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How to investigate and analyse clinical incidents: Clinical Risk Unit and Association of Litigation and Risk Management protocol

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Why do things go wrong? Human error is routinely blamed for disasters in the air, on the railways, in complex surgery, and in health care generally. However, quick judgments and routine assignment of blame obscure a more complex truth. The identification of an obvious departure from good practice is usually only the first step of an investigation. Although 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. This more complex picture is gaining acceptance in health care,[1 2] but it is seldom put into practice in the investigation of actual incidents.

The Clinical Risk Unit has developed a process of investigation and analysis of adverse events for use by researchers.[3–7] Two years ago a collaborative research group was formed between the unit and members of the Association of Litigation and Risk Management (ALARM). This group has adapted the research methods to produce a protocol for the investigation and

Summary points

Analyses of clinical incidents should focus less on individuals and more on organisational factors

Use of a formal protocol ensures a systematic, comprehensive, and efficient investigation

The protocol reduces the chance of simplistic explanations and routine assignment of blame

Experience with the protocol suggests that training is needed for it to be used effectively

Analysis of incidents is a powerful method of learning about healthcare organisations

Organisational analyses lead directly to strategies for enhancing patient safety

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Further details of the investigation process are available on the BMJ's website

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Table 1 Framework of factors influencing clinical practice[5]

Factor types	Influencing contributory factors	Examples
Institutional context	Economic and regulatory context; national health service executive; clinical negligence scheme for trusts	Inconsistent policies, funding problems
Organisational and management factors	Financial resources and constraints; organisational structure; policy standards and goals; safety culture and priorities	Lacking senior management procedure for risk reduction
Work environment factors	Staffing levels and skills mix; workload and shift patterns; design, availability, and maintenance of equipment; administrative and managerial support	High workload, inadequate staffing, or limited access to essential equipment
Team factors	Verbal communication; written communication; supervision and seeking help; team structure (consistency, leadership, etc)	Poor communication between staff
Individual (staff) factors	Knowledge and skills; competence; physical and mental health	Lack of knowledge or experience of specific staff
Task factors	Task design and clarity of structure; availability and use of protocols; availability and accuracy of test results	Non-availability of test results or protocols
Patient factors	Condition (complexity and seriousness); language and communication; personality and social factors	Distressed patient or language problem

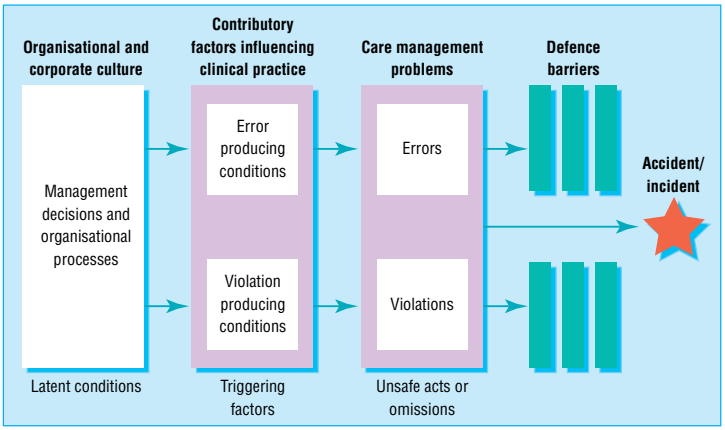
analysis of serious incidents for use by risk managers and others trained in incident analysis. The protocol gives a detailed account of the theoretical background and process of investigation and analysis together with case examples.[8] In this article we introduce the main ideas and present a section of a case analysis to illustrate the methods used.

Research foundations

The theory underlying the protocol and its application derives from research in settings outside health care. In the aviation, oil, and nuclear industries, for instance, the formal investigation of incidents is well established.[9] Studies in these areas and in medicine have led to a much broader understanding of the causes of accidents, with less focus on the individual who makes the error and more on pre-existing organisational factors. Such studies have also illustrated the complexity of the chain of events that may lead to an adverse outcome.[4 6 10–12] The root causes of adverse clinical events may lie in factors such as the use of locum doctors and agency nurses, communication and supervision problems, excessive workload, and educational and training deficiencies.

In health care the development of prevention strategies from such analyses has not yet been fully exploited. However, the potential for these approaches is apparent in other domains. For instance, the inquiry into the Piper Alpha oil disaster led to a host of recommendations and the implementation of several risk reduction strategies throughout the industry. These included the setting up of a single regulatory body for offshore safety, relocation of pipeline emergency shutdown valves, the provision of temporary safe refuges for oil workers, new evacuation procedures, and requirements for emergency safety training. Most interestingly, oil companies were required to demonstrate that hazards had been minimised and were as low as could reasonably be expected.[13–15]

In the original research we used a combination of record review, staff interviews, and a checklist of human factors highlighting psychological and organisational factors. We applied Reason's model of organisational accidents to clinical incidents,[2] reviewing both errors made and the background organisational factors that were implicated. We have extended Reason's generic model and adapted it for use in a healthcare setting, classifying the error producing conditions and organisational factors in a single broad framework of factors affecting clinical practice. Both Reason's model and our framework are described elsewhere.[5] The figure and table 1 show the essential components of the model and the framework.



Model of organisational causes of accidents (adapted from Reason[9])

Essential concepts and overview of process

The model requires that the investigator starts by examining the chain of events that led to an accident or adverse outcome and considering the actions of those involved. The investigator then, crucially, looks further back at the conditions in which staff were working and the organisational context in which the incident occurred. Below, we detail the application of the model in a healthcare setting.

Care management problems

The first step in any analysis is to identify the care management problems, which are broadly speaking the healthcare equivalent of Reason's "unsafe acts."[2 7] Care management problems are actions or omissions by staff in the process of care. These may be slips, such as picking up the wrong syringe, lapses of judgment, forgetting to carry out a procedure, or, rarely, deliberate departures from safe operating practices, procedures, or standards.

Care management problems have two essential features: firstly, care deviated beyond safe limits of practice and, secondly, the deviation had a direct or indirect effect on the eventual adverse outcome for the patient. (In cases where the impact on the patient is

unclear it is sufficient that the care management problem had a potentially adverse effect.) Each care management problem is identified individually and the reason for its occurrence analysed separately.

Clinical context and patient factors

For each care management problem identified, the investigator records the salient clinical events or condition of the patient at that time (for example, bleeding heavily, blood pressure falling) and other patient factors affecting the process of care (for example, patient very distressed, patient unable to understand instructions).

Specific contributory factors

After the care management problems have been identified, the investigator considers the conditions in which errors occur and the wider organisational context. Using the framework (table 1) both during staff interviews and afterwards, the investigator identifies the factors that led to each care management problem. Any combination of different level factors might contribute to the occurrence of a single care management problem.

General contributory factors

Once the investigator has identified the various factors that contributed to the incident, a further distinction needs to be drawn between specific contributory and general contributory factors. For instance, a failure of communication between a doctor and a nurse may have contributed to a care management problem. If this is an isolated occurrence, then it is a specific contributory factor with no more general implications. If, on the other hand, the problem is quite common the investigator would also note a general contributory factor of "poor communication." The general factors are those longstanding features which have clear implications for the safe and effective running of the unit or hospital. When trying to decide whether to record a general contributory factor the investigator might consider such questions as:

- Does the lack of knowledge shown on this occasion imply that this member of staff requires additional training?
- Does this particular problem mean that the whole clinical protocol needs to be revised?
- Is the high workload due to a temporary and unusual set of circumstances or is it a more general problem affecting patient safety?

Investigation process

More details on the investigation process are available on the *BMJ*'s website and in the protocol.[8] The box below provides a summary.

Case example

The box on the next page shows an example based on real clinical events, but it has been altered in various respects to preserve anonymity. The case is described and fully analysed in the protocol.[8] The main care management problems identified were non-communication of formulated care plan, inadequate fetal monitoring in first and second stage of labour, inadequate pain control in first stage of labour, and delay in management in second stage of labour. Each of these care management problems was analysed separately. Table 2 shows the contributory factors for the problem with fetal monitoring.

The final report of this case concluded that "with the benefit of hindsight, the outcome of this delivery might, on a balance of probabilities, have been different."[8] After analysis of this case and discussion of the implications, changes were made to the organisation and policies of the unit. These included a new protocol stipulating that when there was a conflict between information provided by different types of monitoring equipment, best practice would be to assume the worst case and seek medical advice; an individual training programme for specific members of staff; a programme of further education for all midwives in the assessment and management of shoulder dystocia; and review and eventual replacement of all outdated fetal monitoring equipment.

Examples of care management problems

Failure to monitor, observe, or act
Delay in diagnosis
Incorrect risk assessment (for example, of suicide or self harm)
Inadequate handover
Failure to note faulty equipment
Failure to carry out preoperative checks
Not following an agreed protocol (without clinical justification)
Not seeking help when necessary
Failure to supervise adequately a junior member of staff
Incorrect protocol applied
Treatment given to incorrect body site
Wrong treatment given

Summary of investigation process

All investigations consist of a series of steps that should be followed, as a matter of routine, when an incident is investigated:

1. Ascertain that a serious clinical incident has occurred and ensure it is reported formally. Alternatively identify an incident as being fruitful in terms of organisational learning
2. Trigger the investigation procedure. Notify senior members of staff who have been trained to carry out investigations
3. Establish the circumstances as they initially appear and complete an initial summary, decide which part of the process of care requires investigation, prepare an outline chronology of events, and identify any obvious care management problems
4. Structured interview of staff:
   Establish chronology of events
   Revisit sequence of events and ask questions about each care management problem identified at the initial stage
   Use framework to ask supplementary questions about reasons for each care management problem
5. If new care management problems have emerged during interviews add them to initial list. Interview again if necessary
6. Collate interviews and assemble composite analysis under each care management problem identified. Identify both specific and, where appropriate, general contributory factors
7. Compile report of events, listing causes of care management problems and recommendations to prevent recurrence
8. Submit report to senior clinicians and management according to local arrangements
9. Implement actions arising from report and monitor progress

Table 2 Contributory factors to care management problem with fetal monitoring during first and second stages of labour

Specific	General
Work and environment factors	
Maternity building undergoing extensive building works while still in use. Normal geography disturbed	None
Team factors	
Notes not retrieved from library promptly. Care plan set out by consultant not seen. Unit normally staffed, workload average	Shift change procedures, need to ensure records recovered fast
Individual factors	
Midwives failed to heed slowing heart rate on cardiotocogram as they were distracted by the mother's distress and resistance to advice	Cardiotocography awareness and training
Task factors	
Midwives not aware of possible dystocia. Delay between crowning and complete delivery. Scalp electrode removal not covered by policy	Lack of clear policy guidelines
Organisational, management, and institutional context factors	
Unit had been without head of midwifery service for 2 years. Functions carried out by G grade supervisors	

Discussion

The method described above has been tested on over 40 incidents, initially in a research context and later by clinicians and risk managers. Incidents have been investigated in obstetrics, anaesthetics, accident and emergency, orthopaedics, general medicine, and psychiatry. A structured and systematic approach means that the ground to be covered in any investigation is already largely mapped out. The protocol helps to ensure a comprehensive investigation and facilitates the production of formal reports. Although the process may initially seem complicated and time consuming, our experience is that using the protocol actually speeds up complex investigations by focusing the investigators on the key issues and bringing out the systemic factors behind the incident. Members of the research team have found that once the general contributory factors are identified, they lead automatically to the implications and action points. The final report "almost writes itself."

Even experienced clinicians find that following the protocol brings additional benefits in terms of comprehensiveness and investigation expertise. Clinicians are accustomed to identifying the problematic features in the management of a case and so can easily identify the care management problems. However, they are less familiar with identifying contributory factors for each care management problem. A systematic approach pays dividends when exploring these. The protocol does not attempt to supplant clinical expertise. Rather, the aim is to use clinical experience and expertise to the fullest extent.

A formal, systematic approach also benefits the staff involved. The methods used are designed to promote a greater climate of openness and to move away from finger pointing and the routine assignment of blame. This differs greatly from the quasijudicial approach often used in formal inquiries. If a consistent approach to investigation is used, staff tend to find the process less threatening than traditional unstructured approaches, especially when the same procedure is being followed with everyone involved.

Early experience with the protocol has shown that some formal training and practice is needed for it to be fully effective. Although the basic ideas can be grasped relatively quickly, the full method takes longer to absorb. Guided practice on the investigation of incidents, preferably in a local context, is essential to become familiar with the methods. Initially this protocol is likely to be used by risk managers, with additional clinical input. However, we suggest that the next step is to designate and train investigators in each clinical area who can carry out an investigation to agreed guidelines.

Although we believe that the protocol is an effective and valuable tool, it is still at a relatively early stage of development, both conceptually and practically. Formal evaluation is needed and a great deal more practical testing is required. We plan to revise and develop the protocol in the light of experience and formal

Case summary: death of baby after difficult delivery

Mrs B was booked for shared care. Her last child weighed 4.4 kg at birth and slight shoulder dystocia was noted at delivery. Mrs B was referred to the consultant by the community midwife at 38 weeks as the baby felt large for dates. The ultrasound scan estimated the weight of the baby as 4.5 kg. A graded response to the findings on palpation and ultrasound was made bearing in mind the woman's previous obstetric history. Firstly, the pregnancy should not progress more than six days beyond the due date before induction of labour, rather than the usual 12-14 days. Secondly, it was recorded that no attempt should be made at a difficult mid-cavity instrumental delivery. Thirdly, the possibility of shoulder dystocia was anticipated and recorded to forewarn the labour ward staff.

Chronology

0555: Mrs B was admitted with ruptured membranes. Labour started shortly afterwards

0650: Vaginal examination showed her cervix to be 3 cm dilated. The fetal heart was monitored by external Doppler probe. At this stage Mrs B requested an epidural, but the anaesthetist was not immediately available as he was finishing handing over on the intensive care unit. Mrs B's labour proceeded rapidly and therefore an epidural was not carried out

0715: A scalp electrode was placed on the baby's head as the midwives were unable to monitor the fetal heart easily in view of maternal size and maternal distress. The trace showed the fetal heart rate to be normal

0750: A further vaginal examination was carried out. Mrs B's cervix was 6 cm dilated, the fetal heart rate was normal with good variability. Pethidine was administered

0805: The cervix was fully dilated and pushing started. Mrs B was unable to cooperate with staff as she was in pain and very distressed

0814: Scalp electrode was removed as the head was crowning. The final readings of the fetal heart before the scalp electrode was removed showed marked decelerations with a decreasing trend. The delivery did not proceed and the head remained stationary. The external Doppler probe was reattached and showed fetal heart rate at 160-170 beat/min

0833: Medical help was sought. The obstetric registrar and the duty consultant came immediately and quickly diagnosed shoulder dystocia. They carried out a McRoberts manoeuvre and then applied suprapubic pressure; the baby was delivered at 0839

0839: The infant was severely compromised with no heart beat. He was resuscitated and ventilated and then transferred to the special care baby unit but died the next day

evaluation. The protocol also has potential as a research instrument since use of a common method will make analyses of case series of incidents more powerful. In the meantime, however, it is already proving a powerful means of investigating and analysing clinical incidents and drawing out the lessons for enhancing patient safety.

Copies of the full protocol and details of training programmes are available from Association of Litigation and Risk Management (ALARM), Royal Society of Medicine, 1 Wimpole Street, London W1.

Contributors: CV and ST-A carried out the research on which the original protocol was based. All authors participated equally in the development of the protocol, in which successive versions were tested in clinical practice and refined in the light of experience. The writing of the original protocol and present paper was primarily carried out by CV, ST-A, EJC, and DH, but all authors contributed to the final version. CV and DH are the guarantors.

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On error management: lessons from aviation

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Pilots and doctors operate in complex environments where teams interact with technology. In both domains, risk varies from low to high with threats coming from a variety of sources in the environment. Safety is paramount for both professions, but cost issues can influence the commitment of resources for safety efforts. Aircraft accidents are infrequent, highly visible, and often involve massive loss of life, resulting in exhaustive investigation into causal factors, public reports, and remedial action. Research by the National Aeronautics and Space Administration into aviation accidents has found that 70% involve human error.[1]

In contrast, medical adverse events happen to individual patients and seldom receive national publicity. More importantly, there is no standardised method of investigation, documentation, and dissemination. The US Institute of Medicine estimates that each year between 44 000 and 98 000 people die as a result of medical errors. When error is suspected, litigation and new regulations are threats in both medicine and aviation.

Error results from physiological and psychological limitations of humans.[2] Causes of error include fatigue, workload, and fear as well as cognitive overload, poor interpersonal communications, imperfect information processing, and flawed decision making.[3] In both aviation and medicine, teamwork is required, and team error can be defined as action or inaction leading to deviation from team or organisational intentions. Aviation increasingly uses error management strategies to improve safety. Error management is based on understanding the nature and extent of error, changing the conditions that induce error, determining behaviours that prevent or mitigate error, and training personnel in their use.[4] Though recognising that operating theatres are not cockpits, I describe approaches that may help improve patient safety.

Summary points

- In aviation, accidents are usually highly visible, and as a result aviation has developed standardised methods of investigating, documenting, and disseminating errors and their lessons
- Although operating theatres are not cockpits, medicine could learn from aviation
- Observation of flights in operation has identified failures of compliance, communication, procedures, proficiency, and decision making in contributing to errors
- Surveys in operating theatres have confirmed that pilots and doctors have common interpersonal problem areas and similarities in professional culture
- Accepting the inevitability of error and the importance of reliable data on error and its management will allow systematic efforts to reduce the frequency and severity of adverse events

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A full explanation of the threat and error management model, with a case study, appears on the BMJ's website

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