Clinical risk management in anaesthesia

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Key points

Risk management is central to the everyday work of the anaesthetist.

Anaesthetists should be involved in risk management at departmental and trust level.

Prospective risk management should be an ongoing day-to-day activity.

A major patient safety incident should result in a root cause analysis.

Risk management is a method of dealing with uncertainty.

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Risk is ubiquitous in medicine but anaesthesia is an unusual speciality as it routinely involves deliberately placing the patient in a situation that is intrinsically full of risk. Patient safety, the anaesthetist's raison d'être and the heart of the clinical governance agenda, depends on management of those risks; consequently, anaesthetists have been at the forefront of clinical risk management (CRM). Formal risk assessment and management in other industries such as aviation and deep sea diving are now routine, and the use of these processes has been successful in producing clear and identifiable improvements in safety. Although clinicians have learned much from other industries and considerable work has been undertaken at an international and national level to develop a robust approach to CRM, there is still a long way to go in healthcare. Much of what needs to be achieved involves education and formalizing the risk assessment and management that forms a part of everyday anaesthetic practice. This article describes a structured approach to CRM in anaesthesia.

Risk management in anaesthesia and critical care can be described in five stages as follows (Table 1): risk awareness, risk identification, risk assessment, risk management and re-evaluation.

Risk awareness

A simple definition of clinical risk is the potential for unwanted outcome. The most obvious concern for patients and clinicians is the risk of personal injury. In the context of anaesthesia, injury can range from temporary discomfort, such as nausea in recovery, to permanent disability or death. The patient can be viewed as being in the centre of a web of complex interactions between disease process, medication, the anaesthetist, equipment and other members of the healthcare team; this complexity brings risk. CRM starts with awareness that these risks exist and may lead to patient safety being compromised.

It follows that, in this complex system, patient safety incidents (PSI) will inevitably occur through mistake, accident or mishap, unless appropriate risk management strategies are implemented. A PSI may be defined as any unintended or unexpected incident that could have, or did, lead to harm (sometimes called a 'critical incident'). The Department of Health estimates that approximately 10% of inpatients experience a PSI while in hospital and there is evidence in the literature that approximately 50% of these incidents are preventable. Frequently, the underlying cause of a PSI is inadequate communication; other common causes are lack of clear policies or guidelines, deficient working practices, poorly defined responsibility, and occasionally inadequate training or supervision.

Robust systems can help reduce risk; for example, the routine anaesthetic machine check, syringe labelling, appropriate supervision of trainees and trained assistants, and competency assessment of anaesthetists to ensure they are capable of performing to the required level. Training has traditionally been focused towards clinical activity but the general principle of risk awareness should be formally established in anaesthetic training from the beginning.

Risk identification

There are a number of methods for identifying clinical risks, both retrospective and prospective.

Table 1 Five stages of clinical risk management

Risk awareness: hospital care constitutes a complex system and that this complexity brings risk
Risk identification: a process for identifying specific risks in a particular set of circumstances. This can be either retrospective or prospective
Risk assessment: an assessment of the magnitude of a particular risk, how likely it is to result in a particular outcome and the impact of that outcome on the patient(s)
Risk management: the development of plans and strategies to minimize identified risks to tolerable levels
Re-evaluation: a continuous process whereby risks are reviewed with the aim of developing safer systems

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Retrospective

Patient safety incident reporting

Most trusts now have well-developed incident reporting systems in place, but these are dependent on staff identifying and reporting relevant incidents. Voluntary incident reporting alone only captures a minority of PSIs, and it appears that there are many barriers to reporting. A variety of techniques to formalize reporting have been tried and tested, including automated reporting of pre-defined events from computerized anaesthetic charts[1] but none is all encompassing. A study in which patients were interviewed during hospitalization and after discharge demonstrated that many patients identified events that were not captured by the hospital reporting system.[2] PSI data are usually collected centrally within a Trust on a database that can be interrogated to identify trends or high-risk areas and activities. It is important that data are reviewed regularly, at department level, so that feedback can be given to staff who report the incidents. A 'just-blame' culture that encourages reporting and separates the process of incident reporting from disciplinary procedures, that has in the past inhibited staff from reporting adverse events, is essential.

The National Patient Safety Agency (NPSA) has established the National Reporting and Learning System to which all Trusts now submit incident data on a routine basis. The aim of this is to assist the NHS to learn as an organization about high-risk activities. These data allow the NPSA to recognize and focus on 'clusters' and inform the publication of 'Patient Safety Alerts' that make recommendations for improving safety. Recent NPSA alerts of relevance to anaesthetic practice include the management of concentrated potassium solutions, naso gastric tube positioning and 'Correct site surgery'.

This model of national collation of PSI reports is not new and has been shown to be effective: the best known example being the Australian Incident Monitoring Study (AIMS) database.[3] The AIMS database started in 1987 and by 2001 had collected 8088 PSIs. A number of issues have been successfully examined by selecting records from this database, including the applications and limitations of pulse oximetry, fatigue in anaesthetists, cardiac arrest, drug errors, awareness under anaesthesia and aspiration.

Complaints and claims

Lessons may also be learned from litigation, although these incidents are highly selected compared with anonymous 'just-blame' reporting. The reports of the American Closed Claims Analysis started in 1985; they have given insight into issues such as the role of monitoring in the prevention of anaesthetic mishaps and airway damage during anaesthesia. Again, at a local level, particular aspects of care may have resulted in complaints and claims and these can form the focus of risk analysis.

Retrospective case note review

Major studies[4 5] published in the late 80s and early 90s, undertaken with the aim of estimating the extent of patient harm from healthcare, relied on a two-stage retrospective case note screening technique to identify adverse events. This approach certainly can identify events that are not reported through incident reporting systems.[6] It is an effective way of looking at individual cases or aspects of care with a view to learning and improving. Routine mortality audit is an example of this approach and, when undertaken in an open and learning environment, can be very effective in identifying particular risks within a unit or patient population.

Root cause analysis

Root cause analysis (RCA) is defined as a structured investigation that aims to identify the true cause of a problem, and the actions necessary to eliminate it.[7] RCA is much more time and labour intensive than routine departmental procedures but provides a thorough and formal analysis of why an adverse event occurred and how it may be prevented in the future, rather than a quick fix focused on the most obvious symptom of a problem. There are four stages of RCA as follows:

i. *Data collection*. All available information that may help the investigation is collected, from local protocols to switchboard records. The patient's whole admission is considered, not just the PSI.
ii. *Presentation of information so that problems can be identified*. The method depends on the case but examples include a simple chronological narrative or a tabular timeline, a table listing what each person involved in the incident was doing for each 5 min block of time
iii. *Root cause identification*. There are many methods of identifying the underlying system errors that cause PSIs. For example, 5 Whys describes a process where one does not accept the first answer for a root cause and keeps asking why each cause happened until all agree that the fundamental cause has been identified. This frequently takes more than 5 whys! Barrier Analysis looks at the control measures in place to prevent error. Physical barriers, such as locking a patient controlled analgesia device, are the strongest but are not possible for every situation. Natural barriers are temporal, for example, waiting between two independent brain stem deaths tests, or distance placement barriers, for example, locking potassium solution for i.v. injection away with controlled drugs. Checking blood before transfusion is an example of a human action barrier. Administrative barriers include protocols, supervision and training. Human and administrative barriers are weak as they are particularly prone to error. There are numerous other techniques and each of these techniques may be used for each problem identified, not for the PSI as a whole.
iv. *Recommendations and implementation*.

RCA is performed by a team of clinicians, risk managers and sometimes lay-people. The people who were involved in the PSI are also included in the RCA process. A single sentinel event such as a major or catastrophic PSI should always trigger the

commissioning of a RCA. Common RCA findings include communication failure and insufficient education and training. A full discussion of RCA is beyond the scope of this article but an interactive description of RCA with case studies can be found on the NPSA website.[8]

Prospective

This is again closely related to the day-to-day work of an anaesthetist. Planning an anaesthetic is a form of prospective risk assessment. Think of how you would plan to transfer an ICU patient to the CT scanner. Your planning for equipment needed, staff required, etc., represents prospective risk management.

Prospective risk management can also be a systematic and comprehensive review of a whole organization looking for potential risks. This will usually involve a risk management team formed from a variety of professional backgrounds from each department. Broad areas of risk such as 'equipment' are analysed and, for each category, key questions are asked, for example, do staff know how to operate this equipment? How do we know they know? Have they been assessed as competent? Do they know what to do if the equipment fails? Conducting such a review is likely to become increasingly common as it is one of the criteria that must be fulfilled in order to demonstrate compliance with the Clinical Negligence Scheme for Trusts (CNST) risk management standards administered by the NHS Litigation Authority. Trusts demonstrating compliance with these standards pay reduced premiums on indemnity insurance.

Prospective risk assessment should be carried out on an ongoing basis, and should involve risk assessment forms being completed by any member of NHS staff, in a similar way to PSI forms. Information gathered should include the nature of the risk, current barriers to the hazard and suggestions about how the risk could be managed.

Risk assessment and analysis

Once a particular risk has been identified, the magnitude of the risk needs to be assessed to determine the extent and nature of the control measures required to bring the risk within acceptable levels. Two aspects of the risk are assessed: the likelihood of occurrence or recurrence; and the most likely outcome should the hazard be realized. A commonly used scale for outcome severity is as follows:

(i) None, no adverse clinical outcome or a prevented PSI;
(ii) Minor, short term injury taking up to a month to resolve;
(iii) Moderate, a semi-permanent injury that may take up to 1 yr to resolve;
(iv) Major causing permanent disability;
(v) Catastrophic, resulting in death.

Other factors or alternative ways of estimating severity are the number of patients involved and the likely cost of litigation. Frequency of occurrence can be assessed using the scale as follows:

(i) Almost certain, and likely to occur on many occasions;
(ii) Likely, an outcome that is expected to occur;
(iii) Possible, an outcome not expected to occur;
(iv) Unlikely, an event that may occur in a large organization on a less than annual basis;
(v) Rare, an event that a clinician would probably not see in their career.

Severity and frequency of the most likely outcome can then be combined in a matrix (Fig. 1) and the position of each risk on the matrix assigned an overall risk rating or numerical value. For elective patients returning to understaffed wards at night (Fig. 1, Example 1), it could be said that the most severe outcome would be that a preventable catastrophic complication was not being referred to medical staff in time and assigned 'high risk'. However, the most likely outcome is that the patient receives inadequate analgesia, a minor consequence as it will be resolved when staffing levels improve in the day. Although this will almost certainly happen, the overall classification is of 'low risk'. It is clear that the interpretations required when measuring risk this way are subjective, but the most likely outcomes can be clarified by audit. In Example 2 (a junior obstetric anaesthetist, unsupervised in a remote location), the most likely consequence resulting from the location is likely to be more serious, for example, mismanagement of major haemorrhage. However, this is less common that Example 1 and is classified 'moderate risk'. In Example 3 (new trainees not knowing the location of the difficult airway equipment), it could be argued that the most likely outcome is failure to oxygenate adequately, and the potential catastrophic outcome makes it 'high risk', even after considering the probability of the event. The numbers for frequency and severity can be multiplied to give an overall score, or risks can be ranked by a traffic light system of colour from the matrix. At Trust level, the ranked risks are held in a risk register. This allows the Trust to prioritize limited resources to reduce risk appropriately. Trust Boards are responsible for managing risk at the highest level within an organization and must use the information within the risk register to determine priorities for strategic planning.

Risk management

The actions taken aim to reduce an identified hazard to a tolerable risk, that is, a risk that has been reduced to the lowest level possible within available resources. A hierarchy of control methods exists from no action to complete removal of a particular risk. As mentioned previously, a physical barrier is one of the most robust methods of risk reduction, for example, a locked drug cupboard. However, there are very rarely absolute physical barriers in place; for example, it is difficult to make it impossible to administer an incorrect drug to a patient (although this has been suggested in the case of intrathecal administration by using a unique syringe connector), and we usually rely on imperfect

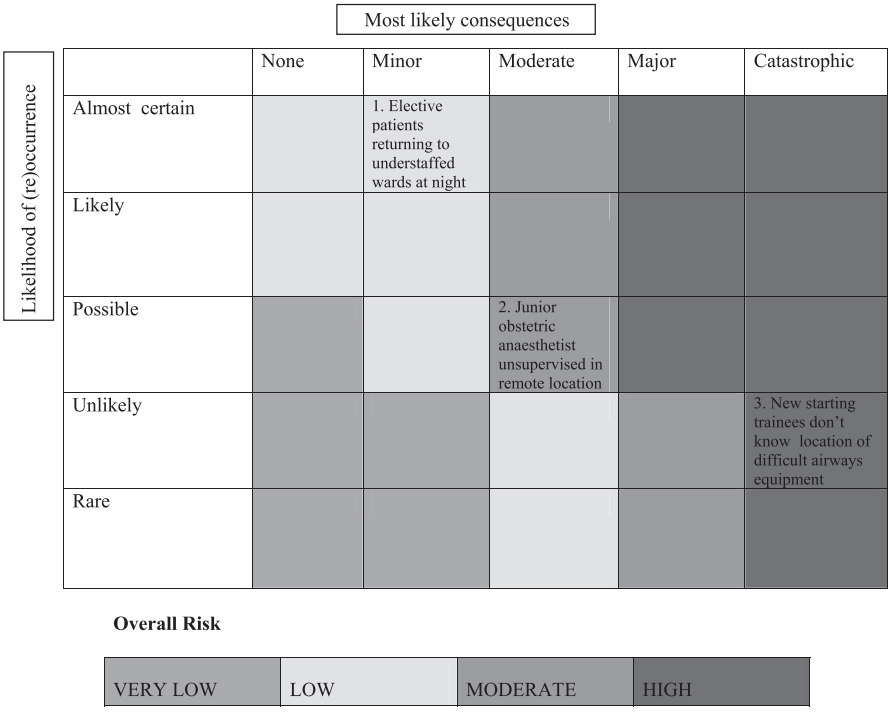

Fig. 1 Risk assessment matrix with three examples

barriers such as syringe labelling. Lower down the hierarchy are policies and protocols to promote safe working practices and education and training. An example of this is the Minimal Mandatory Monitoring Guidelines[9] that have been almost universally followed in anaesthesia in the developed world; although there is no level 1 evidence that this has affected mortality, it is generally considered that the benefits are beyond doubt and that such a trial would be unethical.

The training, and possibly selection, of staff is a target for risk management. The level of supervision of trainees in anaesthesia is also clearly linked with clinical risk. There is inevitably a learning curve in any area of anaesthetic practice and the assessment of the appropriate levels of competence for various levels of supervision is becoming an increasingly prominent part of anaesthetic training in the UK. Competence is a point on a spectrum of ability from absolute beginner to expert. Deciding what competence is and how it should be assessed is subjective and often open to debate, balancing what is an acceptable level of risk to the patient within the resource limitations of the NHS.

Ultimately, dealing with risks involves managing uncertainty, especially if assessing risks prospectively.

Re-evaluation

Risks should be regularly reviewed and reassessed to ensure the assessments remain accurate and new risks have not been introduced by controls intended to reduce risk. Any new practice, service activity or procedure should prompt a clinical risk assessment to ensure appropriate controls and salvage strategies are implemented. It is essential to embed within the organization the routine collection of relevant information, analysis and feedback with appropriate actions to relevant staff and to promote a just-blame and safety culture.

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Please see multiple choice questions 22–24.