Adverse Event (Identification, Reporting, Review and Learning) Policy

Date: May 2014
Version number: 3
Author: Catriona Oxley, Safety and Risk Manager
Review Date: (Holding policy - for immediate review)

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HRSSPOL002
### NHS SHETLAND DOCUMENT DEVELOPMENT COVERSHEET

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#### Proposed groups to present document to:
- Risk Management Group
- Area Medical Committee & Consultants’ Group
- Health and Safety Committee
- Strategy and Redesign Committee
- Healthcare Governance Reference Group

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#### Examples of reasons for presenting to the group
- Professional input required re: content (PI)
- Professional opinion on content (PO)
- General comments/suggestions (C/S)
- For information only (FIO)

#### Examples of outcomes following meeting
- Significant changes to content required – refer to Executive Lead for guidance (SC)
- To amend content & re-submit to group (AC&R)
- For minor revisions (e.g. format/layout) – no need to re-submit to group (MR)
- Recommend proceeding to next stage (PRO)
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| January 2014 | • Title of document changed to reflect standardised national approach and terminology – in particular use of the term ‘adverse event’ – and emphasis on sharing learning from adverse events across services and NHS boards.  
  • Throughout the document the term ‘incident’ has been changed to ‘adverse event’ and ‘investigation’ to ‘review’.  
  • ‘Significant adverse events’ [SAEs] are referred to as ‘Category I adverse events’.  
  • Restructuring of the local adverse event management process to encompass the six stages of adverse event management outlined in the national approach.  
  • Clarification that all review documentation – whether clinical or non-clinical – must be attached to the adverse event record on Datix in keeping with the national approach to electronic information management. The requirement to add to the Datix record all contact/communication with patients, families and carers involved in an adverse event is emphasised.  
  • Timescales for review revised commensurate with national approach.  
  • Inclusion of HIS Adverse Events flowchart (Appendix A).  
  • Appendix B has been revised and the narrative section deleted.  
  • Inclusion of DoH list of ‘Never’ Events (Appendix D).  
  • Inclusion of NCC MERP index (Appendix F).                                                                                                                                 |
| March 2014  | • Rewrite of paragraphs 2 and 3 of Section 5 to clarify reporting by external agencies and Primary Care.  
  • Inclusion of Chief Social Work Officer in Clinical Risk Advisory Team [CRAT] (7.4.1 and Appendix E). Differentiation between ‘community’ and ‘acute’ services when a CRAT is called.  
  • Clarification that the detailed list of ‘never’ events must be consulted as Appendix D gives only headline categories.  
  • Addition of a statement which makes it clear that no part of a patient’s case notes/medical record should be uploaded to Datix as part of a review (Appendix E).  
  • Amendments to reflect new roles, responsibilities and titles of Director of Nursing and Acute Services and Director of Community Health and Social Care.                                                                 |
| May 2014    | • Definition update and clarification (Section 3)  
  • Mention of plans to extend adverse event reporting to Community Pharmacies in the future (Section 5)  
  • Rewording of part of Section 7.2  
  • Cross-reference to Safety Notice Procedure (7.3.4)  
  • Inclusion of a separate section describing the Yellow Card reporting scheme for adverse drug reactions (7.3.5)                                                                 |
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1. Executive Summary

The potential for error presents a constant challenge in the safe delivery of health services. When things go wrong, or adverse events are narrowly avoided, there must be an opportunity for organisations to identify why this happened and act to improve the safety of patients, staff and others, both at the time and in the future.

High levels of adverse event reporting are usually an indicator that people within a healthcare organisation are aware of risks to patients, staff and others and prepared to learn and share experiences and lessons with colleagues. Adverse event reporting is, therefore, encouraged.

The Adverse Event (Identification, Reporting, Review and Learning) Policy is one of a suite of policies, procedures and guidelines which comprise Shetland NHS Board’s Safety and Risk Management arrangements. The policy defines the various terms used when describing adverse events and lays out the legislative framework on which the adverse event reporting process is based as well as the principles underpinning adverse event management in NHS Shetland. The policy also describes how to report and review adverse events using the organisation’s electronic risk management system (Datix) and signposts staff to a series of user guides that elaborate on this process.

This third version of the policy has been produced to reflect the national approach to learning from adverse events (through reporting and review) developed by Healthcare Improvement Scotland [HIS] - following consultation and engagement with, among others, NHS Boards, clinicians and patients - a key aim of which is to “maximise the opportunities for NHS Boards to share and actively learn from one another in order to put improvements into practice”1.

2. Introduction

The primary aim of safety and risk management is to prevent people from being harmed or becoming ill as a consequence of work activities. In the context of NHS Shetland, ‘people’ covers a wide range of individuals and groups including patients, staff, visitors and many others who use our premises and services.

Managing safety and risk involves five key components:

- Risk assessment
- Risk registers
- Adverse event reporting and review
- Audit and inspection

1 Healthcare Improvement Scotland Learning from adverse events through reporting and review: A national framework for NHSScotland September 2013 p. 6
• Training.

The first two of these components are proactive, i.e. they are methods designed to identify hazards, work out the risks associated with them and either eliminate or control exposure to these. The objective is to intervene in the accident causation process and prevent something untoward occurring.

Occasionally, however, despite our best efforts, things can go wrong. Adverse event reporting and review is a reactive method of safety and risk management which supports us to learn from mistakes and helps to prevent their recurrence. It is not about apportioning blame but promoting a just, fair and responsible culture which fosters learning and improvement when adverse events occur.

This policy sets out the actions required to effectively identify, report, review and learn from adverse events across Shetland NHS Board (‘the Board’). Staff should also be aware of the Board’s Clinical Governance\(^2\) and Risk Management Strategies\(^3\) and the Risk Assessment Procedure and Risk Register Guidance which complement this process.

The Board operates an integrated adverse event reporting system which is used to report and review all adverse events, both clinical and non-clinical, using the Datix electronic risk management system.

Disclosure of adverse events (including near misses) is a professional duty of all NHS Shetland staff members.

3. Definitions\(^4\)

An adverse event is defined as an event that could have caused, or did result in, harm to people or groups of people.

Harm is defined as an outcome with a negative effect. Harm to a person or groups of people may result from worsening of a medical condition, the inherent risk of an investigation or treatment, system failure, provider performance issues, service disruption, financial loss or adverse publicity.

All harm is not avoidable, for example the worsening of a medical condition or the inherent risk of treatment. Clinicians should consider any deterioration carefully and consider undertaking adverse event review processes if they think that clinical deterioration may have been due to avoidable factors e.g. negligence or understaffing.

People are defined as:

- Service users

\(^4\) Healthcare Improvement Scotland Learning from adverse events through reporting and review: A national framework for NHSScotland September 2013 p. 8
Groups of people include any functional grouping of individuals such as an organisation. In this way, adverse events that result in, for example, reputational harm or financial harm are included within the scope of the national approach.

The national approach does not use the term ‘significant’ as a qualifier in the context of adverse events. Instead, adverse events are categorised as follows:

**Category I – Events that may have contributed to or resulted in permanent harm**, for example death, intervention required to sustain life, severe financial loss (£>1m), ongoing national adverse publicity (likely to be graded as major or extreme impact on NHSScotland risk assessment matrix, or category G, H or I from NCC MERP index (Appendix F)).

**Category II – Events that may have contributed to or resulted in temporary harm**, for example initial or prolonged treatment, intervention or monitoring required, temporary loss of service, significant financial loss, adverse local publicity (likely to be graded as minor or moderate impact on NHSScotland risk assessment matrix, or category E or F from NCC MERP index).

**Category III – Events that had the potential to cause harm but i) an error did not result, ii) an error did not reach the person iii) an error reached the person but did not result in harm (near misses)** (likely to be graded as category A, B, C or D from NCC MERP index). These results can occur either by timely intervention or due to good fortune.

More information about categorisation of adverse events is given in Section 7.4 below and Appendices C and D describe the types of adverse events designated as Category I.

### 4. Legislative Framework

#### 4.1 The Management of Health and Safety at Work Regulations 1999

In terms of health and safety arrangements, the Management of Health and Safety at Work Regulations 1999 require every employer to "make and give effect to such arrangements as are appropriate, having regard to the nature of his activities and the size of his undertaking, for the effective planning, organisation, control, monitoring and review of the preventive and protective measures". Adverse event reporting and review are essential parts of this process.

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5. Management of Health and Safety at Work Regulations 1999; Regulation 5 (1)
4.2 The Reporting of Injuries, Diseases and Dangerous Occurrences Regulations [RIDDOR] 2013

There is also a legal requirement under the Reporting of Injuries, Diseases and Dangerous Occurrences Regulations [RIDDOR] 2013 which puts duties on employers, the self-employed and people in control of work premises (the Responsible Person) to report work-related deaths, serious accidents, occupational diseases and specified dangerous occurrences (near misses). Further detail is given in Section 7.4 below.

4.3 The Health Facilities Scotland Incident Recording and Investigation Centre [IRIC]

NHSScotland staff have a responsibility to report adverse events involving, health, social care, estates and facilities equipment. The Health Facilities Scotland Incident Recording and Investigation Centre [IRIC] logs user-generated adverse incident reports from NHS Boards and Local Authorities in Scotland and co-ordinates investigation and remedial action on behalf of the Scottish Government. Section 7.5 of the policy describes how reports to IRIC are submitted.

4.4 The National Approach to Learning from Adverse Events Framework

Although not strictly part of any legislative structure, CEL(2013)20 sets out the expectation that NHS Boards ‘adopt this framework to improve their local approaches to handling adverse events’. The framework underpinning the national approach supports consistent definitions and a standardised approach to adverse event management across NHSScotland applicable to both clinical and non-clinical events and across specialties and services. As a consequence the terminology, definitions, overarching principles and methodology outlined in this policy document reflect this framework.

5. Scope of the Policy

All employees and workers at NHS Shetland must follow this policy for reporting adverse events involving patients, staff, visitors and others using our premises and services. ‘Workers’ includes contractors, temporary, agency and bank staff, volunteers, students and people on work experience.

All GP Practices have access to the Datix electronic reporting system and are able to use it to report adverse events which interface between primary and secondary care and/or involve more than one practice or service.

Adverse events involving other services (e.g. NHS Grampian, Scottish Ambulance Service, Red Cross etc.) should also be recorded on Datix however such services do not have access to the system and so this must be done by NHS Shetland staff. The Safety and Risk Support Team can advise if necessary.

A mechanism through which Community Pharmacies are able to flag relevant adverse events to the Board will be developed in due course.

The policy relates to all types of clinical and non-clinical adverse events including:
- Patient safety events or near misses including medication errors. This includes events classified by the Department of Health in England as ‘never events’. A list is attached as Appendix D but more detail is available via the following link: https://www.gov.uk/government/publications/the-never-events-list-2012-to-2013 which should always be referred to for full descriptions.
- Provision of services including staffing availability and delays to treatment
- Health and safety issues including violence and aggression
- Psychosocial issues such as bullying and harassment and specific incidences of work-related stress
- Events involving medical, scientific and estates related devices and equipment
- Security issues
- Fire, vandalism and damage to property/vehicles
- Financial irregularities including fraud and non-compliance with standing financial instructions
- Information governance and data protection breaches or near misses
- IT security related events.

The above list is not exhaustive and the exclusion of a particular category of adverse event does not mean it falls outwith the scope of the policy. If staff are unclear as to whether or not an adverse event should be reported, they should seek guidance from their line manager and/or the Safety and Risk Support Team.

“A safety culture is comprised of many things, including openness, honesty, fairness and accountability. It requires and encourages the reporting of adverse events and safety hazards. It supports opportunities for safety training and preparedness. It promotes understanding, learning and improvement. It requires flexibility and resilience so that people and unexpected situations and priorities can be managed in a timely and effective manner. Importantly, it includes the principles of patient and family-centred care”7.

7 McIlhenny, C., 2013. A Just Culture: Safe to Report. HIS AEPB/13/05

6.1 Overarching principles

NHSScotland’s key values are:

- Care and compassion
- Dignity and respect
- Openness
- Honesty and responsibility
- Quality and teamwork.8

The national approach to learning from adverse events is designed to support and build on these values and does this in a number of ways. Primarily, the focus of the approach is on learning – both locally and nationally – and for this to be effective there has to be an openness about failures coupled with a ‘just culture’ which treats staff fairly, supporting them to recognise, report and learn from adverse events. The approach also emphasises personal, professional and organisational accountability, underlining the fact that everyone is responsible for taking action to prevent adverse events and that “the principal accountability of all NHS care providers is to patients, their families and carers”.9

6.2 NHS Shetland principles

Supporting the national approach is a set of Board-wide principles underpinning the Management of adverse events at local level:

- Adverse events make us reflect on what we do and how we do it
- The Board has sought to develop and embed an open, just and non-punitive culture where all staff feel able to report adverse events, near misses and hazards in the knowledge that these are not normally investigated through the disciplinary procedure (see 7.5.2 below). As a consequence, staff feel empowered to be open and honest when reporting an adverse event and participating in a review
- Staff who report adverse events receive feedback from the reviewer via the ‘Communication and Feedback’ function of the Datix risk management system thereby keeping them in the loop and providing assurance that the adverse event is being taken seriously
- The procedure for identifying, escalating and managing a Category I adverse event is clear and well understood by all managers and staff
- Staff reviewing an adverse event have a positive approach to the review seeing it as an opportunity to learn and change things for the benefit of patients, staff, visitors and others who use our services and facilities

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9 Healthcare Improvement Scotland Learning from adverse events through reporting and review: A national framework for NHSScotland September 2013 p. 9
• Reviews are thorough and continued until the reviewer(s) is/are satisfied that, where possible, root causes have been identified
• Reviews are objective and supportive of the staff involved. Line managers consider whether or not staff might need additional support during the course of a review and take appropriate action on this, if necessary, with advice from their line manager, the Human Resources Department, Occupational Health Service and/or a member of the Senior Management Team
• There is a systematic approach to creating and implementing action plans as a consequence of reviews and progress is monitored via the line management structure
• Learning happens as a consequence of adverse event reviews and is disseminated appropriately to enable the organisation to facilitate any wider local change and improvement. There is a clear governance framework for reporting and learning from the most serious adverse events
• Patients, their families and carers and staff receive an apology for distress caused if appropriate, and expressions of sympathy and concern. There is recognition that apologising does not necessarily mean acceptance of responsibility but rather creates a basis for improving stakeholder confidence and trust.

7. Managing an Adverse Event

The circumstances surrounding each adverse event will vary in terms of:

• Levels of harm
• Numbers of people involved
• Risk exposure
• Financial loss
• Media interest, and
• The need to involve other stakeholders.

The response to each adverse event, therefore, should be proportionate to its scale, scope and complexity.

As per the national approach, there are six stages of adverse event management. This section describes each of these in turn and Appendix A summarises them in the form of a flowchart.

7.1 Risk assessment and prevention

Adverse event management is one part of effective risk management. Avoidance, prevention and reduction of risks should be the primary defence to prevent adverse events occurring. It is important that risk assessment and prevention is seen as the first step in effective adverse event management and, therefore, this policy should be
implemented in conjunction with the Board’s Risk Assessment Procedure and Risk Register Guidance\textsuperscript{10}.

7.2 Identification and immediate actions following an adverse event

Following an adverse event the immediate safety of staff and patients is a priority. Clinical assistance should be sought for any adverse clinical event where there is an ongoing risk to (a) patient(s) and appropriate support service assistance for any event where there is an ongoing risk due to environmental issues. If it is relevant to the adverse event, equipment or medication should be retained and isolated. If necessary, relevant documentation should be copied and secured to preserve evidence and facilitate review and learning.

Statements taken at the time of an adverse event can contain valuable information that may be lost if statement taking is delayed. Prompt information gathering from staff and patients should be facilitated where this is necessary for adverse event review and practicable for clinicians who are still caring for patients.

The most senior person in the area must make an immediate assessment about whether or not an adverse event should be managed as a Category I adverse event (see section 7.4 below and Appendices B and C) and act accordingly. This person will also ensure support is made available to staff involved in the adverse event as required.

If a patient has been directly involved in an adverse event, the senior clinician with responsibility for that patient should explain the adverse event to the patient, or, in the event of a death, his/her family, at the earliest opportunity. The patient, or family, should be advised by that senior clinician of the process of adverse event review and asked if they want to give a statement. The senior clinician should also ensure that the patient or family is/are made aware of the final outcome of the review.

All staff involved in and interviewed about an adverse event must be treated appropriately in the spirit of the Board’s commitment to a fair and open culture and staff side representatives should be involved as requested.

\textsuperscript{10} http://www.shb.scot.nhs.uk/board/policies/RiskAssessmentProcedureAndRiskRegisterGuidance.pdf
7.3 Initial reporting and notification

All adverse events and near misses – both clinical and non-clinical – must be recorded on Datix, NHS Shetland’s electronic risk management system. Access to the Datix system is via the home page of the intranet. As per Figure 2 below, clicking on the top ‘Report an Adverse Event...’ link takes the user straight into the online report form.

As well as reporting adverse events on Datix, staff members must inform their line manager as soon as possible after an adverse event occurs. This is important because although the Datix system is set up to do this automatically, for various reasons this does not always happen.

The adverse event reporting form should be completed as soon as possible after the event, within one working day, unless there are exceptional reasons for delay, for example the event was identified retrospectively following a complaint or claim. All adverse events should be reported, even if some time has passed since the event occurred.

To facilitate adverse event reporting, review and management, staff training, Datix user guides and a template for Category I Adverse Event Review have been created.
for staff. These are available on the intranet within Datix or via the Risk Management page.

It is imperative that the person(s) reporting the adverse event reports on fact. There is no place for any opinion or assumptions. It is important that details are accurate and factual for any future review.

7.3.1 Other Reporting Systems

Some departments have additional error and adverse event monitoring arrangements (e.g. Laboratory and Medical Imaging) as part of specific legal, accreditation or quality assurance framework requirements for these services. Staff using these additional systems will ensure that adverse events with learning wider than the department and all Category I adverse events are recorded on the Datix system as well.

7.3.2 Bullying and Harassment

Due to the sensitivities involved in reporting events of bullying or harassment by staff (e.g. to other staff) where, for example, the line manager may be the alleged perpetrator, the Datix system allows for the completed adverse event report form to be forwarded to an alternative manager.

The procedure for review and management of events relating to the reporting of bullying or harassment is the same as for other types of adverse event reporting. The Human Resources Department will not play an active role in the review process unless the adverse event relates to an issue raised by a member of the Human Resources team.

Further advice on reporting such events can be obtained via:
- The Eliminating Bullying and Harassment Policy [http://www.shb.scot.nhs.uk/board/policies/hr-EliminatingBullyingHarassment.pdf](http://www.shb.scot.nhs.uk/board/policies/hr-EliminatingBullyingHarassment.pdf)
- Confidential Supporters
- The Human Resources Department.

7.3.3 RIDDOR

As indicated in Section 4.2 above, in addition to locally determined adverse event reporting there is a legal requirement to report serious workplace accidents, occupational diseases and specified dangerous occurrences at work to the Health and Safety Executive [HSE]. All reports to the HSE under RIDDOR are co-ordinated by the Safety and Risk Manager. In practice this means that a face-to-face or telephone conversation takes place between the Safety and Risk Manager and the affected party to agree the detail of the report to the HSE. A copy of the RIDDOR
report is provided for the affected party and uploaded to the Datix record by the Safety and Risk Manager.

7.3.3.1 Deaths and injuries

If an employee, worker or contractor has died or been injured because of a work-related accident this may have to be reported. Types of reportable injury include:

- The death of any person
- Specified injuries to workers – there is a list of reportable specified injuries on the HSE website
- Over-seven-day incapacitation of a worker – defined as injuries that lead to an employee or self-employed person being away from work, or unable to perform their normal work duties, for more than seven consecutive days as the result of an occupational accident or injury (not counting the day of the accident but including weekends and rest days). The report must be made within 15 days of the event.

7.3.3.2 Occupational diseases

Employers and self-employed people must report diagnoses of certain occupational diseases, where these are likely to have been caused or made worse by their work\(^\text{11}\).

7.3.3.3 Dangerous occurrences

Dangerous occurrences are certain listed near-miss events. Not every near-miss event must be reported. The HSE website contains a list of those that are reportable.

7.3.3.4 Reporting injuries, diseases and dangerous occurrences in health and social care: Guidance for employers

There is a requirement under RIDDOR to report to the HSE accidents which result in a person not at work (e.g. a patient, service user or visitor) suffering an injury and being taken to a hospital, or if the accident happens at a hospital, suffering a major injury which would otherwise have required hospital treatment. This is a complex area and the HSE has issued specific guidance to clarify the reporting requirements for certain types of injury, some occupational diseases and dangerous occurrences that arise out of or in connection with work in the health and social care sector. This guidance is available via the Safety and Risk Support Tool and on the Risk Management page on the intranet.

The Datix system incorporates a section for reviewers on reporting under RIDDOR and if validated the Safety and Risk Manager is automatically notified by email. This should not be relied on, however, and all relevant managers (i.e. the line manager, Head of Department, Director/Assistant Director and Safety and Risk Manager) should personally be alerted to RIDDOR reportable events immediately.

\(^{11}\) [http://www.hse.gov.uk/riddor/occupational-diseases.htm](http://www.hse.gov.uk/riddor/occupational-diseases.htm)
7.3.4 **IRIC**

As noted above (Section 4.3), all staff working in NHS Scotland have a responsibility to report adverse events involving medical, scientific and estates related devices and equipment. As well as the line manager, the reporting of such events should be directed to the Chief Medical Physics Officer or the Estates and Facilities Manager for investigation in the first instance, and referral onto IRIC if required. Events involving medical supplies must be directed to the Equipment Co-ordinator (Safety and Risk Manager) for joint investigation.

The Datix reporting form includes a mandatory question relating to the involvement of equipment in an adverse event and an equipment details form is incorporated.

The decision to report an adverse event to IRIC is taken by the review team and the online report submitted by the Chief Medical Physics Officer, Estates and Facilities Manager and/or Equipment Co-ordinator (Safety and Risk Manager). The reporter is responsible for attaching a copy of the report to the Datix record.


7.3.5 **Yellow Card Centre Scotland**

NHS Scotland staff need to report adverse drug reactions to medicines in normal therapeutic use. YCC Scotland is a joint venture between the Medicines and Healthcare products Regulatory Agency [MHRA] and the Scottish Government. Its aim is to improve drug safety in Scotland. The Yellow Card website ([www.yccscotland.scot.nhs.uk](http://www.yccscotland.scot.nhs.uk)) gives clear guidance on how to report an adverse drug reaction either online or by post, the information that is required and contacts for help and advice.

7.4 **Analysis and categorisation**

When an adverse event is entered into the Datix system, the reporter is asked to select from a drop-down menu the manager they feel is most appropriate to deal with the event. If the reporter is a manager, they can select themselves. This person – and it can only be one – is designated as the ‘handler’ of the adverse event. The handler is the person who:

- Ensures that the adverse event report is documented fully
- Appoints the reviewer(s) and co-ordinates the review of the event
- Feeds back to the reporter
- Ensures that actions are completed
- Requests final approval for the adverse event when the investigation is complete.

A key part of this process is the requirement for the handler to assess the adverse event reporting form to consider whether or not a more in-depth review of the event is required.

The Datix report form includes a risk matrix which allows the handler to grade the adverse event by assessing the likelihood and consequence of the event taking place again. Assessing the grade also helps the handler to determine the significance of the adverse event and the required management actions, i.e. low, medium, high and very high level adverse events will have differing levels of urgency and review requirements. This is illustrated in Figures 3 and 4.

Figure 3: Risk Assessment Matrix

<table>
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<th>Likelihood</th>
<th>Negligible</th>
<th>Minor</th>
<th>Moderate</th>
<th>Major</th>
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<tr>
<td>Almost certain</td>
<td>Medium</td>
<td>High</td>
<td>H</td>
<td>Very High</td>
<td>VH</td>
</tr>
<tr>
<td>Likely</td>
<td>M</td>
<td>M</td>
<td>H</td>
<td>H</td>
<td>VH</td>
</tr>
<tr>
<td>Possible</td>
<td>Low</td>
<td>M</td>
<td>M</td>
<td>H</td>
<td>H</td>
</tr>
<tr>
<td>Unlikely</td>
<td>L</td>
<td>M</td>
<td>M</td>
<td>M</td>
<td>H</td>
</tr>
<tr>
<td>Remote</td>
<td>L</td>
<td>L</td>
<td>L</td>
<td>M</td>
<td>M</td>
</tr>
</tbody>
</table>

The categorisation of adverse events (based on impact of harm) in terms of the matrix is as follows:

**Category I – Events that may have contributed to or resulted in permanent harm**, for example death, intervention required to sustain life, severe financial loss (£ >1m), ongoing national adverse publicity (likely to be graded as major or extreme impact on NHSScotland risk assessment matrix)

**Category II – Events that may have contributed to or resulted in temporary harm**, for example initial or prolonged treatment, intervention or monitoring required, temporary loss of service, significant financial loss, adverse local publicity (likely to be graded as minor or moderate impact on NHSScotland risk assessment matrix)

**Category III – Events that had the potential to cause harm but i) an error did not result, ii) an error did not reach the person iii) an error reached the person but did not result in harm (near misses).**
### ADVERSE EVENT CATEGORY

<table>
<thead>
<tr>
<th>Category</th>
<th>PRIORITY</th>
<th>LEVEL OF REVIEW</th>
</tr>
</thead>
<tbody>
<tr>
<td>Category I</td>
<td>High/Very High</td>
<td>Level 1 - Comprehensive adverse event analysis and review</td>
</tr>
<tr>
<td>Category II</td>
<td>Medium</td>
<td>Level 2 - Local management review in consultation with appropriate Director</td>
</tr>
<tr>
<td>Category III</td>
<td>Low/Medium</td>
<td>Level 3 - Departmental management action. Further inquiries/questions. Trends should be considered for further review</td>
</tr>
</tbody>
</table>

Line managers must be informed immediately about a potential Category I adverse event (escalate until a line manager is available) and the event reported directly to the relevant Director to consider whether or not:

a) The categorisation is correct and,

b) A comprehensive adverse event analysis and review is required.

Examples of relevant directors are given in Figure 5 but if there is doubt any Director will advise. The Datix system should not be relied on for this – it is a recording and management system and does not replace normal channels of communication.

### Figure 5

<table>
<thead>
<tr>
<th>Type of Adverse Event</th>
<th>Relevant Director</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clinical</td>
<td>Director of Nursing and Acute Services</td>
</tr>
<tr>
<td></td>
<td>Director of Community Health and Social Care</td>
</tr>
<tr>
<td></td>
<td>Medical Director</td>
</tr>
<tr>
<td></td>
<td>(Any of these can be approached)</td>
</tr>
<tr>
<td>Estates and Facilities</td>
<td>Chief Executive</td>
</tr>
<tr>
<td>Child protection</td>
<td>Director of Public Health</td>
</tr>
<tr>
<td>Data protection</td>
<td>Director of Human Resources</td>
</tr>
<tr>
<td>Health and Safety</td>
<td>Director of Human Resources</td>
</tr>
<tr>
<td>Financial</td>
<td>Director of Finance</td>
</tr>
</tbody>
</table>

If the decision is reached that a Category I adverse event has occurred, the relevant Director will convene a Category I Adverse Event Team [CAET], which will vary according to the adverse event but will include relevant manager(s) and, if clinical in nature, appropriate medical staff/General Practitioners/other clinicians. For clinical adverse events, the relevant Director will decide on whether or not a Level 1 review is needed, taking advice as appropriate from members of the Clinical Risk Advisory Team.
7.4.1 The Clinical Risk Advisory Team [CRAT]

The CRAT is a tactical team which is established as required to carry operational responsibility for managing Category I clinical adverse events and consists of:

- Director of Nursing and Acute Services
- Medical Director
- Director of Community Health and Social Care
- Director of Human Resources and Support Services
- Chief Social Work Officer (at the discretion of the Director of Community Health and Social Care and dependent on whether or not the adverse event affects community services).

Appendix E describes the procedure for managing a Category I clinical adverse event and the role of the CRAT.

7.5 Review

7.5.1 Appointing the reviewer(s)

The adverse event handler is asked to select from a drop-down menu in the ‘Review’ section of the Datix report form the most appropriate staff member(s) to review the adverse event. The options are limited to senior managers (the Chief Executive, Directors, Assistant Directors and Heads of Department/Senior Charge Nurses/Sisters/Team Leaders) lead clinicians and staff with key functions such as infection control and moving and handling. The list also includes, however, the names of the Health and Safety Committee staff side representatives since it is Board policy (in line with the Safety Representative and Safety Committee Regulations 1977) that they are involved in health and safety incident investigations\(^\text{12}\).

For adverse events graded as low and medium priority (see Figure 4 above) one reviewer is normally all that is required and it should be noted that this reviewer can also be the handler of the event. For more serious or multi-stranded events it may be necessary to appoint a team of reviewers following input from a CAET and/or CRAT.

7.5.2 Conducting a review

The purpose of a review is to determine what happened, how it happened, why it happened, and whether there are learning points for a service and/or the wider organisation. Reviews should follow the principles of a just culture outlined in Section 6 above and take a systems approach.

\(^\text{12}\) NHS Shetland Health and Safety Policy; para. 5.7; p. 10
Key prompts and considerations for conducting a review are provided in Appendix B. The Datix user guides (available on the intranet via a link on the Risk Management page) will also be helpful.

Adverse event review may involve interviewing those involved (whether as the affected party, employee involved in the event or a witness to the event) and taking statements in order to create a timeline and identify root causes. For some adverse events site visit(s) and liaison with manufacturers and/or suppliers, contractors and/or other agencies/individuals involved may be needed. For all adverse events the evidence gathered should be uploaded to the Datix record in the form of documents, photographs, emails, letters, faxes etc., in order to maintain a comprehensive, accessible file of review documentation. For Category I adverse events a final report and action plan must also be produced and added. A template is available to facilitate the latter and can be accessed via Datix and the intranet.

If a patient has been directly involved in an adverse event, the senior clinician with responsibility for that patient should explain the event to the patient, or, in the event of a death, his/her family, at the earliest opportunity. The patient, or family, should be advised by that senior clinician of the process of adverse event review and asked if they want to give a statement. The senior clinician should also ensure that the patient or family is/are made aware of the final outcome of the review. All contact with patients, families and carers must be recorded and attached to the Datix record.

A thorough and structured review should:

- Identify the sequence of events and conditions that led to the adverse event happening
- Identify the immediate causes
- Identify the underlying causes i.e. the actions in the past that have allowed or caused undetected unsafe conditions or practices
- Identify root causes (i.e. organisational and management issues)\(^\text{13}\).

The objective is to establish not only how the adverse event happened but also, more importantly, what allowed it to happen.

There are many tools and techniques available for structuring a review, analysing adverse events and identifying root causes.

Root cause analysis [RCA] is a class of problem solving methods aimed at identifying the root causes of problems or events. Staff are encouraged to use structured, systematic review analysis tools such as the toolkit sponsored by NHS England: [http://www.nrls.npsa.nhs.uk/resources/collections/root-cause-analysis/](http://www.nrls.npsa.nhs.uk/resources/collections/root-cause-analysis/)

The Health and Safety Executive [HSE] has also published guidance on how to review adverse events. *Investigating accidents and incidents: A workbook for employers, unions, safety representatives and safety professionals* (HSE ref. HSG245); p. 7

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\(^{13}\) Investigating accidents and incidents: A workbook for employers, unions, safety representatives and safety professionals (HSE ref. HSG245); p. 7
employers, unions, safety representatives and safety professionals (HSE ref. HSG245) is available to download from the HSE: http://www.hse.gov.uk/pubns/books/hsg245.htm or from Barbour Environment, Health and Safety (access online via ATHENS).

If an individual reviewing an adverse event is concerned regarding any aspect of their review and feels they need assistance, they should involve their line manager at the earliest opportunity. The Clinical Governance and Safety and Risk Support Teams are also able to provide advice and support regarding the use of best practice review techniques and methodologies in relation to adverse event review and analysis.

If, during the course of a review, evidence comes to light of a deliberate attempt to disguise an error and/or dangerous practice or it appears that an adverse event involves negligence or poor standards of care, then the Board’s Disciplinary Procedure will be invoked, the appropriate Director notified, and the evidence gathered used to support the disciplinary process.

7.5.3 Timescales for reviews

Timescales for the completion of investigations are given in Figure 6 below. Level 2 and 3 reviews should be completed within 10/20 working days. In recognition of the often complex nature of multi-stranded reviews, longer timescales are given but the decision whether or not to convene a CAET must be made as soon as possible.

Note that it is the lead reviewer’s responsibility to ensure that if the initial review cannot be completed in the timescale specified a new deadline is negotiated and put in place.

Figure 6

<table>
<thead>
<tr>
<th>Level of review</th>
<th>Timescale in days</th>
</tr>
</thead>
<tbody>
<tr>
<td>Level 1</td>
<td>20 working days for initial investigation and feedback to reporter</td>
</tr>
<tr>
<td>Level 2</td>
<td>20 working days for completion of investigation and initial management actions and feedback to reporter</td>
</tr>
<tr>
<td>Level 3</td>
<td>Adverse event approved and closed within 10 working days of being reported</td>
</tr>
</tbody>
</table>

7.6 Improvement planning and monitoring

The national adverse events framework requires that Level 1 and Level 2 adverse event reviews must have an improvement plan developed in response to the findings and recommendations.
Once a review has been carried out, it is the responsibility of the reviewer to analyse the outcomes and use this information to identify the risk control measures that were missing, inadequate and/or unused and create an action plan to deal effectively with these shortcomings.

The 'Review' section of the Datix report form includes free text boxes which allow the reviewer to record details of:

- The review (tasks carried out in respect of reviewing the adverse event)
- Action taken as a consequence of the adverse event review.

This form is likely to be adequate for concise reviews of the type most commonly conducted by a single reviewer that resulted in no, low or moderate harm.

Datix also has a separate ‘Actions’ section that allows reviewers to record in much greater detail actions arising as a consequence of adverse events as well as allocating action owners and setting completion dates. This section should be used for multi-stranded (Level 1) reviews and those requiring longer term actions.

The handler of the adverse event is responsible for making sure that actions are completed and that this is recorded on the Datix system. Progress should be monitored via the line management structure.

Adverse event reporting and risk management are the responsibility of all staff, and it is the responsibility of all staff to learn from adverse events and risks identified, for the benefit of patients and the service. Line managers have additional responsibilities for ensuring the frameworks and processes highlighted in this policy and the principles highlighted in the Clinical Governance and Risk Management Strategies are adhered to.

In particular line managers have responsibilities for communicating with staff about adverse events they are involved in, the outcome of adverse event reviews and for delivering the actions arising from them in a timely manner.

In addition to this, the line manager also has a responsibility to ensure that adverse event reporting and review is linked where appropriate to the local complaints procedure (especially in terms of recognising patterns in adverse event trends and feedback through formal and informal complaints) and to team, directorate and corporate risk registers. Line managers should recognise the importance of communicating feedback to patients and carers in relation to patient safety events.

As noted in Section 6 above, one of the basic principles of adverse event reporting, review and management is that learning happens as a consequence of reviews of events and is disseminated appropriately to enable the organisation to facilitate any wider local change and improvement. In particular, a thematic approach to learning from Category 1 adverse events must support staff to change and adapt (clinical) practice accordingly.
Locally, a variety of mechanisms are used to disseminate learning from adverse events such as: committee, working group and team meetings, case reviews, mortality and morbidity meetings, Team Brief and Message of the Day.

As required by the national approach, NHS Shetland will contribute to the development and implementation of a national system to collate and share learning as well as integrate data from adverse events, complaints and claims.

Appendix F illustrates the current organisational risk management reporting mechanisms.

8. Equality and Diversity Impact Assessment [EDIA]

As previously indicated, the Adverse Event Identification, Reporting, Review and Learning Policy is one of a suite of documents developed to support the Board’s Risk Management Strategy by giving more detail about the process of reporting and reviewing adverse events. The EDIA carried out as part of the Risk Management Strategy recognises that in complying with the Health and Safety at Work etc Act 1974 and subordinate legislation the Board meets its duty of care towards not just employees but others who may be affected by its activities e.g. patients, visitors, members of the public, contractors and delivery personnel. Additionally, the strategy recognises the statutory requirement to give special consideration to other groups including night workers, lone workers and workers with disabilities.

As the strategy also makes clear, the promotion of a fair and open culture is regarded as an essential component of an effective risk management system.

The impact of the Risk Management Strategy and supporting documents has been assessed as positive in relation to equality and diversity.

9. Appendices

APPENDIX A – ACTIONS TO BE TAKEN TO EFFECTIVELY MANAGE ADVERSE EVENTS
APPENDIX B - REVIEW OF AN ADVERSE EVENT
APPENDIX C - PROCESS FOR REVIEWING A CATEGORY I ADVERSE EVENT
APPENDIX D – DEPARTMENT OF HEALTH ‘NEVER’ EVENTS LIST 2012/13
APPENDIX F - NHS SCOTLAND CORE RISK ASSESSMENT MATRICES AND NCC MERP INDEX
APPENDIX G - ORGANISATIONAL RISK MANAGEMENT REPORTING MECHANISMS
Appendix A – Actions to be taken to effectively manage adverse events

1. Risk assessment and prevention

2. Immediate actions following an adverse event
   - Adverse event occurs
   - Make person/area safe and attend to any medical requirements
   - Implement any immediate operational actions to reduce risk of recurrence e.g. removal of trip hazard or faulty equipment

3. Initial reporting and notification
   - Report to local reporting systems

4. Analysis and categorisation
   - Categorise adverse event
   - Review categorisation with relevant manager

5. Review
   - Establish appropriate review
   - Undertake review keeping patient, their family and staff members informed
   - Submit review report and action plan via the appropriate governance mechanism
   - Governance mechanism quality assurance and closure of review
   - Share learning and implement key learning points
   - Implement action plan
   - Review of implementation of actions

6. Improvement planning and monitoring
Appendix B - Review of an Adverse Event

**Key prompts and considerations for a review**

- Ensure that a review is carried out as soon as is possible by a designated competent person or team and that the following are considered:
  - How anyone injured was attended to;
  - Whether or not the area was isolated following the event;
  - The identity of key staff; witnesses, responsible persons who had influence over the circumstances surrounding the event;
  - Whether or not there was a breach of statutory legislation;
  - Whether or not there was a written procedure which should have been followed (i.e. safe system of work);
  - Whether or not there are any omissions within that policy or procedure which allowed the event to happen;
  - Whether or not there was a need for training and if so, was it given;
  - Details of who gave the training;
  - Was appropriate equipment used, was it maintained and are there maintenance records;
  - Were precautions necessary and if so, were they followed;
  - That all staff interviewed are treated appropriately in the spirit of the Board’s commitment to a fair and open culture and that Staff Side Representatives are involved as requested.
# Appendix C - Process for Reviewing a Category I Adverse Event

<table>
<thead>
<tr>
<th><strong>Category I Adverse Events</strong></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>All incidents rated as HIGH/VERY HIGH on Datix</td>
<td></td>
</tr>
<tr>
<td>Incidents reportable to the Scottish Fatalities Unit (SFU) e.g. maternal deaths</td>
<td></td>
</tr>
<tr>
<td>Incidents reportable to the Mental Welfare Commission</td>
<td></td>
</tr>
<tr>
<td>Incidents reportable as part of a Fatal Accident Inquiry (FAI)</td>
<td></td>
</tr>
<tr>
<td>Incidents reportable as ‘avoidable deaths’ (identified via the Mortality and Morbidity Review process)</td>
<td></td>
</tr>
<tr>
<td>Incidents reportable via SHOT or SABRE (e.g. transfusion incidents)</td>
<td></td>
</tr>
<tr>
<td>Incidents reportable to the HSE under RIDDOR</td>
<td></td>
</tr>
<tr>
<td>Any other ‘Never Event’ (very serious, largely preventable patient safety incident that should not occur if the relevant preventative measures have been put in place e.g. wrong site surgery)</td>
<td></td>
</tr>
<tr>
<td>Incidents resulting in an Internal Case Review (Clinical and Non Clinical e.g. systems failure for a piece of equipment, adult/child protection QA etc.)</td>
<td></td>
</tr>
</tbody>
</table>

Contact the appropriate Senior Manager to agree upon the process for review

<table>
<thead>
<tr>
<th><strong>Possible Outcomes</strong></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Act now. Put immediate controls in place, start review</td>
<td></td>
</tr>
<tr>
<td>Next working day. Put controls in place, start review</td>
<td></td>
</tr>
<tr>
<td>Within 1 week. Put controls in place, start review within 7 days</td>
<td></td>
</tr>
<tr>
<td>You may also agree to DOWNGRADE the event if the manager does not assess it to be a Category I event.</td>
<td></td>
</tr>
</tbody>
</table>

Review Requirements

<table>
<thead>
<tr>
<th><strong>Review Requirements</strong></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Communicate adverse event details to staff, patient and relatives (as appropriate to the adverse event type)</td>
<td></td>
</tr>
<tr>
<td>Start a timeline/chronology of events. Ask staff to start writing statements/recollections</td>
<td></td>
</tr>
<tr>
<td>Complete an initial assessment/recommendations</td>
<td></td>
</tr>
<tr>
<td>Bring together a Category I Adverse Event Team [CAET] to agree, manage and implement actions</td>
<td></td>
</tr>
<tr>
<td>Agree a timescale for the completion of the initial review</td>
<td></td>
</tr>
<tr>
<td>Agree a timescale for the completion of the actions</td>
<td></td>
</tr>
<tr>
<td>Record stages of the review process on Datix</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th><strong>Reporting, Monitoring &amp; Feedback</strong></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Findings and actions will be fed back to staff in the form of a report and debriefing</td>
<td></td>
</tr>
<tr>
<td>Wider sharing of the findings and actions will be circulated to the ‘governance meetings’.</td>
<td></td>
</tr>
<tr>
<td>A summary of adverse events, reviews and key findings will be presented to HGRG and CGC on a quarterly basis.</td>
<td></td>
</tr>
<tr>
<td>All individual review reports will be reviewed at the Risk Management Group on a regular basis.</td>
<td></td>
</tr>
</tbody>
</table>
Appendix D – Department of Health ‘Never’ Events List 2012/13

The ‘never’ events list for reference is as follows but it is essential to refer to the full list for a complete description and guidance:

1. Wrong site surgery
2. Wrong implant/prosthesis
3. Retained foreign object post-operation
4. Wrongly prepared high-risk injectable medication
5. Maladministration of potassium-containing solutions
6. Wrong route administration of chemotherapy
7. Wrong route administration of oral/enteral treatment
8. Intravenous administration of epidural medication
9. Maladministration of Insulin
10. Overdose of midazolam during conscious sedation
11. Opioid overdose of an opioid-naive patient
12. Inappropriate administration of daily oral methotrexate
13. Suicide using non-collapsible rails
14. Escape of a transferred prisoner
15. Falls from unrestricted windows
16. Entrapment in bedrails
17. Transfusion of ABO-incompatible blood components
18. Transplantation of ABO-incompatible organs as a result of error
19. Misplaced naso- or oro-gastric tubes
20. Wrong gas administered
21. Failure to monitor and respond to oxygen saturation
22. Air embolism
23. Misidentification of patients
24. Severe scalding of patients
25. Maternal death due to post partum haemorrhage after elective Caesarean section.

Published 20 January 2012
Appendix E - Procedure for Managing a Category 1 Clinical Adverse Event and the Role of the Clinical Risk Advisory Team [CRAT]

The following directors will be asked to consider whether a clinical adverse event warrants a level 1 review:

- Director of Community Health & Social Care (community and social care)
- Medical Director (primary care and other medical)
- Director of Nursing & Acute Services (hospital and specialist services).

They will lead on the respective areas shown in parentheses but any of them can be approached to initiate/facilitate a CRAT.

The Clinical Risk Advisory Team will consist of:

- Director of Nursing and Acute Services
- Medical Director
- Director of Community Health and Social Care
- Director of Human Resources and Support Services
- Chief Social Work Officer (at the discretion of the Director of Community Health and Social Care and dependent on whether or not the adverse event affects community services).

It will be convened to carry the responsibility for agreeing, instigating and overseeing the appropriate course of action for suspected poor performance and for potential Category I adverse events.

If the decision is reached that it is a Category I adverse event, an appropriate director will convene a Category I Adverse Event Team [CAET], which will vary according to the adverse event but will include a relevant manager, key medical and nursing staff and/or other clinicians and the adverse event handler.

The purpose of the CAET is to:

a. Ensure that all immediate necessary actions have been implemented to safeguard patients, staff and the Board;

b. Ensure that the confidentiality of the patient(s) and/or member(s) of staff is/are maintained in the context of the adverse event;

c. Identify an appropriate named person to communicate with the patient first and with their relatives;

d. Establish the accurate facts of the adverse event from whomever it deems necessary, ensuring that a full review is carried out as soon as possible;
e. Ensure that all documentation, instruments and equipment relative to the adverse event are clearly identified and kept in a safe condition until the review is deemed closed;

f. Agree the content of any statement and means of dissemination to other health care professionals including, specifically, feedback on the event and actions to be taken as a result of the review;

g. Agree the content and the timing of any press release (if appropriate) with the Chief Executive and make sure that any patient, their relatives and any staff involved have a copy before release to the media;

h. Ensure that all other agencies and organisations are informed as necessary e.g. the Board; the Health and Safety Executive; the Scottish Government Health Directorate; Medicines and Healthcare products Regulatory Agency; IRIC; manufacturers and suppliers;

i. Ensure that a full written report – using the standard template available via Datix - is produced that covers all aspects of the review, including outcomes and actions arising;

j. Decide when the adverse event review is completed and the file closed and ensure this is communicated to all involved;

k. Ensure that a comprehensive, accessible file of review documentation is maintained as part of the electronic Datix record which should include (but is not limited to):

   - Adverse event report including the notification process (and documentation of decision to proceed to review)
   - Any staff statements submitted as part of the review
   - All contact/communication with the patient/family/carer
   - Any reports/documented information provided to support review
   - Details of any equipment involved in the adverse event including location, and
   - Final report and action plan (including sign-off sheet)

Note that no part of a patient’s case notes/medical record should be uploaded to Datix as part of a review.
### Appendix F - NHS SCOTLAND Core Risk Assessment Matrices and NCC MERP Index

<table>
<thead>
<tr>
<th>DESCRIPTOR</th>
<th>Negligible</th>
<th>Minor</th>
<th>Moderate</th>
<th>Major</th>
<th>Extreme</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Objectives / Project</strong></td>
<td>Barely noticeable reduction in scope, quality or schedule.</td>
<td>Minor reduction in scope, quality or schedule.</td>
<td>Reduction in scope or quality of project, project objectives or schedule.</td>
<td>Significant project over-run.</td>
<td>Inability to meet project objectives. Reputation of the organisation seriously damaged.</td>
</tr>
<tr>
<td><strong>Injury (physical and psychological) to patient / visitor / staff</strong></td>
<td>Adverse event leading to minor injury not requiring first aid.</td>
<td>Minor injury or illness. First Aid treatment required.</td>
<td>Agency reportable, eg Police (violent / aggressive acts). Significant injury requiring medical treatment and / or counselling.</td>
<td>Major injuries / long term incapacity or disability (loss of limb) requiring medical treatment and / or counselling.</td>
<td>Incident leading to death or major permanent incapacity.</td>
</tr>
<tr>
<td><strong>Complaints / Claims</strong></td>
<td>Locally resolved verbal complaint.</td>
<td>Justified written complaint, peripheral to clinical care.</td>
<td>Below excess claim</td>
<td>Claim above excess level.</td>
<td>Multiple claims or single major claim. Complex justified complaint.</td>
</tr>
<tr>
<td><strong>Service / Business Interruption</strong></td>
<td>Interruption in a service, which does not impact on the delivery of patient care or the ability to continue to provide service.</td>
<td>Short term disruption to service with minor impact on patient care.</td>
<td>Some disruption in service with unacceptable impact on patient care. Temporary loss of ability to provide service.</td>
<td>Sustained loss of service, which has serious impact on delivery of patient care, resulting in major contingency plans being invoked.</td>
<td>Permanent loss of core service or facility. Disruption to facility leading to significant &quot;knock on&quot; effect.</td>
</tr>
<tr>
<td><strong>Staffing and Competence</strong></td>
<td>Short term low staffing level temporarily reduces service quality &lt;1 day. Short term low staffing &gt;1 day, where there is no disruption to patient care.</td>
<td>Ongoing low staffing level reduces service quality. MINOR ERROR due to ineffective training / implementation of training.</td>
<td>Late delivery of key objective / service due to lack of staff. MODERATE ERROR due to ineffective training / implementation of training.</td>
<td>Uncertain delivery of key objective / service due to lack of staff. MAJOR ERROR due to ineffective training / implementation of training.</td>
<td>Non-delivery of key objective / service due to lack of staff. CRITICAL ERROR due to ineffective training / implementation of training. Loss of key staff.</td>
</tr>
<tr>
<td><strong>Financial (including damage / loss / fraud)</strong></td>
<td>Negligible organisational / personal financial loss £1-10k.</td>
<td>Minor organisational / personal financial loss £1-10k. Significant organisational / personal financial loss £10k-£100k.</td>
<td>Major organisational / personal financial loss &gt;£100k.</td>
<td>Severe organisational / personal financial loss &gt;£1m.</td>
<td></td>
</tr>
<tr>
<td><strong>Inspection / Audit</strong></td>
<td>Small number of recommendations, which focus on minor quality improvement issues.</td>
<td>Recommendations made, which can be addressed by low level management action.</td>
<td>Challenging recommendations that can be addressed with appropriate action plan.</td>
<td>Enforcement action.</td>
<td>Prosecution.</td>
</tr>
</tbody>
</table>

Locally resolved verbal complaint. - Multiple claims or single major claim. Complex justified complaint.
<table>
<thead>
<tr>
<th>DESCRIPTOR</th>
<th>Rare</th>
<th>Unlikely</th>
<th>Possible</th>
<th>Likely</th>
<th>Almost Certain</th>
</tr>
</thead>
<tbody>
<tr>
<td>Probability</td>
<td>Can’t believe this event would happen - will only happen in exceptional circumstances.</td>
<td>Not expected to happen, but definite potential exists - unlikely to occur.</td>
<td>May occur occasionally, has happened before on occasions - reasonable chance of occurring.</td>
<td>Strong possibility that this could occur - likely to occur.</td>
<td>This is expected to occur frequently / in most circumstances - more likely to occur than not.</td>
</tr>
</tbody>
</table>

## Risk Matrix

<table>
<thead>
<tr>
<th>Likelihood</th>
<th>Impact</th>
<th>Negligible</th>
<th>Minor</th>
<th>Moderate</th>
<th>Major</th>
<th>Extreme</th>
</tr>
</thead>
<tbody>
<tr>
<td>Almost Certain</td>
<td>Medium</td>
<td>High</td>
<td>High</td>
<td>Very High</td>
<td>Very High</td>
<td></td>
</tr>
<tr>
<td>Likely</td>
<td>Medium</td>
<td>Medium</td>
<td>High</td>
<td>High</td>
<td>Very High</td>
<td></td>
</tr>
<tr>
<td>Possible</td>
<td>Low</td>
<td>Medium</td>
<td>Medium</td>
<td>High</td>
<td>High</td>
<td></td>
</tr>
<tr>
<td>Unlikely</td>
<td>Low</td>
<td>Medium</td>
<td>Medium</td>
<td>Medium</td>
<td>High</td>
<td></td>
</tr>
<tr>
<td>Rare</td>
<td>Low</td>
<td>Low</td>
<td>Low</td>
<td>Medium</td>
<td>Medium</td>
<td></td>
</tr>
</tbody>
</table>
NCC MERP Index for Categorizing Medication Errors

Category B: An error occurred that may have contributed to or resulted in the patient's death.

Category A: Circumstances or events that have the capacity to cause error.

Category H: An error occurred that required intervention necessary to sustain life.

Category G: An error occurred that may have contributed to or resulted in permanent patient harm.

Category F: An error occurred that may have contributed to or resulted in temporary harm to the patient and required initial or prolonged hospitalization.

Category E: An error occurred that may have contributed to or resulted in temporary harm to the patient and required intervention.

Category D: An error occurred that reached the patient but did not cause patient harm.

Category C: An error occurred that reached the patient and required monitoring to confirm that it resulted in no harm to the patient and/or required intervention to preclude harm.

Definitions

Harm: Impairment of the physical, emotional, or psychological function or structure of the body and/or pain resulting therefrom.

Monitoring: To observe or record relevant physiological or psychological signs.

Intervention: May include change in therapy or active medical/surgical treatment.

Intervention Necessary to Sustain Life: Includes cardiovascular and respiratory support (e.g., CPR, defibrillation, intubation, etc.)


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Appendix G - Organisational Risk Management Reporting Mechanisms

- **CGC**
  - Incident Reporting Summary
  - Safety Notice Summary

- **CGCG**
  - Incident Reporting Summary
  - Safety Notice Summary

- **RMG**
  - Corporate Risk Register
  - Departmental Risk Register
  - Risk Management Action Plan Update

- **SRC**
  - Corporate Risk Register Update
  - Risk Management Strategy

- **CoIC**
  - Corporate Risk Register
  - CoIC Incident Reporting Summary

- **H&S**
  - Incident Reporting Summary
  - H&S Action Plan Update
  - H&S Annual Report

- **SGC**
  - H&S Report (Quarterly)
  - H&S Action Plan Update
  - H&S Annual Report

- **CGC**
  - Incident and Risk Management Report (Quarterly)