it as a set of principles for gathering data rather than a rigid set of rules. Flanagan set out a series of defined steps to collect and analyse critical incidents: specifying the aims of the work to be studied, specifying the incidents to be collected, methods of data collection, analysis and interpretation. The technique was applied to a variety of areas, mostly with the aim of describing and specifying the key skills involved in a particular kind of work, often by collecting and contrasting specific instances of skill or lack of skill. Flanagan also notes that although the procedures for collecting the factual data appear sound, methods of classification of incidents and interpretation of the findings remained relatively subjective.</p> <p>In healthcare, a considerable number of studies refer to the CIT and to Flanagan's original paper. However, few make specific use of his principles and the reference to the technique sometimes seems little more than a justification for collecting information on a series of unrelated incidents. The true ancestor of most healthcare papers is Cooper and colleagues' pioneering study¹²⁰ on preventable anaesthetic mishaps. They state specifically that the study is a modification of the CIT.</p> <p>Critical incidents may be collected by a variety of methods, but are usually based on a system of voluntary reporting. Early studies¹¹³ initially used interviews with members of staff, sometimes focusing on open questions about critical incidents and in a second phase using more targeted questions about specific types of incidents. Once staff were familiar with the method, voluntary reporting was introduced. Later studies have generally relied on voluntary reporting of incidents using a questionnaire with both free text and specific questions</p>
When would the technique be used?	<p>The most substantial and wide-ranging studies have been in anaesthesia, where the approach has had considerable influence.</p>
Outputs, e.g. are recommendations provided as a result of the investigation and analysis?	<p>Studies have also been carried out in intensive care,²⁸ on deaths in general practice²⁴ and uncomfortable prescribing decisions.²⁵ However, no other speciality has produced a sustained series of studies in which an understanding of the causes of incidents has been followed by the introduction of preventative measures</p>
Positives of technique	<p>Cooper and colleagues provide a table of strategies for prevention of incidents based not only on the specific clinical problems identified but also on the more general problems underlying a number of different kinds of errors</p>
Negatives of technique	<ul style="list-style-type: none"> • More easily applied than large-scale epidemiological studies. • Original CI studies used to develop a set of strategies for preventing recurrence. • Cooper and colleagues' work draws on human factors and the psychology of human error anticipating later thinking on human error in healthcare • Most studies give little or no information on the methods of investigation or analysis. • Highly reliant on the intuition and expertise of the investigators. • Technique has been very little developed since Cooper and colleagues' pioneering studies
References	<p>Cooper and colleagues, 1978¹²⁰ Cooper and colleagues, 1984¹¹³ Flanagan, 1954³² Anon., 1988¹²¹</p>

TABLE 17 Summary of individual techniques: Significant event auditing (SEA)

Technique	
Overview of SEA	<p>SEA involves 'audit' of a single case or event, where things went badly or sometimes where things went well.⁹⁹ SEA was not designed to address patient safety issues, but as a quality improvement technique which can be applied more generally to improving the organisation and delivery of care. Significant event audit meetings are conducted with groups of people or teams as a work-based reflective activity. It is potentially anti-hierarchical and the effective functioning of the participating small group is generally accepted as a prerequisite for successful significant event auditing.¹²²</p> <p>One member of the team presents the details of an incident considered significant and leads the SEA process¹²³ or an outsider, skilled in managing small group work, facilitates the process.¹²² The account of what happened is presented with assistance from clinical notes if relevant. Frameworks have been suggested to help guide the analysis of the case and leading to action points (see summary in Appendix 9 for details). SEA is important as a vehicle for identifying opportunities for improvement⁹⁹ or for creating a safe environment for members of staff to share worries and concerns or to congratulate each other on good practice</p>
When would the technique be used?	<p>SEA is widely used as an educational approach in the general practice setting in the UK, where adverse events including deaths, patient complaints or administrative mistakes may be used as a starting point for SEA</p>
Outputs, e.g. are recommendations provided as a result of the investigation and analysis?	<p>The educational value of SEA (at least in well-functioning and highly motivated teams with time and resources available) is not disputed, but the capacity of the SEA to promote improvement in practice has not as yet been demonstrated. This will depend on the links between the generation of recommendations and their implementation. In relation to improving the quality of care, SEA is, however, an information gathering strategy, not a change strategy as such</p>
Positives of technique	<ul style="list-style-type: none"> ● SEA can provide a valuable opportunity to further develop quality improvement activities in any clinical setting where there are regular meetings of work-based teams. (In the absence of such meetings, changes in the organisation are required in order to proceed.) ● Experience shows that over time the culture and communication of teams participating in SEA can change. ● It is a good screening tool for identifying problems in the quality of healthcare and its delivery and in helping to set an audit agenda. ● Its inclusion in a practice's audit programme balances the intellectual and the emotional content of performance review
Negatives of technique	<ul style="list-style-type: none"> ● The capacity of the SEA to promote improvement in practice has not as yet been demonstrated (this will depend on the links between the generation of recommendations and their implementation). ● Some clinical settings are more hierarchical than others and clinicians may be closed to the views of other members of staff. ● Significant event auditing is complementary to and not a substitute for more conventional audit methods. ● In relation to improving the quality of care significant event auditing is an information gathering strategy, not a change strategy as such. ● In some settings SEA may simply not be acceptable
References	<p>Pringle and colleagues, 1995⁹⁹ Westcott and colleagues, 2000¹²³ Flanagan, 1954³² Robinson and colleagues, 1995¹²² Pringle, 1998¹²⁴</p>

TABLE 18 Summary of individual techniques: root cause analysis (RCA)

Technique	
Overview of RCA	<p>RCA is essentially a total quality management tool. It is a systematic approach that drills down deep to identify the basic reasons for a problem – the root causes. RCA is not based on any specific theory of human error or system failure, but it does provide a toolbox of useful techniques and tools for use by incident investigators.</p> <p>RCA was originally developed more than 30 years ago within the industrial sector, e.g. transport, chemical and nuclear industries, as a methodology to investigate serious accidents. In healthcare, in both the USA and UK, there is huge interest in the use of RCA tools as a mechanism to investigate serious incidents. This has been fuelled by the publication of key documents such as OWAM¹ in the UK and the work on RCA undertaken by the Joint Commission on Accreditation of Healthcare Organisations (JCAHO) in the USA.</p> <p>JCAHO (www.jcaho.org) provides the most comprehensive guide on how to complete a successful RCA based on 21 separate steps, making it an extremely thorough approach (see Appendix 9 for an outline of the RCA process). Examples of the 21 steps include defining the problem; using brainstorming, TA, FMEA and Gantt chart techniques; studying the problem; determining what happened; identifying contributing process factors and other human, equipment and environmental factors; measuring, collecting and assessing data of proximate and underlying causes; confirming root causes. Some investigators, e.g. Handley,¹²⁵ have simplified this technique and reduced RCA to just 7 steps</p>
When would the technique be used?	<p>Since 1996, JCAHO in the USA has required hospitals to use the RCA process to investigate serious incidents, e.g. inpatient suicide, infant abductions and deaths related to delays in treatment. In addition to the 21-step process, JCAHO also outline a number of RCA tools and techniques which can be used by the incident investigator both to collect data and to analyse the system failures. The National Patient Safety Agency (NPSA) in the UK has recently been set up to coordinate and enhance organisational safety learning through the investigation and analysis of serious adverse events in UK hospitals.</p>
Outputs, e.g. are recommendations provided as a result of the investigation and analysis?	<p>In addition to this, RCA could be used locally to investigate a critical incident or a near miss</p> <p>The analysis identifies changes that could be made in systems or processes that would improve the level of performance and reduce the risk of a particular serious adverse event occurring in the future. RCA focuses primarily on systems and processes, not individual performance; the analysis progresses from special causes in clinical processes to common causes in organisational processes, and the analysis repeatedly digs deeper by asking 'why?' questions until no additional logical answer can be identified</p>
Positives of technique	<ul style="list-style-type: none"> ● Focuses on how to improve systems rather than blaming an individual. ● Helps identify system weak points. ● Utilises a variety of techniques to investigate and analyse error. ● Provides investigators with a complete accident methodology. ● RCA, if done correctly, is generally a cost-effective methodology
Negatives of technique	<ul style="list-style-type: none"> ● Limited documentation exists in the healthcare sector on the range of RCA tools available and in particular worked examples showing their applicability to certain types of accident investigations. ● Accident investigators must be fully trained in a variety of RCA techniques if they are to analyse incidents successfully. ● RCA can be a time-consuming process if a variety of detailed techniques are used. ● RCA can very easily be made overly complicated and does not guarantee a complete answer
References	<p>Joint Commission on Accreditation of Healthcare Organisations, 2000⁷⁸ Hirsch and Wallace, 1999¹²⁶ Berry and Krizek, 2000¹²⁷ Beyea and Nicoll, 1999¹²⁸</p>

TABLE 19 Summary of individual techniques: organisational accident causation model (OACM)

Technique	
Overview of OACM	<p>OACM is a category in which studies reporting analysis of incidents have been grouped together on the basis of using primarily interview techniques and applying a framework for analysis based on Reason's OACM.³⁷</p> <p>The focus of this description is on Vincent and colleagues' model,¹²⁹ also known as the CRU/ALARM protocol for the investigation and analysis of clinical incidents. This model is essentially a guide to how to conduct an investigation using interviews, applying a framework when gathering and analysing the data and producing recommendations for change.</p> <p>The framework is based on human factors literature, particularly the work of Reason, Rasmussen and Norman. These theorists proposed their ideas as a result of studying accidents in industry, transport and the military which led to a widening of focus of the causes of error to include pre-existing organisational factors rather than limiting the focus of blame entirely on the individual.</p> <p>The framework is used during the interviewing process to explore the key acts that led to the adverse outcome. The framework helps the investigator to identify contributing factors such as patient factors (e.g. the patient's condition and comorbidities), task design, the availability and utility of protocols, individual or staff factors (knowledge, skills and experience), team factors (e.g. communication, support and supervision), management actions or decisions (e.g. policies regarding the use of locum or agency staff, continuing education, training and supervision and the availability of equipment and supplies) and the institutional context (e.g. financial constraints, external regulatory bodies and the broader economic and political climate)</p> <p>This technique is used to investigate critical incidents, adverse events and near misses. It has been used for the latter as a learning process, where the emotional impact of an adverse event is not as great for the staff.</p> <p>The classification system proposed by Vincent and colleagues has also been incorporated into the NPSAs adverse incident investigation and analysis tools</p> <p>During the analysis process, investigators identify the implications and action plans from each case, particularly where these are associated with general contributing factors rather than those specific to the case under investigation. The end result is a summary of the chronology, identification of all clinical management problems and the associated contributory factors, positive features of the process of care and recommended action and timescales for each general factor requiring attention</p> <ul style="list-style-type: none"> ● Focuses on how to improve systems and working environment rather than focusing blame on an individual. ● Identifies a range of weakness in systems, teams and/or individuals. ● Some methods provide investigators with a complete investigation tool. ● Based on current accepted models of human performance ● Some investigators have had difficulty with some terms. ● Incident investigators need to be trained in human error theory if they are truly to understand error typology and translate this knowledge into practical accident investigation and analysis. ● Models and theories have not been formally evaluated
When would the technique be used?	
Outputs, e.g. are recommendations provided as a result of the investigation and analysis?	
Positives of technique	
Negatives of technique	
References	<p>Rasmussen, 1982⁸⁴ Reason, 1997⁴⁵ Stanhope and colleagues, 1997³⁸ Vincent and colleagues, 1999¹²⁹ Norman, 1981¹³⁰</p>

TABLE 20 Summary of individual techniques: comparison with standards (CWS)

Technique	
Overview of comparison with standards approach	<p>CWS is an extremely broad method. The application of the approach to maternal deaths preceded the institutionalisation of audit as a quality improvement technique in other areas of healthcare. The underlying theoretical assumption is that healthcare staff and healthcare managers generally want to perform well, but have little appreciation of the standard of their own performance.</p> <p>Typically efforts are made to identify all incidents of interest (usually deaths) in a defined population over a defined time period, using statutory reporting systems, voluntary notification (especially enquiries into perinatal mortality) and through additional hospital and community-based enquiries. Medical records are examined, but this approach was also supplemented by questionnaire enquiries or interviews with healthcare staff or relatives. The information assembled was then appraised against implicit or explicit standards for care of such patients. A panel of experts typically conducts the appraisal, and results are presented as levels of performance against expectation</p>
When would the technique be used?	<p>The majority of confidential enquiries are into maternal, perinatal or postoperative deaths or suicides. Other examples include stroke deaths in a single locality, asthma deaths reviewed by an expert or speciality group</p>
Outputs, e.g. are recommendations provided as a result of the investigation and analysis?	<p>Although data are generally presented as numerical summaries, occasionally vignettes of individual cases may be presented or more depth insights will be alluded to within published papers. There is some potential for confidential enquiries to incorporate both clinical and organisational issues in a systematic way, although there is little sign of this to date</p>
Positives of technique	<ul style="list-style-type: none"> ● Confidential approach and voluntary participation were reassuring for clinicians who might worry about professional credibility and litigation. ● Close involvement of professional organisations helps to endorse ownership by participants and to institutionalise involvement without the need for statute. ● Complete ascertainment of cases improves generalisability of findings and for many events and enables meaningful links to be made with denominator populations at risk of the adverse outcome. ● Use of standardised data collection methods enables comparable data collection across sites and over time. ● Analysis at both regional and local levels promotes local review and implementation of change
Negatives of technique	<ul style="list-style-type: none"> ● Only feasible to conduct serial confidential enquiries for a relatively small number of adverse outcomes of significant public health importance. ● Can be used to assemble data on structural and process issues of relevance to patient safety, but study design reduces scope for emergent findings. ● Historically have tended to focus more on clinical activity, rather than contextual issues, which might determine patient safety. ● Findings of confidential enquiries still remote from individual cases and influence on implementation of change mainly through dissemination of findings through professional organisations and scientific literature
References	<p>Cartledge and colleagues, 1999¹³¹ Walker and colleagues, 1986¹³² Burr and colleagues, 1999¹³³</p>

TABLE 21 Details of country setting and specialty of appraised papers grouped by core technique

Technique	Country setting	Specialty	No. of key papers
AIMS	Australasia (8) Asia (2)	Family practice Acute care: anaesthesiology (6); intensive care; obstetric anaesthesia Psychiatry	10
CIT	N. America (6) UK (3)	Family practice Acute care: A&E; paediatrics; anaesthesiology (4); paediatrics and anaesthetics; nursing	9
SEA	UK(6)	Family practice (6)	6
RCA	N. America (9) UK and N. America	Family practice Acute care: intensive care (2); transfusion medicine; anaesthesiology (3); medical services; A&E and obstetrics; pharmacy	10
OACM	UK (5) N. America (2)	Acute care: Obstetrics (2); nursing; intensive care; anaesthesiology, cardio-thoracic surgery Psychiatry	7
CWS	UK (8) Africa Caribbean	Acute care: neonatology; neonatology and obstetrics; respiratory medicine (2); infectious diseases; interventional radiology; obstetrics (2); obstetrics and paediatrics General practice and cardiology	10

TABLE 22 Details of the source of critical incidents and median and range of critical incidents featured, grouped by core technique

Technique	Source of critical incidents	Median and range of critical incidents
AIMS	Reporting system (10)	Median = 160 Range = 35–1556
CIT	Staff recall (5) Staff recall and reporting systems (2) Observation, reporting and review Illustrative case	Median = 96 Range = 1–1089
SEA	Reporting system (2) Staff recall and reporting system Illustrative case Review Observation	Median = 168 Range = 1–1263
RCA	Illustrative case (5) Reporting system Reporting system, review, claims and cases brought to attention Review Reporting system and review Not clear	Median = 3 Range = 1–191
OACM	Staff recall Illustrative case (4) Report system and review Not clear	Median = 1 Range = 1–264
CWS	Population-based surveillance Reporting systems and review Reporting system (6) Staff recall, report and review Not clear	Median = 166 Range = 42–309

TABLE 23 Details of both injury suffered and treatment required for critical incidents featured

Technique	Severity of critical incidents featured (injury suffered)	Severity of critical incidents featured (treatment required)
AIMS	Death, permanent, temporary and no injury Death, permanent and no injury Death, temporary, some and no injury Death, temporary and no injury (2) Temporary and no injury (2) Some and no injury Not clear (2)	Major, some and no intervention required (3) Some and no intervention required (2) Some intervention required Not clear (4)
CIT	Death, permanent, temporary and no injury Death, permanent and no injury Death, some and no injury (2) Temporary, some and no injury Some and no injury No injury Not clear (2)	Major, some and no intervention required (2) No intervention required Not clear (6)
SEA	Death (5) Death, permanent, temporary and no injury	Major, some and no intervention required Not clear (5)
RCA	Death (3) Death, some and no injury (2) Temporary injury (2) No injury (2) Not clear	Major intervention required (4) Some intervention required No intervention required (2) Not clear (3)
OACM	Death Temporary, some and no injury Temporary injury (3) Some injury No injury	Major intervention required (2) Some intervention required (4) Some and no intervention required
CWS	Death (10)	Major and some intervention required Some intervention required Not clear (8)

Section B – ‘Conduct of the investigation(s)’

Section B focuses on ‘who’ is conducting the investigation, their professional background and investigation experience. *Table 24* gives information on the person responsible for the field investigation and, where present, details of the profession and investigation training/experience of the person conducting the field investigation. Details of the agency conducting the investigation and the relationship between the agency and the healthcare unit are included in Appendix 10 (*Table 41*).

Key papers using AIMS methods relied entirely on individuals reporting the incident to provide details concerning the event. CIT studies used both individuals reporting the incident and investigators. The remaining sets of studies used only investigators, where this was clearly reported. Most techniques used investigators who were either internal or external to the unit or external

to the organisation or a mixture of these. Key studies using the OACM technique tended to use only external investigators.

All techniques used individuals with a medical or nursing background as the person responsible for the investigation. Some studies using SEA or RCA have included managerial staff. Thirty-eight (73%) publications did not report whether the person responsible for the field investigation had previous training or experience. Only two techniques (CIT and RCA) included studies which used trained investigators.

Section C – ‘Data collection and causal analysis’

This section of the appraisal form is divided into three subsections: (1) interviews and self-reports, (2) primary document review and (3) physical/logistic assessment. The main methods of collecting data for the various techniques are displayed in *Table 25*. ‘Not clear’ in the columns

TABLE 24 Details of agency responsible for the investigation, person responsible for the field investigation, their profession and investigation training/experience

Technique	Person responsible for field investigation	Profession of person responsible	Training/experience in accident investigation
AIMS	Individual reporting the incident (10)	Medical (4) ICU staff Not clear (5)	Previous experience Interviewer tried incident form at service Introduction Not clear (7)
CIT	Individuals reporting the incident Investigator internal to unit (2) Investigator external to organisation (3) Investigator (relation not clear) (2) Not clear	Medical (2) Nursing Research Non-anaesthetic investigator Not clear (4)	Previous training (2) Not clear (7)
SEA	Investigator internal to unit (3) Investigator external to organisation (2) Investigators internal to unit and external to organisation	Medical (4) Psychology Medical, nursing, manager and other non-medical staff	Previous experience Brief meeting to explain SEA and list Not clear (4)
RCA	Investigator internal to unit (2) Investigator external to unit (3) Investigators internal and external to unit Investigators internal to unit and external to organisation Investigator (relation not clear) (2) Not clear	Medical (2) Nursing Medical, nursing and pharmacy Nursing and management Management (2) Not clear (3)	Previous training (2) Previous experience (2) Not clear (6)
OACM	Investigators external to organisation (4) Investigators external to unit and to organisation Investigators (relation not clear) (2)	Nursing (2) Psychology (4) Not clear	Previous experience (2) Not clear (5)
CWS	Investigator internal to unit Investigators internal and external to unit Investigators internal to unit and external to organisation Investigator external to organisation (6) Investigators (relation not clear)	Medical (4) Medical and nursing (3) Medical and malaria control manager Medical and non-medical staff Not clear	Previous experience Not clear (9)

refers to the number of publications which did not include any information on that particular type of data collection. Three techniques, CIT, RCA and CWS, included one or two publications which conducted physical or logistic assessment as part of their data collection process. Almost all techniques (except AIMS) used primary document review and all techniques used interviewing or self-reporting methods. SEA, RCA and OACM used interview but not self-reporting methods.

Tables 26–31 provide comparative information of data collection and analysis and only include information from papers which used the method of data collection described.

Table 26 gives details of the profession of staff involved in providing data relating to the critical incident or near miss. The profession of individuals interviewed or reporting the critical

incident were mentioned in 33 of 45 publications that used these methods. However, it was not always clear who was involved in the data collection process. Only the CWS technique collected data from relatives as well as from staff.

Table 27 gives details of the type of method, which additional techniques were used, the mean number of interviewees per case and the duration of each interview. The interval between incident and investigation was not reported in the majority of publications. Exceptions include: one RCA study which conducted their investigation within 7 days of the incident, another RCA study within 4 days, a third immediately after the incident, an OACM paper within 48 hours and a CWS publication within 5 days. Where information was available, the number of interviewees per case varied, with SEA and OACM techniques using up to eight interviews. Appraised RCA publications

TABLE 25 Overview of the types of data collection methods used

Technique	C1 – Interviews and self-reports	C2 – Primary document review	C3 – Physical/logistic assessment
AIMS	Yes (10): 1 interview 8 self-reporting forms 1 self-report and meeting	Not clear (10)	Not clear (10)
CIT	Yes (8): 5 interviews 2 self-reporting forms 1 interview + self-reports Not clear (1)	Yes (1) Not clear (8)	Yes (1) Not clear (8)
SEA	Yes (4): 3 group interviews 1 individual interview Not clear (2)	Yes (5) Not clear (1)	Not clear (6)
RCA	Yes (7): 3 group interviews 3 individual interviews 1 not clear whether interview or self-reports Not clear (3)	Yes (5) Not clear (5)	Yes (2) Not clear (8)
OACM	Yes (7): 5 individual interviews 1 group interview 1 self-reporting form	Yes (4) Not clear (3)	Not clear (7)
CWS	Yes (9): 5 individual interviews 1 individual interview + confidential statements 2 self-reporting forms 1 individual + group interviews Not clear (1)	Yes (8) Not clear (2)	Yes (1) Not clear (9)

did not specify the number of interviewees, although the backgrounds of interviewees are described in *Table 26*.

Table 28 gives details of the method used for interview or report critique and quality assurance for data collection and critique. Most techniques used established or emergent frameworks, with the exception of CWS methods, which used mostly expert opinion or explicit criteria for assessing data. Two techniques, CIT and OACM, used all three methods, that is, established frameworks, emergent frameworks and expert opinion. One of three main methods of checking the quality of data collection were used in the majority of techniques. Triangulation was used by all except AIMS and SEA, a transcribed record was used by CIT, SEA and RCA and records were reviewed by investigators using CIT and OACM investigation techniques. Duplicate assessment with or without inter-rater reliability checks were conducted by AIMS, CIT, OACM and CWS methods. Consensus panels were used in CIT, RCA and CWS methods.

Table 29 shows the source of document data and, where available, methods of data extraction. Sources of document data include medical and prescribing records, protocols, post-mortem reports, death certificates, coroner's court reports and public and mortuary reports. Investigators using RCA and CWS methods tended to use a variety of primary documentation. For about half (13 out of 23) of the papers it was not clear how the data were extracted, whereas other publications indicated whether narrative summaries (SEA, RCA, CWS), abstraction forms (SEA, CWS) or questionnaires (CWS) were used.

Table 30 gives details of methods used for document critique and quality assurance for data collection and critique. Only key publications describing the OACM method used an established framework to analyse data from primary sources. Papers grouped under SEA and RCA techniques used emergent frameworks for document critique, whereas RCA, OACM and audit techniques made use of expert opinions. There is little information

TABLE 26 Persons involved in interviews or reports, their recruitment and protection

Technique	Person(s) interviewed/reporting	Recruitment of informants	Protection of informants	Total
AIMS	Medical staff (4) Not clear (6)	Entirely voluntary (10)	Anonymity assured (9) Not clear (1)	10
CIT	Medical staff Nursing Medical and nursing staff (3) Medical, nursing and pharmacy staff Not clear (2)	Voluntary and statutory reporting Entirely voluntary (6) Not clear (1)	Confidentiality and anonymity assured (3) Confidentiality assured Not clear (4)	8
SEA	Medical and nursing staff Medical, nursing and health promoter Admin., medical, nursing manager, trainee and student Medical, nursing, management, trainee and other	Entirely voluntary Not clear (3)	Confidentiality and anonymity assured Confidentiality assured (2) Not clear	4
RCA	Medical staff and those directly involved Medical, nursing and pharmacy staff Medical, nursing and technical staff, assistant manager and risk management representative Nursing and other staff Nursing staff and agency manager Technical staff, supervisor and other staff Not clear	Entirely voluntary Not clear (6)	Not clear (7)	7
OACM	Medical and nursing staff (4) Medical, nursing and pharmacy staff Nursing staff Nursing and other staff	Entirely voluntary (3) Not clear (4)	Confidentiality and anonymity assured Confidentiality assured (4) Not clear (2)	7
CWS	Medical staff (4) Relative and medical staff Relative, medical and nursing staff Not clear (3)	Entirely voluntary (4) Not clear (5)	Confidentiality and anonymity assured (2) Confidentiality assured (6) Anonymity assured	9

TABLE 27 Type of interview/report, additional techniques used and mean number of interviewees per case

Technique	Type of interview/report	Additional techniques used (interviews)	Mean number of interviewees/case	Mean duration of each interview	Total
AIMS	Questionnaire (7) Questionnaire and open departmental meeting Not clear (2)	Assign % contribution to the accident Not clear (9)	1 interviewee Not clear (9)	Not clear (10)	10
CIT	Narrative description Interview (6) Questionnaire (1)	Checklist Not clear (7)	1 interviewee (2) Not clear (6)	Not clear (8)	8
SEA	Group interview (4) Individual and group interview	Preparation of case summary by informant 8-point framework Not clear (2)	3-8 interviewees Not clear (3)	20-40 minutes 20-60 minutes Not clear (2)	4
RCA	Group interview (3) Individual interview (3) Not clear	Conceptual framework Brainstorming using documentation Diagrams and flow charts Fault tree (2) Not clear (2)	Not clear (7)	Not clear (7)	7
OACM	Interview (5) Group interview – to clarify events Questionnaire	Checklist (3) Conceptual framework Not clear (3)	1 interviewee 4 interviewees 6 interviewees 8 interviewees Not clear (3)	20-30 minutes (4) Not clear (3)	7
CWS	Questionnaire (3) Individual interview (2) Individual and group interview Narrative description and interview Questionnaire and interview (2)	Not clear (8)	1 interviewee Not clear (8)	Not clear (9)	9

TABLE 28 Method used for interview/report critique and quality assurance for data collection and critique

Technique	Method used for interview/report critique	Quality assurance – data collection	Quality assurance – data critique	Total
AIMS	Established framework (5) Emergent framework (2) Established framework and emergent framework Computer program Not clear	Not clear (10)	Duplicate assessment Re-examination of narratives Not clear (8)	10
CIT	Expert opinion Established framework (2) Emergent framework (4) Emergent framework and explicit criteria	Not clear (4) Triangulation and record check Transcribed record (3)	Duplicate assessment (3) Consensus panel Careful checking Inter-rater reliability Not clear (2)	8
SEA	Emergent framework (4)	Transcribed record (3) Decision recorded	Not clear (4)	4
RCA	Established framework (2) Emergent framework (2) Established framework and emergent framework Not clear (2)	Not clear (3) Triangulation Transcribed record	Not clear (4) Consensus panel	7
OACM	Established framework (3) Established framework and expert opinion Expert opinion Emergent framework Not clear	Triangulation and document check (2) Triangulation Documentation checked Not clear (3)	Discussion with clinicians Inter-rater reliability Not clear (5)	7
CWS	Expert opinion (6) Explicit criteria (2) Not clear	Triangulation (3) Not clear (6)	Consensus panel (4) Duplicative assessment (2) Not clear (3)	9

TABLE 29 Source of document data and methods for data extraction

Technique	Source of document data	Methods used for data extraction	Total
AIMS	This method was not used in any papers appraised for this technique		0
CIT	Medical record	Not clear	1
SEA	Medical record (4)	Data abstraction form (2)	5
	Medical record and post-mortem report	Not clear (2) Narrative summary	
RCA	Medical record (2)	Narrative summary	5
	Protocol(s)	Not clear (4)	
	Medical record and protocols Medical and prescribing record and protocols		
OACM	Medical record (3)	Not clear (4)	4
	Not clear		
CWS	Medical record (3)	Data abstraction form (4)	8
	Medical record and post-mortem report (2)	Questionnaire	
	Medical record, prescribing record and death certificate	Narrative summary and questionnaire	
	Medical record and death certificate Police, Coroner's court reports, public and mortuary reports	Not clear (2)	

TABLE 30 Method used for document critique and quality assurance for data collection and critique

Technique	Methods used for document critique	Quality assurance – data collection	Quality assurance – data critique	Total
AIMS	This method was not used in any papers appraised for this technique			0
CIT	Not clear	Not clear (3)	Not clear	1
SEA	Emergent framework (2) Not clear (3)	Not clear (5)	Consensus panel Review by second researcher Not clear (3)	5
RCA	Emergent framework Expert opinion Not clear (3)	Duplicate abstraction Not clear (4)	Consensus panel (2) Not clear (3)	5
OACM	Established framework and expert opinion Chronology of events Not clear (2)	Triangulation Not clear (3)	Inter-rater reliability Not clear (3)	4
CWS	Expert opinion (5) Explicit criteria (2) Explicit criteria and expert opinion	Duplicate abstraction Not clear (7)	Duplicate abstraction Consensus panel (4) Inter-rater reliability Not clear (2)	8

TABLE 31 Source of physical/logistic data, observational techniques used, interval between incident and investigation and methods for judging this type of data

Technique	Source of physical/logistic data	Observational techniques used to gather data	Interval between incident and investigation	Methods used for judging physical/logistic aspects	Total
CIT	Site visit	Inspection	Immediately after the event	Not clear	1
RCA	Site visit (2)	Chemical analysis (2)	'Within days' Not clear	Expert opinion (2)	2
CWS	Site visit	Not clear	5 days	Not clear	1

on quality assurance for this type of data collection in published papers, with RCA and audit models using duplicate abstraction and OACM using triangulation. In contrast, appraised publications have provided information on the different types of reliability checks for data analysis, using consensus panels (all except AIMS and OACM), inter-rater reliability (OACM, audit) or duplicate abstraction (audit) or a combination of two or three of these methods (CIT, SEA, audit).

Only publications which collected and analysed physical or logistic data (one using CIT, two using RCA and one using CWS methods) are presented in *Table 31*. Information on this type of data was particularly sparse with no information on the

time taken for assessment and quality assurance both for the collection and analysis of data. Only one RCA paper had information on checking the reliability of analyses where a drug sample was sent to two laboratories for analysis.

Section D – ‘Presentation and interpretation of data’

Section D focuses on outcomes of investigated cases. *Table 32* presents information on the formulation of outcomes and the use of underlying models to explain accident causation. All techniques included papers which either (i) focused on clinical or pathophysiological issues, (ii) included a classification of different types of errors or (iii) contained the elucidation of causes of errors

TABLE 32 Formulation of outcomes of investigation and underlying model of accident causation

Technique	How are the outcomes of the critical incident investigation(s) formulated?	Do the outcomes relate to any underlying model of accident causation?
AIMS	Focus on clinical and patho-physiological issues Classification of different types of errors Clinical and patho-physiological issues and classification of errors Elucidation of causes of errors (3) Classification and causes of error Clinical and patho-physiological issues and classification and causes of errors (3)	Allnutt model ¹³⁴ (2) Active and latent failures Not clear (7)
CIT	Focus on clinical and patho-physiological issues Elucidation of causes of errors (2) Classification and causes of error (2) Clinical and patho-physiological issues and causes of errors Clinical and patho-physiological issues and classification and causes of errors (3)	Active and latent failures Active and latent failures + contributing factors Not clear (7)
SEA	Clinical and patho-physiological issues and classification of errors (2) Clinical and patho-physiological issues and contributory factors (e.g. communication) Classification of different types of errors (2) Clinical and patho-physiological issues, classification of errors and factors related to patients, GP practice or hospitals	Not clear (6)
RCA	Classification of different types of errors Elucidation of causes of errors (5) Clinical and patho-physiological issues and causes of errors Classification and causes of error (2) Not clear	Active and latent failures Decision-making and Eindhoven classification model ¹³⁶ Not clear (8)
OACM	Elucidation of causes of errors (3) Classification and causes of error (3) Clinical and patho-physiological issues, classification of errors and illustration of contributory factors	Active and latent failures (4) Contributory factors Active and latent failures + contributory factors (2)
CWS	Focus on clinical and patho-physiological issues (2) Classification of different types of errors Clinical and patho-physiological issues and classification of errors (4) Clinical and patho-physiological issues and identification of factors (i.e. disease, patient and doctor factors) Clinical and patho-physiological issues and classification and causes of errors (2)	Active and latent failures Contributory factors Quality assurance/audit Not clear (7)

or a combination of two or three of these. All studies using the OACM technique analysed the causes or contributing factors associated with the critical incident. In 35 papers (67%) it was not clear if the outcome was related to any underlying model of accident causation. We based our judgements of such models on cited theories. Key papers appraised for the SEA technique did not include any references to such models. The remaining papers included at least one publication which referred to Reason's active failures and latent conditions. In addition, two AIMS publications referred to Allnut's 'human factors in accidents' model;¹³⁴ a CIT publication, two OACM publications and one comparison with standards publication included Vincent and colleagues'²³ contributory factors model; and an RCA paper refers to Rasmussen's decision-making model¹³⁵ and Van der Schaaf's Eindhoven classification model.¹³⁶

Table 33 includes information on the recommendations of the investigation and whether any implementation of these recommendations took place or were intended. Each technique had key papers which discussed the approach used or the size or scope of the problem or both issues. Four of the investigation techniques (AIMS, CIT, SEA and CWS) included general suggestions for improvement whereas when RCA and OACM methods presented recommendations they restricted them to those based on errors or causes identified as a result of the investigation.

At least half of the papers categorised in AIMS, CIT, OACM and CWS had no discussion of implementation of any changes as a result of the investigations. Two AIMS, two SEA, four RCA and one CWS papers gave descriptions of the implementation of changes. A further two AIMS, one SEA and two RCA papers also included evaluations of such implementations.

Assessment of techniques according to set criteria

Assessment of methods (i.e. each technique) is based on the tables in Chapter 2 and on investigation and analysis methods in high-risk industries outside healthcare.

Table 34 outlines some of the important factors of each technique reviewed and shows the similarities and differences between approaches.

Table 35 provides an assessment of the health incident investigation and analysis techniques

based on the sample of appraised papers. The assessment form is essentially that used to evaluate techniques used in high-risk industries in Chapter 2 (*Table 14*). Minor modifications include moving the comprehension item to the end of the form and adding a question on applicability of the technique to other specialties. We did not give techniques a value score, as some techniques are in their infancy and a low score might reflect low usage due to a lack of awareness or maturity of particular techniques and this will be reflected in the number of publications. The format of the tables differs slightly to those in Chapter 2 to allow for comments on each assessment criterion.

The assessment of the six techniques revealed the following similarities: the validity of EEM, PEM and PIF was low or moderate in all techniques; all techniques had moderate to high auditable documentation; and applicability was high for all techniques.

Differences in technique assessments were as follows: there was low or low-moderate consistency for most techniques, except in OACM, which had high consistency; model-based theoretical validity was low or moderate in most techniques, but again high in OACM; error reduction, an important objective in incident investigation and analysis, was mostly moderate-high, except in OACM, where the focus was on the investigation method, the need for resources varied, independence varied with RCA and OACM being the best as they consider a wide range of factors and acceptability or usage of the techniques also varied.

Textual commentary on strengths and limitations

The techniques focus on different aspects of the investigation and analysis process and subsequently they offer different strengths and limitations. This commentary on strengths and weakness of each technique is based on the tabulated summaries in *Tables 15–20*.

Strengths

AIMS and CWS to some extent offer confidentiality and anonymity, resulting in a greater number of staff reporting incidents and increasing their involvement in the investigation process. These two techniques also collect standardised data which for each technique can be compared both between institutions and over time. Any common factors identified will help to justify changes and where relevant the need to fund these changes.

TABLE 33 Recommendations and implementations of changes

Technique	Are recommendations made which might lead to improved patient safety?	Implementation of changes?
AIMS	<p>Discussion of methods/approach used</p> <p>Discussion of methods/approach used and the size of problem</p> <p>General suggestions for improvement</p> <p>Discussion of size/scope of problems and general suggestion for improvements (2)</p> <p>Discussion of size/scope of problems and solutions based on causes</p> <p>Discussion of methods/approach used, size of the problem and solutions based on causes identified</p> <p>Discussion of size of problem, general suggestions improvements and solutions based on errors identified</p> <p>Discussion of methods used, size of problems and general suggestions for improvements</p> <p>Discussion of method/size of problem and solutions based on errors and causes identified</p>	<p>No discussion of implementation (6)</p> <p>Description of implementation of changes (2)</p> <p>Implementation and informal evaluation</p> <p>Implementation and formal evaluation</p>
CIT	<p>General suggestions for improvement</p> <p>Specific solutions based on causes identified (2)</p> <p>Discussion of methods and general suggestion for improvements</p> <p>Discussion of methods and solutions based on causes identified</p> <p>Discussion of methods and solutions based on errors identified</p> <p>Discussion of methods/size of problem and specific solutions based on causes identified</p> <p>Discussion of methods/size of problem, general suggestions for improvement and specific solutions based on error identified</p> <p>Discussion of methods and specific solutions based on errors and causes identified</p>	<p>No discussion of implementation (8)</p> <p>Individual reports of implementation of changes in individual practice</p>
SEA	<p>Discussion of methods and size of problem (2)</p> <p>Discussion of methods used, size/scope of problem and general suggestions for improvements</p> <p>Discussion of methods and general suggestions for improvements</p> <p>Discussion of methods and specific solutions based on errors identified (2)</p>	<p>No discussion of implementation (2)</p> <p>Statement of intention for implementation</p> <p>Description of implementation of changes (2)</p> <p>Implementation and formal evaluation</p>
RCA	<p>Discussion of methods/approach used (2)</p> <p>Specific solutions based on errors identified (4)</p> <p>Specific solutions based on causes identified (3)</p> <p>Discussion of method/size of problem and solutions based on errors and causes identified</p>	<p>No discussion of implementation (4)</p> <p>Description of implementation of changes (4)</p> <p>Implementation and informal evaluation</p> <p>Implementation and formal and informal evaluation</p>
OACM	<p>Discussion of methods/approach used (3)</p> <p>Discussion of methods and size of problem</p> <p>Discussion of methods and specific solutions based on causes (2)</p> <p>Discussion of methods/size of problem and solutions based on causes identified</p>	<p>No discussion of implementation (6)</p> <p>Statement of intention for implementation</p>
CWS	<p>General suggestions for improvement (3)</p> <p>Specific solutions based on errors identified (3)</p> <p>Discussion of methods/approach used and size/scope of problem (2)</p> <p>Discussion of methods and solutions based on errors identified</p> <p>Discussion of methods/approach used, the size/scope of problem, general suggestions for improvement and solutions-based causes identified</p>	<p>No discussion of implementation (7)</p> <p>Statement of intention for implementation (2)</p> <p>Description of implementation of changes</p>

TABLE 34 Summary of important factors of each technique

Technique	A	B	C	D	E	F	G	H
AIMS	Public	Primary	Anaesthetics	Yes	Fully applicable	Yes, also computer program used to analyse data	Medium, some training given to staff for reporting incidents, but little information on training for analysis	Yes, internal for collecting data and external for analysis
CIT	Public	Stand-alone, although very limited method	Anaesthetics	Yes, transferable	Yes, widely applicable (but note limited method)	Yes, need to be familiar with CIT	Little training for technique per se (as limited) but considerable speciality expertise needed	Participation. No special features to encourage participation
SEA	Public		General practice	Yes, transferable. Also used in mental health	Yes	Yes, or at least experience of SEA	Medium	Yes
RCA	Public – JCAHO document	Primary and secondary	Mixed	Yes	High applicability	Yes, need to be reasonably well trained to use and apply all tools correctly	Medium/high level of training required depending on level of expertise required	Yes
OACM	Public – on CRU website	Primary and secondary	Obstetrics and coronary care	Yes to any speciality	High applicability	Training required	Medium level of training necessary	Yes
CWS	Public	Primary	General	Yes	Mainly very serious events	Expert opinion required	Not clear	Yes

A, Technique available to public or proprietary.
 B, Primary (stand-alone technique) or secondary (provides special input to supplement another method) method.
 C, Speciality origin.
 D, Transferable to other specialities?
 E, Applicability to investigation/analysis of serious incidents and near misses.
 F, Need for expert to facilitate investigation and analysis using technique.
 G, Need for training in technique (low, < 1 week's training; medium, > 1 week's training; high, > 2 weeks' training).
 H, Does the investigation and analysis methodology encourage all parties (internal or external to an organisation) to participate in the investigation?

TABLE 35 Assessment of health incident investigation and analysis techniques

Technique	Assessment criteria
AIMS	Consistent (accuracy)
CIT	Moderate-high consistency
SEA	Low (not well specified enough)
RCA	Low? (low-moderate)
OACM	Low-moderate, a mixture of established and emergent framework and not clear responses from appraised papers
CWS	Moderate-high Low-moderate, mainly based on expert opinion
AIMS	Theoretically valid: (i) model-based
CIT	Moderate, few studies make reference to a model
SEA	Low, one or two studies make reference to Reason's active and latent failures (original work based on Fitts and Jones ^{3,7})
RCA	Low, a loosely defined framework is included ⁹
OACM	Low-moderate model-based theoretical validity
CWS	High theoretical validity, model used in all analyses Low - little reference to theoretical models
AIMS	Theoretically valid: (ii) EEM - what/PEM - how/PIF - why
CIT	Moderate - difficult to assess, some studies refer to all three questions, others just consider what happened or how it happened
SEA	Sophisticated in Cooper and colleagues' original paper. ¹²⁰ Little developed since Low-moderate; some studies focus on one or two of the questions: EEMs and PIFs, but no classification system
RCA	Difficult to assess, as a framework is presented which may include exploration of these three questions
OACM	Low-moderate; some studies focus on one or two of the questions: EEMs and PEMs, but little information on underlying causes
CWS	Difficult to assess because of contrast of theory and evidence in papers. Depends on the skill of the assessor. Technique has capacity to answer all three questions Moderate, focus on why question, with some how questions answered Moderate, focus on EEMs, with some PEM and occasionally PIF
AIMS	Error reduction
CIT	Moderate - some generation of error reduction mechanisms Potential for error reduction to follow; partially realised in practice
SEA	Moderate-high, general or specific solutions made in all papers appraised
RCA	Moderate-high
OACM	Moderate or possibly high generation of error reduction mechanisms
CWS	Low-moderate, focus on method with some solutions offered Moderate-high, mostly generates error reduction mechanisms, but some publications focus on approach and size/scope of problem
AIMS	Resources (usage)
CIT	Low-moderate, completion of forms mainly
SEA	Low-moderate, depending on the type of incident
RCA	Moderate
OACM	Moderate, this depends on the severity of the case under investigation
CWS	Moderate, mainly use interviews and re-interview if necessary High, use of record review and interviews of staff and sometimes relatives

continued

TABLE 35 Assessment of health incident investigation and analysis techniques (cont'd)

Technique	Assessment criteria
AIMS	Auditable documentation This is difficult to assess as there is conflicting evidence. The summary and knowledge of this technique suggest high documentation, but appraised papers indicate moderate documentation
CIT	Moderate
SEA	Moderate
RCA	Moderate-high, conflicting evidence
OACM	Moderate-high, use of checklist for staff and forms for investigator
CWS	Moderate-high, use of data abstraction forms and questionnaires
AIMS	Independence Low-moderate, few studies reported balanced and fair outputs. Dependent on local involvement and investigator focus
CIT	Low-moderate, as relies on local knowledge, local involvement
SEA	Low-moderate
RCA	Moderate-high, conflicting evidence
OACM	Moderate-high, theories consider wide range of factors
CWS	Low, few papers use theoretical models to analyse data
AIMS	Acceptability (usage) High – an established system of incident monitoring
CIT	Good/high, has been widely used for some time as until recently there was little alternative
SEA	High – particularly in primary care and mental health
RCA	Moderate, but beginning to be more widely used and accepted
OACM	Moderate, starting to be used by NPSA and also for some local investigations
CWS	Possibly wide use of audit and peer review methods, but confidential enquires are led by few specialist groups
AIMS	Comprehensive Difficult to judge – some of the three criteria of comprehension in some publications
CIT	Yes, potentially so, if expert investigators
SEA	Low-moderate
RCA	Moderate-high, depends mainly on the skill of the assessor
OACM	High, when used correctly
CWS	Low-moderate, some focus on errors, but breadth of coverage and ability to identify all possible errors are not clear
AIMS	Applicability High
CIT	Wide range of specialties
SEA	Moderate, some focus on deaths
RCA	High applicability
OACM	High, can be used for any incident within healthcare
CWS	Wide range of specialties, but the focus of confidential enquires is on deaths

The CWS tends to include all cases of a particular population and therefore statements for recommendations can be general; other techniques have relied on single case examples and as a result it may be difficult to argue the case for changes, except where analysis includes questions on whether the problems or difficulties identified are general to the unit or specific to that particular case as in OACM.

Human factors approaches are used to analyse critical incidents in CIT, RCA and OACM, where attention is given to systems rather than focusing entirely on individuals. This in turn leads to the development of strategies to prevent reoccurrence, particularly in CIT. CWS uses local and regional analysis to promote local review and implement change and SEA provides the opportunity of quality improvement including setting the agenda for audit and providing a balance of intellectual and emotional content of performance which could result in changes to culture and communication of teams.

RCA uses a wide variety of techniques and provides the supporting documentation. There is a lot of information for investigators using this approach and OACM for incident investigation. A lot of data collection information are also available for those involved in AIMS. Historically CWS, in particular confidential enquires, have had the close involvement of professional organisations.

Limitations

The availability for the training of investigators varies between techniques, with little information on the investigation or analysis for CIT, which is highly reliant on intuition and expertise of investigators. In contrast, for OACM incident investigators need to be trained in human error theory if they are truly to understand error typology and translate this knowledge into practical accident investigation and analysis. Similarly, accident investigators must be fully trained in a variety of RCA techniques if they are to analyse incidents successfully.

Limitations of the type of data collected will confine progress and implementation of any changes. At national level, AIMS has limited data, that of secondary documentation and in relation to improving the quality of care. SEA is an information-gathering strategy, not a change strategy as such. CWS conducts serial confidential enquiries for a relatively small number of adverse outcomes of significant public health importance. This limitation has a lot to do with the feasibility

of conducting such large enquiries. Similarly, RCA can be a time-consuming process if a variety of detailed techniques are used.

Historically, CWS has tended to focus more on clinical activity than contextual issues which might determine patient safety. Hence the study design reduces the scope for emergent findings. Some clinical settings are more hierarchical than others and clinicians may be closed to the views of other members of staff when using SEA. As already mentioned, CIT is highly reliant on the intuition and expertise of investigators, which reduces reliability, and AIMS data cannot be investigated further. In contrast, RCA can very easily be made overly complicated and does not guarantee a complete answer.

Another general limitation of some techniques is that of dissemination and acceptability. In some settings SEA may simply not be acceptable and findings of confidential enquiries are still remote from individual cases. Any influence on implementation of change is mainly through dissemination of findings through professional organisations and the scientific literature. Regarding the availability of RCA tools, there is limited documentation in the healthcare sector; in particular worked examples showing their applicability to specific types of accident investigations.

In terms of the further development of techniques, there is little work on the CIT, the capacity to promote improvement in practice has not as yet been demonstrated for SEA and models and theories have not been formally evaluated for OACM.

Despite these limitations, there is further scope for the development, implementation and testing of the various methods of investigating and analysing critical incidents.

Summary and interim conclusions of healthcare methods

This section provides a summary of the results of the appraised publications and the assessment of each technique of investigation and analysis of critical incidents in healthcare.

Most of the techniques have focused on the investigation and analysis of critical incidents in acute or primary care, usually in both general areas of healthcare. Psychiatry is featured in

studies from just two techniques, AIMS and OACM. However, all techniques have the potential of being applied in all specialties and disciplines related to healthcare.

Key studies using the audit and peer review method looked solely at death as an outcome, whereas studies using one of the other techniques used a variety of outcomes including near misses. This is due to the nature of the framework of enquiry and the focus of this review is on confidential enquiries as an example of this method of investigation and analysis.

We found little information in the studies on the experience or training of the investigators. Often individuals from a medical or nursing background were responsible for the investigation. Only studies using the CIT or RCA reported the use of trained or experienced investigators.

All techniques used interviewing or self-reporting methods or both, with SEA, RCA and OACM using interviews but not self-reporting methods. Most techniques (except AIMS) used primary document review and three techniques, CIT, RCA and CWS, included publications which conducted physical or logistic assessment as part of their data collection process. Thus, CIT, RCA and CWS used the three types of data collection groupings. Using a wide variety of type of sources is important to establish the causes or contributory factors involved in a particular incident.

Although publications were appraised as far as possible, there was very little or no information on the following aspects:

1. who was involved in the data collection process
2. the interval between the incident and investigation
3. the number of interviewees involved
4. how the data were extracted, particularly in relation to document review
5. time taken for assessment
6. quality assurance for data collection and analysis
7. little description or use of physical or logistic data.

Most techniques used established or emergent frameworks for the critique of interview or self-reported data, with the exception of CWS methods, which used mostly expert opinion or explicit criteria for assessing these data and primary document data. Two techniques, CIT and OACM, used all three methods. Publications describing the OACM method used an established

framework to analyse data from interviews and primary documentation. This method also made use of expert opinions for document critique, as did studies using RCA and audit techniques. RCA also used expert opinion for judging physical or logistic data.

The majority of techniques used one of the following methods for checking the quality of data collected from interviews or self-reports: triangulation, transcribed records and record reviewed. There was little information on quality assurance for data collection from primary documentation in published papers, except in RCA and CWS, which used duplicate abstraction, and in OACM, which used triangulation. There was no information on quality assurance for the collection of physical data.

Regarding quality assurance of data critique for interviews or self-reports, most techniques used duplicate assessment with or without inter-rater reliability checks being conducted or consensus panels. SEA did not use any reliability checks for interview data. Reliability checks for analysis of primary document data used one or more of consensus panels, inter-rater reliability and duplicate abstraction.

All techniques included papers where the results included at least one of the following: (i) clinical or pathophysiological issues; (ii) a classification of different types of errors; or (iii) the elucidation of causes of errors. Studies using the OACM technique consistently included the causes or contributing factors associated with the critical incident. Only one-third of papers referred to an established model of accident causation. These papers represented most of the techniques, except SEA. The most frequently cited model was Reason's active failures and latent conditions.³⁷

Each technique discussed the approach used or the size and/or scope of the problem. In addition, all techniques included suggestions for improvement, with papers using RCA and OACM methods containing recommendations based on errors or causes identified as a result of the investigation. In many papers there was little or no discussion of implementation of any changes as a result of the investigations. One-quarter of publications gave descriptions of the implementation of changes and one-third of these also included evaluations of such implementations.

The assessment of techniques proved difficult, particularly where appraised information was not

consistent with the supporting literature on a specific technique. This raises the question regarding the extent to which the investigators adhered closely to a particular investigation methodology or how this is described in the publications and the level of detail included.

The summary of important factors indicates that all techniques are similar in terms of availability, type of method, transferability to other specialties, applicability to the investigation and analysis of serious incidents and near misses and that there is a need for an expert to facilitate the investigation and analysis. There was some variation in the level of expertise and training required and the extent to which the technique encouraged all parties to participate in the investigation.

The formal assessment of techniques revealed the following similarities: validity of external error modes/psychological error mechanisms/performance-influencing factors (EEM/PEM/PIF) was low or moderate in all techniques. This shows that there is room for improvement in all techniques. Although each had a low or moderate score, the techniques varied in terms of which type of question was answered. All techniques had moderate to high auditable documentation. This is especially useful as it will allow further evaluation of each investigated event. Finally, the applicability of the technique to other areas or specialties of healthcare was considered high for all techniques.

Differences in technique assessments were as follows: there was low or low–moderate consistency for most techniques, except in OACM, which had high consistency. This has important implications for the reliability of a technique; model-based theoretical validity was low or moderate in most techniques, but again high in OACM; error reduction, an important objective in incident investigation and analysis, was mostly moderate–high, except in OACM where the focus was on the investigation method; the need for resources varied and this may depend on type of incident, resources available or may reflect discrepancies between theory of technique and its practical application; independence varied, with RCA and OACM being the best as they consider a wide range of factors; acceptability or usage of the technique varied, which may be because many techniques have not been around very long and therefore were difficult to assess; comprehensiveness was also difficult to judge in some techniques.

In summary, the techniques vary in most of the formal assessment criteria, but do have some similarities of important factors. As the investigation and analysis of critical incidents in healthcare is beginning to be more widely used and is relatively new in relation to other industries, formal evaluations of the techniques would be considered premature. These and other issues are discussed in more detail in the final chapter.

Chapter 6

A guide for the investigation and analysis of critical incidents and adverse events in healthcare

This chapter consists of the guide for the investigation and analysis of critical incidents and adverse events in healthcare and its development and piloting. The process of developing and piloting was conducted in three specialties: acute care, mental health and primary care. The guide is a self-contained document with accompanying case analyses in the appendices designed to assist clinicians, risk managers and others in investigating and learning from clinical incidents.

Introduction and development of the guide

The purpose of the guide

The purpose of the guide is to permit a comprehensive and thoughtful investigation and analysis of an incident, going beyond the more usual quick identification or assumption of fault and blame. Case examples from three specialties are given in Appendix 11 to illustrate the approach and a simple format for presenting the analysis and recommendations. The cases have been fictionalised to preserve the anonymity of all involved. Fictional cases are always based on real events, but incorporate events and details from more than one case from different locations.

Context of use

The way in which the guide is used is likely to vary between different contexts, as do the various factors that contribute to the breakdown of healthcare systems. We have aimed the guide at clinicians, clinical teams and risk managers, trying to provide a guide that gave sufficient information for understanding and implementation, yet without unnecessary detail. We discuss other options, such as structured team discussion or use in training and education. The guides can equally be used by individual clinicians or by senior clinicians and management concerned with major incidents.

Developing a method for research and for use in major incidents

Our review of methods of accident investigation in

high-risk industries shows that there are a number of potentially useful techniques that could be used in healthcare. A variety of data collection techniques exist (e.g. interviewing relevant personnel, observation, simulation techniques, hierarchical task analysis, fault and event trees and record review). Formal approaches for analysis include human error analysis and human reliability assessment. In addition, a number of comprehensive human error taxonomies have been produced to categorise error.

As indicated in the previous chapter, the techniques reviewed in healthcare have their strengths and limitations. Two techniques, RCA and OACM, scored highly for the majority of evaluation criteria. Examples of such criteria include the use of triangulation for checking the quality of data, using a comprehensive list to consider the errors, their causes and contributing factors to an incident and providing recommendations based on these errors and causes. Therefore, we aimed to incorporate this and other learning during the development of the guide. We already had access to a comprehensive, step-by-step protocol¹²⁹ and amended this to incorporate some of the RCA tools, such as cause and effect charts, to produce a draft version of the guide. Similarly, commentaries on the use of group rather than individual interviewing approaches link to experience of other researchers in developing significant event auditing^{32,99,122–124} and particular adaptations of RCA,^{78,126–128} Finally, the use of action plans and implementation cycles is, of course, well established among those using audit and peer review approaches^{131–133} and the development of taxonomies for classifying incidents is possibly greatest amongst researchers who have developed AIMS and related approaches.^{115–118}

For the three specialties acute care, mental health and primary care, a research group was set up to test and pilot the guide. Members for each research group were recruited following a presentation which described the various investigation and analysis techniques used in healthcare, such as OACM. Presentations were

given at specialist meetings, such as a Specialist Mental Health Day convened by the (then) North Thames Regional Office and a seminar run by two of the authors (CV and SR) in collaboration with a local Multidisciplinary Audit Advisory Group for staff who worked in local primary care organisations. At these meetings the audience was asked for volunteers to take part in the development and testing of the draft guide.

Members of each team used the draft guide and tested this out on cases. In the first instance this was done either as a workshop, where case examples were provided, or individually where actual current incidents were investigated and analysed. The groups met to discuss any difficulties or issues which arose as a result of this exercise and amendments made to the guide. There were many discussions around comprehensibility versus usability and that the taxonomy could be perceived as too complicated. This process of testing and discussion was repeated until consensus was reached by each group on a version that the clinicians could use. During testing telephone support was also provided for team members.

Examples of comments and difficulties are as follows:

- The contributory factors framework that identifies patient factors, staff factors, team communication, work environment and organisation and management factors as areas influencing patient safety was directly applicable to the specialist settings. The piloting teams found these broad factor headings useful; it was only as the factors were further specified that healthcare domain variabilities became apparent. Therefore, a high level of common cause failures was considered useful for all healthcare areas.
- In primary care, GP records tend not to be detailed and include written and computerised notes. Chronologies are often spread across wide time frames and so agreeing an appropriate time window can be difficult. There is little by way of cross-referencing between records held by GPs, district nurses and pharmacists, so recreating an accurate chronology requires some time. Similarly, mental health case notes vary in detail and again chronologies are often spread across wide time frames.
- Some GPs expressed sensitivities about the outcomes of investigations moving beyond a confidential interaction between informant and interviewer. Those in the mental health and acute care teams were less concerned with these sensitivities, but rather that any cases in the

public domain would identify them or their institutions.

- There was concern that the approach as presented identified problems but not solutions. If problems are identified there is an ethical obligation to seek to address them and there needs to be a further stage to ensure that improvements are implemented.

The guide was changed as a result of these group meetings to address the difficulties and limitations as far as possible. Examples of changes include the following: attempts to simplify both the structure and the language have been made where possible; the term 'care delivery problem' (CDP) has replaced 'care management problem', as the preferred term by the piloting teams; the distinction between 'specific' and 'general' contributory factors has been removed, although the importance of identifying contributory factors that are of wider significance remains; the forms used for recording data have been removed to allow teams and individuals more flexibility when producing case summaries. However, we have attempted to summarise cases in a standard manner, which we find to be a straightforward and helpful template (see Appendix 12); there is more emphasis on following through with recommendations and action and we have incorporated tools used in RCA. Since the development and testing of the guide, one member of the mental health team uses it formally for training in addition to investigating and analysing incidents in their mental health trust.

A guide to the investigation and analysis of critical incidents and adverse events in healthcare

Background

'A protocol for the investigation and analysis of clinical incidents' was published in 1999 by Vincent and colleagues.¹²⁹ This protocol outlined a process of incident investigation and analysis developed in a research context, which was adapted and refined by clinicians and researchers to produce a tool to be used by risk managers and others trained in incident investigation. This approach has been modified and developed in the light of experience and research into incident investigation both within and outside healthcare as described in earlier chapters.

The purpose of this guide is to ensure a comprehensive and thoughtful investigation and

analysis of an incident, going beyond the more usual quick identification of fault and blame. Most incidents involve a chain of problems and a wide variety of contributing factors that need to be considered. A structured process of reflection is more successful than either casual brainstorming or the suspiciously quick summaries of 'experts'. A further benefit of a structured approach is that it is less threatening and promotes an openness and thoughtfulness about problems that occur.

The approach described does not attempt to supplant clinical expertise or deny the importance of the reflections of individual clinicians on an incident. Rather, the aim is to utilise clinical experience and expertise to the fullest extent. The approach that we describe assists the reflective investigation process because:

- Although it is sometimes straightforward to identify a particular action or omission as the immediate cause of an incident, closer analysis usually reveals a series of events leading up to adverse outcome. The identification of an obvious departure from good practice is usually only the first step of the investigation.
- A structured and systematic approach means that the ground to be covered in any investigation is, to a significant extent, already mapped out. This guide can help to ensure a comprehensive investigation, and facilitate the production of formal reports when needed.
- If a consistent approach to investigation is used, members of staff who are interviewed will find the process less threatening than traditional unstructured approaches.
- The methods used are designed to promote a greater climate of openness and to move away from finger pointing and the routine assignation of blame.

This guide is restricted to the process of investigation and analysis of incidents. In practice, the details of this process will be set, and perhaps constrained, by the local context and conditions of use. Thus, we have not been prescriptive about how incidents should be identified or which should be investigated. Whatever the details, however, we believe that decisions and actions following inquiries would be more effective if grounded in a thorough and systematic investigation and analysis of the initial circumstance, irrespective of the nature of the incident and the complexity of the issues stemming from it or the motivation for the enquiry.

Different ways of using the guide

The guide can be 'investigator led' by one or two individuals, who would assemble and collate the information, carry out the interviews and then report back to the board or the clinical team to consider what action should be taken.

Alternatively, a team of individuals with different skills and backgrounds could be assembled. Serious incidents are likely to require a team of people using interviews, other documents and various sources of information. This document describes a full investigation of that kind, but we emphasise that much quicker and simpler investigations can also be carried out using the same basic approach.

Experience has shown that it is possible to adapt the basic approach of the guide to many different settings and approaches. For instance, it can be used for quick 5–10-minute analyses, just identifying the main problems and contributory factors. It can be effectively used by a clinical team to guide and structure reflection on an incident, to ensure that the analysis is full and comprehensive. The group approach is also useful for teaching, both as an aid to understanding the guide itself and as a vehicle for introducing systems thinking. Although reading about systems thinking is helpful, taking an incident apart in a structured manner brings the approach alive for a clinical team.

Context of the guide's use

In practice, the use of this guide will almost always be set within the context of local procedures and practices. We have deliberately not discussed the broader context of clinical governance or other arrangements for assuring the quality of care. We intend that this document should be a stand-alone module set within other procedures for the reporting of incidents, reporting to the team or board and so on. We would only emphasise that this approach needs to be separated, as far as possible, from any disciplinary or other procedures used for dealing with persistent poor performance by individuals.

All too often when something goes wrong in healthcare, those in charge will over-emphasise the immediate problem. Attempts to pin blame may then follow, with a concomitant lack of appreciation of the less obvious contributory factors, which, if allowed to persist, can create the same circumstances again. Effective risk reduction means taking account of all the factors and changing the environment in addition to dealing with personal errors and omissions. This cannot

take place in a culture where disciplinary considerations are always put first. Therefore, as stated earlier, this approach emphasises the need for accident investigation to take place in a culture where cause can only be applied fairly, without any focus on blame.

Research foundations

Even if the reader has no interest whatever in research and just wants a 'simple practical guide', it is necessary to give some thought to the concepts underlying the approach and in particular what we have learnt from reviewing the literature on techniques both within healthcare and from other industries. Healthcare generally is too focused on individual failings and gives insufficient attention to systemic problems. In contrast, studies of accidents in industry, transport and military spheres have led to a much broader understanding of accident causation, with less focus on the individual who makes the error and more on pre-existing organisational factors. Thinking of accidents and clinical incidents in this way brings a different approach to an investigation that in turn influences the kind of remedial action taken afterwards. Simply put, one is more likely to think of changing systems rather than retraining or disciplining people. Consequently, techniques such as MORT, RCA (which includes cause and effect charts, change analysis, BA, etc.) identified earlier in this report can aid this systems thinking and hence the investigation and analysis process.

The way in which a person conceptualises clinical incidents and adverse outcomes determines how they go about investigating and analysing them and also influences their recommendations for prevention. Each of us has our own bias and perspective. Clinicians may tend to focus on the disease and the inevitability of complications, managers on administrative problems, psychologists on individual and team factors and so on. We cannot escape from our own perspective, but we can reflect on its validity. Most importantly, for serious incidents, we can make a virtue of differences in perspective and choose a team of investigators with a range of viewpoints.

The theory underlying the guide and its application is based on research in settings outside healthcare, in particular on the organisational accident model of Reason.^{34,37,45,85,138} Both this model and our own adaptations of it have been described in a number of papers³⁷⁻³⁹ and only a summary is given here. The essential ideas of Reason's model can be simply stated. Incidents and accidents are usually preceded by some kind

of unsafe act, in which a person makes an error or mistake. However, to understand how this occurred, it is necessary to look further back to the 'error-producing conditions' which led to the unsafe act. These in turn may be due to 'latent failures': specific fallible decisions taken in the management structure. Reason also considers the presence, or absence, of defences and barriers, which are designed to protect against hazards and to mitigate the consequences of equipment and human failure. These may take the form of physical barriers (e.g. fence), natural barriers (e.g. distance), human actions (e.g. checking) and administrative controls (e.g. training) (see *Figure 2*).

A framework of contributory factors in healthcare

We have extended Reason's model and adapted it for use in a healthcare setting. We have substituted the term 'care delivery problems' for unsafe acts. This is because we have found, in healthcare, that this more neutral terminology is helpful and because a problem often extends over some time and is not easily described as a specific unsafe act. For instance, a failure of monitoring of a patient may extend over hours, days or months. It is also possible to change this and any other terminology to more acceptable terminology, as long as it is used consistently and staff are aware of its meaning.

We have also brought error-producing conditions and latent factors together in a single broad framework of contributory factors that influence clinical practice²³ (see *Table 36* for a summary and *Appendix 12* for a full listing). The framework essentially summarises the major influences on clinicians in their daily work and the systemic contributions to adverse outcomes, or indeed to good outcomes.

At the top of the framework are 'patient factors'. In any clinical situation, the patient's condition will have the most direct influence on practice and outcome. Other patient factors such as personality, language and psychological dysfunction may also be important as they can influence communication with staff and hence the probability of an incident. The design of the task, the availability and utility of protocols and test results may influence the care process, as deficiencies in this area will affect the quality of care.

Higher up in the framework are individual (staff) and team factors. Individual factors include the knowledge, skills and experience of each member

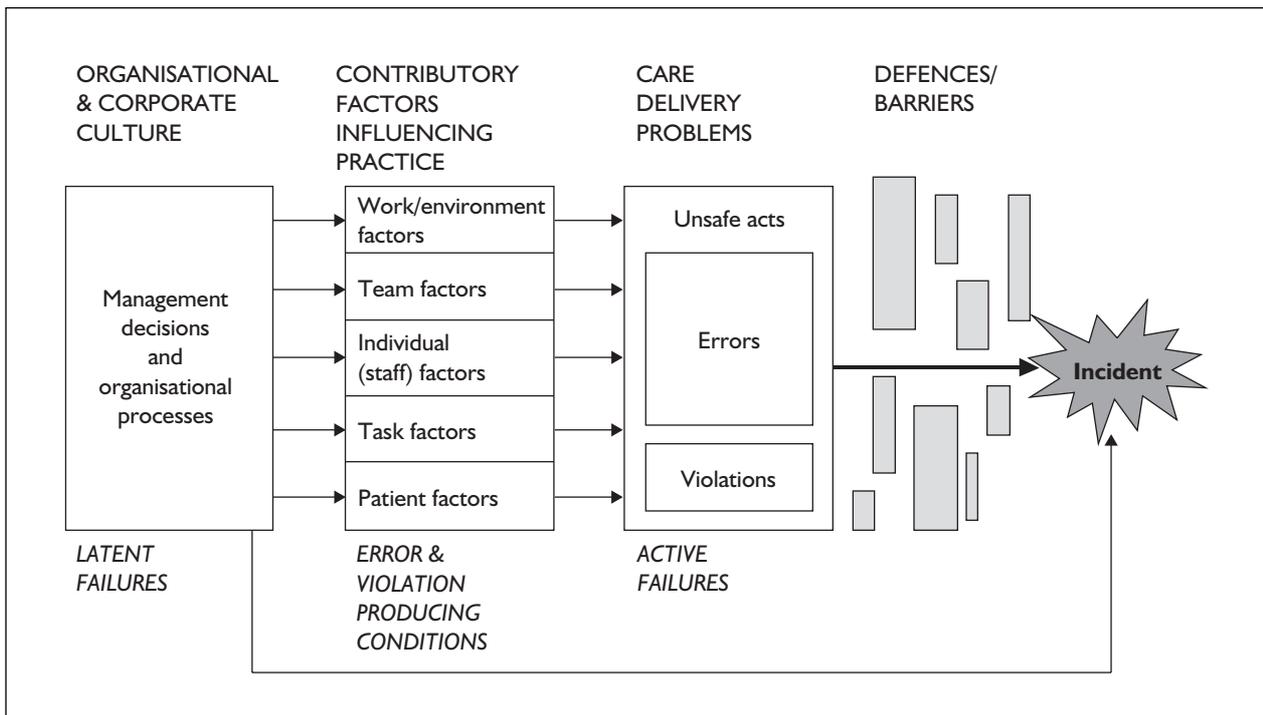


FIGURE 2 Adapted organisational accident causation model^{23,37}

TABLE 36 Framework of contributory factors influencing clinical practice

Factor types	Contributory influencing factor
Patient factors	Condition, e.g. complexity and seriousness Language and communication Personality and social factors
Task factors	Task design and clarity of structure Availability and use of protocols Availability and accuracy of test results Decision-making aids
Individual (staff) factors	Knowledge and skills Competence Physical and mental health
Team factors	Verbal communication Written communication Supervision and seeking help Team structure (congruence, consistency, leadership, etc.)
Work environmental factors	Staffing levels and skills mix Workload and shift patterns Design, availability and maintenance of equipment Administrative and managerial support Environment Time delays
Organisational and management factors	Financial resources and constraints Organisational structure Policy, standards and goals Safety culture and priorities
Institutional context factors	Economic and regulatory context National health service executive Links with external organisations

of staff, which will obviously affect their clinical practice. Each staff member is part of a team within the inpatient or community unit and part of the wider organisation of the hospital or primary care trust. The way in which an individual practises, and their impact on the patient, is constrained and influenced by other members of the team and the way in which they communicate, support and supervise each other. The team is influenced in turn by management actions and by decisions made at a higher level in the organisation.

These include policies regarding the use of locum or agency staff, continuing education, training and supervision and the availability of equipment and supplies. The organisation itself is affected by the institutional context, including financial constraints, external regulatory bodies and the broader economic and political climate.

An overview of the process: how the concepts translate into practice

Having sketched out the theory underlying our approach, we can now see how this informs our process of investigation. First, the chronology of the event in question must be understood. Some people prefer the term 'story', which emphasises that the most useful perspective may be a narrative that shows how the events unfolded. However, other methodologies, such as timelines, time-person grids and charting (see text on section E, p. 72) are also equally valid approaches that have come from the RCA set of tools. The choice of approach in mapping the chronology will be dependent on personal choice and whether the investigation is being undertaken in a group or individually. The next step is to identify the CDPs. These may be slips, such as picking up the wrong drug, lapses of judgement, forgetting to carry out basic observations or, rarely, deliberate departures from safe practices, procedures or standards.

Having identified the CDPs, the investigator then considers the conditions in which errors occur and the wider organisational context. These are the contributory factors. These conditions include factors such as high workload and fatigue, inadequate knowledge, ability or experience, inadequate supervision or instruction, a stressful environment, rapid change within an organisation, poor communication between professional groups, poor planning and scheduling, inadequate maintenance of equipment and buildings and personal and attitudinal factors affecting relationships with the patient. These are the factors which influence staff performance and which may precipitate errors and affect patient

outcomes. Reason³⁷ showed how incidents might have their origins in more general systemic problems, which, in combination with particular circumstances, eventually lead to specific incidents. The primary task of the investigator is to uncover not only the course of events, but also the underlying systemic problems, which can affect the actions of individuals in the course of their work.

Essential concepts

Reason's model and our framework provide the conceptual foundations of the investigation and analysis process. However, before incident investigation can be undertaken, key essential concepts need to be defined.

The incident

This is essentially something that happened to a patient, member of staff or the general public, a clinical outcome probably with harmful or potentially harmful effects. The criteria for selection of an incident for investigation using the guide are discussed in the following paragraphs.

Care delivery problems

CDPs are problems that arise in the process of care, usually actions or omissions by members of staff. Several CDPs may be involved in one incident. They have two essential features:

- Care deviated beyond safe limits of practice.
- The deviation had at least a potential direct or indirect effect on the eventual adverse outcome for the patient, member of staff or general public.

Examples of CDPs are:

- failure to monitor, observe or act
- incorrect (with hindsight) decision
- not seeking help when necessary.

Clinical context

Salient clinical events or condition of the patient at the time of the CDP (e.g. the admission of a patient with a serious head injury following a car crash, who is confused and does not understand instructions).

Contributory factors

Contributory factors are those which affect the clinical performance of individuals and hence the likelihood of CDPs occurring. Many factors may contribute to a single CDP, for example:

- Patient factors might include the ability of the patient to communicate effectively.

- Task factors might include the non-availability of test results or protocols.
- Individual factors may include lack of knowledge or experience of particular staff.
- Team factors might include poor communication between staff.
- Work environment factors might include an unusually high workload or inadequate staffing.

The accident or incident investigation and analysis process

The accident investigation and analysis process flow chart (see *Figure 3*) shows the sequence of steps to be taken in the incident investigation and analysis process. The flow chart is also split into four main areas:

1. planning your investigation and analysis
2. conducting your investigation and analysis
3. reporting on your investigation and analysis
4. implementing and evaluating recommendations generated via your investigation and analysis.

The basic process of incident investigation and analysis is the same for major investigations carried out by a full team and for quick analyses when only one or two colleagues might quickly review an incident or near miss. In each case the task is to understand the story and the chronology, identify the CDPs and then the contributory factors and then use this information to develop useful improvement strategies to prevent similar problems in the future. The differences come in the scale of the investigation, the range of techniques employed, the use of interviews and the formality of the proceedings and final report.

Section A. Deciding whether to investigate a clinical incident

There are a number of reasons for considering that an incident warrants detailed investigation. Broadly, the incident will either be investigated because of its seriousness for the patient and family, the staff, the general public or the organisation, or alternatively, it may be examined because of its potential for learning about the functioning of the department or organisation. Even incidents without serious repercussions have great potential for learning. Indeed, from the learning point of view, incidents with either positive or negative outcomes or mitigating factors might be investigated.

Serious incidents will always, by definition, be reportable on the trust incident reporting forms. What marks out a serious incident as requiring detailed investigation are the nature, scale and

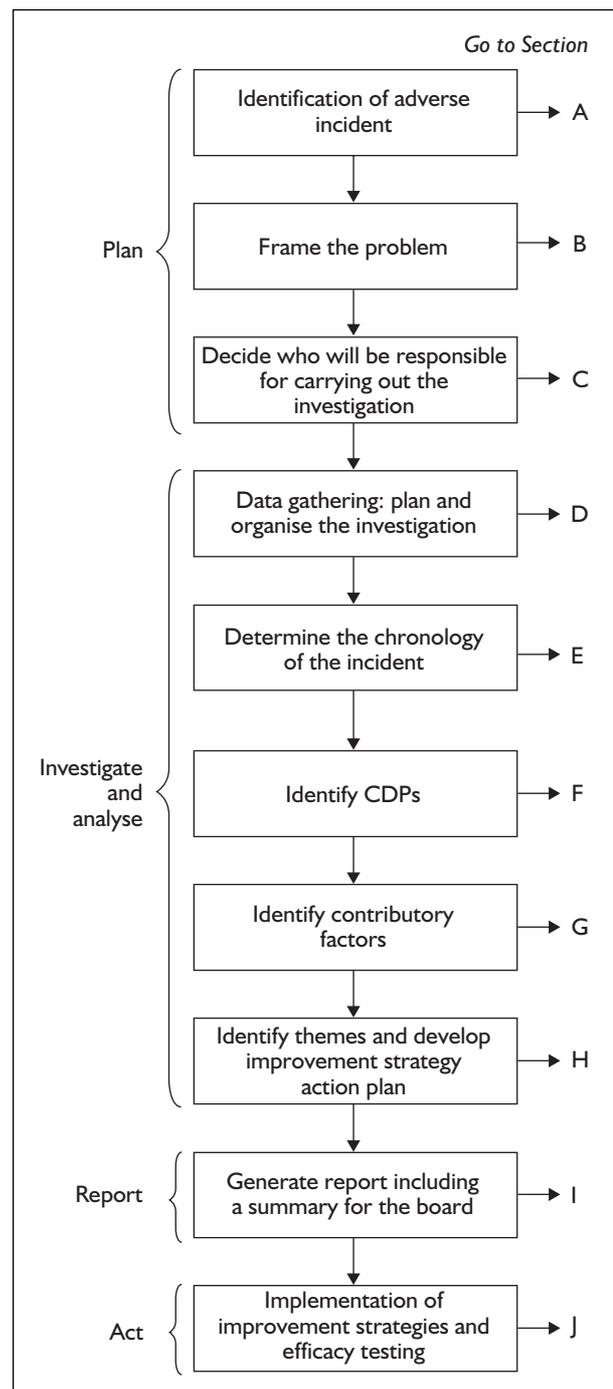


FIGURE 3 Accident investigation and analysis process flow chart

consequences. Some incidents require immediate initial investigation, whereas others can wait. The precise action to be taken is a decision for the most senior person on duty at the time. Account will need to be taken of what has actually happened, the patient's clinical status, how the staff who were involved are feeling and external pressures such as media exposure. Each organisation clearly describes the circumstances that initiate when an adverse incident investigation

should be started. Therefore, local systems should be used to indicate specifically the type of incidents that an organisation should investigate.

Section B. Frame the problem

The reported incident may not reveal the final outcome for the patient. For instance, a patient may assault a member of staff in the accident and emergency department (A&E) (and this may be reported), but the subsequent fracture may not be diagnosed for 3 days and the final outcome for the injured nurse may not be known for some months. Therefore, the investigator needs to take a pragmatic look at the problem and decide what timescale is to be the focus of immediate attention, while allowing that a more elaborate and complex story may unfold. Therefore, which section of the process of care should be examined? Analysis should initially focus on the time period where problems were most apparent, but that should not preclude looking further back in the event if it is considered useful.

Section C. Decide who will be responsible for carrying out the investigation

We have emphasised that this guide may be used in a variety of formats, by individual clinicians, researchers, risk managers or clinical teams. This section addresses the formation of an investigation team for a particularly serious or complex incident. Ideally, the investigation team should consist of three or four people facilitated by the investigation leader. It is important to identify team members with multiple skills and the time to commit to the process. For very serious incidents the team may need leave from 'normal duties' to focus on incident investigation and analysis.

Appropriate experts are essential for serious incident investigation. Experience with the guide suggests that some formal training is necessary for at least some members of any team carrying out an investigation. Just as in any other skill, a familiarity with the concepts and methods is essential if the approach is to be consistent and the investigation of adequate depth and rigour.

Typically the range of expertise may include a combination of the following:

1. Incident investigation and analysis expert(s).
2. External expert(s) view (this can be a non-executive Board member with no specific medical knowledge).
3. Senior management expertise (e.g. Medical Director, Director of Nursing, Chief Executive or Practice Manager in primary care).

4. Senior clinical expertise (Medical Director or Senior Consultant or Senior General Practitioner in primary care).
5. It is also preferable to have someone with knowledge of the affected system or department (but they must not have been involved in the incident).

For less serious incidents and near misses, a full team may not be necessary. A departmental or ward manager, GP or practice manager with appropriate training could facilitate the incident investigation and analysis. He or she would lead the process, but may call for specific information from people involved in the incident. However, it is important to ensure these individuals have adequate accident investigation and analysis training, so that they conduct their investigations efficiently and effectively.

Section D. Data gathering: plan and organise the investigation

In the case of a serious incident, it is necessary to collect all facts, knowledge and physical items related to the incident as soon as possible. This may include assembling:

- all medical records (e.g. nursing, medical, community, social workers, GP) and all correspondence, including internal communications
- documentation and forms related to the incident (e.g. relevant protocols and procedures)
- immediate statements, or observations
- physical evidence (e.g. ward or incident site layout/schematics)
- secure equipment involved in the incident (e.g. a cardiocography machine or medication pump implicated in a case)
- information about relevant conditions affecting the event (e.g. staff rota, availability of trained staff)
- results of interviews or collation of statements from persons involved in the incident early, so that memorable information is not lost.

Obtaining the basic information at an early stage ensures an accurate description of the incident, including the sequence of events leading up to the incident. This provides the initial direction to the investigation team, which helps focus additional enquiries and interviews. Where the matter could lead to formal proceedings of any kind, information should be secured to ensure it is available for use during the investigation and later if the case were to go to court. Accident

investigation and analysis techniques used in other high-risk industries, such as RCA, MORT and the wheel of misfortune, all conclude that collecting data from a wide range of sources is an important component of the accident investigation process.

Section D1. Interviews with staff

While a considerable amount of information can be gleaned from written records and other sources, interviews with those involved are perhaps the most important route to identifying the range of background contributory factors to an incident. This is especially so if the interviewer systematically explores these factors and allows the member of staff to collaborate effectively in the process of both investigation and analysis. Decisions about who to interview and for how long will depend on the complexity of the events and the time and resources available. For major incidents, full interviews with several members of staff may be advisable. However, for quicker investigations much can be achieved with brief telephone calls, provided they are focused and explore the key issues in the same manner as a longer interview. In a general practice setting, much could be achieved in a facilitated multidisciplinary group meeting that includes all members of staff involved in an incident.

In the interview sequence that follows, the story and 'the facts' are just the first stage. The staff member is then encouraged to identify both the CDPs and the contributory factors, which greatly enriches both the interview and investigation. The contribution of a patient to an investigation has yet to be fully explored using this process. However, we would actively encourage patients or their relatives to be interviewed if it is considered useful by the accident investigator(s). Deciding on whether to include patients/family in this stage of the accident investigation and analysis is largely left to the discretion of the trust or practice. For some individuals, being party to the investigation process might be psychologically beneficial and may prevent a subsequent complaint or claim against the organisation. Yet for others, the process of interviewing will be too traumatic and will not aid organisational learning. Irrespective of patient/family involvement in interviews, it is most important that these persons are fully informed of the result and the action(s) taken following the incident.

Full interviews generally take between 30 minutes and 1 hour depending on the degree of involvement of the member of staff (they may, however, take considerably longer if the person concerned is distressed by what has occurred).

There are several distinct phases to the interview and it is generally most effective to move through these phases in order.

Setting the scene. Interviews should be undertaken in private and, if at all possible, away from the immediate place of work in a relaxed setting. If a member of staff wishes someone else to be present, this should be permitted. The style adopted should be supportive and understanding, and not judgmental or confrontational. It is good practice to have one interviewer and another person recording the conversation. This enhances the flow of the interview and ensures that information is not lost.

Establishing the chronology. First, establish the role of the member of staff in the incident as a whole. Record the limits of their involvement. Next, establish the chronology of events as the staff member saw them. Compare this new information with what is known of the overall sequence.

Identifying the care delivery problems (CDPs). In the second phase, first explain the concept of a CDP and possibly provide an example of a CDP. Then, ask the member of staff to identify the main CDPs as they see them, without concerning themselves about whether or not anyone is or is not to blame for any of them. Identify all-important acts or omissions made by staff, or other breakdowns in the clinical process, that were (with hindsight) important points in the chain of events leading to the adverse outcome.

If clinical practice is specified by guidelines, protocols or pathways, it may be possible to specify major departures with some precision. Generally, however, there will be a degree of acceptable variation in practice. Look for points in the sequence of events when care went outside acceptable limits. Clinicians, whether those involved or those advising, will have an implicit knowledge of the clinical process as it should ideally occur, allowing for acceptable levels of variation and fluctuation. Where there are disagreements as to whether a particular action or omission is acceptable, these should be recorded and resolved later in the investigation process.

Identifying the contributory factors. In the third phase, go back and ask specifically about those CDPs that the staff member may have information about or experience of. Ask questions related to each CDP based on the framework (see *Table 36*). Suppose, for instance, that the person identifies a failure in the routine observation of a disturbed

patient or failure to attend an emergency call in primary care. The interviewer can prompt the staff member by asking in turn about the relevance of patient factors, the clarity of the task, individual staff factors, team factors and so on.

Section D2. Reviewing case records

Accounts of an incident may be taken from written reports of staff members, case notes or interviews with staff. The analysis may be limited if only written reports are considered, in that it may not be possible to explore the full range of conditions that allowed the event to occur. These guidelines incorporate analyses from both interviews and case records and assume that much important material can only be gained from interviews. It is possible, if there is no option, to carry out a less detailed and inevitably more superficial analysis from the case records alone, although the input of an expert clinician in the area will be essential if the clinicians involved in the incident are not available to be interviewed.

Case records in primary care are often brief, serving as an aide memoir to an individual general practitioner, or as a basic record for consultations with practice partners. Sometimes important information (e.g. drug records, allergies) is recorded electronically on the computer, but not in the notes, and sometimes (e.g. family histories) the reverse. Additional information required to reconstruct chronologies might also be found in message books or nursing records. In practice, the investigation will be heavily dependent on the reports of interviewees, who themselves may require access to case records to reconstruct events.

Section E. Determine the chronology of the incident

Once the medical records and other such documents have been examined and some initial interviews conducted, it should be possible to describe the chronology of the incidents and gain some understanding of how events unfolded, by making a composite of the data sources. The investigation team will need to ensure that this information is integrated and that any disagreements or discrepancies are clearly identified. The mechanism by which healthcare staff and investigators represent this chronology

should be agreed at Board level. However, some RCA techniques, which are useful, are listed below, along with an example of each.

Narrative of chronology

This was the approach previously recommended in the protocol.¹²⁹ This approach is best suited when one individual is responsible for incident investigation and analysis, rather than a team. A narrative chronology is also best used in the final report or when reporting to the board. See *Box 4* for an example.

Timelines

This tracks the incident and allows the investigators to discover any parts of the process where problems may have occurred (see *Box 5*). This approach is particularly useful when a team meeting is used to discuss an incident. Ideally an outline chronology is prepared beforehand, whether as a handout or round the wall on large sheets of paper. This allows the group time to be used more appropriately to identify CDPs and the contributory factors, rather than wasting time plotting the chronology.

Cause and effect charts

These draw a picture of the movement of people, materials, documents or information within a process. In determining the sequence of the incident, it may be useful to develop separate flow charts that illustrate (a) the sequence of events as documented in the policies and procedures, (b) the sequence of events that occurred during the incident and (c) an improved sequence of

BOX 4 An example of a narrative of chronology

Monday 17 March 2001, 09.15

Patient A was prepared for theatre; his left leg was marked with a skin pencil for amputation.

Monday 17 March 2001, 10.00

Patient A was taken to theatre, and the theatre list noted that the right leg was to be amputated.

Monday 17 March 2001, 10.45

A locum Registrar amputated the right leg.

Monday 17 March 2001, 15.15

It was realised the wrong leg had been amputated.

BOX 5 Example of a timeline

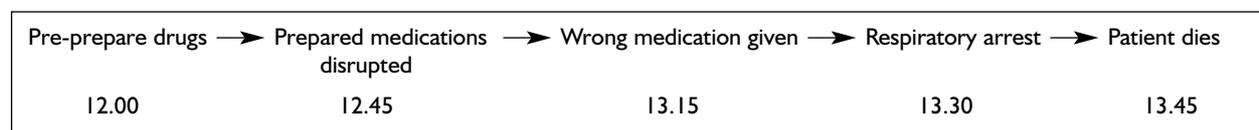


TABLE 37 Chronological mapping of CDPs and associated contributory factors

Chronology
Time
CDPs
Contributory factors
Recommendations

events. The process for determining the sequence of events may flag 'issues' associated with but not directly relevant to the incident. It is useful, however, to maintain a record of these in order to address them separately, if considered important.

Section F. Identify CDPs

Having identified the sequence of events that led to the incident, the investigation team should now commence the formal identification of CDPs. Many of these may have been provided by interviewees or from the investigator's own knowledge and experience of the clinical process or the organisational system. Ensure that all CDPs are specific actions or omissions on the part of the staff, rather than more general observations on the quality of care, which should be recorded elsewhere. It is easy, for example, to put down 'poor teamwork' as a CDP which may be a correct description of the team, but should be recorded as a contributory factor as it was likely that poor teamwork influenced the CDP.

It is often useful to organise a meeting with all the people (from consultant to porter) involved in the incident to let them tease out the CDPs, especially if few interviews have been used. The people involved in an incident are often well placed in identifying what went wrong and why this occurred and thus sign up to the implementation of improvement strategies. It is important that the choice of methods used in this session allows the views and opinions of all participants to be provided safely. Skilful facilitation may be needed.

Section G. Identify the contributory factors

The next step is to specify the contributory factors associated with each of the CDPs, using *Table 36* and Appendix 12 as a guide. Using the documentation and the results of interviews as a basis, the investigation team should reflect systematically on the different levels of the framework. What patient factors were involved in

the occurrence of this CDP?; what task factors?; what individual staff factors?; What team factors?; and so on. In practice CDPs and contributory factors may be identified simultaneously during both interviews and later analysis. However, the discipline of systematically going through the framework in the final stages of the analysis ensures a comprehensive approach.

A variety of methods can be used to record the contributory factors associated with a specific CDP. The case examples (see Appendix 11) show a simple narrative format that is useful for reports. For team meetings and discussion, it may be helpful to use a chart that summarises all the key points. *Table 37* (best placed on A3 paper in landscape format or on wallpaper lining paper) provides the investigator with a mechanism to record the basic incident chronology along with the CDPs and associated contributory factors as a sequence.

Section H. Identify themes and develop improvement strategy action plan

Once the CDPs and contributory factors have been identified, they are used to reflect on the healthcare system to reveal gaps and problems in the process of care and other systemic issues. Most investigations identify a number of important contributory factors and these need to be prioritised for action. An important initial step is to consider which of the contributory factors reveal these systemic issues and highlight these as requiring attention. For instance, a pattern of communication problems may be revealed, or longstanding problems with obtaining test results. It is also necessary to decide which of these factors can be changed and not become entirely absorbed with problems for which there is no immediate solution (e.g. financing of the healthcare system). Recommendations can be categorised as needing to occur at either the individual/group, local (team), directorate or organisation level.

Note that it is not necessarily wise to implement major changes after one incident, no matter how catastrophic the outcome; in fact, making changes following an idiosyncratic case could do more harm than good. Where obvious deficiencies in the process of care are identified, then action can be taken immediately. However, more fundamental changes to protocols and policies will also require consideration of the wider effects and perhaps further investigation using other information that may be available (e.g. research, survey results, previous incident investigations). Consequently, the impact of the recommendations on any aspect of the organisation must be fully considered prior to implementation so as to ensure that they have the desired effect and do not lead to further potential for error.

Table 38 provides a recommendation/error reduction recording and tracking system, which may be useful to ensure that implementation has taken place. Hence the organisation can immediately identify where the main emphasis of change management needs to occur and who is responsible for making the required changes happen. As previously mentioned, it is normal to identify more than one major contributory factor for each CDP, and consequently the investigation team will need to prioritise the solutions.

Section I. Generate report, including a summary for the board

The final incident investigation and analysis report should convey the results of the investigation in a manner that will help the reader understand what happened (the incident description, chronology and CDPs), how and why it happened (the contributory factors) and what can be done to prevent a recurrence (the proposed improvement strategies). The incident investigation should also contain a listing of all attachments and references to support the report such as interview transcripts, photographic evidence, policies and procedures. This information should generally be reported in the appendices.

A full incident investigation report should contain the following sections:

- executive summary
- introduction
- investigation procedure/methodology
- analysis and findings
- recommendations
- mitigating factors/learning points
- positive features of the case
- appendices (containing supporting evidence).

The executive summary of the incident investigation is particularly important, as many people, for example members of the Board will not have time to read the full document. The summary should follow the same basic format of the report and provides the following information:

- nature of the incident such as maternal death in A&E
- brief chronology of the incident
- main problems identified with care (CDPs)
- principal contributory factors and systemic problems identified
- positive features of the case
- recommendations (which must be approved by the Board).

Note that the structure of the report follows the structure of the interviews, the analysis and indeed the whole investigation process. Obtaining and recording information in the form in which it will appear in the final report greatly simplify the final report writing. Rather than sifting through a heap of unstructured narratives, the investigator simply assembles the CDP contributory factors in the same format. When this is done systematically, the report, as one risk manager put it, 'writes itself'. Further inputs might be required to link the findings of the investigation to appropriate improvement strategies and this is discussed below.

Section J. Implementation of improvement strategies and testing their efficacy

The improvement strategies/recommendations that have been approved by the Board must be implemented within the organisation and the mechanism by which this occurs will be dependent on local systems. Often the clinical governance team or Board is made responsible for implementing and tracking recommendations. *Table 38* is a blank document for recording the proposed action plan and can be used as a mechanism to track these recommendations. Planning the implementation of corrective actions may include communicating results throughout the organisation, reviewing policies and procedures, implementing training, establishing plans for on-going monitoring and so on. Once all related improvement strategies have been implemented and been given time to bed-in within the system (e.g. 6 months), it will be necessary to undertake some evaluation as a validation that the suggested changes have had the desired effect(s) on the system. This is to ensure that:

1. The systemic problems identified have been addressed.

TABLE 38 Summary document for recording the proposal action plan

Issues identified	Actions to address problems	Level of recommendation (Individual, Team, Directorate, Organisation)	By whom?	By when?	Resource requirements	Evidence of completion	Completion sign-off

2. Recurrences have been reduced or eliminated.
3. Lessons have been learnt and communicated.
4. Identified barriers to change have been unfrozen.
5. The loop is closed to ensure organisational learning.

A variety of methods and approaches can be used to test the efficacy of improvement strategies. Some can be fairly simple, for example:

- Observation of an obstetric ward to see if a fully operational CTG machine is available when needed.
- Review of training and competency assessment policies and registers to see if all relevant staff have been trained in using the CTG machine.

Other methods might involve the audit department auditing some component of practice, which may take slightly longer to complete, but none the less is an effective checking mechanism. Small research projects can also be implemented to assist in validating the success of improvement strategies, for example a safety culture audit that specifically looks at team communication. It does not really matter what methods are used provided

that some form of evaluation takes place, as this will ensure that the organisation becomes a forward-thinking, learning organisation that is open to change and can improve its safety performance.

References corresponding to the guide

- Reason, 1990⁸⁵
Reason, 1993³⁴
Reason, 1995³⁷
Reason, 1997⁴⁵
New Zealand Standards Ministry of Health, 2001¹³⁹
Stanhope and colleagues, 1997³⁸
Taylor-Adams and colleagues, 1999³⁹
Vincent and Bark, 1995¹⁴⁰
Vincent and colleagues, 1998²³
Vincent and colleagues, 1999¹²⁹

Further reading

- Cooper and colleagues, 1984¹¹³
Center for Chemical Process Safety of the American Institute of Chemical Engineers, 1992⁵²
Cook and Woods, 1994³⁶
Eagle and colleagues, 1992³⁵
Ferry, 1981⁵⁰

Chapter 7

Overview and conclusions

This chapter draws together the conclusions of the reviews of incident and accident investigation within and outside healthcare. We give an overview of the strengths and weaknesses of different approaches in high-risk industries, with particular attention to those techniques with potential for use in healthcare. The method of the review of high-risk industry techniques is fully described earlier and we did not feel it necessary to discuss it further here. We have, however, offered some comments and reflections on the methods of the more substantial review of studies in healthcare. The salient features of six healthcare techniques are then summarised and discussed. The importance of understanding the context of a particular technique is highlighted, as a strict comparative evaluation of methods makes little sense when the context and purpose of the techniques differ widely. However, some methods show particular strengths and should provide the foundation for the next generation of techniques, which it is hoped will draw on a much wider range of research and practical experience than has hitherto been the case. Finally, we assess the major implications for incident investigation in healthcare and identify areas where further research is needed.

Techniques of accident analysis in high-risk industries

The review of high-risk accident investigation techniques, as was intended, framed our approach to the healthcare review in a number of respects. The review gave us an understanding of the theoretical and practical background to incident investigation and helped us develop methods of assessment. However, its importance went well beyond this initial aim, in that it also gave us much food for thought on how healthcare techniques might develop in the future. The diversity of techniques used in other industries greatly impressed us, as did the power and conceptual development of some of the methods. We did not attempt to review and evaluate all the approaches used in other high-risk industries, which would have been a major undertaking and would have required a separate research project. Because of the richness of this material, however,

we reviewed a larger number of papers and a larger number of techniques than we originally expected, selecting those that we considered to be of particular relevance to healthcare.

Summary of findings

Accident investigation methodologies in high-risk industries were generally more clearly defined than those in healthcare. In contrast to health, where most methods are described in the context of a study, investigative approaches outside healthcare can be identified and described as specific methodologies and techniques. Manuals and descriptions of the methods of investigation and analysis were available, in addition to reports of actual investigations.

Twelve techniques were reviewed in detail. All had some strong points, although the approaches varied in comprehensiveness, theoretical adequacy, use of resources and the extent to which they were used and accepted. Following a formal assessment according to specified criteria, an evaluation was made of the 12 techniques. However, as with healthcare, such an evaluation was not thought to give an adequate representation of the strengths and limitations of techniques because all had their merits in particular circumstances. For instance, some techniques in the third group, such as STEP and change analysis, were strong on error reduction but were less favourably evaluated because they were not well explained in the literature and were based on experience rather than models of human behaviour. They were not necessarily poor techniques, but may be in need of additional specification and further development. Some techniques, such as BA and change analysis, were not evaluated particularly highly as stand-alone techniques. However, they were not developed as stand-alone techniques and are nevertheless very useful as part of a more comprehensive strategy.

MORT, RCA and wheel of misfortune stood out as being of particular value. MORT, if carried out completely, is certainly the most comprehensive approach in that an accident is examined from several perspectives using a toolbox of techniques. A MORT investigation and analysis, however, requires trained investigators and is expensive in

terms of both time and resources. Only where substantial resources are available, such as in a major enquiry or perhaps a Healthcare Commission for investigation, might such a technique be fully implemented in the NHS.

RCA, like MORT, performed particularly well as an accident investigation and analysis technique. Once again this result could be due to the fact that it is composed of a variety of smaller more specific techniques useful at different stages of the investigation and analysis process. Fault trees and flow diagrams are very useful in the early stages of investigation, when an incident is plotted as a chronological event, but task analysis, FMEA and change analysis are more appropriate at the analysis stage of the investigation, when one needs to understand why problems have occurred.

The wheel of misfortune is a recent accident investigation and analysis technique, which has received minimal explanation and review in the literature. On paper, it appears to be a complete approach to accident investigation and analysis. It also seems simple and quick to understand and perform, yet is based on accepted models of human performance. It would be useful to apply this methodology formally to the medical domain to see how it copes with investigating and analysing medical accidents.

Many other techniques provide useful methods of solving specific accident investigation or analysis problems. For example, barrier analysis is an exceptionally quick and useful approach to identifying where and how to implement specific types of defences and barriers within an organisation. Events and causal charting is useful for depicting the chronology of the event and will give some indication of the causes, but it is best used with other more evaluative specific techniques such as barrier analysis and change analysis. Fault trees are helpful in identifying where faults in the system are likely to occur, but need to be integrated with techniques such as FMEA, or BA to identify solutions to the problems identified. These specific techniques may well be useful in a healthcare environment as part of a broader package. Such a multi-technique approach would make accident investigation more versatile and use limited resources more effectively, provided that the different techniques are set within an overall framework and process. The precise purpose and utility of each technique must be clearly specified, or a potentially comprehensive toolbox degenerates into a

miscellaneous jumble of inappropriately used techniques.

In summary, healthcare can learn much from other industries regarding accident investigation and analysis. Applying some of the techniques available outside healthcare to clinical settings has much potential, although it will be necessary to provide training and support to accident investigators and to build an accepted 'toolbox' of approaches. These issues are discussed further below. In addition, we should be aware, as discussed in Chapter 1, that although healthcare has many similarities to other high-risk industries, there are also a number of differences, particularly the unpredictable nature and variability of healthcare in terms of disease presentation, diagnosis, choice of treatments and so on. Further differences relate to organisational and regulatory matters such as the centralisation and structure and the various 'external' organisations involved in this. We consider, however, that these differences do not prevent the use of techniques from outside healthcare but they may require some modification in practice.

Review of techniques of incident and accident investigation in healthcare

Reflections on the review process

The literature on the analysis of critical incidents and adverse events in healthcare proved, as expected, to be diverse and not well integrated. There were studies of single and multiple incidents in many hospital specialities, in primary care and in mental health, but few defined a particular method in any detail. Descriptions of approaches taken in healthcare were, for the most part, embedded in particular studies. This severely limited the range of approaches that could be described as separate and distinctive techniques.

There were a larger number of potentially relevant studies than we originally expected. In addition to the specific techniques discussed below, we also identified a range of well-established frameworks in which the investigation and analysis of clinical incidents play some part. For example, analysis of clinical incidents occurs to a greater or lesser extent in confidential enquiries into maternal or postoperative deaths, reviews of complaints and malpractice cases and the reports of regulators. These traditions and

frameworks, although not central to this review, are nevertheless important both as approaches in their own right and because they demonstrate the potential value of examining single incidents in depth. They also represent an important tradition of healthcare professionals cooperating and collaborating in the investigation of serious incidents. Nevertheless, few of the studies within these frameworks employed any clearly identifiable technique of enquiry and many such studies might benefit from employing some of the techniques reviewed here, both those from high risk industries and from healthcare.

Distinguishing a core set of identifiable techniques was further complicated by the lack of any existing over-arching framework or taxonomy. We endeavoured to develop a conceptually coherent classification of studies as representing particular techniques, but some studies seemed to draw on more than one of the basic techniques. For instance, a study might refer both to Reason's organisational accident model and the critical incident technique. The lack of any available assessment instrument meant that we had to develop one from scratch. This also proved to be a difficult undertaking, requiring many iterations.

The increased time taken in the review of high-risk industry techniques, the volume of healthcare papers and other challenges eventually limited the time available for formal double appraisal of healthcare studies. However, in the event, we believe that the increased time devoted to high-risk industry techniques and development of appraisal instruments was well worthwhile. These were highly productive avenues and the development of the appraisal instrument provides a foundation for later, more extensive reviews in this area.

We do not believe at this point that techniques can be formally compared on all criteria. Although adequacy of documentation, for instance, can reasonably be assessed and compared, the overall value and power of a technique are highly dependent on its context of use. Generally, it is not sensible to assess these techniques as simply strong or weak or to employ formal statistical analyses comparing them on different parameters. Rather, it is a question of assessing their utility and fitness for purpose in the context in which they are employed. For instance, the purpose and use of a large-scale reporting system such as AIMS is very different from that of the OACM approach used for examining individual incidents in depth.

Summary of findings of healthcare review

A substantial literature was reviewed from healthcare and six techniques were appraised in detail: AIMS, the CIT, SEA, RCA, OACM (including our own investigation and analysis protocol) and CWS.

Most of the techniques have focused on the investigation and analysis of critical incidents in acute or primary care. Only two techniques, AIMS and OACM, examine incidents from mental health settings. However, all techniques have the potential of being applied in all specialties and disciplines related to healthcare. Although a few studies looked solely at death as an outcome, most used a variety of outcomes including near misses.

Most techniques used interviewing and primary document review to investigate incidents. AIMS, being a large-scale reporting system, did not use interviews or primary document review, basing the analyses on submitted reports. CIT, RCA and CWS also included publications which conducted physical or logistic assessment as part of their data collection process. Thus CIT, RCA and CWS were notable for using the three types of data, which potentially enhanced the possibility of examining a wide range of causes or contributory factors involved in a particular incident.

In most studies examined, there was little or no information on who collected the data, the interval between the incident and investigation, the number of interviewees involved, how the data were extracted, the time taken for assessment or any information on quality assurance for data collection and analysis. In many cases this probably means that the data were available but simply not reported. However, quality assurance was seldom discussed and this reflects the fact that research on these techniques has not yet evolved sufficiently to consider their validity in any depth. We found little information in the studies on the experience or training of the investigators. Often individuals from a medical or nursing background were responsible for the investigation. Only studies using the CIT or RCA reported the use of trained or experienced investigators.

All techniques included papers which identified clinical issues, some kind of classification of different types of errors and some attempt to assess underlying causes and contributory factors. However, the extent and sophistication of the various attempts varied widely. Only studies using the OACM technique consistently included the

causes or contributing factors associated with the critical incident, as this is specified within the method. Only one-third of papers referred to an established model of accident causation, usually Reason's active failures and latent conditions.³⁷ In many cases it was difficult to differentiate clearly the underlying model from the specific data collection techniques and the overall framework of enquiry.

In many papers, there was little or no discussion of implementation of any changes as a result of the investigations. One-quarter of publications gave descriptions of the implementation of changes and one-third of these also included evaluations of such implementations. Most techniques were assessed as being easily available, transferable to other specialties and applicable to a range of incidents and near misses. There was some variation in the level of expertise and training required and the extent to which the technique encouraged all parties to participate in the investigation, but all required some expertise to undertake the investigation to an acceptable depth.

Although a formal ranking of techniques is neither useful nor valid, there were nevertheless some significant differences between techniques on specific criteria. Most techniques, for instance, were rated as having low or low-moderate consistency, except OACM, which had high consistency. This has important implications for the reliability of a technique; model-based theoretical validity was low or moderate in most techniques, but again high in OACM. Error reduction, an important objective in incident investigation and analysis, was mostly moderate-high, except in OACM where it was low as the focus was on the investigation method. RCA and OACM considered the widest range of contributory factors and AIMS had the greatest attention to fine clinical detail. Acceptability or usage of the technique varied and in any event was difficult to assess. This may reflect the fact that many techniques are relatively new and because there is generally little information on the extent of their usage, though AIMS is certainly widely used in Australia.

In summary, the techniques vary in most of the formal assessment criteria, but do have some similarities of important factors. As the investigation and analysis of critical incidents in healthcare are beginning to be more widely used and are relatively new in relation to other industries, formal comparisons of the techniques would be considered premature.

The future of incident investigation in healthcare

The reviews of techniques in healthcare and high-risk industries suggest a number of areas for further refinement of these approaches. The recommendations and suggestions that follow seem to us to be the most important areas of development.

Purpose and context of use

Although all the healthcare techniques are of value and have much to contribute in certain contexts, two are not really suitable for routine local review of clinical incidents. Comparison with standards is more useful in the context of major studies, such as the confidential enquiries. AIMS is primarily a high-level reporting system, ideal for flagging and warning of hazards and incidents. Such a system can identify high-volume incidents but also incidents that may be rare at a local level but show a pattern of recurrence when examined nationally. The remaining four, CIT, RCA, SEA and OACM, are all primarily aimed at local investigation and analysis, although they also have potential for more formal studies or series of incidents.

The general point that emerges from this is that both authors of individual studies and developers of techniques and methods need to specify the purpose of the approach much more clearly than hitherto. Equally important, the context of use should also be specified. A technique developed for use by a primary care team may, or may not, be applicable in other contexts but some indication should be given as to whether it might potentially transfer.

Defining the technique and providing manuals and guidelines

As indicated above, accident investigation methodologies in high-risk industries were generally more clearly defined than those in healthcare. Manuals and descriptions of the methods of investigation and analysis were available, in addition to reports of actual investigations. Healthcare should now move to the definition and specification of both the process of investigation and the techniques employed. Even major investigations, such as those by the Healthcare Commission contain very little information on how the investigation was conducted and employ few, if any, of the wide range of techniques available. Developers of healthcare techniques need to provide manuals and protocols, such as are available for RCA and OACM. Researchers need to provide much more

detail on the process of investigation, either by developing separate documents or by providing more detail of the study methods (perhaps on an accompanying website).

Individual investigators and team approaches

The way in which a technique is used varies considerably according to the technique and the context. The most noteworthy example of this is the varying roles of the investigators or researchers. Some methods, such as the OACM protocol of Vincent and colleagues,¹²⁹ were originally designed with an individual investigator, usually a risk manager, at the heart of the process. However, this is only one way of approaching the investigation, and this protocol has also been used in other formats, such as structured team discussion and in training and education. SEA in primary care was extremely instructive as regards encouraging team interaction and driving change at the clinical level. In our own view, this approach could profitably be combined with other techniques, such as OACM, which are stronger on the analytical framework but less so on staff involvement at a local level.

Those developing or using techniques should firstly specify the way in which they are to be used, or give guidance on any changes in approach which might be necessary according to whether the process is researcher or investigator led or whether it is a team-based group discussion. Looking further ahead, there are a range of interesting and potentially important research questions on the power and validity of these different approaches. Team approaches, for instance, might be useful for creating ownership of proposed solutions but may not work so well if a patient has been seriously harmed or if staff are too traumatised to speak openly in a group.

Resources and the need for training

Investigation has historically been one of the tasks most difficult to teach because good investigators often have difficulty describing what they do. However, in recent years, all high-risk industries have developed extensive accident investigation training programmes for their employees. Initial courses usually require at least 7 days of dedicated study, often followed by more advanced and specific training courses at regular intervals thereafter. These organisations recognise that accident investigation is a specialist and complex task, which requires substantial investment in training dedicated accident investigators. Healthcare has yet to learn this lesson, although

the National Patient Safety Agency is now driving a programme or education and training ultimately aimed at producing a cadre of trained investigators in every Trust in the NHS.

Healthcare professionals engaged in investigations are seldom allocated sufficient time, or relieved of other duties, to enable them to produce a thorough report with serious attention to implementing changes and error reduction strategies. In the long-term, however, it may be less expensive, as regards both the human and financial costs, to devote time and resources to investigating incidents to enhance safety and so reduce the overall burden on the healthcare system.

Making changes

A general shortcoming of all the healthcare techniques reviewed, perhaps reflecting the early stage of evolution of the techniques, is that too little attention was given to recommendations for change and implementation of changes. It is unreasonable to expect that all research studies should consider the whole cycle of investigation, analysis, implementation and evaluation, but as the techniques develop more attention should be given to directly linking findings to future prevention. At a local level an investigation team may lack the time, information or competence to evaluate financial, operational and policy impacts of recommendations. It is therefore wise to suggest a further phase in which the plan can be developed, costed and implemented.

A further problem, both within healthcare and outside, is the continuing tendency for reports primarily to highlight the shortcomings of individuals. Personal accountability is undoubtedly important, but only one aspect of the maintenance of a safe system. Many accident reports from industry fail to extend recommendations beyond the behaviour and shortcomings of individuals to the wider systems which allowed the problems to occur. Ultimately, the value of investigations will depend on a top management's injunction to 'tell it the way it is'. This depends on the ability of senior management to take a mature approach and recognise that systemic factors, for which they have some responsibility, are implicated in many accidents. They also need to provide a clear direction for the investigation. A directive to take a broad systemic approach is much more likely, in the long run, to lead to safer operations than a directive that requires the identification of individuals for disciplinary action.

The integration of techniques

Our review of methods of accident investigation in high-risk industries made us aware that there were a number of potentially useful techniques that could be used in healthcare. A variety of data collection techniques exist (e.g. interviewing relevant personnel, observation, simulation techniques, hierarchical task analysis, fault and event trees, record review). Formal approaches to analysis include human error analysis, human reliability assessment and a human reliability management system. In addition, a number of comprehensive human error taxonomies have been produced to categorise error. Most of these approaches are complementary to the guide described in Chapter 6. This is particularly true of the current guide, which has been very much influenced by the review of high-risk industry approaches. The inclusion of these additional techniques, described in this report, would, however, have made the guides longer, more complex and less accessible to front-line clinical staff. We therefore decided to keep the main guideline to a manageable length, but to consider longer specialist versions in a future project.

The diversity of accident scenarios and the range of effective approaches available suggest that accident investigators should think in terms of a 'toolbox' of approaches, which should be utilised at different stages of investigation and which would vary according to the context and type of accident. Many of the techniques available within RCA and MORT should feature in this 'toolbox' approach, along with added specialist approaches such as the wheel of misfortune or the CRU/ALARM protocol. If such a 'toolbox' of approaches is to be used in the healthcare sector, it is important that significant information is provided to the accident investigator on when these techniques should be used, along with worked medical examples. It would be useful to categorise when each accident investigation and analysis tool could be used in medical accident analysis, such as causal charting and flow diagrams. HTA should be used at an early stage in the investigation where a chronology of the event is needed. Once a chronology of the event is available, the investigators will want to understand how and why the incident occurred. At that point tools such as fault trees, FMEA and the wheel of misfortune will be particularly helpful. Finally analysis will focus on what we can do to prevent this problem in the future and here techniques such as change analysis and BA are useful.

A greater emphasis on proactive approaches

In the last few decades, some powerful investigation and analysis methods have been developed for analysing serious accidents in technologically complex safety critical systems. However, it is important to note that in many of these high-risk/high-consequence industries, such as aerospace, the emphasis on postaccident corrective measures has shifted to the assurance of safe functioning prior to commissioning of the safety critical system.⁶⁴ For instance, some early precommissioning risk analysis techniques such as sneak circuit analysis^{65,66} and HAZOP⁶⁷ examine the system hardware to ensure that it is safe before it goes into operation. The scope of risk assessment, control and accident analysis has been broadened in industry to encompass the safety management system of the entire operation. Patient safety has yet to evolve to encompass these proactive approaches, but they are likely to assume a greater importance in the future. Nevertheless, although these proactive forward-looking processes have grown in importance, accident investigation continues to serve a vital function within the overall safety programme.

Future research

A number of research priorities are indicated for the in-depth investigation and analysis of incidents. High-risk industries have more than 30 years of experience of investigating and analysing complex accidents. It would therefore seem appropriate that accident investigators from other industrial sectors are interviewed to generate a view on what they believe makes a successful accident investigation and on what techniques they would use.

Within healthcare there is, first, a need to extend the findings of the current review to assess overlap in techniques and to consider how existing techniques might evolve or adapt. For instance, we believe that SEA in primary care is consistent with the OACM investigation model, and that each would benefit from incorporating features of the other. Those techniques which are sufficiently evolved to be separately described would benefit from formal evaluation of their outcomes and effectiveness. Although the present review has gone some way to achieving this, there is now a need to undertake specific studies to evaluate techniques in different contexts. Examination of context of use is vital, as although we believe that all the techniques are fairly widely applicable, there is no doubt that

some have evolved in particular settings and may turn out to be better adapted to those settings than others. Studies should examine depth of investigation and analysis, adequacy and feasibility of recommendations and cost-effectiveness. Examining the implementation of recommendations is clearly a key issue, but one which extends beyond the examination of a particular technique to consider the quality and safety initiatives of the healthcare unit or system in which the technique is embedded.

A final word

The establishment of the National Patient Safety Agency (NPSA), the growth in patient safety initiatives around the world and the recent involvement of the WHO indicate that reflection and learning from adverse incidents is set to become a mainstream healthcare activity no longer

confined to enthusiasts and specialists. Large-scale reporting systems, excellent for providing flags and warnings of problem areas, are inevitably limited in the depth of causal and descriptive information that they can collect. More detailed analyses of specific classes of incidents, defined by reporting data and other sources, will be necessary to establish the array of causes and contributory factors and develop and evaluate methods of prevention. Although proactive approaches to patient safety are destined to grow in importance, the investigation and analysis of incidents will remain a key component of patient safety programmes at both local and national levels. Our reviews demonstrate that although much valuable work has been accomplished, there is considerable potential for further development of techniques, the utilisation of a wider range of techniques and a need for validation and evaluation of existing methods.



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Contributions of the authors

Maria Woloshynowych (Lecturer in Clinical Safety) was involved in the design, analysis and interpretation of data, drafting and revising the report and approving the version to be published. Maria also conducted the search, review and assessment of methods of investigation and analysis of critical incidents and adverse events in healthcare; contributed to writing the corresponding chapters of the report; and

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Steven Rogers (Senior Lecturer, Department of Primary Care and Population Sciences) obtained original funding; was involved in the design, analysis and interpretation of data, drafting and revising the report and approving the version to be published. Steven also conducted the search, review and assessment of methods of investigation and analysis of critical incidents and adverse events in healthcare; managed the development and testing of guidelines in primary care; and contributed to writing the corresponding chapters of the report.

Sally Taylor-Adams [Assistant Director of Patient Safety (Midlands and East)] was involved in the design, analysis and interpretation of data, drafting and revising the report and approving the version to be published; conducted the search, review and evaluation of methods of investigation and analysis of critical incidents and adverse events in industry; and managed the development and testing of guidelines in mental health and acute care. Sally also contributed to writing the corresponding chapters of the report.

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Appendix I

Literature terms used to search PsycINFO, including hit rate

Search term	Number of hits
Incident investigation and (english in la)	2
Accident investigation and (english in la)	30
Incident analysis and (english in la)	21
1. Accident analysis and (english in la)	738
2. Industrial accident analysis and (english in la)	0
3. (accident analysis NOT road) and (english in la)	577
4. (#3 NOT motor) and (english in la)	314
5. (#4 NOT traffic) and (english in la)	240
6. (#5 NOT occupational) and (english in la)	213
7. (#6 NOT work) and (english in la)	203
8. (#7 NOT driving) and (english in la)	94
Looked at first 50 records displayed under #8. They did not contain information about industrial accidents but items like falls in the home and the role of seatbelts in injury prevention	
Incident investigation and analysis and (english in la)	1
Accident investigation and analysis and (english in la)	12

Appendix 2

Literature terms used to search MEDLINE, including hit rate

Search term	Number of hits
Human factors method* and (english in la)	2
Accident investigation and (english in la)	19
Incident investigation and (english in la)	7
Accident analysis and (english in la)	11
Incident analysis and (english in la)	15
Management Oversight & Risk Tree (english in la)	5
Tripod Beta and (english in la)	0
Tripod Delta and (english in la)	0
Root cause analysis and (english in la)	12
Barrier analysis and (english in la)	3, but none relevant
Change analysis and (english in la)	16, but relating to changes at the cell level
Human reliability analysis and (english in la)	1
Task analysis and (english in la)	5791. Inspected the first 100 records: none related to medical accidents
Influence diagram approach and (english in la)	0
Sequentially timed events plotting and (english in la)	0
Intelligent Safety Assistant and (english in la)	58, but none relevant
Multilinear events sequencing and (english in la)	0
Technic of operations review and (english in la)	1 record in domain of occupational health
Hazard and Operability Study and (english in la)	0
Critical incident technique and (english in la)	24
Accident evolution and barrier function model and (english in la)	1 record relating to occupational health
Object – Z and (english in la)	0

Appendix 3

Summary of techniques excluded from those used in high-risk industries

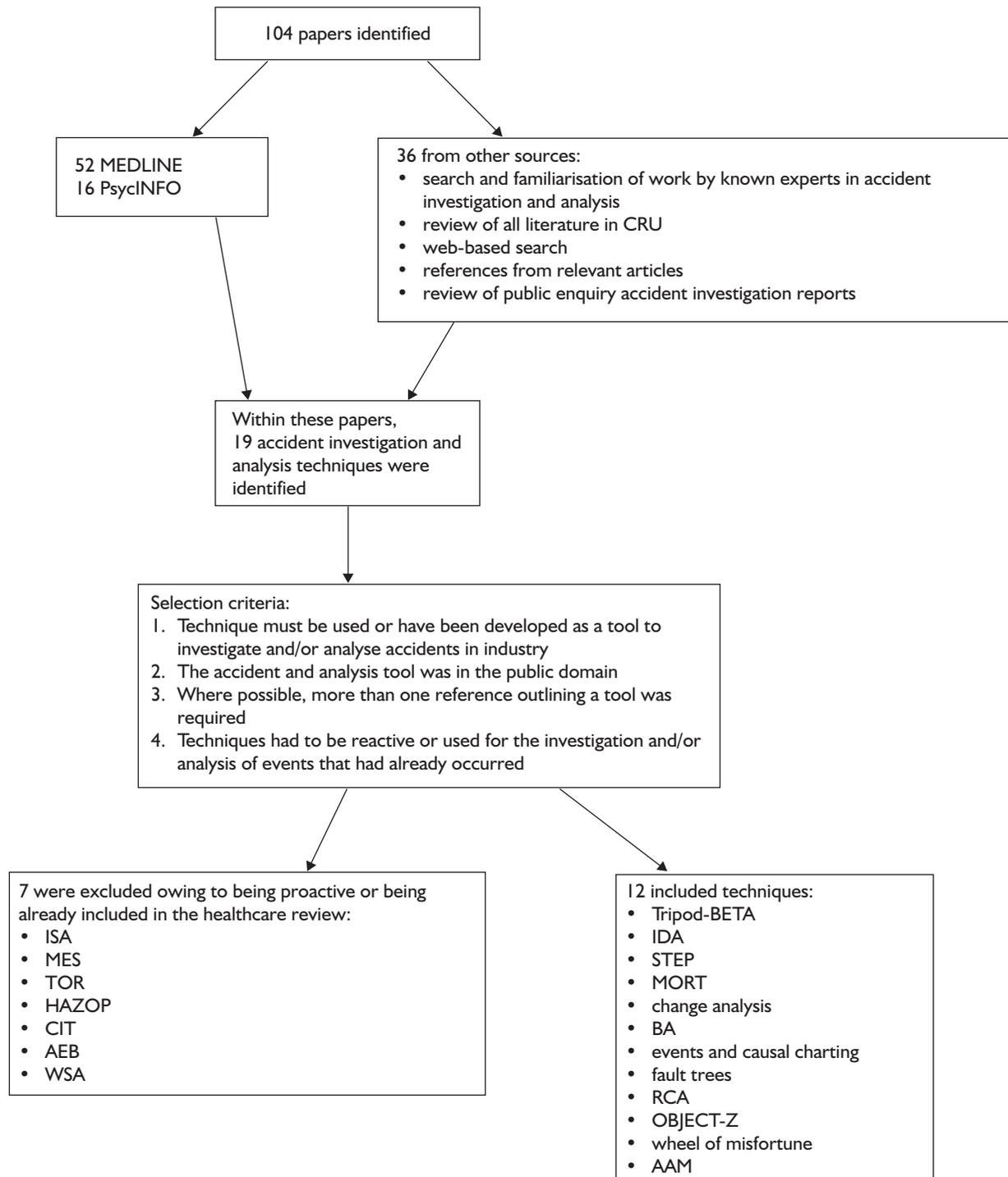
Technique	Overview and reference
Intelligent safety assistant (ISA) system	This is a computer-based system founded on the principles of MORT. The operator feeds data into ISA guided by the system. Only those topics relevant to the analysis of the incident are considered. These focus on the control of hazard sources, barriers between hazard and target and the nature of the target. The system then generates a report about the organisation and causal factors underlying the incident. If the analysis is major, the operator will be instructed to initiate an in-depth investigation. This is beyond the scope of the ISA, which is confined to learning from minor accidents. ⁴⁸
Multi-linear events sequencing (MES)	MES is a charting technique, which explores the chronological relationship of events involved in an accident. The technique arranges events on a time-line basis by using events and causal factor charting. A mishap begins when a stable situation is disturbed and ends with the last injurious event in the mishap sequence. Events in the sequence are always brought about by an actor. In the MES process, the investigator must account for the action of every actor who (or which) brought about a change in the state of the sequence. Each event is broken down until each event is described by one actor and one action. A description of the event is written on a card so that reordering of the event sequence is easy. Events are then ordered in sequence with arrows indicating a clear, sequential connection between actions. Then a logic chart is completed and events are examined in series to see where changes could be introduced to alter the process and allow remedial action to be taken. ^{49,50}
Technic of operations review (TOR)	<p>TOR was developed as a diagnostic training and mishap prevention tool, but can also be used for incident investigation. TOR analysis centres on detecting management oversights and omissions, rather than errors committed by those at the sharp end. A TOR analysis occurs once an accident has been investigated. The facts are analysed using a four-stage TOR analysis: state; trace; eliminate; seek steps. In the first stage, the TOR group is briefed about the incident. In the second stage, the group decides on the main cause of the mishap via consensus. The 'trace step' commences using the TOR analysis sheet. This sheet centres on the main and supervisory factors in an operating system, which are organised under the following headings:</p> <ul style="list-style-type: none"> • training • responsibility • control • personal traits • work groups • supervision • decision and direction. <p>Each of these is considered as the cause of the accident in turn. In the third stage, the group considers the list of factors and their contribution to the event before finally seeking to correct the circumstances that led to the accident. This technique has several features in common with expert opinion-type approaches.^{51,52}</p>

continued

Technique	Overview and reference
Hazard and operability study (HAZOP)	HAZOP was developed to identify and evaluate safety and environmental hazards and to identify operability problems, which could compromise a plants productivity. HAZOP uses a group of experienced personnel systematically to identify potential problems in a system's design and operation. It involves the detailed and structured consideration of engineering diagrams and uses a keyword system to identify problems that could occur. The review takes place using property words that refer to the physical characteristics of the item and guide words that refer to deviations that can occur and may result in safety problems. One variant of HAZOP deals more specifically with human factors issues – these are considered by the human factors practitioner in the group. Often they are best placed to offer design solutions to the problems identified by the group. It is important to consider all problems and recommended solutions in relation to each other. The Chairman of the group can often guide the team most effectively. ⁵³⁻⁵⁶
Critical incident technique (CIT)	CIT is based on the premise that the critical incident will be memorable to those working in a system. This technique is designed to be used on rare events but can also be used for those events occurring more frequently. CIT is typically used in the early stages of a large-scale analysis because it rapidly indicates the key problems within a system. There are several steps in CIT: determination of the objectives of the activity; preparation of plans for collecting factual information about the event; collection and analysis of the information. Information is collected in a variety of ways using personal and group interviews, observation, questionnaires and checklists. Then, during analysis, items of information are categorised and the level of specificity or generality of the information is determined. This is an important consideration when reporting findings. CIT should be used with other accident investigation and analysis methods, e.g. MORT, when gathering data about human operator activity within a system. ^{32,53,57-59}
Accident evolution and barrier function (AEB) model	The AEB model focuses on a particular sequence that may lead to an accident. Sequences modelled in the AEB consist of the interactions between the technical and human organisational systems that end in an accident. For an accident to occur all barrier functions in the event sequence must be broken. Therefore, the objective of an AEB analysis is to understand why barrier functions failed and how they can be reinforced in the future. There are seven steps in an AEB analysis. First, a general account of the incident is studied, then an important failure in the incident is identified. Earlier failures leading to the first identified failure are identified and incorporated into a flow diagram, as are real or hypothetical failures further down the path towards the accident. Next the diagram is completed by adding the barrier functions that did or could have prevented the accident. Each of the barrier functions is analysed and its weak and strong points are identified. The characteristics of the technical and human factors or organisational systems that may change the strength of each barrier are identified. Finally, an analysis of the incident is provided. ⁶⁰
Work safety analysis (WSA)	WSA was developed by the Safety Engineering Department of the Technical Research Centre of Finland. It is a systematic investigation of working methods, machines and working environment to identify direct incident potentials. The principle aim is to identify hazards and their contributors associated with a system. The search for accident contributors is based on breaking a task down into a sequence of steps. The search begins with a consideration of known hazard types at each of the steps. Relevant contributors to the hazards and the contributors necessary to expose a worker to the hazards are then sought. The factors contributing to a particular hazard are then studied in greater detail. All types of system functions and states should be critically considered, even normal situations. Deviations and determining factors (barrier functions) are also included in the analysis. The main search for deviations and determining factors focuses on the physical and human subsystems. The 'information' subsystem is partly reviewed and the management subsystem completely excluded. Therefore, if the management system requires consideration, other techniques such as MORT should be employed. WSA requires a multidisciplinary team effort and is completed via a worksheet. ^{52,61}

Appendix 4

Flowchart of screening process to identify techniques used in high-risk industries



Appendix 5

Summary of Benner's review⁴⁷ of accident investigation and analysis models and approaches

In 1985, Benner⁴⁷ reviewed all the accident analysis approaches used by 18 governmental agencies in the USA. This was the only paper we identified that attempted a similar review to our own and provided an invaluable template and guide for the present review. Benner identified 14 accident models and 17 methodologies for accident analysis. Benner suggests that an accident analysis model should be:

- realistic
- supportive
- definitive
- satisfying
- impose discipline
- comprehensive
- direct
- functional
- visible.

The accident investigation methodology should:

- encourage participation
- be independent

- be blame free
- support personal incentives to come up with positive suggestions
- discover health and safety problems
- increase competence
- systematically define counter measure options
- support enforcement of effective standards
- encourage governmental responsibilities
- help test accuracy of investigation outputs
- be compatible with preinvestigation methodologies.

Benner found that few of the techniques and investigation methodologies he reviewed met all the stated requirements. Benner concluded that modelling an accident as a process with multiple series of events offers the best approach for analysing safety problems. The investigation methodologies assessed found event analysis, using the STEP⁶⁴ and MORT techniques, to be the most useful tool.

Appendix 6

Search strategy: identification of publications featuring methods for the investigation of critical incidents in healthcare

The search strategy is a modification of the classical search for systematic review based on crossing concepts.

We identified three concepts that we felt would be featured in publications for examination:

- **Concept A** – methods of enquiry, investigation or analysis.
- **Concept B** – errors, omissions or mistakes.
- **Concept C** – incident(s) or adverse event(s) in clinical care.

Searching on **Concept A OR Concept B OR Concept C** generated large numbers of citations, but in our view was too low in specificity to be of value.

Searching on **Concept A AND Concept B AND Concept C** generated a small number of citations, but in our view was too low in sensitivity to be of value.

Searching on **(Concept A AND Concept B) OR (Concept A AND Concept C) OR (Concept B AND Concept C)** generated a manageable number of citations which in our view were likely to be of high sensitivity and reasonable specificity.

For each concept we aimed to be as comprehensive as possible, by including both thesaurus terms and free text terms.

The final search was constructed as follows:

**Concept A: methods of enquiry, investigation or analysis*

- | | | |
|---|------|--|
| 1 | 4922 | “RISK-MANAGEMENT”/without-subheadings, methods, organization-and-administration, statistics-and-numerical-data |
| 2 | 1236 | “SAFETY-MANAGEMENT”/without-subheadings, methods, organization-and-administration, statistics-and-numerical-data |
| 3 | 2709 | “ACCIDENT PREVENTION”/without- |

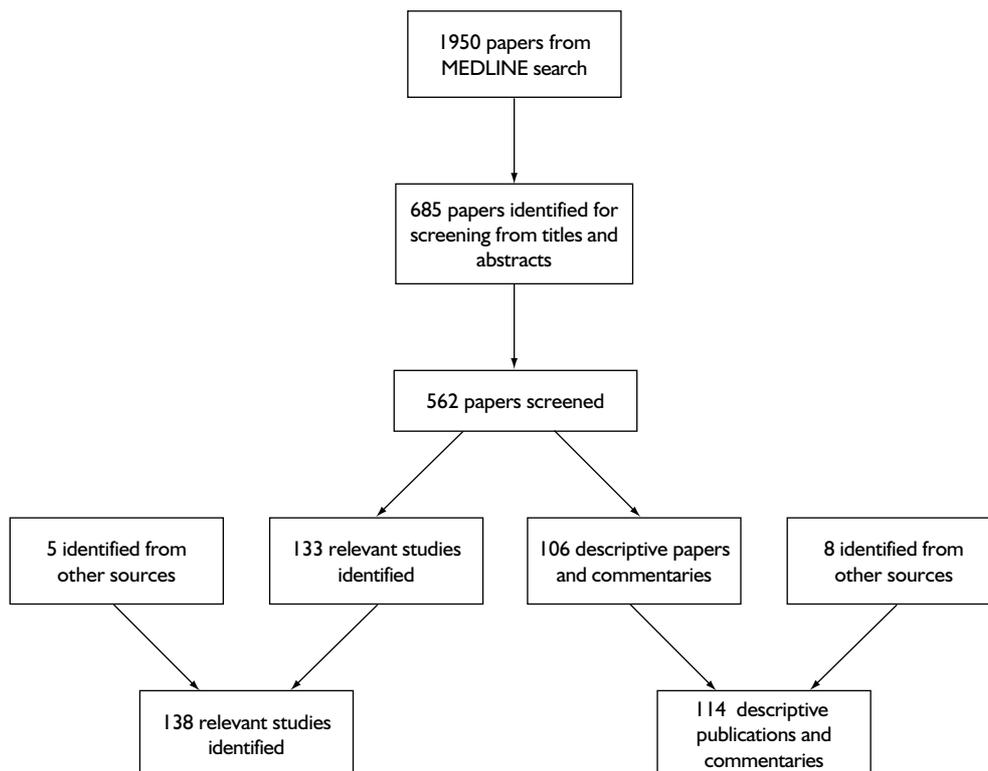
- | | | |
|----|-------|--|
| 4 | 933 | subheadings, methods, organization-and-administration, statistics-and-numerical-data
explode “EQUIPMENT FAILURE ANALYSIS”/ALL SUBHEADINGS |
| 5 | 7102 | explode “TASK-PERFORMANCE-AND-ANALYSIS”/ALL SUBHEADINGS |
| 6 | 598 | explode “SENTINEL SURVEILLANCE”/ALL SUBHEADINGS |
| 7 | 5663 | explode “MODELS,- ORGANIZATIONAL”/ALL SUBHEADINGS |
| 8 | 8604 | explode “SYSTEMS ANALYSIS”/ALL SUBHEADINGS |
| 9 | 1488 | explode “CRITICAL-PATHWAYS”/ ALL SUBHEADINGS |
| 10 | 13612 | (RISK MANAGEMENT) OR (SAFETY MANAGEMENT) OR (ACCIDENT PREVENTION) |
| 11 | 1240 | (ACCIDENT INVESTIGATION*) OR (ACCIDENT ANALYS*) |
| 12 | 934 | (EQUIPMENT FAILURE INVESTIGATION*) OR (EQUIPMENT FAILURE ANALYS*) |
| 13 | 5530 | (TASK PERFORMANCE INVESTIGATION*) OR (TASK PERFORMANCE ANALYS*) |
| 14 | 6491 | (SENTINEL SURVEILLANCE) OR (ORGANIZATIONAL MODEL*) |
| 15 | 2385 | (SYSTEMS ANALYS*) OR (CRITICAL PATHWAY* ANALYS*) |
| 16 | 3 | (SIGNIFICANT EVENT AUDIT) OR (SIGNIFICANT EVENT ANALYS*) |
| 17 | 137 | (INCIDENT INVESTIGATION) OR (INCIDENT ANALYSIS) OR (CRITICAL INCIDENT TECHN*) |
| 18 | 154 | (CONFIDENTIAL ENQUIR*) OR (CONFIDENTIAL INQUIR*) |
| 19 | 25 | (PUBLIC ENQUIR*) OR (PUBLIC INQUIR*) |
| 20 | 28 | (ROOT CAUSE INVESTIGAT*) OR (ROOT CAUSE ANALYS*) OR (ROOT CAUSE TECHN*) |

21 32	(HUMAN FACTOR* INVESTIGAT*) OR (HUMAN FACTOR* TECHN*) OR (HUMAN FACTOR* ANALYS*)		
22 38485	#1 or #2 or #3 or #4 or #5 or #6 or #7 or #8 or #9 or #10 or #11 or #12 or #13 or #14 or #15 or #16 or #17 or #18 or #19 or #20 or #21	29 4662	CLINICAL or ANAESTHETIC or SURGICAL or MEDICATION or DIAGNOSTIC) near2 (ACCIDENT? or INCIDENT? or INJURY?) (ADVERSE or UNTOWARD or UNWANTED) near2 (OUTCOME? or OCCURRENCE?)
	*** <i>Concept B: errors, omission or mistakes</i>	30 14911	(ADVERSE or CRITICAL or SIGNIFICANT or UNTOWARD or UNWANTED) near2 (INCIDENT? or EVENT?)
23 25731	explode "MEDICAL-ERRORS"/ without-subheadings, adverse-effects, classification, mortality, methods, nursing, prevention-and-control, psychology, statistics-and-numerical- data	31 27115	(UNTOWARD or UNEXPECTED or MATERNAL or PERINATAL or NEONATAL or INFANT or PADIATRIC or PEDIATRIC ORPERIOPERATIVE OR SURGICAL OR DIABETIC OR ASTHMA) NEAR2 (DEATH* OR MORTALITY)
24 3936	explode "IATROGENIC-DISEASE"/ without-subheadings, epidemiology, prevention-and-control	32 47267	#28 or #29 or #30 or #31
25 16293	(MEDICAL or SURGICAL or OBSTETRIC or NURSING or ANAESTHETIC or SURGICAL or MEDICATION or DIAGNOSTIC) near2 (ERROR\$ or MISTAKE*)		*** <i>Concept (A+B) or (B+C) or (A+C)</i>
26 4305	IATROGENIC near2 (DISEAS* or ILLNESS*)	33 968	#22 and #27
27 30675	#23 or #24 or #25 or #26	34 734	#22 and #32
	*** <i>Concept C: incidents or adverse events in clinical care</i>	35 567	#27 and #32
28 1531	(MEDICAL or SURGICAL or OBSTETRIC or NURSING or	*36 1961	#33 or #34 or #35

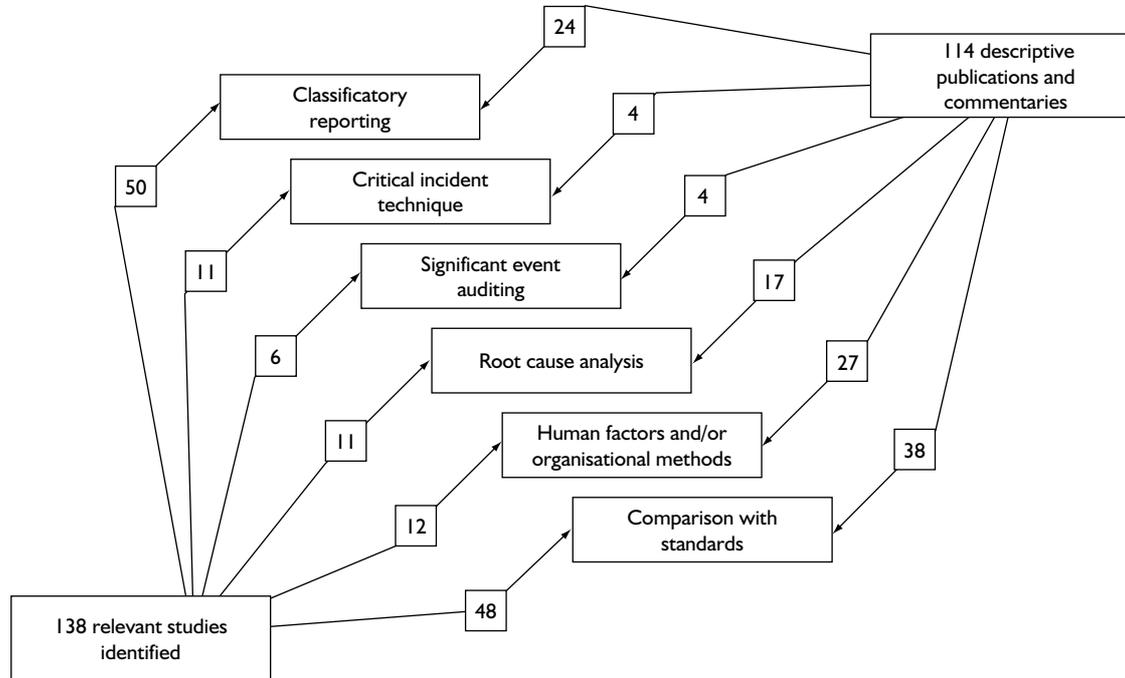
Appendix 7

Selection of relevant literature and classification of techniques

Selection of relevant literature



Classification of techniques in healthcare



Appendix 8

Appraisal form

Author _____ Year _____ Journal _____ PUBREF

Appraised by: SR MW AB CV SA

If more than one response is applicable to any question, then tick all relevant boxes

A. DETAILS OF THE APPRAISED PUBLICATION

1. Country setting

- [1] Multi-national
- [2] UK
- [3] Europe
- [4] Australasia
- [5] N America
- [6] Africa
- [7] Asia
- [8] other _____
- [9] not clear

2. Level of care

- [1] primary or community care
- [2] secondary or specialist care
- [3] pharmacy
- [4] laboratory
- [5] radiology
- [6] other _____
- [9] not clear

3. Speciality _____

4. Source of critical incidents

- [1] staff recall
- [2] participant/non participant observation
- [3] reporting system (specify)
 - [31] voluntary
 - [32] obligatory
 - [33] statutory
 - [39] not clear
- [4] review/occurrence screening
- [5] claims/patient complaints
- [6] other _____
- [9] not clear

5. Number of critical incidents featured _____

6. Summary description of critical incidents

featured _____

7. Class of critical incidents featured

- [1] unrestricted within the named specialty
- [2] in a patient group (e.g. age, sex, ethnic group)
- [3] in a diagnostic group (e.g. asthma, pregnancy)
- [4] associated with an intervention (e.g. drug-related, associated with a surgical procedure)
- [5] with a common proximate cause
- [6] with a common contributory cause
- [7] other _____
- [9] not clear

8. Severity of critical incidents featured (injury suffered)

- [1] patient died
- [2] permanent injury
- [3] temporary injury
- [4] no injury
- [5] other _____
- [9] not clear

9. Severity of critical incidents featured (treatment required)

- [1] major intervention required
- [2] some intervention required
- [3] no intervention required
- [4] other _____
- [9] not clear

B. CONDUCT OF THE INVESTIGATION(S)**10. Agency responsible for the investigation(s)**

- [1] professional organisation
- [2] healthcare institution
- [3] academic department
- [4] government or state
- [5] insurance company
- [6] legal representatives
- [7] other _____
- [9] not clear

11. Organisational relations of agency to unit investigated

- [1] internal to the healthcare unit
- [2] external to the healthcare unit
- [3] external to the organisation(s)
- [4] other _____
- [9] not clear

12. Person(s) responsible for field investigation

- [1] individual(s) reporting the incident
- [2] individual(s) designated to conduct investigation
- [21] internal to the healthcare unit
- [22] external to the healthcare unit
- [23] external to the organisation(s)
- [29] not clear
- [3] other _____
- [9] not clear

13. Profession(s) of person(s) responsible for field investigation

- [1] medical
- [2] nursing
- [3] psychology
- [4] management
- [5] other _____
- [9] not clear

14. Training/experience in accident investigation

- [1] previous experience
- [2] previous training
- [3] written guidance
- [4] other _____
- [9] not clear

15. Reference to established technique for accident investigation?

- [1] critical incident monitoring (e.g. AIMS)
- [2] critical incident method (e.g. Flanagan)
- [3] significant event auditing (e.g. Pringle)
- [4] root cause analysis (e.g. JHACO)
- [5] contributory factors models (e.g. Vincent)
- [6] audit models (e.g. CEDSI)
- [7] other _____
- [9] not clear

16. Reference to established investigative framework?

- [1] reporting systems (e.g. AIMS, MDA)
- [2] occurrence screening studies (e.g. HMPS)
- [3] population based incidence studies: patient denominator (e.g. review of 1000 operations)
- [4] population based incidence studies: process denominator (e.g. review of 1000 prescriptions)
- [5] confidential enquiry (e.g. CESDI)
- [6] medico legal investigations (e.g. MDU series)
- [7] other _____
- [9] not clear

C. DATA COLLECTION AND CAUSAL ANALYSIS**C1. INTERVIEWS AND SELF REPORTS** [1] Yes [9] Not clear**17. Person(s) interviewed/reporting**

- [1] patient
 [2] relative
 [3] staff (specify which)
 [31] administrative
 [32] medical
 [33] nursing
 [34] technical
 [35] paramedic
 [36] other _____
 [39] not clear
 [4] other _____
 [9] not clear

18. Recruitment of informants

- [1] entirely voluntary
 [2] institutional obligation
 [3] statutory obligation
 [4] other _____
 [9] not clear

19. Protection of informants

- [1] open or public enquiry
 [2] confidentiality assured
 [3] anonymity assured
 [4] protection from subpoena
 [5] other _____
 [9] not clear

20. Interview/reporting technique(s) used

- [1] reporting (specify which)
 [11] paper based
 [12] electronic
 [19] not clear
 [2] interview (specify which)
 [21] face to face
 [22] telephone
 [29] not clear
 [3] group interview
 [4] other _____
 [9] not clear

21. Type of interview/report

- [1] narrative description
 [2] questionnaire
 [21] closed questions
 [22] open questions
 [29] not clear
 [3] interview (specify which)
 [31] semi-structured
 [32] open interview
 [39] not clear
 [4] group interview (specify which)
 [41] nominal group
 [42] focus group
 [43] other group _____
 [49] not clear
 [5] other _____
 [9] not clear

22. Additional techniques used (interviews)

- [1] conceptual framework
 [2] explicit criteria
 [3] barrier analysis
 [4] process flow diagram
 [5] fault tree
 [6] other _____
 [9] not clear

23. Interval between incident and investigation

(specify) _____
 [9] not clear

24. Mean number of interviewees/case _____ [9] not clear**25. Mean duration of each interview _____** [9] not clear**26. Methods used for interview/report critique**

- [1] established guidelines
 [2] conceptual framework
 [3] explicit criteria
 [4] expert opinion
 [5] other _____
 [9] not clear

27. Quality assurance: data collection

- [1] scribe accompanies interviewer
 [2] audio record/transcribed account
 [3] informant confirms account
 [4] triangulation between informants
 [5] other _____
 [9] not clear

28. Quality assurance: data critique

- [1] consensus panel
 [2] duplicate assessment and interpretative checks
 [3] inter-rater reliability documented
 [4] other _____
 [9] not clear

C2. PRIMARY DOCUMENT REVIEW

[1] Yes [9] Not clear

29. Source of document data

- [1] medical record
 [2] prescribing record
 [3] protocol(s)
 [4] training manuals
 [5] other _____
 [9] not clear

33. Methods used for document critique

- [1] established guidelines
 [2] conceptual framework
 [3] explicit criteria
 [4] expert opinion
 [5] other _____
 [9] not clear

30. Methods used for data extraction

- [1] narrative summary
 [2] data abstraction form
 [3] coding sheet/precoded
 [4] other _____
 [9] not clear

34. Quality assurance: data collection

- [1] duplicate abstraction and interpretative checks
 [2] inter-rater reliability documented
 [3] other _____
 [9] not clear

31. Interval between incident and investigation

(specify) _____
 [9] not clear

35. Quality assurance: data critique

- [1] consensus panel
 [2] duplicate assessment and interpretative checks
 [3] inter-rater reliability documented
 [4] other _____
 [9] not clear

32. Time taken per document set _____

- [9] not clear

C3. PHYSICAL/LOGISTIC ASSESSMENT

[1] Yes [9] Not clear

36. Source of physical/logistic data

- [1] site visit
 [2] site maps and plot plans
 [3] equipment checks
 [4] contacts with other manufacturers/
healthcare organisations with
similar processes
 [5] commercial materials
 [6] other _____
 [9] not clear

- [3] inspection (checklist)
 [4] inspection (implicit standards)
 [5] equipment testing
 [6] video/photographs
 [7] other _____
 [9] not clear

38. Interval between incident and investigation

(specify) _____
 [9] not clear

37. Observational techniques used to gather data

- [1] observation (checklist)
 [2] observation (implicit standards)

39. Time taken for assessment _____

- [9] not clear

40. Methods used for judging physical/logistic aspects

- [1] established guidelines
- [2] conceptual framework
- [3] explicit criteria
- [4] expert opinion
- [5] other _____
- [9] not clear

41. Quality assurance: data collection

- [1] duplicate observations and interpretative checks between assessors

- [2] inter-rater reliability documented
- [3] other _____
- [9] not clear

42. Quality assurance: data critique

- [1] consensus panel
- [2] duplicate assessment and interpretative checks
- [3] inter-rater reliability documented
- [4] other _____
- [9] not clear

D. PRESENTATION AND INTERPRETATION OF DATA**43. How are the outcomes of the critical incident investigation(s) formulated**

- [1] focus on clinical and pathophysiological issues
- [2] classification of different types of errors
- [3] elucidation of cause(s) of errors
- [4] other _____
- [9] not clear

44. Do the outcomes relate to any underlying model of accident causation?

- [1] active and latent failures (e.g. Reason)
- [2] contributory factors (e.g. CRU/ALARM)
- [3] chain of causation (e.g. AEB, Toxic cascade)
- [4] decision making models (e.g. Rasmussen)
- [5] other _____
- [9] not clear

45. How is the data synthesised

- [1] general discussion
- [2] synthesis of narrative
- [3] numerical summaries
- [4] other _____
- [9] not clear

46. Are recommendations made which might lead to improved patient safety?

- [1] discussion of methods/approach used
- [2] discussion of size and scope of problems
- [3] general suggestions for improvement
- [4] specific solutions based on *errors* identified
- [5] specific solutions based on *causes* identified
- [6] other _____
- [9] not clear

47. Implementation of changes?

- [1] no discussion of implementation
- [2] statement of intention for implementation
- [3] description of implementation of changes
- [4] implementation and *informal* evaluation
- [5] implementation and *formal* evaluation
- [6] other _____
- [9] not clear

Appendix 9

Technique descriptions

Australian Incident Monitoring System (AIMS)

AIMS is intended to provide a national mechanism for reporting problems arising from health management for collecting, classifying and analysing data. AIMS is run by the Australian Patient Safety Foundation (APSF), a non-profit, independent organisation for promoting patient safety in Australia.

Historical background

The origins of the APSF derive from an incident monitoring study in anaesthesia (AIMS-Anaesthesia) that began in 1988. In 1994, the system was broadened to develop an incident monitoring model that could be used on an institutional basis, rather than being specialty focused. A pilot study was conducted in six tertiary facilities in different Australian States. AIMS, introduced in 1996, is a mechanism for any incident (actual or potential) in healthcare to be reported, using a single standard form. Incidents are then classified on corresponding software, using two unique classification systems developed by the APSF.

AIMS has since been implemented in several Australian States and also individual health units. In 2000, the system was introduced into a healthcare site in New Zealand and it may be implemented in other countries. A new, simpler, more comprehensive version, with the option of reporting electronically via the web, AIMS+, is currently being trailed and introduced. Specialty-based pages on these forms have been developed for anaesthesia, intensive care, emergency medicine, surgery, pathology, general practice and so on.

Data from AIMS are classified using the Generic Occurrence Classification (GOC), a classification which evolved directly from AIMS data. In essence, it is a large tree structure with multiple choices at a number of levels. Although it has the virtue of allowing very precise coding of the minutiae of incident circumstances, it is highly complex and earlier versions lacked an overall classificatory structure. As part of a process of

review and improvement, the GOC is currently being redeveloped to provide simpler entry of data into the classification, and more effective analysis and reporting.

An important feature of the GOC is that it provides a common framework into which information from various sources (such as coroners' recommendations, complaints, medico-legal 'closed-claims', retrospective medical record analyses, incident reports, structured reviews of the literature and routine collection of information, e.g. automated anaesthetic record, routine reporting of problems) are included.

Essential features

The AIMS report forms consist of two components: part A – a confidential incident report form; and part B – an anonymous incident monitoring section.

Incident reporting – part A

For incident reporting at health unit sites, incident information is collected throughout the health unit on paper form and data are then entered and coded using the APSF software. These data are protected from legal discovery under Australian Commonwealth Quality Assurance legislation. The coding of the information provides the means for understanding the underlying causes of the incident and for analysing the contributing factors. This analysis supports the preparation of a range of comprehensive reports to assist management in identifying problems and remedial action.

Incident monitoring – part B

APSF collects data from the health units with all identifying information removed. These anonymous data are then entered into an aggregated database that allows all health units to receive comparative information linking their performance with other 'like' organisations. The de-identified data support the aggregation of low-frequency events at international level and are therefore very effective for identifying and coordinating system-based strategies to better detect, manage and prevent problems.

Theoretical basis

The analysis of AIMS data is broadly based on a number of theories, including those of the Gaba, Reason, Norman and Rasmussen groups.¹⁴¹ Norman's slip/mistake distinction, Reason's categories of knowledge-based mistakes, rule-based mistakes and skill-based slips and lapses, along with the conceptual framework put forward by Rasmussen were modified and further expanded to result in Runciman's model, where an error occurs anywhere in the chain from intention through planning action to outcome. This was used to analyse the AIMS data. Whether such specific cognitive analyses can really be derived from incident reports is not clear, although certainly some incidents may suggest that certain types of error occurred.

Applications in healthcare

AIMS uses a classification system of software specifically designed for 'things that go wrong' in healthcare. The software elicits the key clinical

information and places the event in context and records the contributing factors, both system-based errors and human errors. An earlier version of this list of contributing factors is included in *Box 6*. Some of the current contributing factors that are recorded are:

- management decisions
- infrastructure, working conditions
- communications, records
- staff quantity and quality
- supervision and tasking
- equipment availability and/or suitability
- policies, protocols and pathways.

The majority of appraised studies are in anaesthetics, with additional studies being carried out in family practice, psychiatry, intensive care and obstetrics. The number of incidents studied ranges from 35 to 1556, and most papers are restricted to one particular specialty. The outcomes of the events vary in severity and

BOX 6 Contributing factors (Part B of earlier version of the AIMS reporting form)

System-based factors	Personal cognitive factors
<p>Management or corporate culture</p> <ul style="list-style-type: none"> <input type="checkbox"/> Pressure to proceed <input type="checkbox"/> Result of poor management decisions <p>Equipment/monitors/support services</p> <ul style="list-style-type: none"> <input type="checkbox"/> Lack of suitable bed or facility <input type="checkbox"/> Lack of suitable equipment <input type="checkbox"/> Lack of suitable monitor <input type="checkbox"/> Lack of other support services <input type="checkbox"/> Malfunction of equipment <input type="checkbox"/> Malfunction of monitor <input type="checkbox"/> Malfunction of other support services <p>Supplies and labelling</p> <ul style="list-style-type: none"> <input type="checkbox"/> Lack of supplies <input type="checkbox"/> Unsuitable supplies <input type="checkbox"/> Poor labelling <p>Staff</p> <ul style="list-style-type: none"> <input type="checkbox"/> Insufficient staff for job or task <input type="checkbox"/> Insufficient training for the job or task <input type="checkbox"/> Staff new or unfamiliar <p>Protocols/policies</p> <ul style="list-style-type: none"> <input type="checkbox"/> Policy/protocol poor or non-existent <input type="checkbox"/> Failure to provide/enforce/protocol <input type="checkbox"/> Failure to instruct/orientate staff members <p>Team cognitive factors</p> <ul style="list-style-type: none"> <input type="checkbox"/> Communication problem <input type="checkbox"/> Lack of supervision <input type="checkbox"/> Poor team work <input type="checkbox"/> Inappropriate behaviour or action 	<p>Knowledge based</p> <ul style="list-style-type: none"> <input type="checkbox"/> Inadequate or wrong knowledge <input type="checkbox"/> Inexperience or inadequate training <input type="checkbox"/> Unfamiliar environment or equipment <input type="checkbox"/> Unfamiliar policies or protocols <p>Rule based</p> <ul style="list-style-type: none"> <input type="checkbox"/> Failure to apply basic medical or patient care <input type="checkbox"/> Failure to synthesise or act on available information <input type="checkbox"/> Failure to check equipment <input type="checkbox"/> Failure to follow policy or protocol <input type="checkbox"/> Use of wrong policy or protocol <input type="checkbox"/> Did not attend (when asked to) <p>Skill based</p> <ul style="list-style-type: none"> <input type="checkbox"/> Haste <input type="checkbox"/> Distraction <input type="checkbox"/> Inattention or absent mindedness <input type="checkbox"/> Fatigue <input type="checkbox"/> Stress <input type="checkbox"/> Unwell <p>Technical</p> <ul style="list-style-type: none"> <input type="checkbox"/> Inexperience with procedure <input type="checkbox"/> Technical problem with procedure <p>Violation</p> <ul style="list-style-type: none"> <input type="checkbox"/> Took a 'short cut' or broke the rules <input type="checkbox"/> Took a risk <p>Chance</p> <ul style="list-style-type: none"> <input type="checkbox"/> Chance event <input type="checkbox"/> Unexpected allergy or anaphylaxis

treatment required. All studies relied on individuals, usually clinicians or nursing staff, voluntarily reporting the incident, but were analysed by individuals outside the organisation. Forms used for reporting are available on the AIMS website. No other form of data collection was used in key publications.

Results usually provided a description of clinical material, a classification of different types of error or a consideration of the causes of error or sometimes a combination of two or three of the outcome formulations. Few studies referred to underlying published models of accident causation. Most studies discussed a combination of some of the following: the methods or approach used, the size of the problem, general suggestions for improvements and solutions based on both errors and causes identified. Some studies gave descriptions of changes to practice, but most did not even discuss any implementation of changes.

Strengths and limitations

Strengths

- The system ensures confidentiality and anonymity, and therefore staff are more likely to report the incident (there is some legal protection).
- Identification of common factors, trends from aggregated data.
- Such identification can assist to justify changes or proposals that require funding.
- National and international system enables comparative data analysis.

Limitations

- The level of information is dependent on the amount of detail provided by the person reporting the incident.
- Cannot further investigate that particular incident (unless done so at a local level).
- Only one type of data is collected and analysed – secondary documentation, giving no opportunity to check accuracy.

Data sources

There are over 100 publications related to AIMS in peer-review academic and medical journals.

Exemplar papers

Morris and Morris, 2000¹¹⁵
 Steven and colleagues, 1999¹¹⁶
 Sinclair and colleagues, 1999¹¹⁷
 Chen and colleagues, 1998¹¹⁸

Supporting papers

Vinen, 2000¹¹⁹

Runciman and colleagues, 1993¹⁴¹
 Runciman and colleagues, 1993¹⁴²

Critical incident technique (CIT)

Historical background

The critical incident technique was first described by Flanagan,³² who described it as a set of principles for gathering data rather than a rigid set of rules. In its original form, it consists of a “set of procedures for collecting direct observations of human behaviour in such a way as to facilitate their potential usefulness in solving practical problems ... the technique outlines procedures for collecting observed incidents having special significance and meeting systematically defined criteria.” Flanagan set out a series of defined steps to collect and analyse critical incidents, specifying the aims of the work to be studied, the incidents to be collected and methods of data collection, analysis and interpretation. The technique was applied to a variety of areas, mostly with the aim of describing and specifying the key skills involved in a particular kind of work, often by collecting and contrasting specific instances of skill or lack of skill. For instance, an early study asked respondents to identify specific instances of combat leadership which had made a difference in action. Flanagan’s aim was to move beyond opinions and informal estimates to a more systematic record of specific behaviours recorded by those in the best position to make the necessary observations. Flanagan also notes that although the procedures for collecting the factual data appear sound, methods of classification of incidents and interpretation of the findings remained relatively subjective.

In healthcare, a considerable number of studies refer to the CIT and to Flanagan’s original paper. However, few make specific use of his principles and the reference to the technique sometimes seems little more than a justification for collecting information on a series of unrelated incidents. The true ancestor of most healthcare papers is Cooper and colleagues’ pioneering study on preventable anaesthetic mishaps.¹²⁰ They state specifically that their study is a modification of the CIT. Critical incidents were defined by Cooper and colleagues as an “occurrence that could have led (if not discovered or corrected in time) or did lead to an undesirable outcome, ranging from increased length of hospital stay to death or permanent disability”. This approach was aimed at identifying specific errors in anaesthetic practice,

or factors associated with those errors, rather than the more usual set of patient-related operative risk factors. The methods of most healthcare studies are closer to those of Cooper and colleagues than to Flanagan, and we will use Cooper and colleagues' paper as our model for the CIT in healthcare. There are, however, some exceptions. Waterston's study of critical incidents in child health aimed to identify the range of skills needed for doctors working in child health, and is much closer to Flanagan's original technique in both purpose and method.^{31,121}

Essential features

Critical incidents may be collected by a variety of methods, but are usually based on a system of voluntary reporting. Early studies^{120,143} initially used interviews with members of staff, sometimes focusing on open questions about critical incidents and in a second phase using more targeted questions about specific types of incidents. Later studies generally relied on voluntary reporting of incidents using a questionnaire with both free text and specific questions. Cooper and colleagues¹¹³ describe the search for causal patterns as "primarily an intuitive process". Incidents are broadly classified as human or equipment error; types of human error; by the nature of the activity, the nature of the problem occurring (e.g. disconnection, drug overdose) and severity of outcome. Cooper and colleagues also discuss "associated factors", such as fatigue or inadequate experience, which describe circumstances that may have contributed to the error or adverse outcome. Importantly, Cooper and colleagues provide a table of strategies for prevention of incidents based not only on the specific clinical problems identified but also on the more general problems underlying a number of different kinds of errors.

Later papers follow the broad outlines of Cooper and colleagues' approach fairly closely, although with different emphases and level of detail. Short and colleagues¹⁴⁴ report similar types of analysis to those of Cooper and colleagues, although with more emphasis on clinical and equipment factors and less on human factors. In later anaesthetic papers, it is also apparent that there is more routine use of the technique, as it moves from being an instrument of research to part of more general quality assurance programmes.

Theoretical basis

No specific theoretical basis is adduced for the critical incident studies, although the work of Flanagan is routinely acknowledged. Flanagan, however, although providing useful principles for

the collection of data, does not claim to provide a theoretical framework for understanding the causes of incidents. Cooper and colleagues' work, however, substantially extended the traditional approach to anaesthetic misadventure, drawing as it does on human factors work and the psychology of human error. Cooper and colleagues 1984 paper¹¹³ provides a remarkably sophisticated analysis of the many factors that contribute to errors and adverse outcomes and provides the foundation of later work in anaesthesia and elsewhere. His use of associated factors for instance foreshadows Reason's⁸⁵ more general descriptions of error-producing conditions and Vincent and colleagues' "contributory factors",¹⁴⁵ even though these were not directly derived from Cooper and colleagues' work.

Applications in healthcare

Appraisal of key papers in healthcare shows that the majority of studies concern anaesthetics with a very wide range in the number of incidents studied (from 1 to 1089). The precise descriptions of the critical incidents featured are highly variable, sometimes specifying certain types of outcome of varying severity, sometimes a particular type of error or presumed causation. This is not necessarily problematic as the technique is robust with respect to different types of incidents, but does make comparison of studies (as opposed to techniques) problematic. Most studies are carried out by clinicians of the relevant specialty, relying primarily on interviews following voluntary incident reporting. The nature of the interviews is not usually well specified, and where questionnaires are used few details are given. Generally there is very little information on the methods of study or of any specific technique of investigation or analysis. Results usually combine a description of clinical material with an analysis of different types of error and, for some studies, a consideration of the causes of error. Most studies discuss error prevention and make general recommendations, but only two describe any actual changes to practice.

The most substantial and wide-ranging studies have been in anaesthesia, where the approach has had considerable influence. Cooper and colleagues, reflecting on the impact of the studies, noted that "they seem to have stirred the anaesthesia community into recognising the frequency of human error in the specialty and generated great interest in reducing the rate of mistakes by instituting many different preventative strategies." The original anaesthetic critical incident studies have been duplicated in the UK,

The Netherlands and Australia and were influential in the formation of the AIMS project (discussed separately).

Outside anaesthesia studies have been carried out in intensive care,²⁸ on deaths in general practice²⁴ and uncomfortable prescribing decisions.²⁵ However, no other specialty has produced a sustained series of studies in which an understanding of the causes of incidents has been followed by the introduction of preventative measures.

Data sources

Exemplar papers

Cooper and colleagues, 1978¹²⁰

Cooper and colleagues, 1984¹¹³

Supporting papers

Flanagan, 1954³²

Anon., 1988¹²¹

Significant event auditing (SEA)

Background

Reviews of individual cases have long been carried out in medicine. Typically these will have focused on the diagnosis and management of disease and clinical teams will have reflected on the difficulties and dilemmas encountered in managing a particular patient. Significant event auditing involves 'audit' of a single case or event, where things went badly, or sometimes where things went well.⁹⁹ SEA was not designed to address patient safety issues, but as a quality improvement technique which can be applied more generally to improving the organisation and delivery of care. It is widely used as an educational approach in the general practice setting in the UK, where adverse events including deaths, patient complaints or administrative mistakes may be used as a starting point for significant event auditing.

Defining the descriptive group

Significant event auditing has been defined as a process in which individual episodes (when there has been a significant occurrence either beneficial or deleterious) are analysed in a systematic and detailed way to indicate what can be learned about the overall quality of care and to indicate changes that might lead to future improvements.⁹⁹ In practice, significant event audit meetings are conducted with groups of people or teams as a work based reflective activity. It is potentially anti-hierarchical and the effective functioning of the participating small group is generally accepted as

a prerequisite for successful significant event auditing.¹²²

Essential features

One member of the team presents the details of an incident considered significant and leads the SEA process¹²³ or an outsider, skilled in managing small group work, facilitates the process.¹²² The account of what happened is presented with assistance from clinical notes if relevant. Frameworks have been suggested to help guide the analysis of the case and leading to action points. For instance, Pringle and colleagues⁹⁹ suggest the following agenda for a significant event meeting: when presenting the case, review of acute/immediate problems, review of possibilities for prevention, plan of action and follow-up, implications for family/community (if any), interface issues (if any), team issues (if any), summary and recommendations (which should reflected changes in policy or procedures designed to remedy any deficiencies in the quality of care exposed by the audit). The importance of SEA is as a vehicle for identifying opportunities for improvement,⁹⁹ or for creating a safe environment for members of staff to share worries and concerns or to congratulate each other on good practice.

Pringle and colleagues⁹⁹ carried out a study in which 10 general practices in Lincolnshire and Manchester held six or more meetings over a year to discuss significant events occurring in their practices. "Any event thought by anyone in the team to be significant in the care of patients or the conduct of the practice should be open for consideration." The study protocol required practices to consider diabetes care and doctor availability as possible problem areas, but in addition they were encouraged to apply the techniques to other aspects of practice.

A total of 489 clinical events (50 events per practice per year) were recorded; 161 were selected as cases for review and included 41 of sudden death, cardiovascular or cerebrovascular disease; 31 events in the care of patients with cancer (mainly around diagnosis); 35 concerned with care of chronic diseases, 15 related to contraception and women's health; 12 related to suicide, attempted suicide, violent deaths and trauma; and 13 related to infections, including four of meningitis.

Practices were also asked to discuss significant events that were primarily administrative in nature. These are also of interest as many represent flaws which might put patients at risk of

adverse outcomes. A total of 345 significant administrative events were recorded (35 events per practice per year) and 94 were discussed; 17 were patients' complaints, 11 arose in connection with the prescribing or dispensing of drugs, six related to practice policies and three related to home visits. As with the clinical events, the types of administrative events described are biased by the way in which they were selected for discussion, but are likely to represent those of greatest interest to the primary care teams involved.

The study by Westcott and colleagues¹²³ included detailed qualitative research to assess the perceptions of SEA by participants. Twelve participants from a range of SEA groups participated in confidential interviews with an experienced qualitative researcher. In this study, participants said that they welcomed the opportunity SEA had brought for them to raise problems and difficulties that they had been previously unable to voice. Furthermore, they reported that having participated in SEA had helped to create trust, understanding and appreciation between staff and, through this, enhanced the work environment and improved morale.

There were also further difficulties, especially finding time and ensuring ongoing support for the meetings, concerns about boundaries and for some staff a continuing sense of concern about speaking out, particularly when all the topics came from one professional group, such as the doctors. Employed staff especially faced a conflict between personal and professional matters on various issues and there was less ownership amongst part-time staff. Finally, leadership and management of the process of SEA could not be assumed, but needed to be sought out and supported.

Theoretical basis

SEA is said to be derived from the CIT developed by Flanagan³² for the investigation of accidents and near misses in the American Air Force. The main feature in common is the study of an incident. Group-based discussions are not a feature of the CIT. Also, in the CIT, the classification of emergent findings was 'grounded' (there was no pre-existing framework) and the method depended on cumulating a group of cases until the underlying causes of particular events were understood (sampling to exhaustion).

Applications in healthcare

SEA is actively promoted as a vehicle for quality improvement in the UK general practice setting.

This is largely on the basis of its likely applicability in this setting. GPs are responsible for managing the delivery of care in addition to providing clinical care to individual patients. Regular team meetings where patient safety, clinical effectiveness, patient satisfaction, staff conditions and administrative efficiency are considered provide a useful framework for informing practice management. Many potential benefits such as the ability to stimulate clinical audit, to inform commissioning and improve quality have been documented.^{99,124} It has also been argued that SEA can improve the morale of primary care teams and improve communication and working environments, but only if it is sensitively and effectively managed.¹²³

Strengths and limitations

SEA can provide a valuable opportunity to develop quality improvement activities further in any clinical setting where there are regular meetings of work-based teams. In the absence of such meetings, changes in the organisation are required in order to proceed. Some clinical settings are more hierarchical than others and clinicians may be closed to the views of other members of staff. Experience shows that over time the culture and communication of teams participating in SEA can change. However, in some settings SEA may simply not be acceptable.

The educational value of SEA (at least in well-functioning and highly motivated teams with time and resources available) is not disputed, but the capacity of the significant event audit to promote improvement in practice has not as yet been demonstrated. This will depend on the links between the generation of recommendations and their implementation. Significant event auditing "is complementary to and not a substitute for more conventional audit methods. It is a good screening tool for identifying problems in the quality of health care and its delivery, and in helping to set an audit agenda. Its inclusion in a practice's audit programme balances the intellectual and the emotional content of performance review." In relation to improving the quality of care, SEA is, however, an information-gathering strategy, not a change strategy as such.

Data sources

Exemplar studies

Pringle and colleagues, 1995⁹⁹
Westcott and colleagues, 2000¹²³

Supporting papers

Flanagan, 1954³²

Robinson and colleagues, 1995¹²²
Pringle, 1998¹²⁴

Root cause analysis (RCA)

Historical background

RCA was originally developed more than 30 years ago within the industrial sector (e.g. transport, chemical and nuclear industries) as a methodology to investigate serious accidents. However, in recent years it has become less widely used, as these industries have developed their own internal methods for investigating accidents that make use of some RCA tools and techniques specific to their own industry or organisation. Furthermore, investment in improving safety in these high-risk industries has focused more on prospective risk assessments to prevent accidents, rather than relying on the more reactive approach of RCA as a means to improve safety. Consequently, the frequency of serious adverse incidents in these industries is rare, because any system failures have been identified and rectified before their ability to make an impact on the organisation. However, in the area of healthcare, in both the USA and UK, there is currently huge interest in the use of RCA tools as a mechanism to investigate serious incidents. This has been fuelled by the publication of key documents such as organisation with a memory (OWAM)¹ in the UK and the work on RCA undertaken by the JCAHO in the USA.

Since 1996, JCAHO has required hospitals to use the RCA process to investigate serious incidents such as inpatient suicide, infant abductions and deaths related to delays in treatment. They outline a 21-step process to achieve a successful RCA and they also describe a number of RCA tools and techniques that can be used by the incident investigator to collect data and analyse the system failures. The NPSA in the UK has recently been set up to coordinate and enhance organisational safety learning through the investigation and analysis of serious adverse events in UK hospitals. In 2002 they piloted RCA training with 30 pilot site organisations, to determine whether the RCA approach is a useful methodology to apply in the UK. This intervention is currently being evaluated by the NPSA and if the training has been useful with an improvement in the quality of incident investigation reports as a direct consequence of this training, then the NPSA will direct national training in this area.

Essential features

The JCAHO document provides the most

comprehensive guide on how to complete a successful RCA (see *Figure 4* for an outline of the RCA process). It can be seen that the JCAHO process of RCA is based on 21 separate steps, which makes it an extremely thorough approach. However, in reality it appears that organisations do not utilise all components of this process as the investigation would be lengthy, unwieldy and resource intensive. Consequently, some papers reviewed have outlined a simplified approach, where many of the component steps within the JCAHO document have been integrated, for example Amo¹⁴⁶ has identified seven steps in RCA. These essentially centre on the following steps: (1) identify the incident to be analysed; (2) organise a team to carry out the RCA; (3) study the work processes; (4) collect the facts;

1. Organise a team
2. Define the problem
 - Brainstorm
 - TA and FMEA
 - Gantt chart
3. Study the problem
 - Witness statements
 - Observation
 - Protocols
 - Equipment, etc.
4. Determine what happened
5. Identify contributing process factors
 - Control chart
 - Brainstorm
 - Flowchart
 - Change analysis
 - TA and FMEA
 - Fault trees
6. Identify other contributing factors
 - Human factors
 - Equipment factors
 - Environmental factors
7. Measure, collect and assess data on proximate and underlying causes
8. Design and implement interim changes
 - Gantt chart
9. Identify which systems are involved – the RC
10. Prune list of RC
11. Confirm root causes
12. Explore and identify risk reduction strategies
13. Formulate improvement actions
14. Evaluate proposed improvement actions
15. Design improvements
16. Ensure acceptability of action plan
17. Implement the improvement plan
18. Develop measures of effectiveness and ensure their success
19. Evaluate implementation of improvement efforts
20. Take additional action
21. Communicate the results

FIGURE 4 JCAHO RCA process

(5) search for causes; (6) take action; and (7) evaluate the actions taken. Others such as Handley¹²⁵ have refined the process further, reducing it to just five steps (scan, target, analyse, act and evaluate). It therefore appears that the exact process of completing a RCA is of less importance than the application of the systems thinking underpinning the RCA process.

The JCAHO document provides examples of 14 RCA tools within a healthcare context, which is very useful to those undertaking such investigations. JCAHO also provides a number of useful worksheets and tables for undertaking an RCA and asking the right type of questions. The negative attributes of the JCAHO document centre on its complexity and the fact that it lacks fluidity and therefore is difficult to follow, unless the investigator is well versed in RCA.

Theoretical basis

RCA is essentially a total quality management tool. It is a systematic approach that drills down deep to identify the basic reason(s) for a problem – the root cause(s). JACHO has defined RCA as

“the process for identifying the basic or causal factors that underlie variations in performance, including the occurrence, or risk of occurrence, of a sentinel event. The analysis identifies changes that could be made in systems or processes that would improve the level of performance and reduce the risk of a particular serious adverse event occurring in the future. RCA focuses primarily on systems and processes, not individual performance; the analysis progresses from special causes in clinical processes to common causes in organisational processes; and the analysis repeatedly digs deeper by asking ‘why?’ questions until no additional logical answer can be identified.”

A sentinel event has been defined by JCAHO “as an unexpected occurrence involving death or serious physical or psychological injury, or the risk thereof”.

RCA is not based on any specific theory of human error or system failure, but it does provide a toolbox of useful techniques and tools for use by incident investigators. More than 40 RCA techniques are available for use and these include such tools as brainstorming, cause and effect charts, change analysis, BA, fault trees and Gantt charts. Choice in what and when specific tools should be used is arbitrary and essentially left to the discretion of the investigator. Therefore, it is vital that accident investigators are well versed in the various competencies necessary to achieve successful RCA. Accident investigators must

therefore be able to undertake witness interviews or guide witness statements, observe and make meaningful assessments of the accident site, undertake photographic or video evidence, collate plant schematics, training manuals and maintenance logs and also use the more analytical tools such as BA and change analysis.

Applications in healthcare

Many of the papers reviewed have come from investigations and analyses undertaken in the USA, therefore suggesting that our US colleagues have more practical experience in using RCA at the current time. It also appears that RCA is a versatile tool, which can be used to investigate both serious adverse events and more minor near misses. RCA has been applied to a variety of medical specialties and problems, for example, drug overdose during cancer therapy, blood transfusion reactions in the ICU and laboratory delays to an A&E department. This shows the versatility of the RCA toolkit in that the techniques can be used in any area of medicine and require little adaptation. Many papers^{127,128,147} largely focus on the early stages of the RCA process such as setting up a team and collecting the factual information to support a full investigation. These papers also only seem to discuss a few RCA tools such as brain-storming and the cause and effect chart, although they allude to the use of Pareto charts and timelines. Hirsch and Wallace¹²⁶ outline in their paper the use of contributory factor trees (also known as fishbone diagrams) and taxonomies to identify root cause(s) of an adverse event. However, on the whole few papers outline the use, success and limitations of using some of the other key RCA techniques (of which there are more than 40).

Therefore, the reviewer is concerned that healthcare investigators are not using a broad range of RCA techniques and are in fact relying heavily on just one or two tools to support their assessments, which could be biasing their results. It would appear that some funding should be secured to evaluate these RCA investigations as a means to achieving an organisation which is fully learning from their serious adverse events. When the RCA has been completed and the investigators are generating recommendations/error reduction strategies for their organisation(s) to prevent similar system failures in the future, most of the papers reviewed utilise brain-storming as the preferred mechanism for generating these ideas. It would be useful to see healthcare investigators using some of the specific RCA tools to assist in this process, such as BA. On completing this

review, it becomes apparent that if the UK is to utilise RCA to investigate and analyse incidents, the investigators must be fully trained in all RCA techniques and be required to implement a variety of RCA approaches in their assessments.

Strengths and limitations

Strengths

- Focuses in on how to improve systems rather than blaming an individual.
- Helps identify system weak points.
- Utilises a variety of techniques to investigate and analyse error.
- Provides investigators with a complete accident methodology.
- RCA, if done correctly, is generally a cost-effective methodology.

Limitations

- Limited documentation exists in the healthcare sector on the range of RCA tools available and in particular worked examples showing their applicability to certain types of accident investigations.
- Accident investigators must be fully trained in a variety of RCA techniques if they are to successfully analyse incidents.
- RCA can be a time-consuming process if a variety of detailed techniques are used.
- RCA can very easily be made overly complicated and does not guarantee a complete answer.

Data sources

Exemplar papers

JCAHO, 2000⁷⁸

Hirsch and Wallace, 1999¹²⁶

Supporting papers

Amo, 1998¹⁴⁶

Berry and Krizek, 2000¹²⁷

Beyea and Nicoll, 1999¹²⁸

Handley, 2000¹²⁵

Shinn, 2000¹⁴⁷

Organisational accident causation model (OACM)

Studies which have based their investigation and analysis of critical incidents on Reason's OACM have been grouped together. These include the approaches of Vincent and colleagues,¹²⁹ Eagle and colleagues,³⁵ Cullen and colleagues¹¹² and the Winnipeg model¹⁴⁸. This summary focuses on Vincent and colleagues' approach as being most closely based on Reason's model.

Historical background

Studies of accidents in industry, transport and military spheres have led to a much broader understanding of accident causation, with less focus on the individual who makes the error and more on pre-existing organisational factors. Reason's model^{34,37} of accident causation was originally developed for use in complex industrial systems as a means of understanding the relationships between the various factors involved in the genesis of accidents and to identify methods of accident prevention.

Reason's model has been adapted for a healthcare environment and used by Vincent and colleagues¹²⁹ to develop a protocol for the investigation and analysis of serious incidents in healthcare. A series of research papers was followed by the development and testing of a practical methodology to assist in the investigation of adverse clinical events. This model is now well accepted in the UK as a tool for accident investigation and analysis in healthcare by risk managers and clinical governance leads. The classification system proposed by Vincent and colleagues is also to be incorporated in the NPSA adverse incident investigation and analysis tools.

Essential features

The protocol gives a detailed account of the investigation and analysis process, including who should conduct the investigation, preparing staff for the investigation, in particular the interviewing procedure and step-by-step instructions on how to conduct the investigation, analysis, identify action points and prepare the report. Accounts of the incident may be taken from written reports of staff members, case notes or interviews with staff. The method incorporates analyses from both interviews and records and assumes that much important material can only be gained from interviews.

The essential process of investigation and analysis is mirrored in the structure of the interviews. The aims of the interview are as follows: (i) to establish the chronology, including the role of the member of staff being interviewed in the incident, and their account or experience of the events; (ii) to identify the 'care management problem' (CMP) or actions or omissions made by staff or other limitations in the system that had an important role in the critical incident; (iii) to apply a framework of contributory factors²³ to each CMP identified and discuss with the interviewee to identify the most important factors and potential

methods of prevention. Checklists of contributory factors may also be used.

Once interviews have been conducted, the analysis process begins, where investigators identify the implications and action plans from each case, particularly where these are associated with general contributing factors rather than those specific to the case under investigation. The end result is a report which summarises the chronology of the incident, identifies all CMPs and associated contributory factors, reports the positive features of the process of care and recommends action with timescales for each general factor requiring attention.

Theoretical basis

The OACM developed by Reason^{45,85} is shown in *Figure 2* in Chapter 6. The direction of causality in this model is from left to right. Fallible decisions at the higher echelons of the management structure seed resident pathogens (or latent failures) within the system. These are then transmitted down departmental pathways to the workplace, where task and environmental conditions can promote unsafe acts. Many unsafe acts may be committed, but very few of them are likely to lead to harm except in combination with other contributory factors and failed or absent defences. Defences and barriers are designed to protect against hazards and to mitigate the consequences of equipment and human failure. In an investigation, each of these elements is considered in further detail, starting with the failed defences and working backwards to the root organisational processes.

Many of the terms used in Reason's model have been changed to more acceptable terminology within a healthcare environment. For example, the term 'unsafe act' has been replaced with 'care management problem'. The error-producing conditions and organisational factors have been reclassified into a single broad framework of factors affecting clinical practice.²³ This framework was developed specifically for healthcare.

Applications in healthcare

Appraisal of key papers in healthcare shows that the majority of studies have been conducted in a number of different settings, including nursing, psychiatry, obstetrics, intensive care, anaesthetics and surgery. The focus of such studies tends to be on illustrative cases, although recent studies consider larger numbers of cases. The descriptions of the critical incidents featured

relate to adverse events or near misses in the specialties represented.

Most studies are carried out by investigators external to the healthcare unit or the organisation with a nursing or human factors background using interviews with some confirmation of events or details from the medical records. Mostly individual, semi-structured interviews lasting up to 30 minutes are usually conducted with a number of staff (range 1–8 interviewees) from a range of disciplines with the application of other techniques, such as a checklist of contributing factors.

Results elucidate the causes of incidents in terms of CMPs and contributory factors. Some studies also report classifications of different types of error or a description of clinical aspects or outcomes. The outcomes of all studies relate to either Reason's⁸⁵ active failures and latent conditions or Vincent and colleagues²³ contributory factors or both models. Three studies report specific solutions based on causes identified, but none describes any actual changes to practice and only one includes a statement of intention to implement any changes.

Strengths and limitations

Strengths

- Focuses on improving systems and working environment rather than blaming individuals.
- Identifies a range of weakness in systems, teams and/or individuals.
- Some methods provide investigators with a complete investigation tool.
- Based on current accepted models of human performance.

Limitations

- Some investigators have had difficulty with some terminology.
- Models and theories have not been formally evaluated.
- Few papers address specific interventions.

Data sources

Exemplar papers

Vincent and colleagues, 2000¹⁴⁹
 Stanhope and colleagues, 1997³⁸
 Eagle and colleagues, 1992³⁵

Supporting papers

Reason, 1995³⁷
 Reason, 1997⁴⁵
 Vincent and colleagues, 1998²³
 Vincent and colleagues, 1999¹²⁹
 Vincent and colleagues, 2000¹⁴⁵

Comparison with standards (CWS)

Historical background

Audit must be the founding father of quality improvement techniques. Well-known, early examples of the application of audit in healthcare include the work of Florence Nightingale during the Crimean war in the 1850s and of an American surgeon, John Bowman, in the 1900s. The range of focus of audit is summarised in terms of structure, process and outcome, a sequence which also represents a progressive development of the focus of audit from the earliest studies. The application of audit to healthcare improvement is extremely broad, but interestingly the application of the approach to the problem of maternal deaths preceded the institutionalisation of audit as a quality improvement technique in other areas of healthcare. In this section, the focus is entirely on the application of audit and peer review to the study of adverse events in health care, in particular the conduct, assumptions, strengths and limitations of audit and peer review in the context of confidential enquiries.

Essential features

Confidential enquiries have basic similarities with respect to the way in which they are conceptualised and conducted, but wide variation in the way in which data are collected.

Typically, efforts are made to identify all incidents of interest (usually deaths) in a defined population over a defined time period, using statutory reporting systems, voluntary notification (especially enquiries into perinatal mortality) and in less developed countries^{132,150} through additional hospital- and community-based enquiries. Medical records were examined in almost all papers that we appraised, but this approach was also supplemented by questionnaire enquiries,^{131,133,151} or interviews with healthcare staff or relatives.^{132,150,152} The information assembled will then be appraised against implicit or explicit standards for care of such patients. A panel of experts typically conducts the appraisal and results are presented as levels of performance against expectation. In two of the papers we appraised, the assessments involved two assessors acting independently, then discussing disagreements,^{132,151} and in three, the assessments involved materials being discussed by a panel until consensus was reached.^{133,150,152}

Typically, confidential enquiries focus on clinical and patho-physiological factors associated with

death, with a variable emphasis on the quality of care as assessed against standards of peers. Some papers nevertheless focused more on organisational issues. Tan and colleagues,¹⁵³ for example, graded cases 0–III based on an assessment of the quality of care (evidence of suboptimal care or not) and the likelihood that different management might have improved the outcome (unlikely, possibly, likely). There is evidence, nevertheless, that the major, ongoing confidential enquiries (maternal, perinatal and intraoperative deaths) have had a positive impact on clinical practice and probably patient safety.

Theoretical basis

Audit is a tool directed at improving the performance of individuals and organisations. The underlying theoretical assumption is that healthcare staff and healthcare managers generally want to perform well, but have little appreciation of the standard of their own performance. Audit with feedback is considered to be a behaviour modification approach where demonstration of underperformance or deficiencies in care is expected to drive change in the behaviour of individuals and groups. Although many studies focus on clinical process and whether stages in patient management are acceptable or unacceptable, the importance of organisation and system factors is also recognised in many enquiries. Where 'structure' in addition to 'process' is considered, enquiries will often include questions on issues such as the presence of staff of a given level of training, particular essential equipment or the availability of policies or guidelines detailing best practice in particular situations.

Applications in healthcare

The majority of publications are derived from confidential enquiries into maternal, perinatal or postoperative deaths^{131,132,154} but there are also a number of examples of the same approach being applied to other problems, typically by an expert or speciality group reviewing deaths from a particular cause within their geographical locality. Payne and colleagues,¹⁵¹ for example, reported the results of a confidential enquiry into stroke deaths in a single locality and Burr and colleagues¹³³ reported the results of a confidential enquiry into asthma deaths in Wales. Given that the confidential enquiry approach emerged and developed in the UK, it is unsurprising that the majority of publications are from there. Nevertheless, we did find examples of the approach from other countries including adaptations to less developed country settings.^{132,150}

Most confidential enquiries investigate deaths of one sort or another, and months or years may pass between the time of death and the conduct of the enquiry. As such, they may be best suited to settings where information on deaths by cause is accessible and where medical records are likely to be available and of reasonable quality. They are framed within an epidemiological paradigm, in the sense that complete case ascertainment is sought and denominator populations are generally available. Although data are generally presented as numerical summaries, occasionally vignettes of individual cases may be presented¹⁵⁵ or more depth insights will be alluded to within published papers.^{150,154} There is some potential for confidential enquiries to incorporate both clinical and organisational issues in a systematic way, although there is little sign of this to date. All said and done, confidential inquiries have been an important source of knowledge about clinical incidents in the UK and it is likely that even in their current form they have been a factor in changing practice for the better.

Strengths and limitations

Strengths

- Confidential approach and voluntary participation were reassuring for clinicians who might worry about professional credibility and litigation.
- Close involvement of professional organisations helps to endorse ownership by participants and

to institutionalise involvement without the need for statute.

- Complete ascertainment of cases improves the generalisability of findings and for many events and enables meaningful links to be made with denominator populations at risk of the adverse outcome.
- Use of standardised data collection methods allows comparable data collection across sites and over time.
- Analysis at both regional and local levels promotes local review and implementation of change.

Limitations

- Only feasible to conduct serial confidential enquiries for a relatively small number of adverse outcomes of significant public health importance.
- Can be used to assemble data on structural and process issues of relevance to patient safety, but study design reduces the scope for emergent findings.
- Historically have tended to focus more on clinical activity, rather than contextual issues, which might determine patient safety.
- Findings of confidential enquiries are still remote from individual cases and influence on implementation of change is mainly through dissemination of findings through professional organisations and the scientific literature.

Appendix 10

Detailed results of appraised papers

TABLE 39 Summary and number of critical incidents featured

Author, year	Summary of critical incidents featured	No. of incidents
AIMS		
Morris and Morris, 2000 ¹¹⁵	Anaesthetics incidents featuring fatigue	152
Steven <i>et al.</i> , 1999 ¹¹⁶	Adverse drug events in general practice patients	1556
Sinclair <i>et al.</i> , 1999 ¹¹⁷	Incidents in obstetric anaesthesia and analgesia	226
Beckmann <i>et al.</i> , 1998 ¹⁵⁶	Incidents in ICUs associated with nursing staff shortages	462
Wright and Parker, 1998 ¹⁵⁷	Incidents which significantly affected or could have affected psychiatric patients' treatment or outcome	98
Short <i>et al.</i> , 1996 ¹⁵⁸	Anaesthesia-related incidents	1000
Short <i>et al.</i> , 1993 ¹⁴⁴	Critical incidents in anaesthesia	125
Holland <i>et al.</i> , 1993 ¹⁵⁹	Cases of oesophageal intubation in anaesthesia	35
Currie, 1989 ¹⁶⁰	Anaesthetic mishap which led or could have led to an undesirable patient outcome	167
Williamson <i>et al.</i> , 1985 ¹⁶¹	Anaesthetic occurrence which could have led or did lead to undesirable outcome	64
CIT		
Cote <i>et al.</i> , 2000 ¹⁰⁷	Paediatric adverse sedation events	59
Boreham <i>et al.</i> , 2000 ¹⁶²	Incidents illustrating the division of labour as a latent condition for accidents and near misses in A&E	7
Meurier <i>et al.</i> , 1997 ¹⁶³	Non-drug errors in nursing practice	129
Ely <i>et al.</i> , 1995 ¹¹⁴	GPs' most memorable error	53
Orser and Oxorn, 1994 ¹⁶⁴	Cardiac arrest following drug administration error in anaesthesia	1
Waterston, 1988 ³¹	Critical incidents in child health. An incident is any desirable human activity which is sufficiently complete in itself to permit inferences or predictions to be made about the person performing the act	438
Cooper <i>et al.</i> , 1984 ¹¹³	Anaesthesia-related human errors and equipment failures	1089
Cooper <i>et al.</i> , 1982 ¹⁴³	Relief-associated critical incidents in anaesthesia	96
Newbower <i>et al.</i> , 1981 ¹⁶⁵	Anaesthetic occurrence which could have led or did lead to undesirable patient outcome	790
SEA		
Holden <i>et al.</i> , 1998 ¹⁶⁶	Deaths in patients registered with GPs	1263
Redpath <i>et al.</i> , 1997 ¹⁶⁷	Suicides in a general practice population	49
Pringle <i>et al.</i> , 1995 ⁹⁹	Any event deemed significant in the clinical care of patients or administration management of the [general] practice	286
Bennett and Danczak, 1994 ¹⁶⁸	Death of a terminal care patient in the community	1
Berlin <i>et al.</i> , 1992 ²⁴	Deaths in a general practice population	8
Tudor Hart and Humphreys, 1987 ¹⁶⁹	Deaths in a general practice population	500
RCA		
Shinn, 2000 ¹⁴⁷	Transfusion incidents in intensive care	2
Linden, 2000 ¹⁰⁹	Transfusion-related near misses associated with use of facsimile machine	3
Berry and Krizek, 2000 ¹²⁷	Near miss with patient-controlled analgesia	1

continued

TABLE 39 Summary and number of critical incidents featured (cont'd)

Author, year	Summary of critical incidents featured	No. of incidents
Graber, 1999 ¹⁰³	Less than ideal quality of care (error) in medical services	191
Weinberg and Stason, 1998 ¹⁷⁰	'Quality problems' in general practice	92
Anon., 1998 ¹⁷¹	Death due to anaesthetic error	1
Haas, 1997 ¹⁷²	Anaesthetic deaths due to drug error	1
Battles and Shea, 2001 ¹⁷³	Illustrative case studies in A&E and obstetrics	3
Rex <i>et al.</i> , 2000 ¹⁷⁴	Adverse drug events	23
Brown and Fay, 1997 ¹⁷⁵	Death following the rapid administration of potassium chloride	1
OACM		
Meurier, 2000 ¹⁷⁶	Self-harm	1
Vincent <i>et al.</i> , 2000 ¹⁴⁹	Attempted suicide	1
Taylor-Adams <i>et al.</i> , 1999 ³⁹	Delayed treatment of postpartum haemorrhage	1
Stanhope <i>et al.</i> , 1997 ³⁸	Asphyxiated newborn	1
Cullen <i>et al.</i> , 1997 ¹¹²	Preventable and potential adverse drug events in intensive care	264
Eagle <i>et al.</i> , 1992 ³⁵	Anaesthetic death following respiration	1
Carthey <i>et al.</i> , 2001 ¹⁷⁷	Near misses in cardio-thoracic operation theatres	2
CWS		
Cartlidge <i>et al.</i> , 1999 ¹³¹	Deaths due to prematurity (excluding congenital abnormalities, congenital infections and incidental deaths)	49
Tan <i>et al.</i> , 1999 ¹⁵³	Stillbirths and neonatal deaths (excluding those <2.5 kg)	238
Bucknall <i>et al.</i> , 1999 ¹⁵²	Asthma deaths, patients aged 15–64 years	95
Burr <i>et al.</i> , 1999 ¹³³	Deaths due to asthma, patients aged <65 years	52
Durrheim <i>et al.</i> , 1999 ¹⁵⁰	Malarial deaths	42
Payne <i>et al.</i> , 1993 ¹⁵¹	Deaths from stroke and hypertension in a general practice population	139
Walker <i>et al.</i> , 1986 ¹³²	Maternal deaths	192
Wood <i>et al.</i> , 1984 ¹⁵⁴	Neonatal deaths (excluding malformed infants)	242
MRWPPM, 1982 ¹⁷⁸	Perinatal deaths	309
Callum <i>et al.</i> , 2001 ¹⁵⁵	Perioperative deaths due to interventional vascular radiology	303

TABLE 40 Classification and severity of critical incidents featured

Author, year	Classification of critical incidents featured	Severity of critical incidents featured – injury suffered
AIMS		
Morris and Morris, 2000 ¹¹⁵	By intervention and common contributory cause	Not clear
Steven <i>et al.</i> , 1999 ¹¹⁶	Associated with an intervention	Death, permanent and no injury
Sinclair <i>et al.</i> , 1999 ¹¹⁷	By patient and intervention	No injury and extent of injury unknown
Beckmann <i>et al.</i> , 1998 ¹⁵⁶	With a common contributory cause	Not clear
Wright and Parker, 1998 ¹⁵⁷	Unrestricted within the named specialty	Temporary injury and no injury
Short <i>et al.</i> , 1996 ¹⁵⁸	Unrestricted within the named specialty	Death, temporary and no injury
Short <i>et al.</i> , 1993 ¹⁴⁴	Unrestricted within the named specialty	Death, temporary, no injury and other classification: mild/moderate/severe injury
Holland <i>et al.</i> , 1993 ¹⁵⁹	With a common proximate cause	Death, temporary and no injury
Currie, 1989 ¹⁶⁰	Unrestricted within the named specialty	Death, permanent, temporary and no injury
Williamson <i>et al.</i> , 1985 ¹⁶¹	Unrestricted within the named specialty	Temporary and no injury

continued

TABLE 40 Classification and severity of critical incidents featured (cont'd)

Author, year	Classification of critical incidents featured	Severity of critical incidents featured – injury suffered
CIT		
Cote <i>et al.</i> , 2000 ¹⁰⁷	By patient and intervention	Death, permanent and no injury
Boreham <i>et al.</i> , 2000 ¹⁶²	With a common contributory cause	No injury and not clear
Meurier <i>et al.</i> , 1997 ¹⁶³	Excluding drug errors	Temporary, no injury and other classification: mild/moderate/severe effects
Ely <i>et al.</i> , 1995 ¹¹⁴	Unrestricted within the named specialty	Death, permanent, temporary and no injury
Orser and Oxorn, 1994 ¹⁶⁴	Case studies/illustration	No injury
Waterston <i>et al.</i> , 1988 ³¹	Unrestricted within the named specialty	Not clear
Cooper <i>et al.</i> , 1984 ¹¹³	Unrestricted within the named specialty	Death, no injury, cardiac arrest and not clear
Cooper <i>et al.</i> , 1982 ¹⁴³	With a common contributory cause	Death, no injury and not clear
Newbower <i>et al.</i> , 1981 ¹⁶⁵	Unrestricted within the named specialty	Not clear
SEA		
Holden <i>et al.</i> , 1998 ¹⁶⁶	Deaths	Death
Redpath <i>et al.</i> , 1997 ¹⁶⁷	In a diagnostic group	Death
Pringle <i>et al.</i> , 1995 ⁹⁹	Unrestricted within the named specialty	Death, permanent, temporary and no injury
Bennett <i>et al.</i> , 1994 ¹⁶⁸	With a common contributory cause	Death
Berlin <i>et al.</i> , 1992 ²⁴	Deaths	Death
Tudor Hart and Humphreys, 1987 ¹⁶⁹	Deaths	Death
RCA		
Shinn, 2000 ¹⁴⁷	Associated with an intervention	Temporary injury
Linden, 2000 ¹⁰⁹	Associated with an intervention and common proximate cause	No injury
Berry and Krizek, 2000 ¹²⁷	Case studies/illustration	Somnolence
Graber, 1999 ¹⁰³	Unrestricted within the named specialty	Not clear
Weinberg and Stason, 1998 ¹⁷⁰	Unrestricted within the named specialty	Death, no injury and clinical deterioration
Anon., 1998 ¹⁷¹	Case studies/illustration	Death
Haas, 1997 ¹⁷²	Case studies/illustration	Death
Battles and Shea, 2001 ¹⁷³	Case studies/illustration	No injury
Rex <i>et al.</i> , 2000 ¹⁷⁴	Associated with an intervention	Death, no injury and actual harm
Brown and Fay, 1997 ¹⁷⁵	Case studies/illustration	Death
OACM		
Meurier, 2000 ¹⁷⁶	Case studies/illustration	Temporary injury
Vincent <i>et al.</i> , 2000 ¹⁴⁵	Case studies/illustration	Temporary injury
Taylor-Adams <i>et al.</i> , 1999 ³⁹	Case studies/illustration	Temporary injury
Stanhope <i>et al.</i> , 1997 ³⁸	Case studies/illustration	Foetal distress and low Apgar
Cullen <i>et al.</i> , 1997 ¹¹²	Intervention and potential adverse event	Temporary, no injury and life threatening
Eagle <i>et al.</i> , 1992 ³⁵	Case studies/illustration	Death
Carthey <i>et al.</i> , 2001 ¹⁷⁷	Case studies/illustration	No injury
CWS		
Cartledge <i>et al.</i> , 1999 ¹³¹	In a diagnostic group	Death
Tan <i>et al.</i> , 1999 ¹⁵³	In a patient group	Death
Bucknall <i>et al.</i> , 1999 ¹⁵²	In a diagnostic group	Death
Burr <i>et al.</i> , 1999 ¹³³	By patient and diagnostic group	Death
Durrheim <i>et al.</i> , 1999 ¹⁵⁰	In a diagnostic group	Death
Payne <i>et al.</i> , 1993 ¹⁵¹	By patient and diagnostic group	Death
Walker <i>et al.</i> , 1986 ¹³²	In a patient group and deaths	Death
Wood <i>et al.</i> , 1984 ¹⁵⁴	Excluding malformed deaths	Death
MRWPPM, 1982 ¹⁷⁸	Unrestricted within the named specialty	Death
Callum <i>et al.</i> , 2001 ¹⁵⁵	Deaths	Death

TABLE 41 Agency responsible for the investigation and relations to the unit being investigated

Author, year	Agency responsible for the investigation	Organisational relations of agency to unit investigated
AIMS		
Morris and Morris, 2000 ¹¹⁵	Healthcare institution and government/state	External to the organisation
Steven <i>et al.</i> , 1999 ¹¹⁶	Professional organisation, academic department and government/state	External to the organisation
Sinclair <i>et al.</i> , 1999 ¹¹⁷	Healthcare institution and government/state	External to the organisation
Beckmann <i>et al.</i> , 1998 ¹⁵⁶	Healthcare institution and government/state	External to the organisation
Wright and Parker, 1998 ¹⁵⁷	Healthcare institution and academic department	External to the organisation
Short <i>et al.</i> , 1996 ¹⁵⁸	Healthcare institution and academic department	Internal to the healthcare unit and external to the organisation
Short <i>et al.</i> , 1993 ¹⁴⁴	Healthcare institution	Internal to the healthcare unit
Holland <i>et al.</i> , 1993 ¹⁵⁹	Healthcare institution, academic department and government/state	External to the healthcare unit and to the organisation
Currie, 1989 ¹⁶⁰	Healthcare institution	Internal to the healthcare unit
Williamson <i>et al.</i> , 1985 ¹⁶¹	Healthcare institution	Internal to the healthcare unit and external to the organisation
CIT		
Cote <i>et al.</i> , 2000 ¹⁰⁷	Not clear	External to the organisation
Boreham <i>et al.</i> , 2000 ¹⁶²	Academic department	External to the organisation
Meurier <i>et al.</i> , 1997 ¹⁶³	Academic department	External to the organisation
Ely <i>et al.</i> , 1995 ¹¹⁴	Academic department	External to the organisation
Orser and Oxorn, 1994 ¹⁶⁴	Healthcare institution	Internal to the healthcare unit
Waterston, 1988 ³¹	Healthcare institution	Internal to the healthcare unit
Cooper <i>et al.</i> , 1984 ¹¹³	Healthcare institution and academic department	Internal to the healthcare unit and external to the organisation
Cooper <i>et al.</i> , 1982 ¹⁴³	Healthcare institution and academic department	External to the organisation
Newbower <i>et al.</i> , 1981 ¹⁶⁵	Healthcare institution and academic department	External to the organisation
SEA		
Holden <i>et al.</i> , 1998 ¹⁶⁶	Academic department	Internal to the healthcare unit
Redpath <i>et al.</i> , 1997 ¹⁶⁷	Government or state	External to the organisation
Pringle and Danczak, 1995 ⁹⁹	Academic department and government/state	External to the organisation
Bennett <i>et al.</i> , 1994 ¹⁶⁸	Healthcare institution	Internal to the healthcare unit
Berlin <i>et al.</i> , 1992 ²⁴	Academic department	External to the organisation
Tudor Hart and Humphreys, 1987 ¹⁶⁹	Healthcare institution	Internal to the healthcare unit and external to the organisation
RCA		
Shinn, 2000 ¹⁴⁷	Healthcare institution	Internal to the healthcare unit
Linden, 2000 ¹⁰⁹	Professional organisation	External to the organisation
Berry and Krizek, 2000 ¹²⁷	External consultant	Not clear
Graber, 1999 ¹⁰³	Healthcare institution	Internal and external to the healthcare unit
Weinberg and Stason, 1990 ¹⁷⁰	Academic department and consultancy	External to the organisation
Anon., 1998 ¹⁷¹	Healthcare institution	External to the healthcare unit
Haas, 1997 ¹⁷²	Healthcare institution	External to the healthcare unit
Battles and Shea, 2001 ¹⁷³	Academic department	External to the organisation
Rex <i>et al.</i> , 2000 ¹⁷⁴	Healthcare institution	Internal to the healthcare unit
Brown and Fay, 1997 ¹⁷⁵	Healthcare institution	External to the healthcare unit

continued

TABLE 41 Agency responsible for the investigation and relations to the unit being investigated (cont'd)

Author, year	Agency responsible for the investigation	Organisational relations of agency to unit investigated
OACM		
Meurier, 2000 ¹⁷⁶	Academic department	External to the organisation
Vincent <i>et al.</i> , 2000 ¹⁴⁵	Academic department	External to the organisation
Taylor-Adams <i>et al.</i> , 1999 ³⁹	Academic department	External to the organisation
Stanhope <i>et al.</i> , 1997 ³⁸	Healthcare institution and academic department	Internal to the healthcare unit and external to the organisation
Cullen <i>et al.</i> , 1997 ¹¹²	Healthcare institution and academic department	Internal to the healthcare unit and external to the organisation
Eagle <i>et al.</i> , 1992 ³⁵	Healthcare institution and academic department	Internal to the healthcare unit and external to the organisation
Carthey <i>et al.</i> , 2001 ¹⁷⁷	Healthcare institution and academic department	Internal and external to unit and external to organisation
CWS		
Cartlidge <i>et al.</i> , 1999 ¹³¹	Healthcare institution	External to the organisation
Tan <i>et al.</i> , 1999 ¹⁵³	Academic department	External to the organisation
Bucknall <i>et al.</i> , 1999 ¹⁵²	Government or state	External to the organisation
Burr <i>et al.</i> , 1999 ¹³³	Healthcare institution and academic department	Internal and external to unit and external to organisation
Durrheim <i>et al.</i> , 1999 ¹⁵⁰	Government or state	External to the organisation
Payne <i>et al.</i> , 1993 ¹⁵¹	Academic department and government/state	External to the organisation
Walker <i>et al.</i> , 1986 ¹³²	Healthcare institution, academic department and government/state	Internal and external to unit and external to organisation
Wood <i>et al.</i> , 1984 ¹⁵⁴	Healthcare institution and government/state	External to the organisation
MRWPPM, 1982 ¹⁷⁸	Healthcare institution, academic department and government/state	External to the organisation
Callum <i>et al.</i> , 2001 ¹⁵⁵	Professional organisation, healthcare institution and National Confidential Enquiry into Patient Outcome and Death (NCEPOD) – expert group	External to the organisation

Appendix I I

Examples of clinical incidents

Acute care case

Case history

This case relates to the management of a 61-year-old lady who had experienced low back pain for several years. Over the previous 2 years (prior to surgery), the pain had become markedly worse and had been treated with epidural pain relief on a number of occasions. Over time this pain management became less effective. The patient was reviewed in an outpatient clinic and it was clear that she was experiencing reduced mobility as a result of the pain. This had prevented her from working and generally getting out and about. The possibility of back surgery was discussed and a magnetic resonance imaging (MRI) scan arranged to assess the degree of problem. The trust treating this patient did not have MRI scanning facilities and arrangements were made for the scan to be carried out at another centre, as was normal practice. The scan revealed lumbar canal stenosis and it was agreed with the patient that a decompressive laminectomy could improve her condition. The consultant explained the risks of surgery to the patient; however, this was not documented in the notes. The patient therefore had limited information on which to give informed consent and although the risk of the complication she experienced was very low, it may have affected her final decision.

Case chronology

10.00 10 September 2000

Patient admitted to hospital for surgery. She was fully continent and assessed as fit for anaesthetic.

09.00 11 September 2000

Patient underwent a routine decompression of the spine performed by the consultant and no untoward features were noted or problems experienced during the operation.

14.00 11 September 2000

Patient returned to ward and when she woke complained of intense pain, which was not eased by her use of the patient-controlled analgesia (PCA) pump. Further pain relief was administered and careful observation continued.

18.00 11 September 2000

Nursing staff noted that the patient had not passed urine, but her pain had settled.

20.00 11 September 2000

Patient had still not passed any urine.

20.30 11 September 2000

The bed linen was changed and the patient stated that she had not experienced any sensation of wanting to pass urine. The wound was checked and found to be leaking and required pressure to be applied. The patient was also catheterised. Nursing assessment indicated that the patient was experiencing increasing pain down her leg, that she had numbness in her toes and could not move them. A further pressure pad was required owing to further leakage. The doctor was informed and further pain relief administered.

20.50 11 September 2000

The doctor's assessment showed that the pain relief was becoming effective and the pressure pad applied to the wound had also been effective.

14.00 12 September 2000

The patient was still experiencing pain and was complaining of not having any sensation or movement in her feet, from ankle to toe. The patient and her family were very concerned. The nursing staff communicated their and the patient's concern to the doctors.

10.00 13 September 2000

The loss of sensation in both feet had not improved and the patient was experiencing increased pain. The consultant was called to review the situation. Limited information was provided to the patient to reduce her fears.

11.30 13 September 2000

The consultant reviewed the patient and arranged for a further MRI scan.

15.15 13 September 2000

The patient was taken by ambulance to another local hospital for the MRI scan. This showed that there was a haematoma outside the spinal cord.

17.00 13 September 2000

Patient returned to original hospital.

19.15 13 September 2000

To assess the impact that the haematoma was having on the problem, it was drained under anaesthetic and a bleeding point was identified. The patient was very anxious about having this further procedure performed and, owing to limited information on what the outcome of this second procedure would be, the patient hung on to the unrealistic hope that this would solve the problem.

16 September 2000

Patient did not improve and she was transferred to a neurosurgical unit for further assessment and advice. The patient was diagnosed as having suffered an ischaemic lesion of the cord, which occurred as a result of the development of a postoperative haematoma. This is a known but rare complication of decompressive laminectomy, which is estimated only to occur in 1–5% of cases. The patient's prognosis for further recovery was poor and it was noted that she would continue to be doubly incontinent.

The patient has subsequently claimed that the potential risks attached to the surgery were not fully explained to her either in outpatients or prior to her operation.

Case analysis**Care delivery problems**

1. Loss of sensation noted but delay in communicating problem to consultant.
2. No protocol to follow when pain and movement were abnormal in patients receiving this type of operation.
3. Level of communication with patient and her relatives was variable, leading to increased anxiety and lack of understanding.

Contributory factors**Clinical context and patient factors**

- Patient had an unusual postoperative recovery: increased pain, lack of movement in her feet and incontinence. Patient was an eloquent individual who had previously worked part-time as a geography teacher at a local school. Supportive partner and family.

Organisational and management factors

- Facilities and equipment: no on-site MRI facilities.

Work/environmental factors

- Delay in calling the consultant to review this lady.

Team factors

- Poor documentation by junior doctors
- Nurses concerned by the problems this lady was having and informed the junior doctors of this concern. They assumed this concern was communicated to the consultant (which it was not).
- Senior nurse should have sought consultant's opinion earlier.
- Poor communication between doctors and patient/family regarding her problems.

Task factors

- No protocol available to staff for dealing with a patient exhibiting unusual postoperative symptoms.
- No MRI scanning facilities in the trust where the operation took place.

Individual factors

- Staff involved in the care of this patient had not experienced this type of complication previously, including the consultant, who had more than 20 years' experience of spinal surgery.

Positive points

- Consultant acted quickly once he realised there was a problem.
- Pain management was good.

Recommendations

- Development of a protocol including extension of the pain assessment tool.
- Training in communicating with patients who have experienced an unexpected outcome for all levels of professional staff.
- Development of printed information on the risks attached to procedures to support verbal information.
- Regular re-evaluation of service, to consider the limited access to scanning facilities.

Outcome

The patient received substantial rehabilitation, but progress has been slow and a full recovery is unlikely.

Mental health case**Summary**

<i>Sex and age:</i>	Female, 43 years.
<i>Ethnicity:</i>	British.
<i>Diagnosis:</i>	Paranoid schizophrenic.
<i>Trust services involved:</i>	Rehabilitation and Continuing Care Directorate and psychiatric ward.

<i>Forensic history:</i>	In 1987 Ms M served a sentence in prison for deception and unpaid hotel bills. The original sentence was for a total of 7 months. She was released after a few weeks for good behaviour.
<i>Risk assessment, 25 October 2000</i>	Harm to others – low. Harm to self – low-/medium. Self-neglect – medium; when mental state deteriorates, Ms M will put inappropriate things on her skin such as bleach, and she refuses food and slashes arms and neck with any sharp object. There was no reference in the care plan or risk assessment with regard to Ms M absconding or going missing from the unit, as she was felt not to be at risk. Ms M had gone missing before; this had been reported to the police, but she had returned 3 days later. The multidisciplinary team reviews all clients daily.
<i>Social circumstance:</i>	Ms M's father had committed suicide in 1990, after a long history of depression. Ms M's mother and brother visited Ms M regularly.
<i>Dependants:</i>	None.
<i>Other agencies involved:</i>	Social worker, social services, GP.

Case history – Ms M

Ms M was first admitted to the hospital in 1985. Since then she had had several admissions and was transferred to the Rehabilitation and Continuing Care Service in 1995. She had been an inpatient at the hospital's hostel since May 1998. In June 1999 Ms M went missing from the hostel for a period of 3 days, but returned of her own accord, saying that she had been staying with friends. On this occasion the police were informed that Ms M was missing.

Her medication at the time of her death was chlorpromazine 600 mg nocte. She was not detained under the Mental Health Act (1983) at the time of her death.

25 October 2000

Ms M was reviewed at the hospital hostel by Dr B, Specialist Registrar, Ms A, Psychologist, Mr SC, Occupational Therapist, Dr E, SHO, Social Worker, Senior Staff Nurse and Care Coordinator. It was noted that there had been signs of deterioration in Ms M's mental state, such as withdrawal and isolation and responding to hallucinations.

13 November 2000

Ms M was watching TV when another resident changed the channel. Ms M was annoyed and an argument ensued between the two. The other resident threw a cup of hot tea at Ms M. Staff intervened and reassurance was given to Ms M, who declined to be seen by the second on-call doctor.

17 November 2000

Ms M was seen by Dr E (SHO) regarding the incident on the 13 November. Dr E noted that Ms M was still angry about the incident, but had been settled and there were no behavioural problems.

20 November 2000

Ms M joined the Occupational Therapy outing to the pub, for the first time in 6 months. She sat quietly with her drink, responding to but not initiating conversation. She appeared settled and stated quietly that she had enjoyed the drink.

10.30 23 November 2000

Ms M had accepted her night-time medication without problem.

12.05 24 November 2000

Ms M left the hostel, without saying where she was going. She did not respond when called by the agency nurse on duty, Mrs S. As Ms M was an informal patient and was not considered at risk, it was not felt that this should cause undue concern.

12.15 24 November 2000

Mrs S reported Ms M's absence to the night duty senior nurse and an entry was made in the Nursing Office Daily Report, but the police were not informed as it was felt that there was no immediate risk. (Ms M had gone missing on a previous occasion, but had returned safely after 3 days, having stayed with friends. She had been reported as a missing person after a period of 10 hours.)

09.00 24 November 2000

Ms M's departure was discussed at the morning Team Handover meeting and it was decided that

she should be reported to the police as a missing person.

17.20 24 November 2000

Police called at the hostel and informed staff nurse J that Ms M's body had been found on Brighton beach, by the West Pier, at 8.30 a.m. A member of the public had found her face down. She was identified by a DSS Benefit Book and her fingerprints. The police also informed Ms M's mother of her death.

Initial results from the post-mortem indicated that Ms M had drowned; further toxicological analysis was to follow. The Coroner's office was to contact the Consultant Psychiatrist when the results were confirmed.

The Coroner's Report stated that the cause of death was drowning in seawater. At the Coroner's Inquest, one point of discussion was the result of the toxicology report, which showed that Ms M's blood had tested negative for chlorpromazine, thus leading to questions about how medication had been administered and whether she was relapsing. However, Dr E (SHO) gave evidence that there were no signs of relapse. This was endorsed by Mrs M, Ms M's mother, who had seen her on the day before her disappearance.

Other relevant information

Although an agency nurse, Mrs S had worked for the trust as a senior nurse on nights for many years, and had worked at the hostel on an agency basis for approximately 3 years and was therefore familiar with practices in the hostel. Agency staff are inducted via an orientation pack, which includes details of what to do in an emergency. New agency staff are given time to read this information and clarify any queries. This information is also in laminated form, in a prominent position on the wall of the staff office.

Case analysis

CDP: door not locked

Contributory factors

Clinical context and patient factors

- The patient was not specifically at risk, but had suffered from paranoid schizophrenia for some time. She was not sectioned, so could come and go as she wished, but had to ask staff first, who would let her out via unlocking the relevant doors. Patients were not allowed to leave the unit between 22.00 and 08.00.

Organisational and management factors

- Maintenance management: the lock on the

main door was notoriously erratic and therefore it was the norm that staff left this door unlocked. The organisation had been notified of this problem and the maintenance team had tried to fix the problem. Unfortunately, a fix was not possible, so a new locking mechanism had been ordered, which was due to be fitted within the next 7 days.

Work environment factors

- The lock on the door was waiting to be fixed, but owing to a delay in getting the relevant parts, the locking mechanism could not be fixed immediately.

Team factors

- None.

Task factors

- This was a busy psychiatric ward, so it was easier to leave the door unlocked than take any other short-term action.

Individual factors

- None.

Improvement strategies/recommendations

- A temporary solution to failing locking mechanisms on psychiatric wards must be found, such as a key-orientated system in this case.
- Contracts with suppliers must be developed further. This locking mechanism had been on order for over 4 weeks. Therefore, purchasing from other suppliers must be considered.
- Risk assessment with temporary solutions should be performed in areas such as this, where a failing door lock can lead to catastrophic consequences.

CDP: failure to notify police immediately of Ms M's disappearance

Contributory factors

Organisational and management factors

- Cultural norm that the disappearance of patients who were not deemed to be at serious risk could wait to be notified to the police until daylight hours.

Work environment factors

- None.

Team factors

- None.

Task factors

- None.

Individual factors

- Night Duty Senior Nurse was not familiar with the procedures for patients who had absconded.

Improvement strategies/recommendations

- Training to all staff on the policies and procedures concerning patients who have gone missing.

CDP: failure to ensure patients are actually taking their prescribed medicines**Contributory factors***Organisational and management factors*

- No policy in place to ensure that patients are taking their medications.

Work environment factors

- Staff generally do not have time to ensure that medications are taken.

Team factors

- None.

Task factors

- None.

Individual factors

- None.

Improvement strategies/recommendations

- Review of the literature to determine how other trusts ensure that psychiatric patients take their medications during an inpatient stay.
- Based on this review, develop a policy and train all staff in the policy and procedures.
- Audit the process 6 months after implementation of new policy.

Positive features of this case

- Documentation for this patient was of a high quality.
- This patient had regular multi-professional case review, which was updated regularly.
- All staff were well trained and experienced, even though some staff were from an agency.
- Good team relations between the medical and nursing staff.

Primary case study**Summary**

This case concerns a 59-year-old Caucasian woman with a history of anxiety and depression with agoraphobia and panic attacks. She is a smoker and has abused alcohol. She has advanced osteoarthritis of both hips and was diagnosed as

having cirrhosis a year ago. She had a recent operation to remove an ovarian tumour (benign). She continues to drink and lives in a gloomy and untidy basement flat. She has been on the waiting list for a right total hip replacement (THR).

Chronology**20 February 2002**

The patient requested a home visit for a sore throat. The visiting GP did not know the patient well. The doctor noted an area of redness and a small ulcer on the soft palate. He assumed this would be a self-limiting condition and prescribed nystatin pastilles, a treatment for thrush. He instructed the patient to call the surgery if she was no better when she had completed her treatment.

13 March 2002

The patient was admitted to hospital for her THR, but was discharged the following day as she had a methicillin-resistant *Staphylococcus aureus* (MRSA) infection of the abdominal wound from her previous operation. The orthopaedic registrar left a message for the GP, but was not available when the GP rang back the following day.

14 March 2002

The patient was visited by a district nurse at home to dress the wound, but the GP knew nothing of this.

15 March 2002

The discharge note arrived from the hospital. This reported that the patient was admitted for THR, and then discharged because of her MRSA-infected abdominal wound.

19 March 2002

The patient requested a further prescription for nystatin. The same GP went to see the patient at home. She still complained of a sore throat. The examination was much the same and the GP took a throat swab.

22 March 2002

The GP saw the result 4 days later; no organism was grown and he decided to refer to the oral surgeons.

4 April 2002

The letter was typed and the patient was seen within weeks of referral.

24 April 2002

She returned to the surgery to tell her GP that the specialists had diagnosed throat cancer. The GP reflected as to whether he could have recognised this sooner.

Case analysis

CDP: the GP assumed that the patient's condition was simple and self-limiting when there were some pointers that this might not be the case

Contributory factors

Clinical context and patient factors

- The patient had a history of anxiety disorder, depression and alcohol abuse; she was unkempt and tended to neglect herself. The doctor in question had seen her at home once before, at which time she was incontinent and the flat smelt of urine.

Institutional context

- Patient's expectations are increasing; promises are made by politicians on behalf of public services.
- Administrative workload has increased; referrals, doctors' letters, benefits paperwork, insurance and legal work.
- Quality initiatives such as audits, prescribing reviews and National Service Frameworks require time.
- Financial and structural limitations constrain capacity to respond to competing demands.

Organisational and management factors

- Good locums are hard to find and doctors try to cover their partners' absences.
- Time required to meet administrative demands detracts from time available to patients.
- Home visits are at the discretion of the doctor, but it can be hard to say no.
- The restrictive nature of the premises constrains communication between doctors.

Work environment factors

- The practice serves a population, which puts high demands on its services. The partners had recently agreed to extend the morning clinic by 30 minutes to help meet this demand. There was typically at least an hour's paperwork to do once patients had been seen.
- The premises have two consulting rooms and can house only two doctors or a doctor and a nurse at any one time. The practice area is compact and home visit requests are unusual.
- Administrative duties compete for the doctors' time.

Team factors

- The doctor did not know the patient well; a different doctor normally saw her.
- There was little opportunity for interaction between doctors on a day-by-day basis.

Task factors

- The patient's home was not a familiar place in which to be conducting an examination.
- The patient sat on a low settee, which made the examination awkward.

Individual factors

- The doctor in question was covering a morning surgery for an absent colleague and did not want to be working into the afternoon.
- The doctor felt that a home visit request for a sore throat was inappropriate.
- He felt apprehensive about the visit. He assumed that the patient would raise issues other than a sore throat and that he would be drawn into more complicated matters.
- He disliked the environment in which he would be examining the patient and was an uncomfortable witness to the patient's self neglect.

CDP: the patient did not contact the surgery for review, even though her symptoms persisted

Contributory factors

Clinical context and patient factors

- The patient had mental health and alcohol abuse problems.
- She might not follow the doctor's advice.
- She did not follow the prescriber's instructions, taking nystatin pastilles one per day rather than four per day.
- She was admitted to hospital for a different problem before she finished her prescription.
- She might have been trying to avoid going to the surgery on account of her arthritis and her agoraphobia, or might have felt she did not wish to bother the doctor unnecessarily.

Institutional factors

- Resource constraints, waiting list targets and other pressures on hospitals constrain the time available for patient assessment and for effective communication.
- Historical, political and structural factors affect the organisation of health services locally.

Work environment factors

- The practice serves a population which puts high demands on its services; telephones are often busy.
- Waiting times for the doctor of one's choice might be long.
- The local hospital sends a discharge note with the patient for delivery to the GP and mails a copy; patients do not necessarily deliver.
- The rapid assessment and disposal of patients means that communication may be compromised.

- The district nurses are not employed by the practice; they operate as part of a sector team out of a purpose-built health centre a few miles from the practice.

Team factors

- The doctor was not made aware of the patient's admission to hospital.
- The hospital telephoned the district nurse to advise of the discharge. A message was left for the doctor by the orthopaedic registrar, but the fact of the admission and subsequent discharge was only clear when the doctor saw a discharge note about 1 week later. There was no communication between the GP and the district nurse.

Individual factors

- The doctor's instructions were for the patient to see him if she did not get better with the medicines.
- The drug was prescribed and labelled appropriately, but not taken as prescribed.
- The doctor recalls that the visit was a swift one and that he might not have checked that the patient understood his instructions.

Task factors

- It can be difficult getting through to the surgery on the telephone.
- The waiting time to see the relevant doctor is about 2 weeks.
- There are steps up from the flat, which the patient would tackle with difficulty.

CDP: there was a long delay between the doctor deciding to refer and the referral letter being sent

Contributory factors

Clinical context and patient factors

- None.

Institutional factors

- Administrative workload has increased; referrals, doctors' letters, benefits paperwork,

insurance and legal work.

- Quality initiatives such as audits, prescribing reviews and National Service Frameworks require time.

Work environment factors

- The practice serves a population which puts high demands on its services. The partners had recently agreed to extend the morning clinic by 30 minutes to help meet this demand.
- There was typically at least an hour's paperwork to do once patients were seen.

Team factors

- The typist found it difficult to deal with the 'batch' system operated by the doctor. Others tended to dictate a similar number of referrals each day. When the 'batch' came the typist would have difficulty meeting all of her demands and so would work through the batch over a few days.

Individual factors

- The doctor concerned was committed to providing quality care to his patients. His clinics tended to be longer than anyone else's. He was involved in teaching and in quality improvement activities. He organised his work by 'batching' referrals and dealing with these on a once per week basis.

Lessons learned

1. Beware of personal responses to people, places and situations and ensure that clinical practice is consistent across all.
2. Assess the patient's capacity to understand and carry out instructions; if follow-up is important, prompts or reminders might be important for the doctor in addition to the patient.
3. Set a target for the dispatch of referral letters and redesign work processes to ensure that referrals are not unnecessarily delayed.

Appendix 12

Framework of factors influencing clinical practice

Institutional context

- Economic and regulatory context
- Department of Health
- Clinical Negligence Scheme for Trusts
- Links with external organisations.

Organisational and management factors components

Contributory factor	Components
Organisational structure	<ul style="list-style-type: none"> • Hierarchical arrangement of staff within the organisational context • Span of control • Levels of decision-making
Policy, standards and goals	<ul style="list-style-type: none"> • Mission statement and objectives • Management arrangements (function) • Contract services • Human resources • Financial resources/constraints • Information services • Maintenance management • Task design • Education and training policy • Policies and procedures • Facilities and equipment • Risk management (e.g. incident reporting, adverse incident investigation and analysis) • Health and safety management (e.g. fire safety, waste management, infection control and occupational health) • Quality improvement
Risks imported/exported	
Safety culture	<p>This is invoked via the other organisational processes and management factors</p> <ul style="list-style-type: none"> • Attitude to work, safety and others in the workplace • Provision of support mechanisms by management for all staff
Financial resources and constraints	
All of the components in the table above involve some or all of the following processes:	<ul style="list-style-type: none"> • goal setting • communicating • organising • managing • designing • operating • building • maintaining

Work environment components

Contributory factor	Components
Administration	<ul style="list-style-type: none"> • Ease of running and review of general administration systems • Notes handling
Building and design	<ul style="list-style-type: none"> • Maintenance management • Functionality (ergonomic assessment, e.g. lighting, space)
Environment	<ul style="list-style-type: none"> • Housekeeping • Control of the physical environment (e.g. temperature, light) • Movement of patients between wards/sites
Equipment/supplies	<ul style="list-style-type: none"> • Malfunction/failure/reliability • Unavailability • Maintenance management • Functionality (e.g. ergonomic design, fail-safe, standardisation)
Staffing	<ul style="list-style-type: none"> • (Un)availability
Education and training	<ul style="list-style-type: none"> • Induction • Management's influence on training • Process • Refresher training • Provision of training (in general)
Workload/hours of work	<ul style="list-style-type: none"> • Regular rest breaks • Optimal workload (neither too high or too low) • Involved in non-job-related duties
Time factors	<ul style="list-style-type: none"> • Delays

Team components

Contributory factor	Components
Verbal communication	<ul style="list-style-type: none"> • Communication between junior and senior staff • Communication between professions • Communication outside the ward/department, etc. • Adequate handover • Communication between staff and patient • Communication between specialties and departments • Communication between staff of the same grade • Voicing disagreements and concerns • Communication between staff and relatives/carers
Written communication	<ul style="list-style-type: none"> • Incomplete/absent information (e.g. test results) • Discrepancies in the notes • Inadequately flagged notes • Legibility and signatures of records • Adequate management plan • Availability of records • Quality of information in the notes
Supervision and seeking help	<ul style="list-style-type: none"> • Availability of senior staff • Responsiveness of senior staff • Willingness of junior staff to seek help • Responsiveness of junior staff • Availability of junior staff
Congruence/consistency	<ul style="list-style-type: none"> • Similar definition of tasks between professions • Similar definition of tasks between different grades of staff • Similar definition of tasks between same grade of staff
Leadership and responsibility	<ul style="list-style-type: none"> • Effective leadership • Clear definitions of responsibility
Staff colleagues response to incidents	<ul style="list-style-type: none"> • Support by peers after an incident • Support by staff of comparable grades across professions, e.g. senior nurse and junior doctor

Individual (staff) components

Factor	Taxonomic components
Competence	<ul style="list-style-type: none"> • Verification of qualifications • Verification of skills and knowledge
Skills and knowledge	<ul style="list-style-type: none"> • These are possibly the same as for competence
Physical and mental stressors	<ul style="list-style-type: none"> • Motivation • Mental stressors (e.g. the effects of workload, sickness, etc. on the individuals' mental state) • Physical stressors (e.g. the effects of workload, etc., on the individuals' physical health)

Task components

Factor	Taxonomic components
Availability and use of protocols	<ul style="list-style-type: none"> • Procedures for reviewing and updating protocols • Availability of protocols to staff • Use of protocols • Availability of specific types of protocol (e.g. administration of controlled drugs) • Quality of information included in the protocol • Accident and incident investigation procedures
Availability and accuracy of test results	<ul style="list-style-type: none"> • Tests not done • Disagreements regarding the interpretation of the test results • Need to chase up test results
Decision-making aids	<ul style="list-style-type: none"> • Availability, use and reliability of specific types of equipment (e.g. ECG) • Availability, use and reliability of specific types of tests (e.g. blood testing) • Availability and use of a senior clinician
Task design	<ul style="list-style-type: none"> • Can a specific task be completed by a trained member of staff in adequate time and correctly?

Patient components

Factor	Taxonomic components
Condition	<ul style="list-style-type: none"> • Complexity • Seriousness
Personal	<ul style="list-style-type: none"> • Personality • Language • External support • Social and family circumstances
Treatment	<ul style="list-style-type: none"> • Known risks associated with treatment
History	<ul style="list-style-type: none"> • Medically • Personally • Emotionally
Staff-patient relationship	<ul style="list-style-type: none"> • Good working relationship



Health Technology Assessment Programme

Prioritisation Strategy Group

Members

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The HTA Programme and the authors would like to know your views about this report.

The Correspondence Page on the HTA website (<http://www.ncchta.org>) is a convenient way to publish your comments. If you prefer, you can send your comments to the address below, telling us whether you would like us to transfer them to the website.

We look forward to hearing from you.