Standards for critical incident reporting in critical care

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1. Introduction

1.1. A critical incident is any event or circumstance that caused or could have caused (referred to as a near miss) unplanned harm, suffering, loss or damage. Incidents are usually categorised as:

- Clinical incident / near miss (see Table 1.1 for examples)
- Medication error / near miss
- Patient accident / incident / near miss
- Staff accident / incident / near miss
- Staff work related ill health
- Staff violence / abuse / harassment
- Security incident
- Other near miss

Table 1.1 Examples of clinical critical incidents

- An event or omission has arisen during clinical care and has caused physical or psychological injury to a patient
- Potential physical or psychological injury to a patient could have been caused by an event or omission
- Matters of communication or consent to treatment which give cause for concern
- Drug errors (failure of proper identification, inaccurate dosage etc.) which cause actual or potential harm to the patient
- Failures or weaknesses in clinical procedures and/or guidelines
- Adverse events in patients involved in research studies
- Clinical adverse events or near misses that are reported via the clinical audit process, that become apparent from complaints being investigated in the Division or from legal claims against the Trust
- Slips, trips or falls

1.2. Incidents within these categories incidents include:

- Injury, no matter how small, being caused accidentally or deliberately, including any cause of known or suspected work- or environment-related ill health
- Any incident where an appropriate or false alarm resulted in the Fire Services attending any Trust premises
- Any incident involving intentional or accidental loss or damage to property, including equipment and buildings, to staff, patients, and visitors to the Trust
- A violent or threatening incident, including verbal abuse, that has caused (or potentially caused) harm, injury or distress to a member of staff, patient, visitor or other person
- Spills, floods, environmental incidents, anonymous or malicious communications, bomb hoaxes, etc.
- Any unplanned or unpremeditated event caused by unsafe acts or conditions where an injury could have resulted but did not occur

1.3. Incident reporting is now widespread amongst intensive care units in keeping with trends in high-risk industries. The purpose of incident reporting is to learn from the incident to improve safety. Incidents are reported for the following reasons:

- To meet Trusts' legal duties as employers to report certain kinds of accident, violent incident, dangerous occurrence and occupational ill health under the Health and Safety at Work etc. Act 1974 and more specifically, the Reporting of Injuries, Diseases and Dangerous Occurrences Regulations 1995 (RIDDOR)
- To ensure that each unit has accurate information on incidents so that trends can be identified and steps taken to prevent similar incidents from occurring in the future
- Where appropriate, to provide evidence in pursuit of litigation claims, both for and against the Trust
- To identify incidents that require reporting to a national body, e.g. Medicines and Healthcare Products Regulatory Agency (MHRA), National Patient Safety Agency (NPSA)

- To record incidents of particular interest for quality assurance, including the ability to demonstrate accident reductions, as part of a Trust's risk management strategy

1.4. For specific roles and responsibilities in the reporting and management of incidents see section 5.

1.5. Reporting of incidents should not lead to disciplinary action except where acts or omissions are malicious, criminal, or constitute gross or repeated misconduct. All reported incidents should be managed in accordance with local guidance within the Trust but the stages of incident management should typically follow the steps in Table 1.2 (less severe incidents may not require all steps to be followed).

> **Table 1.2 Stages of incident management**
>
> 1   Notification
> 2   Pre-investigation
> 3   Investigation
> 4   Analysis of investigation results
> 5   Conclusions and recommendations for action
> 6   Implementation of actions
> 7   Feedback to staff
> 8   Monitoring of actions

1.6. These standards for critical incident management in critical care aim to focus on the specific needs of critical care while covering the wider NHS reporting and management systems promoted by the NPSA. Critical incident reporting should be:
- capable of being used across the entire spectrum of the national healthcare system by staff, patients and relatives
- sufficiently flexible to meet the requirements of both specialty-based units such as critical care and generic reporting
- capable of web-based reporting and rapid analysis and feedback
- suitable for both local use and national data collection

2. The history and development of critical incident reporting systems

2.1. The history of critical incident reporting dates back to World War II when both the military and industry recognised the value of having a voluntary reporting system. In the USA, the Air Commerce Act of 1926 charged the Secretary of Commerce with, amongst other things, improving and maintaining safety standards[1]. The Department of Commerce initially concentrated on establishing safety rules and certifying pilots and aircraft. In 1934, the Bureau of Air Commerce encouraged a group of airlines to form three centres for air traffic control to help separate aircraft travelling along designated routes between cities. In 1938, federal civil aviation responsibilities were transferred to a new independent agency, the Civil Aeronautics Authority, subsequently split into two agencies with different responsibilities; the Civil Aeronautics Administration (CAA) and the Civil Aeronautics Board (CAB). The latter is responsible for safety rule-making and accident investigation[2].

2.2. The Federal Aviation Act of 1958 was passed in response to a series of mid-air collisions and the impending introduction of jet aircraft[3]. The need for a US incident data system was recognised. In 1967 accident investigation become the responsibility of the National Transportation Safety Board[4].

2.3. Following a series of violent aircraft hijackings in 1972 a landmark change in aviation security was initiated[5]. A bill, signed in 1974, sanctioned universal screening of passengers and their luggage.

2.4. All of these measures, designed to increase security and improve safety, were introduced after problems had arisen. Following the crash of flight TWA 514 at Dulles airport, Washington, in December 1974 a study of the National Air Transportation System was

conducted and in 1976 the Aviation Safety Reporting System (ASRS) was established by the FAA and National Aeronautics and Space Administration (NASA). The ASRS collects, analyses and responds to voluntarily submitted aviation safety incident reports in order to reduce the likelihood of accidents. Information is shared by the publication of a monthly safety bulletin. It is well recognised that there are usually a number of events leading up to an accident and that the same pattern of failures will precede a near miss[6,7]. Collecting these data may be just as valuable in risk management as focusing solely on adverse events. Other organisations such as Shell Petroleum and British Nuclear Fuels have reporting systems in place. The latter routinely look for events within and outside the company and seek information that can be shared in the interests of safety and quality improvement.

2.5.   These industries have well-developed reporting systems because of the human, environmental and financial consequences of actual incidents. Despite the Department of Health issuing formal guidance on incident reporting in 1955[8] there is no universally accepted process within the National Health Service for identifying or reporting critical incidents nor is there a comprehensive system for gathering data. Systems such as the Confidential Enquiries into Perioperative Deaths and Maternal Mortality, Audit Commission reports and the NHS complaints procedure may generate information on critical incidents as a by-product but this is not their primary aim. There has been further advice from the NHS Executive[9], as a result of the Allitt Inquiry[10], recommending the use of protocols as a simple method of reporting untoward incidents to the Chief Executive or Regional Office. The Clinical Negligence Scheme for Trusts (CNST), established in 1995, gave Trusts an incentive to develop critical incident reporting systems but there is still wide variation in the procedures adopted and none foster the concept of 'an environment to learn'. Where learning does occur, the pace of change is inexorably slow or not sustained.

2.6.   Clinical governance was introduced by the government in 1997[11]. It gave NHS providers a statutory responsibility to improve the quality of care provided to NHS patients. New structures were established: National Service Frameworks and the National Institute of Clinical Excellence (NICE) to set standards, the NHS Performance Assessment Framework to assess performance against these standards and the Commission for Health Improvement (CHI) to review local clinical governance systems. Despite these systems being introduced, there are still almost one million incidents in the UK each year that harm or could have harmed NHS hospital in-patients. The costs in terms of human suffering, staff recruitment and retention and the financial implications are great and yet still the NHS does not reliably collect data regarding such incidents nor is there an established process in place to facilitate learning from these mistakes.

2.7.   In June 2000, the Government accepted all recommendations made in the report of an expert group, led by Dr Liam Donaldson, Chief Medical Officer, called An Organisation with a Memory[12]. The report accepted the lack of data collection and learning surrounding these incidents and also drew attention to the scale of the problem. The document recommended "….solutions based on developing a culture of openness, reporting and safety consciousness within NHS organisations". Building a Safer NHS for Patients, published in 2001[13], sets out the Government's commitment to implementing these recommendations as part of the NHS plan and supported the development of an integrated, national reporting system. The NPSA, a Special Health Authority, was established in July 2001 to "…implement and operate the system with one core purpose – to improve patient safety by reducing the risk of harm through error." As well as ensuring that incidents are reported it encourages all healthcare personnel to report without fear of reprisal by adopting a fair and open culture within the NHS. Data from around the country will be collated and measures put in place to prevent recurrence of the incident while ensuring that the whole NHS learns from the experience, in order to improve patient safety. Since April 2005 the Agency has expanded and is now responsible, amongst other things, for safety issues regarding hospital design, cleanliness and food. The NPSA also takes a proactive approach to developing national solutions aimed at the prevention of incidents that may cause harm to patients. It encourages collaboration between specialties and the dissemination of information through its 17 clinical specialty advisors to raise the profile of patient safety within the Royal Colleges.

3. Data collection systems

3.1. Voluntary reporting systems are important to help reduce adverse events. It is not only important to record such occurrences but also to collect data that enable the organisation to identify the factors that lead to such incidents. A survey of critical incident reporting in UK intensive care units (ICU) shows a degree of variability[14]. Paper-based, non-specific reporting systems (e.g. the NHS IR1 forms) are available in most NHS Trusts. Local paper-based systems, and in some cases local electronic systems, are increasingly used to populate Trustwide risk management databases which interface to and feed the national NPSA database. Such systems may have specialty or area-specific subsets of information requested / collected (e.g. the DATIX incident management reporting system widely used in NHS Trusts, the Australian Incident Monitoring system (AIMS), the National Reporting and Learning System (NRLS) from the NPSA).

3.2. Specialty-specific incident reporting systems relate to a circumscribed area of activity and often have characteristics of or have grown out of a research project to collect and analyse information on events, complications and outcomes for a specific treatment area (e.g. The Royal College of Anaesthetists critical incident form and database). The Society of Critical Care Medicine (SCCM) has developed a voluntary and anonymous, web-based ICU Safety Reporting System (ICUSRS). The ICUSRS is used to report unsafe conditions and events in ICUs that could or did lead to patient harm (see http://www.icusrs.org/). It considers a "system factors" approach to patient safety, focusing on the conditions under which ICU staff work, to prevent and limit the effect of medical errors. This relatively new approach stands in contrast to the traditional "person approach" which blames individuals for causing errors[15].

3.3. The commonest reporting system in UK critical care seems to be a form that is completed but there is little UK consensus regarding the dataset of such forms[14]. Local electronic systems have allowed confidential reporting with no risk of handwriting recognition if anonymity is sought (although the use of password systems may allow identification of the reporter). They allow immediate insertion into an analysable database without transcription delay and error.

3.4. In order to encourage incident reporting access to reporting tools must be freely available. Free-hand style allows for clear details to be reported and adds to subsequent data analysis but structured answer choices allow easier analysis and, perhaps, encourage reporting by making the process simple.

3.5. Standard forms often include information to aid the grading of severity, to confirm that reporting an incident does not constitute an admission of liability and to ensure the incident is reported to appropriate people within the organisation. Data collection templates contain sections for recording a description of the incident, patient details, description of any injury, description of any treatment and immediate actions taken to minimise a recurrence of the incident.

Characteristics of incident reporting systems

3.6. Barach and Small describe the characteristics of incident reporting systems in non-medical industries[16]. Established systems share the following characteristics:
- They focus on near misses
- They provide incentives for voluntary reporting
- They ensure confidentiality
- They emphasize systems approaches to error analysis

3.7. Attitudes to anonymity of reporters vary. Some systems in operation require identification of the reporter, some allow voluntary identification, some do not require the name of the reporter but require the names of staff involved in the incident and others are truly anonymous. The merits of anonymous reporting, including the encouragement to report in a blame-free environment, are contested by the view that reporters are often keen to be identified; it is clear to all that incidents are regarded as indicators of potential problems in the systematic process of critical care delivery and are rarely the fault of one individual. Aside from being true, this encourages reporting of incidents and those reporting

incidents are rarely protective of their anonymity. Identification of reporter and those involved in the incident enable error chain analysis to detect patterns of event or behaviour that would not necessarily be evident within an anonymous system.

3.8. In one system in use each clinical adverse incident form generates individual feedback to the person completing the form which is a clear advantage for identification of the reporter. Factors promoting incident reporting include[16]:

- Confidentiality
- Culture of discussion and learning from incidents
- Immunity from blame
- Effective training in use of incident reporting tools
- Easy access to incident reporting tools
- Outsourcing of report collation
- Rapid feedback to all involved and interested parties
- Sustained leadership support
- Evidence that incident reporting is used to make system improvements

3.9. It has been suggested[17] that the ideal system should have the following attributes:

- an independent organisation to coordinate patient safety surveillance
- agreed frameworks for patient safety and surveillance systems
- common, agreed standards and terminology
- a single, clinically useful classification for things that go wrong in health care
- a national repository for information covering all of health care from all available sources
- mechanisms for setting priorities at local, national and international levels
- a just system which caters for the rights of patients, society, and healthcare practitioners and facilities
- separate processes for accountability and "systems learning"
- the right to anonymity and legal privilege for reporters
- systems for rapid feedback and evidence of action
- mechanisms for involving and informing all stakeholders

Problems with many existing data collection systems

3.10. Critical incident reporting systems have been studied and limitations identified in their use for subsequent analysis to establish areas where systems improvement may be used to increase patient safety[18]. Incident reports by themselves provide comparatively little information about causes and prevention, a fact which has long been understood in aviation. Reports are often brief and fragmented and are therefore not easily classified or pigeon-holed.

3.11. Making sense of them requires clinical expertise and a good understanding of the task, the context, and the many factors that may contribute an adverse outcome. At a local level, review of records and, above all, discussions with those involved can lead to better understanding of the causes an incident.

3.12. Table 3.1 shows an improved model, as used in the Vermont Oxford Neonatal Intensive Care Network, which records events under casual factors to enable further analysis[19].

3.13. Even in the best systems some critical incidents may not be reported by staff. There needs to be a link to other systems that identify incidents such as surveillance of healthcare associated infection, investigations of complaints, review of unexpected deaths or cardiac arrests and review of readmission to the ICU.

Table 3.1 The dataset used in the Vermont Oxford Neonatal Intensive Care Network reporting system

Did the event cause harm?
(please choose one)
- No, event did not have the potential to cause harm
- No, event had potential to cause harm but did not reach patient
- No, event reached patient but did not cause harm
- Yes, minor harm (increased monitoring, treated with intervention, etc)
- Yes, serious harm (life-threatening, impaired outcome, etc)
- Yes, resulted in death
- Unknown

Where was the patient when the error or near miss occurred?
(please choose one)
- Neonatal intensive care unit
- Intermediate care or step-down unit
- Well-infant newborn nursery
- Delivery room
- Newborn resuscitation room
- Mother's hospital room
- Other hospital inpatient unit
- During transport from another hospital
- During transport to another hospital
- During transport within your hospital
- Operating room
- Radiology department
- Other

How long ago did the event occur?
(please choose one)
- <4 hours
- 4 to 24 hours
- 1 to 3 days
- 4 to 7 days
- 8 to 28 days
- >28 days
- Unknown

Categories of errors
- (check all that apply)
- Medication or drug
- Breast milk
- Enteral feeding other than breast milk
- Parenteral nutrition
- Central line or vascular access
- Infusion or infiltrate
- Fluid or electrolyte
- Anesthesia, analgesia, or sedation
- Respiratory care or ventilator
- Glucose or insulin
- Monitoring or alarms
- Radiology or diagnostic imaging
- Surgery
- Transportation in or between hospitals
- Transfusion
- Laboratory testing
- Family or visitors
- Security
- Patient misidentification
- Informed consent
- Resuscitation
- Medical devices or equipment
- Enter any other categories of errors that apply

Factors that contributed to the event
(check all that apply)
Environment
- Inadequate lighting
- Lack of space or room
- Noise
- Unfamiliar environment

Equipment
- Equipment failure
- Inadequate equipment maintenance
- Necessary equipment unavailable
- Poor equipment design
- Unfamiliar equipment

Human factors
- Confrontational or intimidating behavior
- Distraction
- Fatigue
- Inadequate training
- Inattention
- Inexperience
- Stress

Practices
- Calculation error
- Communications problem
- Error in charting or documentation
- Error in computer entry
- Failure to follow policy or protocol
- Inadequate protocol
- Inadequate security
- Labeling error
- Lack of supervision
- Nursing handoff or shift change
- Physician handoff or shift change
- Poor teamwork
- Inability to contact needed staff
- Wrong protocol used

Staffing
- Consultant or subspecialist unavailable
- High census in unit
- High patient acuity in unit
- Low levels of clerical or support staff
- Low levels of other professional staff
- Low nursing staff levels
- Low physician staff levels

4. Classification of critical incidents

4.1.   Critical incidents will include many incidents where the patient came to no harm (which may be referred to as 'near misses') but will also include adverse incidents that can be defined as an event that leads to some patient harm.

4.2.   The broad definition of critical incidents will include many incidents that are often not reported by staff. These include delayed admissions to and discharges from ICU and hospital acquired infections. There are, therefore, a very large number of incidents that fall within these definitions and it would be difficult to make any sense of so many different incidents if they were not classified in some way. Classification of incident data provides structure enabling more efficient identification of improvements to the quality of

ICU care[20]. Many of the potential advantages of classification of critical incidents are shown in Table 4.1.

> **Table 4.1 Advantages of classification of critical incidents:**
>
> - Identification of trends and patterns in incidents
> - Identification of which incidents are more common or dangerous so resources can be targeted to their reduction
> - Allow comparisons between units to identify how variations in practice affect patterns of incidents
> - Identification incidents that are serious enough to warrant detailed investigation
> - Simplify the identification of rare but catastrophic incidents where patterns can only be identified across whole health care systems
> - Allow an analysis of changes in the pattern of incidents over time. This would hopefully identify the effects of interventions to reduce incidents

4.3.   Several systems of classification of critical incidents in critical care have been developed[15,21]. In deciding how incidents should be classified the following should be considered:

- Will the system minimise the work for the reporter? If not then fewer incidents will be reported and additional training will be required
- Does the system make clinical sense?
- Does the system reflect the organisational, environmental and team characteristics of the ICU?
- Will the critical incident reporting system collect data that is detailed enough to be useful for the purpose of quality improvement?
- Can the system be consistently applied by different individuals and different units categorising incidents?
- Will it work across the spectrum of ICU practice?
- Is it simple and is it adaptable to IT systems?
- Does it allow free text to continue to form the basis of critical incident reports?
- Is the time and effort practical for the potential advantages of the system?
- Some consistency with other international systems would be an advantage

4.4.   A single NHS system for classification of critical incidents would potentially allow many of the advantages suggested in Table 4.1[22]. The development of a classification system should first allow classification by consequence in terms of the harm, or potential for harm, experienced by patients or staff. This will define (and increase) the response level required. It will also define the response to victims in terms of management, communication and compensation. A typical classification of level of harm is shown below in Table 4.2.

4.5.   Further subdivisions of harm by body systems affected may then identify common root causes for incidents. For example, adverse incidents resulting from healthcare associated infections should be classified (e.g. ventilator associated pneumonia, catheter related sepsis, urinary infections, other) using the EPIC guideline groupings [23] and by common reportable organisms (e.g. MRSA, *C difficile* and glycopeptide-resistant enterococci). Identified trends should inform infection control procedures.

Table 4.2 Typical calibration tool to asses the severity of an incident

Consequence	Score	Actual or potential impact on patients and others	Numbers potentially affected	Actual or potential impact on the Trust
Catastrophic	5	Unexpected death	Many (>50)	International adverse publicity / severe loss of confidence in the Trust. Extended service closure. Litigation>£1million
Major	4	Major permanent harm Major clinical intervention required	16 – 50 persons	National adverse publicity or major loss of confidence in the Trust. Temporary service closure Litigation £500,000 - £1 million. Increased length of stay > 15 days
Moderate	3	Temporary harm Additional treatment required	3 – 15 persons	Local adverse publicity / moderate loss of confidence in the Trust. Litigation £ 50,000 - £ 500,000 Increased length of stay 8-15 days Increased level of care 1-7 days.
Minor	2	Minor injury or illness	1-2 persons	Litigation <£500,000 Increased length of stay 1-7 days Increased level of care 1-7 days.
Insignificant	1	No obvious harm.	None	Minimal impact. No service disruption

4.6.   Identification of critical incident patterns across many ICUs requires a standardised national reporting system; the most highly developed is the Australian AIMS[21]. This originally described a broad classification of incidents as shown in Table 4.3.

Table 4.3 Classification of incidents used in the Australian AIMS

1.   Airway and ventilation: e.g. unplanned extubation and disconnections.
2.   Drugs and medications: e.g. allergic reactions and drug errors.
3.   Procedures, equipment and catheters: e.g. inadvertent carotid artery cannulation.
4.   Patient environment: e.g. a lack of appropriate beds causing pressure sores.
5.   ICU management: e.g. incidents caused by an over reliance on agency staff.

4.7.   Many critical incidents can obviously be categorised into multiple headings and each broad classification will then require a detailed sub-classification. The AIMS[25] also uses a

key word system similar to that used in the medical literature to classify publications. This allows easier identification of similar incidents. It would also potentially allow searching for words and meanings in free text. This is an important advantage as free text contains detailed information that would otherwise be lost in any classification system. One of the disadvantages of critical incident monitoring systems is that errors of omission may not be captured so there is no analysis of the factors (in particular team and individual factors) underlying incidents[24,25]. The use of free text can overcome this problem by allowing for such factors to be identified and detailed.

4.8.   Severity grading is usually done by staff other than the incident reporter. Both structured and free text data are used to grade severity. Table 4.4 describes the likelihood of recurrence of an incident using a simple numerical scale. A major incident does not have to have directly harmed a patient. An example would be a failure of a steriliser where no cross infection occurred. Only chance may have prevented many patients being harmed so a detailed investigation should follow and resources should be allocated to correct and publicise the underlying problems.

Table 4.4 Likelihood of recurrence of an incident		
Likelihood of recurrence	**Score**	**Descriptor**
Almost certain	5	Likely to recur on many occasions, a persistent issue
Likely	4	Will probably recur but is not a persistent issue
Possible	3	May recur infrequently
Unlikely	2	Do not expect it to happen again but it is possible
Rare	1	Can't believe that this will ever happen again

4.9.   It is also important to note that the response of the organisation to minor critical incidents can also be crucial. It has been demonstrated[20] that minor critical incidents could play a key role in the detection of system failures in, for example, drug therapies. This is consistent with human factors theory for high-risk environments which suggest that apparently minor near misses or accidents can be indicative of wider system failures[26].

4.10. Once the consequence and the likelihood of recurrence have been assessed a simple traffic light grading system can be used to identify the urgency of response required, the resources that should be allocated to the investigation and correction of the problem and the need to communicate the incident to other parts of the NHS. Fig 4.1 shows a typical incident severity grading tool using the consequence and likelihood scores multiplied to produce the traffic light grade.

Consequence ▶ ▼ Recurrence	Insignificant 1	Minor 2	Moderate 3	Major 4	Catastrophic 5
Almost certain 5	5	10	15	20	25
Likely 4	4	8	12	16	20
Possible 3	3	6	9	12	15
Unlikely 2	2	4	6	8	10
Rare 1	1	2	3	4	5

Fig 4.1 Traffic light incident grading tool

5. Roles and responsibilities in incident management

5.1.   All incidents, whether clinical or non-clinical, and irrespective of whether serious or not, must be reported to the Trust's risk management department. If serious the risk management department should be telephoned, as should senior management, in advance of completion of the of the incident report form.

5.2.   The incident report form should be completed as fully and as close to the time of the incident as possible. As full an account of the incident as possible should be noted not forgetting the patient ID number and the names of all the staff involved.

5.3.   Any person who is an employee of the Trust, or who is working for the Trust on a locum or agency basis, has a responsibility to report critical incidents or accidents. The senior person to whom the incident is first reported has the responsibility for ensuring that any immediate action is taken to make safe the situation and/or prevent recurrence of the incident. In the case of a serious untoward incident the risk management department (or the senior on-call manager) must be informed immediately. In the event of theft, vandalism or violence the police together with the security department must also be informed.

5.4.   Specific roles and titles will vary across Trusts. These guidelines delineate areas of responsibility according to seniority. Emphasis is placed throughout on the need for clear communication channels and contemporaneous record-keeping.

5.5.   Each Trust is responsible for ensuring that suitable and sufficient training is provided for staff about clinical risk management[27] and on the specific incident reporting system(s) in use. It is the responsibility of ICU managers (or equivalent other appropriate delegated authority) to ensure that employees are made aware of their responsibilities regarding risk management procedures.

Role of all intensive care staff

5.6.1.   To report any accident or incidents immediately to their line manager or to the person in charge of the unit at the time.

5.6.2.   To complete an incident report form in accordance with Trust policy.

5.6.3.   To take appropriate remedial action at the time of the incident to prevent further harm to patients, members of staff or to the general public.

5.6.4. To make a contemporary record of events to ensure that details surrounding the incident are accurate.

5.6.5. To assist in the investigation of any incident (e.g. statement writing).

Role of the ICU manager or other appropriate delegated authority

5.7.1. To review all incident report forms and, where possible, take appropriate remedial action, to prevent a recurrence.

5.7.2. To ensure staff involved in an incident have access to appropriate support (see section 13).

5.7.3. To be as open as possible about planned actions.

5.7.4. To record any remedial action taken on the incident form.

5.7.5. To report any incident involving medical device failure to MHRA.

5.7.6. Inform the health & safety manager without delay and certainly within 72 hours of the incident occurring where required by Health and Safety legislation and if an incident results in:

- Three or more days of lost time from work of a member of staff due to injury
- Any fracture, other than to fingers, thumbs or toes
- Any amputation
- Dislocation of the shoulder, knee, hip or spine
- Loss of sight in an eye (temporary or permanent) or a penetrating injury, chemical or hot metal burn to an eye
- Any injury leading to hypothermia, heat induced illness or unconsciousness or requiring resuscitation
- Loss of consciousness caused by asphyxia or by exposure to a harmful substance or biological agent
- Acute illness requiring medical treatment caused by exposure to a harmful substance or biological agent
- Any other injury which results in the person being admitted to hospital for more than 24 hours

Role of Senior Management

5.8.1. To review all incident report forms relating to their areas to ensure that appropriate remedial action has been taken or to instigate such action.

5.8.2. To inform the risk management department by telephone of any incidents whose severity, following an initial grading assessment, is orange or red status.

5.8.3. To monitor compliance with any action plans produced as a result of incident investigations.

5.8.4. To ensure that any actions highlighted as a result of an incident investigation and which cannot be completed are placed on the ICU risk register.

Role of Clinical Director / Matron

5.9.1. To be the lead investigator for any incidents deemed by the risk management department as being orange or red status.

5.9.2. To investigate orange or red incidents using root cause analysis and, where appropriate, obtain witness statements.

5.9.3. To inform the relevant manager of the outcome, including actions, of any investigations of orange or red incidents. This will often be the medical director.

5.9.4. To feed back the outcome of investigations to appropriate staff.

Role of the Risk /Health and Safety / Investigations Manager

5.10.1. To notify the relevant Trust board Executive Director of all serious untoward incidents.

5.10.2. To provide training and advice to ICU staff in the reporting and classification of incidents.

5.10.3. To assist staff in the investigation of all incidents.

5.10.4. To report all relevant accidents and dangerous occurrences to the Health and Safety Executive and to ensure that appropriate remedial action is taken to prevent recurrence.

5.10.5. Ensure that all incident information is entered onto the risk management database

5.10.6. To provide quarterly reports on the types of incidents and actions taken to the Trust risk management committee.

6. Incident management

6.1.   Each category of incident (green, yellow, orange, red) will require specific action by the individual(s) involved in the incident, the ICU manager, the directorate manager or the risk management department.

6.2.   In general green and yellow status incidents require local remedial action by the Critical Care Directorate (or equivalent). Orange status incidents will usually be formally investigated within the Directorate utilising root cause analysis with input from the risk management department. Red status incidents will be investigated as required by the local serious incident policy & procedure. A flowchart for reporting and managing incidents is shown in Fig 6.1 and an example of incidents that would usually require investigation in ICU is shown in Table 6.1.

Table 6.1 Incidents that would usually require investigation

- Unexpected deaths
- Clusters of infection
- Medical devices failure
- Disconnection from ventilators
- Unplanned extubation
- Nasogastric tube malposition, e.g. to lungs
- Accidental loss of lines
- Complications of cannulation
- Serious complaints

Incidents graded green

6.3.   After completion of the incident report form detailing the facts of the incident and any actions taken to minimise harm or to prevent recurrence of the incident, the ICU manager or appropriate delegated authority should assist to grade the incident and implement any actions to minimise harm or prevent recurrence. These actions should be clearly noted on the incident report form and forwarded to the directorate manager. Some green status incidents will require further local investigation that may result in the development of an action plan which can be monitored by the directorate and the risk management department.

6.4.   The Directorate Manager should review the grading of the incident and if necessary re-grade. If they feel that further action is required to prevent harm or recurrence, they should document this on the incident report form and implement that action. If they feel that an incident requires re-grading they should ensure that the incident is managed at the re-graded status. An explanation for the re-grading and any additional managerial action taken should also be recorded on the incident report form before sending the document to the risk management department.

Incidents graded yellow

6.5.   The procedure described above should be followed. Most yellow status incidents will require further local investigation and this should result in the development of an action plan to be monitored by the directorate to ensure the actions are implemented. The action plan should have defined leads for each action point identified with a target implementation date and a review date.

Incidents graded orange

6.6.   There is clearly greater priority for orange status incidents. The ICU manager or appropriate delegated authority review the grade and, if agreed, should ensure that the Risk Management Department is contacted immediately.

6.7.   Investigation of orange status incidents should be led at Directorate level by the Clinical Director, Matron or Directorate Manager. This investigation will require the development of an action plan following an analysis of the event to identify factors that may be addressed to prevent recurrence or further harm. A root cause analysis (see section 8) protocol should be used to assist with this process. The action plan should have defined leads for each action point identified with a target implementation date and a review date.

6.8.   The investigation findings must be reported formally to the directorate and copied to the risk management department. If statements were obtained these should be appended to the report submitted to the risk management department.
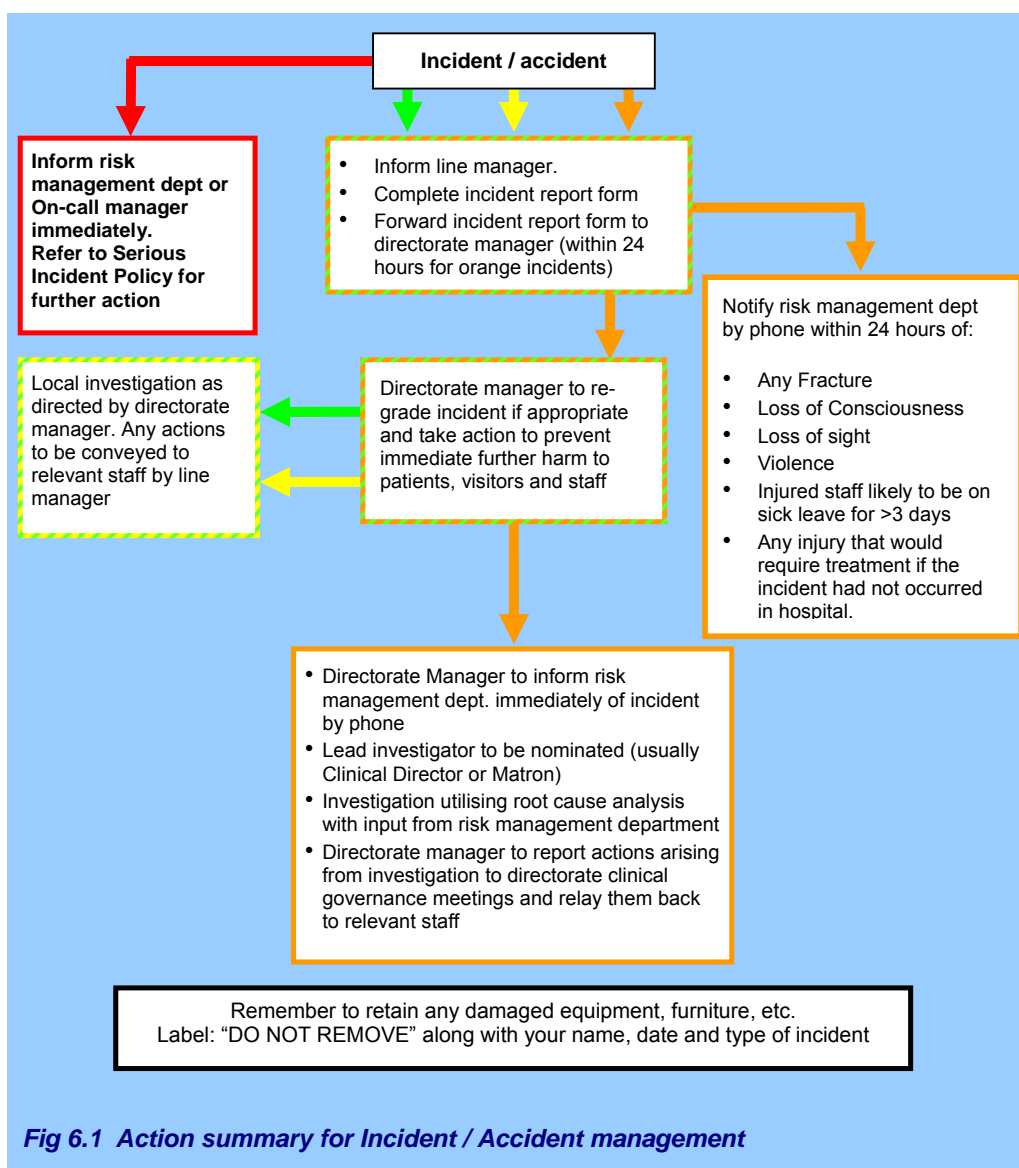
Fig 6.1 Action summary for Incident / Accident management

Incidents graded red

6.9. These incidents must be managed within the framework of the Trust serious incident policy. Following notification of a serious incident, there are six stages to follow:

- **Pre-Investigation** - The meeting will discuss any immediate effects of the incident, determine terms of reference for a subsequent investigation and identify any issues relevant to a disciplinary process.
- **Investigation** – Investigation will entail formal recorded interviews with staff, review of medical records, Trust policies and any other relevant documentation.
- **Analysis of Investigation Results –** Analysis will be undertaken using a variety of methodologies to determine the root causes of an incident. Examples of techniques include setting a chronology of events, timeline analysis, barrier analysis, fishbone diagrams etc.
- **Implementation of Action Plan** – any actions identified as a result of the analysis will be agreed by the Clinical Director or Matron etc. Care is taken to ensure that they are specific, measurable, achievable, realistic and have a time for implementation (SMART).
- **Feedback to Staff** – Staff involved in the incident are invited to attend a meeting to discuss the investigation findings, conclusions and recommendations and to ask any questions.
- **Monitoring of Action Plan** – Work with the department to ensure that the actions agreed from the investigation are monitored. Where action is not possible, ensure that the issue is placed on the directorate's risk register.

Management of culpable staff

6.10. The complexities of critical care mean that most staff involved in adverse events have carried out actions and made judgements that other reasonable staff could have made in the same circumstances. In other words, they have been in the wrong place at the wrong time. Figure 6.2 shows a decision-support tool for assessing the need for action against an individual involved an incident.
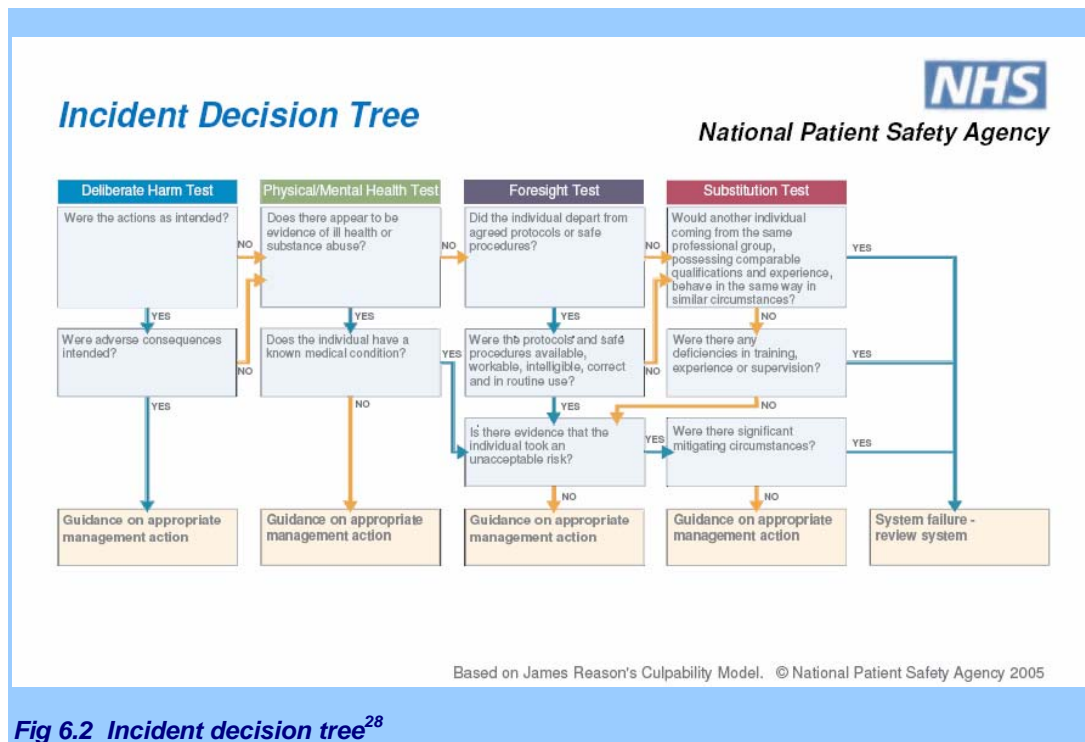

Fig 6.2 Incident decision tree[28]

6.11. We cannot, however, always assume this is the case. It is possible the individual may have been incapable of carrying out their duties, or may have shown a serious lack of

foresight, and there is also a very rare possibility that harm was deliberately intended. It is important to establish which of these categories describes each individual's responsibility in the incident. This is because different actions will be required to protect patients and support staff in each situation.

6.12. Although critical incident management is intended to avoid blame, disciplinary action must be taken where there is evidence to suggest an employee has acted in one of the following ways, for example:

- Intended to take action which they knew would result in harm
- Recklessly took an unjustifiable risk where they either knew of the risk or deliberately closed their mind to its existence (e.g. administering a non-prescribed controlled drug or undertaking a procedure without relevant training)
- Negligently and repeatedly brought about a consequence which a reasonable, competent person with their skills should have foreseen and avoided (e.g. failing to heed and act upon signs and symptoms of an impending clinical crisis)
- Committed an illegal act which may or may not include circumstances resulting in a police investigation or prosecution (e.g. deliberately hastening the death of a patient by excessive use of pain killing medication, or removing pages from the clinical record to attempt to cover up involvement in an incident)
- Carelessly or deliberately failed to comply with protocols or policies deemed to be applicable by the Trust (e.g. repeated failure to follow the consent procedure)

7. Analysis of critical incidents

7.1. Many Trusts use commercial software to aid data analysis on a Trustwide basis, forwarding anonymous data to the NPSA. Where a Trustwide system is the sole method of data analysis there is usually, but not always, a reporting system to feed collated information back to departments. One of the major limitations of this approach is the lack of critical care expertise in centralised incident management which can lead to poor interpretation of the event as reported. There is often more focus on non-clinical incidents and limited usefulness in comparing such incidents between dissimilar departments. Critical Care departments find more focussed reports more useful.

7.2. Local analysis includes reporting from a local critical care database, analysis of a subset of data relevant to critical care from a Trustwide database, regular critical incident meetings to discuss action required as a result of incident trends and audit of implementation of action plans. Some critical care departments have developed their own databases and reporting formats to aid the discussion and action planning around critical incidents (Figure 7.1). In some areas critical care networks have organised network-wide data collection and analysis with feedback and comparison between participant units.

7.3. Analysis is aimed at identifying failures of process which might have contributed to the incident and what changes could be introduced to reduce the probability of a recurrence. By understanding that critical incidents are rarely the result of one individual and are more likely the result of failures of the system at several times, blame of one individual is specifically avoided. Rather, organisational improvements are sought which would improve early detection and help avoid a recurrence. The certainty of human error is acknowledged and the system adapted to protect for this.

7.4. Most critical incidents are caused by multiple factors coming together to cause the event. A correct analysis of the incident should therefore disassemble and review all of these factors. The investigation of clinical and technical factors contributing to critical incidents is evidently crucial for any analysis and subsequent response, as is the investigation of individual and team errors. Individual and team factors, for example communication failures or a lack of situation awareness (the degree to which one's perception of the situation mirrors reality), are frequently identified as contributory factors in medical errors [29,30,31,32]. However, the analysis of critical incidents should recognise that individual or team errors frequently indicate deficiencies in systems rather than people.

7.5. Error management in other high-risk environments operates on the premise that individual and team errors resulting in accidents and near misses are usually indicative of latent failures in the organizational environment, e.g. the quality of the safety climate, or a

reluctance to speak up[33,34]. By identifying the team and individual factors underlying critical incidents, changes can be made to systems which enable error-producing conditions to be avoided. Furthermore, data from critical incident monitoring can provide information regarding the training requirements for interpersonal skills (e.g. leadership and teamwork) and cognitive skills (e.g. situation awareness and decision-making). In high-risk industries such as aviation, and increasingly in medical domains such as anaesthesia, data from accidents and near misses have been used to develop non-technical skills (interpersonal and cognitive skills not directly related to technical expertise, but crucial for maintaining safety, e.g. teamwork, leadership, situation awareness and decision-making[27,35]). Such skills would appear particularly important for the ICU, with studies examining critical incidents and errors demonstrating the contributory role of factors such as inadequate communication between team members, poor supervision, failure to communicate priorities, not sharing patient status information, and team members not combining their knowledge and skills effectively[21,31,36,37].
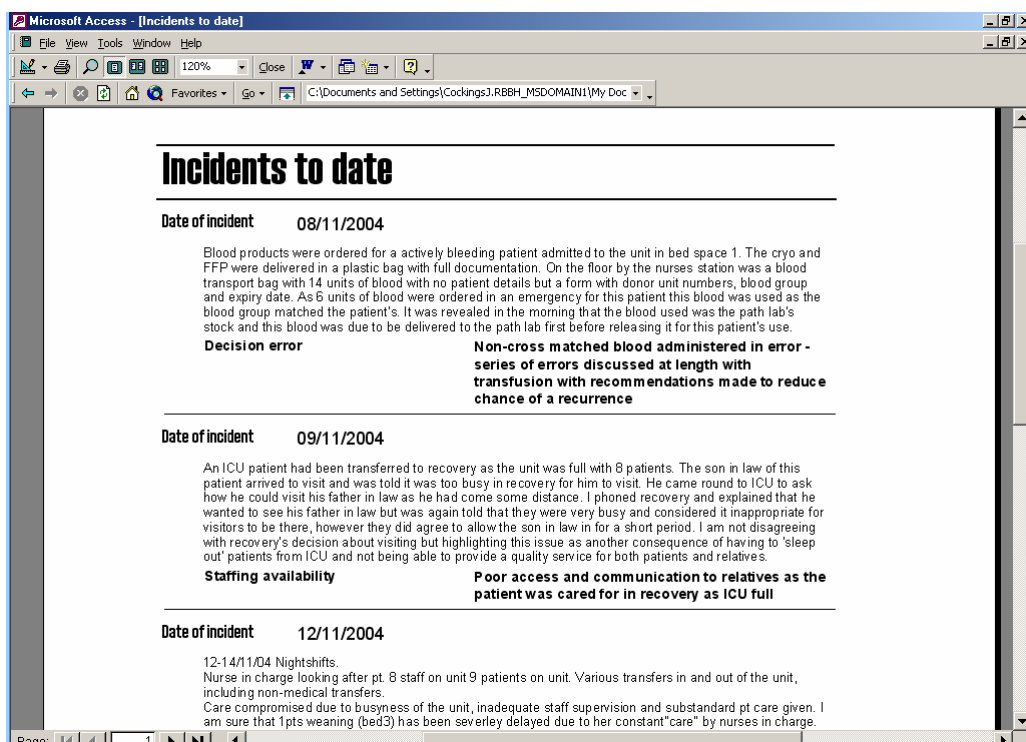
Fig 7.1 Report of incidents – summary of incidents for a date range for presentation to critical incident meeting

7.6.   A recently published health technology assessment of investigations[27] and analysis of critical incidents suggested a model shown in Fig. 7.2 to help understand the process of events leading to an incident. Definitions and explanations of the contributory factors are shown in Table 7.1. It follows that analysis of the incident should work back through the factors and defence barriers to understand the causes. Defence barriers should be identified at each stage in the process and not only the final stage of patient care as suggested by the figure. Any analysis should also include an analysis of the defence barriers that worked to contain the incident and stop it being worse than it was.

7.7.   An extension of this framework (communication has been included as a separate heading under the contributory factors) has been adopted by the NPSA and its adoption throughout critical care would greatly facilitate a common language for communication about causes of critical incidents in critical care. Although not obvious from Fig 7.3, the analysis should also include a review of what went well to contain the incident[21,39]. The analysis of most critical incidents will result in identification of multiple 'care delivery problems' in the events leading up to the incident and many latent organisational failures

allowing these to occur. For serious incidents a detailed investigation will be appropriate. This would, however, be impractical for most critical incidents, where the analysis is carried out in open discussion in critical incident meetings. This discussion could be better directed by using the accident causation model shown in Fig.7.2.

Fig. 7.2 Accident causation model for heath technology assessment

7.8.   Two examples of the use of this model are shown in the boxes below:
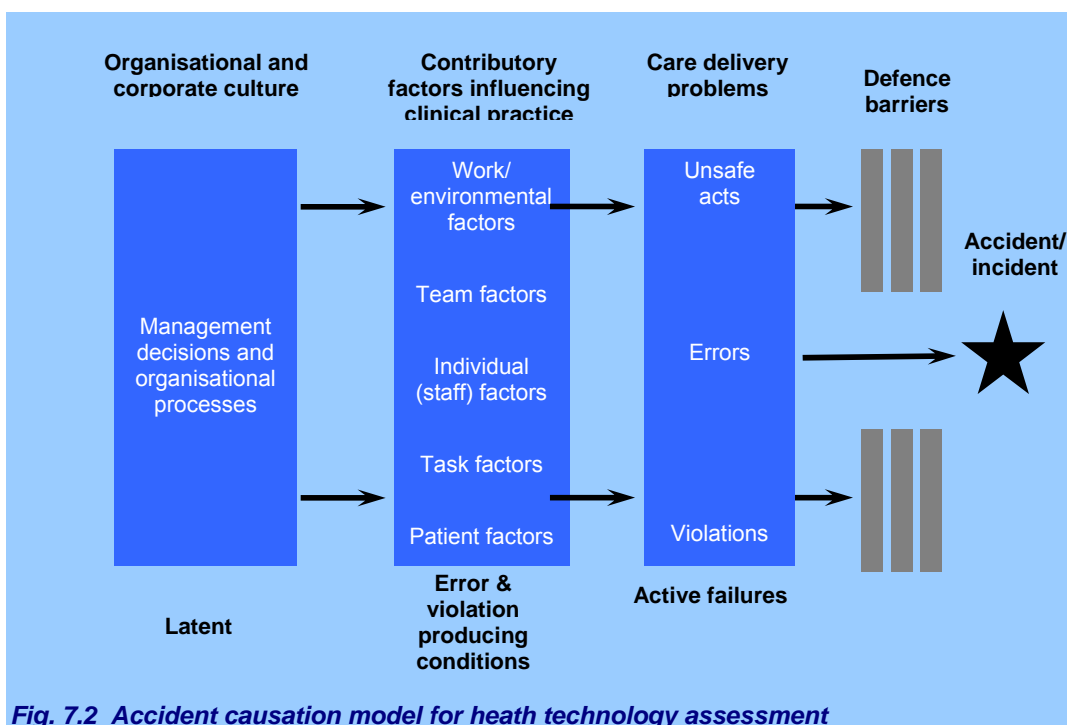
> A member of staff deliberately injects insulin to injure a patient.
>
> **Analysis:** Individual staff factors and rule violations are central to this incident. Detailed analysis of the incident may also identify organisational factors in the recruitment and management of staff and task factors relating to protocols for looking after insulin. Team factors in communicating concerns may also be important. A similar exploration of factors associated with the intrathecal injection of intravenous drugs, which at first sight appeared only to be issue of staff competency, went on to reveal many areas for reducing similar incidents[38].

> A level 3 patient is ventilated in recovery. The SHO attempts to site a central venous catheter but cannulates the carotid artery.
>
> **Analysis**: Individual and task factors seem to be central to this incident. However, organisational factors as to why the patient was outside the ICU are important. This limited the supervision of the SHO and caused problems with communication with the consultant, who had left a message that the line was not to be placed prior to ICU admission so team factors were important. Equipment factors were also important as the ultrasound machine was broken. The abnormal anatomy of the patient's neck was also a contributory factor. A defence mechanism of sampling the blood oxygen saturation prior to line placement was then not used. Fortunately, an experienced member of staff noted that the arterial pressures on the monitor so the line was not used, a final defence that in this case limited any harm to the patient.

7.9.   These cases are shown to illustrate the complexities of most apparently straightforward critical incidents and how careful analysis of incidents will usually demonstrate multiple problems. It is important to review both what did and what did not happen as well as what should have happened to protect the patient. This detailed analysis of incidents could produce a view that incidents are too complex ever to be prevented and no one holds any responsibility for them. Although blaming individuals is unhelpful, the analysis of incidents should not allow patients to believe that no one will accept any responsibility for

critical incidents. To avoid this we need to move beyond the analysis to devise action plans to try to remove the root causes of critical incidents.

Table 7.1 Examples and definitions of factors that may have contributed to a critical incident[15].

Factor types	Contributory influencing factor	Example
Patient factors	Condition, e.g. complexity and seriousness	Patient with ARDS and multi-organ failure
	Language and communication	Patient does not speak English
	Personality and social factors	Patient agitated
Task factors	Task design and clarity of structure	Ability to connect oral syringe to IV cannula
	Availability and use of protocols	Spontaneous breathing trial protocol not used
	Availability and accuracy of test results	Chest X-ray not available
	Decision-making aids	Alarms not set appropriately
Individual (staff) factors	Knowledge, skills and competence	Lack of skill in intubation
	Fatigue	Being on-call for 24 hours
	Physical and mental health	Anxiety, depression or physical limitation
Team factors	Verbal communication	No mention during handover of difficult airway
	Written communication	Illegible physician order
	Supervision and seeking help	Did not seek advice regarding stridor
	Team structure (congruence, consistency, leadership, etc.)	ICU director has limited sessions for ICU
Work/environmental factors	Staffing levels and skill mix	Inadequate health care assistants
	Workload and shift patterns	No senior nurse assigned to a shift
	Design, availability and maintenance of equipment	Malfunction of CO_2 analyser
	Environment	Patient room too small for equipment needed
	Time pressure	Premature discharge of patient
Organisational and management factors	Financial resources and constraints	No financial support for ICU pharmacist
	Organisational structure	No ICU director
	Policy, standards and goals	No policy on aggressive patients
	Safety, culture and priorities	Physician does not adopt patient safety recommendations
Institutional context factors	Economic and regulatory context	Failure to fund NICE approved drug
	Links with external organisations	Critical care network failed to adopt an agreed bed management policy

8. Root cause analysis

8.1.   Root cause analysis is a structured investigation that aims to identify the true cause(s) of a problem, via its contributory factors, and the actions necessary to eliminate it (see

http://www.npsa.nhs.uk/health/resources/root_cause_analysis/conditions). The principles are useful in the investigation of any incident but are particularly important in the formal investigation of a serious untoward incident which requires a more comprehensive and structured approach.

8.2. A root cause is a fundamental cause which, if resolved, will eradicate or significantly contribute to the resolution of the identified problem, both within the local department and more widely across the organisation. The process of root cause analysis is listed in Table 8.1. Those causes that are verified as being true are then subjected to the same set of questions. The process continues until clear root causes are identified.

> **Table 8.1 Analyzing root causes of events**
>
> - What happened? (Sentinel event)
> - What should have happened?
> - How did it happen?
> - Why did it happen?
> - What were the most proximate factors?
> - Why did that happen?
> - What systems and processes underlie this?

8.3. Root cause analysis requires a multidisciplinary team to undertake the analysis. The first stage of the process is data gathering since there will not be adequate data for analysis within the critical incident record. Data sources might include the medical record, relevant policies and protocols, statements, rotas or training records.

8.4. Data needs to be assembled in a way that it can be analysed in a process known as information mapping. This might include the construction of a narrative chronology or the use of timeline tools or time person analysis (Fig. 8.1) to track individuals' involvement where many were involved in a concentrated timeframe.

A patient with limited cardiac reserve in bed 7 suffered acute pulmonary oedema at 1607 after 1000 ml of fluid was connected at 1600 to a 14g central venous catheter. The bag was found to be empty at 1608 by Nurse B.

	1600	1605	1607	1608	1609	1612
SHO	Bed 12	Bed 12	Bed 12	Bed 12	At bedside	At bedside
SpR	Bed 12	Coffee room	Coffee room	Coffee room	At bedside	At bedside
Nurse A	At bedside	Drug cupboard	Drug cupboard	Drug cupboard	At bedside	At bedside
Nurse B	Bed 8	Bed 8	Bed 8	At bedside	At bedside	At bedside
Consultant	Interview room	Interview room	Interview room	Interview room	Interview room	At bedside
Patient's wife	At bedside	Relatives' room	Relatives' room	Relatives' room	Relatives' room	Relatives' room

Fig. 8.1 Example of a time person analysis grid

8.5. The next stage of analysis is to identify problems. A number of techniques may be used to do this within a multidisciplinary group. Brainstorming allows a list of potential problems to be produced from any of the groups' participants. Brainwriting achieves a similar purpose but is done by members of the team contributing their ideas anonymously. This may be particularly appropriate where members of the multidisciplinary team investigating the incident were also involved in it. Once the list of potential problems has been collected a system is required to agree the most likely problems. A nominal group

technique allows anonymous voting for or against all ideas until a final agreed list of problems is approved.

8.6.   A variety of management 'tools' can be used to analyse data but the simplest, traditional approach is known as the 'Five Whys' Model. This can be used for general analysis of the cause of any incident or more formally, usually in a multi-disciplinary team setting, when contributory factors are discussed and in-depth causal factors are written down and traced back until a clear understanding of the root cause is reached. Potential contributory factors may be identified by the team using the same techniques of brainstorming, brainwriting and nominal group voting. However, re-visiting and asking why each potential cause happened and then again asking why these happened produces a more detailed understanding of the root causes of the contributory factors. In general (but not always) up to five rounds of asking why something happened is required to get to the root cause.

8.7.   Using these techniques to identify the root cause(s) of incidents allows the multidisciplinary team to recommend appropriate solutions.

What are the benefits of root cause analysis?

- Dangerous assumptions are avoided
- Investigators avoid jumping to conclusions
- The logic required highlights questions, and facts that need to be obtained
- The investigation is unavoidably thorough
- It reduces the temptation to blame
- It identifies action steps or recommendations
- Conclusions can be presented in a rational manner

9. Beyond the analysis

9.1.   The multiple contributing factors should be resolved to those that:
- Can be resolved in the ICU team
- Can only be resolved with help from outside the ICU
- Are unlikely to be resolved

9.2.   However, investigation, classification and analysis of incidents are pointless exercises without this final stage. There must, therefore, be a clearly identifiable clinical lead within the team to make sure actions are being followed though. The opportunities of improving patient care and safety should be well worth the effort.

Issues that can be addressed in the ICU team:

9.3.   Issues within the ICU team should be addressed by the use of action plans and SMART objectives as described previously. Actions may require additional funding but the identification of risk is important in making the case for this funding.

Issues that require outside help:

9.4.   Outside help from within the Trust, for example provision of more staff or resources or changing working practices across the organisation will only be made available if the ICU team communicates the risks across the organisation and explains the actions required. The risk register is important in keeping identified risks on the agenda. Many actions both within the ICU and the Trust will take months or even years to resolve. Maintaining risk registers and action plans current is therefore, essential to keep track of progress.

Apparently insoluble issues:

9.5.   It is most important that these issues do not obscure other issues that can be improved. Issues that seem insoluble should also be communicated within the Trust and held under review. Future service planning should consider these risks, which may be resolved by

future changes to service or new technologies. Identification of these risks could also be important in commissioning research.

10. Follow-up of actions arising from incidents

10.1. For all green, yellow and orange incidents it is the responsibility of local line managers to:
- Feedback to the individual(s) concerned conclusions and action taken as a result of the incident
- Communicate any action resulting in changes affecting other individuals within the local ward / department
- Ensure staff affected are made aware of and offered the opportunity to access occupational health support
- Ensure risks that cannot be resolved locally are recorded and managed in accordance with the Trust Risk Register procedure

10.2. One aspect of follow up that is sometimes overlooked is communication with the patient / family where they have been directly involved in the incident. This should be handled sensitively, with advice from the Trust legal adviser and reference to any local policies regarding disclosure. All discussions with patient and family should be timely, open and honest.

Follow-up action and feedback for incidents graded green

10.3. Formal action plans will not always be required as a result of incidents graded green. Should it be required it will be the responsibility of the unit management and will be monitored for progress at a local level. However, the Directorate must ensure that actions are implemented and minimise the potential of recurrence.

Follow-up action and feedback for incidents graded yellow

10.4. The development of a simple action plan to prevent recurrence of the incident (where possible) is expected as a result of yellow status incidents. Again implementation must be monitored by the Directorate.

Follow-up action for incidents graded orange

10.5. Action plans developed as a result of the investigation into an incident graded orange must again be reviewed by the Directorate to ensure that the agreed actions take place. The risk management department must ensure that it receives root cause analysis documentation and action plans of all orange graded incidents. The action plan should contain clear detail of what action is required, together with timescales and the name of the person responsible for the action. This information should be entered onto the risk management database and compliance with the action plan monitored by the risk management staff. Such action may need reporting to the Trust clinical governance committee or equivalent.

Follow-up action for incidents graded red

10.6. Follow-up for red-graded incidents should adhere to the same principles as those for orange-graded incidents. Red-graded incidents may be treated as a serious untoward event. Such incidents will usually be managed according to a defined policy within the Trust since they are likely to produce significant legal, media, or other interest. Serious untoward events are ones in which the consequences are:
- catastrophic - contributing to, leading to or causing death
- major - contributing to, leading to or causing permanent injury
- moderate - contributing to, leading to or causing semi-permanent injury which might take up to a year to resolve
- minor - relatively minor accident or injury to each individual, but a number of people are involved

- major defects in plant, equipment, drugs or devices causing harm to patients, staff or visitors
- the incident or individual involved may have a high media profile

10.7. Critical care units will usually be responding to such incidents rather than being the cause of them. It is therefore important that critical care staff are familiar with their local serious untoward incident procedure.

11. Communication following critical incidents

Communication with the patient, relatives and carers

11.1. Patients, their relatives and carers increasingly wish to participate in their healthcare in partnership with the NHS. Openness when things go wrong is fundamental to this partnership. To this end NPSA has developed a 'Being open policy' (http://www.npsa.nhs.uk/health/resources/beingopen)

11.2. When something goes wrong most patients, relatives or carers want to be given information about what has happened. Many want someone to say sorry.

11.3. Being open about what has happened and discussing the problem promptly, fully and compassionately can help patients cope better with the consequences.

11.4. Openness and honesty can help prevent incidents from becoming formal complaints and litigation claims[39]

11.5. The three most important elements of being open are:
- providing an apology and explanation
- a thorough investigation following the incident
- support in coping with the physical and psychological consequences of what happened.

Communication within the ICU team

11.6. Critical incident meetings are an essential method of communication about critical incidents[40]. Open discussion of critical incidents in a monthly meeting should help with root cause analysis and with the identification of actions to avoid future incidents. Information concerning previously planned actions and actions already taken to reduce incidents should also be discussed. As many members of all staff groups as is practical should attend the meeting which should not be incorporated into anaesthetia audit sessions as the staff groups and issues will not be the same.

11.7. Staff unable to attend the meeting should be kept informed by circulated minutes and an updated critical incident action plan. An example of an action plan is shown in Fig.11.1. This plan should allow staff to review actions being taken to avoid future critical incidents. It is therefore important for them to feel part of this process if future incidents are to be reported.

11.8. Many methods could be used to disseminate the minutes and action plan within the ICU team. Some of those are summarised in Table 11.1. Using several methods will increase the chances of success. Care should, however, be taken to protect patient and staff confidentiality. In choosing the methods it is important to consider whether confidentiality maintained, whether there are opportunities for staff to feed back comments so that communication is a two way process, whether there are risks the message may be confused and whether some groups, for example administrative staff or therapists, are being excluded.

ACTION PLAN	Date of Issue:	Ref:			
Required Outcome	Action & Responsibility	Date Given	Check Date	Date Due	Progress / Comments
Syringes containing different drugs will be identified by correct colour coded labels.	Prototype labels to be taken to sister charge nurse meeting for discussion and agreement: J.H.	Jan 04	Feb 04	Feb 04	Minor changes made and agreed February 04.
	Printer to make labels to be identified (check who makes anaesthetic labels): T.S.	Jan 04	Feb 04	Feb 04	Printer identified, quoted obtained. Jan 04 Labels delivered Feb 04, stored in anaesthetic dept.
	Contact works dept. to make racks for labels in prep room: TS	Feb 05	March 04	March 04	Quotes obtained Feb 04 to discuss with T.T. re funding. March 04 funding agreed: work to be done by end of month.
	Education of staff: TT: Management meeting. And write briefing paper TS to circulate. SE: Shift hand over and ward based training	Feb 04	March 04	April 04	Staff education complete April 04. Launch date for new labels 12 April 04. TT to write to other directorates.
	Audit of new labels/ staff feed back: TT to allocate SHO to audit.	March 04	June 04	Next SHO change over	July 04. Audit complete: New labels for ventricular drains required: Contact manufactures: J.H. No further critical incidents reported due to confusion with syringe labelling.

Figure 11.1 An example of an action plan tracking the introduction of coloured syringe labels.

Feedback to individual staff members

11.9. Staff will report incidents if they perceive the report will produce some response to improve patient care and constructive feedback. A copy of the manager's report should be given to the incident reporter. The report should protect confidentiality and not be seen as overtly critical or dismissive of any individuals.

> **Table 11.1 Methods to disseminate information about critical incidents and actions to reduce them.**
>
> - Critical incident meeting
> - Published minutes, action plans and other written summaries of progress
> - E-mails or circulars to staff lists
> - Reports on shift handovers and ward rounds
> - Posting information on notice boards or in 'communication books' held on the nurses' station
> - Dissemination of team briefing papers
> - Through mentoring groups

Communication with other departments and the wider NHS

11.10. 'An organisation with a memory'[12] and 'Building a safer NHS'[13] both set out a vision where incidents in one part of the NHS allow learning through the whole organisation. The broad structures of this are shown in Fig.11.2.
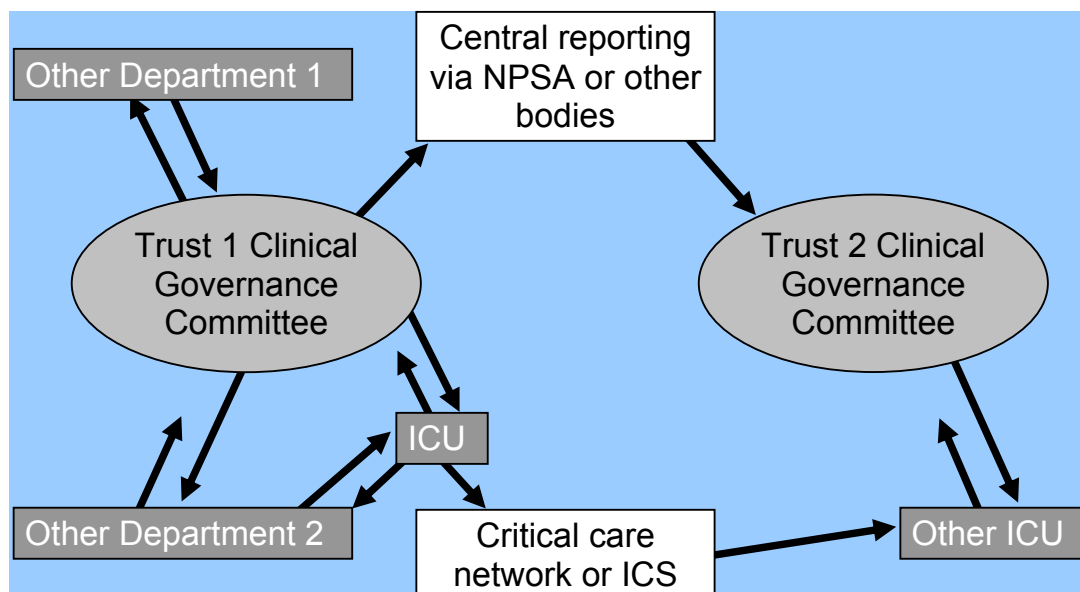
Fig 11.2 Pathways of communication for critical incident reporting:

11.11. An individual ICU has limited responsibilities in this system. These are to:
- submit all incidents reported in the department to the Trust Clinical Governance Committee (CGC) for them to disseminate
- submit critical incidents identified as originating from other departments to those departments to allow them to conduct root cause analysis
- investigate incidents submitted from other departments where those departments believe factors originating in ICU may have contributed to the incident
- circulate and implement, guidance from the clinical governance committee. This guidance may come from the wider NHS or from with in the Trust

Direct contact with other departments

11.12. Incident reports from another department may be interpreted as external criticism. Reports between departments should, therefore, be carefully considered and investigated and written responses should be given. Joint meetings to review patient care should allow open discussion of cases and share actions to improve care[41]. They should also allow discussion of critical incidents, improve joint working and allow reports from other department to be viewed as constructive.

Communicating with the clinical governance committee / Trust executive

11.13. Routine forwarding of critical incidents to the Trust clinical governance committee or executive is not enough on its own to protect patient safety. Additional responsibilities include:

- Making sure the ICU is represented and engaged. The ICU is a very important 'cross roads' in the hospital and unplanned critical care admissions could, even on their own, be regarded as an opportunity to review care. The ICU therefore has an important role to play in any central review of incidents and should be engaged in the Trust clinical governance process.
- Reporting serious incidents and concerns to senior management. Following a meeting a written summary should be sent to the Executive. This avoids ambiguity and may help any future review.

Communicating the level of risks represented by critical incidents

11.14. Risk registers (an example is shown in Fig. 11.3) can be used to define and manage risks in a critical care unit and critical incidents should help identify these risks. The register identifies risks, defines their importance in terms of how likely they are to occur and their potential damage if they do occur. It then identifies systems in place and gaps in these systems to protect against these risks. Finally, a register should identify actions and progress in actions to reduce risks and improve safety systems. A completed and updated register is an important tool in communicating information about risks identified by critical incident reporting.

Cutting across the communication pathways

11.15. Occasionally information should be disseminated rapidly to protect patient safety. It is most important that the individuals with responsibility for central reporting are made aware of particular concerns about specific incidents so they can be rapidly disseminated throughout the NHS. Opportunities also exist for direct central reporting to, for example, the Medicines and Healthcare Products Regulatory Agency or the Committee for Safety of Medicines.

Risk Register Form

Key
L = Likelihood Score (1-5)
C = Control Score (1-5)
I = Impact Score (1-5)
R = Risk Profile Score (1-15)

Department: *Intensive Care Unit*
Responsibility: *The ICU management team*

Date	Principal Objectives (Reference to detail)	Principal Risks (Reference to detail)	L	I	Key Control Established (Reference to evidence)	Key Gaps in Control (Reference to evidence)	C	Assurance on Controls (Reference to evidence)	Gaps in Assurance (Reference to evidence)	R	Action Plan (Reference to Detail)	Review Date
	No patient will suffer a preventable healthcare associated infection	Transfer of infection from Health Care workers	3	4	Provision of hand cleaning equipment uniforms, plastic aprons Training in infection control Uniform policy Role model of senior staff Aseptic technique ICU work closely with the infection control team through the ICU MAGIC team to address infection control and HCAI issues	Pressure of work Lack of time Gaps in knowledge / attitudes of ICU and visiting staff	3	Feedback from users Infection control audits Cleaning audit E-learning records Hand washing audit MRSA investigation	No audit of visiting staff.	10	See action plan	Jan 05

Figure 11.3 An example of part of a risk register showing risk associated with transmission of infection by staff

12. Creating an environment to support staff through incidents

12.1. It is essential that the ICU provides a supportive and informative environment that allows personal and professional development and supports a patient safety culture. Individuals working in such an environment are more likely to report adverse events honestly and should be better able to cope with the personal effects of being involved in a serious adverse event.

12.2. There are many views as to what constitutes a supportive clinical environment since individual needs vary widely. However, developing an environment that offers support throughout employment and is tailored individually will offer strong support and guidance for the individual(s) involved in an adverse incident. In addition, such an environment contributes to the development of all staff. A useful checklist for what should be in place is contained in the National clinical assessment service tool kit (http://www.ncaa.nhs.uk/toolkit/developing).

Staff Induction

12.3. Multidisciplinary staff starting work in critical care work may not have adequate knowledge and skills regarding incident reporting. Therefore, it is essential that systems of incident identification, reporting, support and supervision, mentorship and access are described during induction.

12.4. The time taken to induct staff to the critical care environment is often limited. However, formal induction and introduction to mentors and clinical supervisors has been shown to reduce stress and encourage team bonding from the onset of employment. There is the opportunity for the development of peer support networks. The development of multidisciplinary induction has begun to break down traditional boundaries and could be seen as a forum for the growth of a more knowledgeable, flexible workforce. Induction is the ideal forum for the commencement of mentorship and clinical supervision.

12.5. To ensure staff are fully conversant with the areas of risk management and incident reporting it is necessary to include these in hospital induction. Local differences in incident reporting in the ICU will need to be covered at local induction to the ICU.

Available support systems

12.6. Critical care is delivered by a multidisciplinary team. A serious incident will often have ramifications for all team participantsand therefore support should be offered across the team. Formal support systems include mentorship and clinical supervision.

12.7. Mentorship is well developed within nursing but in its infancy within other healthcare professions. Although strictly regulated in nursing the system can place considerable additional burden on all individuals involved in an incident. Maintaining the Trust and confidentiality of the individuals involved in an incident and promoting the mentor role as one of support rather than management are essential if staff are to learn from incidents.

12.8. Clinical supervision allows a supportive relationship to develop between peers, individuals or even groups, managed closely by a supervisor. The support through incidents that have occurred is offered as an informal discussion, allowing time for reflection on practices away from the clinical area. Building up a trusting, confidential relationship for individuals and groups is paramount to the clinical supervision.

12.9. Developing multidisciplinary clinical supervision can offer good opportunities for team building and learning and therefore offer excellent support for members involved.

12.10. Early identification of support mechanisms can enable staff to feel secure in the knowledge that incident discussion is not only encouraged as a part of learning and development but also portrayed as a 'minimal blame' supportive culture that recommends learning from incidents rather than punishment.

12.11. Identification of formal support, e.g. occupational health, psychological and social support, management procedures and counselling should also occur at induction.

13. Staff support after a serious critical incident

13.1. Staff working in critical care are motivated by a wish to help people. It is therefore potentially devastating for them to be involved in an incident where a patient is permanently harmed or dies as a result of treatment or care they have given. This may result in a mixture of emotions; guilt, shame, embarrassment, fear and potentially anger. The loss of self-esteem, even if unjustified to colleagues, may result in a sense of bereavement with its psychological and physical consequences[42,43].

13.2. Supporting staff after a serious critical incident may be a long-term process, which may be distressing for all involved. Maintaining the best interests of patients, openness, seeking advice, careful record keeping and good communication are essential.

13.3. Successful resolutions will build strong teams who care for patients more effectively and will help maintain a highly skilled and valuable workforce.

13.4. It is essential that staff are supported after an incident, especially if they have significant responsibilities for causing the event. The reasons why this support is important are set out in Table 13.1.

Table 13.1 Why staff should be supported after a significant adverse incident

- The organisation has a duty of care to its staff[44]
- Organisational failures will probably have contributed to the incident
- Support in the early stages after a traumatic event encourages return to work[45]
- Lack of support will damage the function of the whole ICU team and so harm patient care
- A supported individual is more likely to contribute to root cause analysis of the incident
- Lack of a convenient scapegoat will force the organisation to address other important root causes of the incident

13.5. Future adverse and critical incidents are more likely to be reported honestly. The support that can be provided to staff can be divided into three stages:
- Immediate care and support
- Medium term care and support
- Long term support in return to full function

Immediate care and support

13.6. It is important to get help and advice in deciding how to respond to support staff after a significant adverse event. Most of us will have had little or no previous experience of serious incidents; we may also be too close to the situation and personalities involved to make a well-judged response. In any case discussing difficult problems will facilitate better responses. Potential sources of advice are shown in Table 13.2.

Table 13.2 Potential sources of advice

- Senior colleagues within the critical care area or other departments
- The manager on-call, the unit general manager
- The Medical Director and Director of Nursing
- Medical protection societies
- The British Medical Association
- Royal Colleges and regulatory bodies

13.7. The Trust Chief Executive is ultimately responsible for clinical governance. It is therefore important that the incident is reported through the management structure and this will also

give an opportunity to seek advice. Attempts to seek advice and advice given should be carefully recorded. This is important in resolving ambiguity and may be needed in future analysis of events.

13.8. Individuals involved in significant events may well be traumatised and should be treated with respect. With the possible exception of attempts to deliberately harm, individuals could be regarded as "the second victim" of an adverse incident[46].

13.9. The care of the individual responsible in the case of deliberate harm is outside the scope of this guidance. It is however likely that most other team members will be very upset and approaches similar to those used to de-brief staff after major incidents may be useful.

13.10. Where staff incapacity has been the cause of an incident support of the staff member is necessary for the reasons listed in Table 13.3. It is, however, essential for patient care and the individual's eventual recovery that they cannot go on to harm another patient, options available include:

- Sick Leave - Early referral to the occupational health department is an essential component of staff support. Individuals referred should understand that they will be given the reasons for referral, their medical records will remain confidential and they have the right to view these records. They should also know that a report setting out facts relating to their employment and ability to work will be sent to their manager
- Discretionary leave - A period of leave may be appropriate while the circumstances of the incident are investigated
- Limitation of duties - Maintaining the individual in work while not allowing them to be in a situation that could damage patients will allow provision of continued support and contact
- Suspension - Should be used in exceptional circumstances only to protect patient safety or allow root cause analysis of the incident. It is likely to have long term damaging consequences and appropriate advice must be sought. The national clinical assessment service should be consulted for further advice (http://www.ncaa.nhs.uk/)

Table 13.3: Why staff should be supported even if their incapacity has resulted in injury to a patient

- The organisation has a duty of care to its staff as well as to patients
- All patients and staff should be treated with dignity and respect
- Appropriate care will greatly improve the chances of return to work
- High levels of suicide and mental illness in health care professionals must in part be related to their work, previous poor support from their employers may have aggravated the situation
- A vindictive approach would discourage staff from seeking help or stop other staff form reporting concerns before patients are harmed
- A supportive approach assures other team members that they are working in a supportive environment

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13.11. Where a serious lack of foresight is the cause of an incident the options available are similar to those for incapacity. The use of sick leave for an individual who is not sick seems dishonest and a period of discretionary leave with a return to work with some limitations to duties seems more appropriate.

13.12. The response of the individual to the incident will depend largely on their own personality; increased responsibility for the incident may, however, increase their loss of self-worth and may affect the support offered by other members of the team. Clear understanding of critical incidents by the team should encourage support by colleagues. Senior colleagues must show clear leadership in supporting the individual concerned.

Specific immediate actions to support staff

13.13. Staff involved in an incident will need to write a full account of events and discuss the incident with colleagues. They must therefore be given time to do this.

13.14. Individuals involved in an incident should be removed from responsibility for having to care for the patient or patients' relatives. The responsibilities for disclosure and explanation of events after an anaesthetic death have been well described[47] and similar rules should apply in critical care.

13.15. The ICU manager or appropriate delegated authority should talk to individuals involved in an incident to establish the facts as they see them, explain the basic process of any investigation and provide guidance with respect to what they should do and who can help support them. During this discussion they should make sure those involved know how to contact senior staff should they require additional support. It should be remembered that an incident may be upsetting. Those involved may need help to think clearly and may not remember what is said. A written record of conversations should be kept and arrangements should be made to keep the channels of communication open. Time should be set aside for further meetings, as the individual may need to go over events repeatedly.

13.16. The ICU manager or appropriate delegated authority should check the individual is happy to travel home on their own after the incident or whether they would like someone to collect them or another staff member take them home.

13.17. If a period of leave is required this may be socially isolating and result in a further sense of loss of self-worth. Support of colleagues may be helpful as they will provide a link with the work place and they will be more able to understand professional issues than family or friends.

13.18. If several individuals are involved in the incident a formal debriefing session should be organised.

13.19. The individual's privacy and dignity should be protected. Where the incident has to be investigated or reported outside the ICU it is important that the individual understands the reasons for this and is confident the matter will not be discussed inappropriately with others who have no legitimate interest in the events. Other colleagues should be reminded of the individual's right to privacy.

Medium term care and support

13.20. A review of the incident should be discussed in an ICU critical incident meeting. Individuals may find it helpful to participate and an open discussion of the events in a supportive and well-chaired meeting should be helpful. If they do not wish to participate this should also be respected.

13.21. Coroner's inquests and fatal accident enquiries may be highly stressful for junior staff. They should be supported by legal representatives if appropriate and should be made fully aware of what to expect before hand and debriefed afterwards.

13.22. In a way similar to grieving, the adjustment of the individual to their new view of themselves will take time. They may value the opportunity to talk through events repeatedly and discuss problems with adjusting to returning to work. For nursing staff, a previously functioning mentoring process should allow this to happen.

13.23. Medical staff should be supported by the process of educational supervision. The itinerant nature of medical training means that medical staff may leave the ICU soon after an adverse incident. If the Educational Supervisor feels the trainee needs further support they should, with the trainee's knowledge, discuss this with their College Tutor or Postgraduate Tutor. If issues of competency or fitness to practice are unresolved they are obviously obliged, again with the trainee's knowledge, to pass on their concerns.

13.24. Although counsellors will not be aware of the clinical circumstances of an ICU, the individual should know what counselling services are provided by the Trust should they

wish to use them. Individuals may also seek support from clinical staff from other departments who are seen as being more independent than those involved with the ICU.

Long term care and support

13.25. Where a staff member has been off work as a result of incapacity fitness to work should be assessed by the occupational health department. Return to work may be a gradual process with goal-setting and review of these goals before the next stage is reached. Any restrictions to working practice must be clearly understood by the individual and their supervisors. With the individual's permission, other staff may have to be made aware of these actions.

13.26. After incidents where issues of competence have been raised any limitations to practice must be clearly understood and be logical. Again a gradual return to function as new goals are repeatedly set and achieved should allow a supportive return to work.

13.27. There is an obligation to communicate unresolved issues of competence or fitness to work with future employees. The individual should be aware that these issues will be included in any reference. For agency staff the agency should also be informed, in writing, of any issues concerning fitness to practice.

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