Learning from adverse events through reporting and review:

A national framework for NHSScotland

September 2013
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“As a universal healthcare system, free at the point of use, with common goals, structures and systems, the NHS is unique in the world, and can do what no other system can. It has the potential to be the safest healthcare system in the world. The best responses to the Francis Report, the best routes to badly needed improvements, will build on the strengths of the NHS, not ignore them or take them for granted. This will take time to bear fruit and require many years of effort, many messages and many deeds. There is no easy fix, but the prize is worth the price.

“Even apparently simple human errors almost always have multiple causes, many beyond the control of the individual who makes the mistake. Therefore, it makes no sense at all to punish a person who makes an error, still less to criminalise it. The same is true of system failures that derive from the same kind of multiple unintentional mistakes. Because human error is normal and, by definition, is unintended, well-intentioned people who make errors or are involved in systems that have failed around them need to be supported, not punished, so they will report their mistakes and the system defects they observe, such that all can learn from them.

“The best way to reduce harm is for the NHS to embrace wholeheartedly a culture of learning.”

Foreword

Our 2020 vision for health and social care and our quality strategy put people at the heart of everything we do, and set out our commitment to deliver high quality healthcare for the people of Scotland.

We know that the NHS in Scotland already provides excellent care but we also know that sometimes things do go wrong.

Improving safety in all healthcare environments is one of our key areas of focus to achieve our 2020 vision. The national approach to learning from adverse events aims to support everyone in NHSScotland effectively manage adverse events, to learn from these events and allow best practice to be actively promoted across Scotland in order that we can continually improve the safety of our healthcare system for everyone.

The importance of this work cannot be understated. For the first time we will have a national definition of an adverse event, and a framework that is applicable to clinical and non-clinical events, across specialities and services. The national approach provides focus and momentum to improve how we learn and make changes in practice following adverse events, so we can deliver the highest quality healthcare services to the people of Scotland.

The principles of the national approach support the Healthcare Principles, as set out by the Patient Rights Act, and our 2020 workforce vision values. The national approach will help to develop a positive safety culture that promotes avoidance, prevention and reduction of risks, where everyone is valued and treated with dignity and respect, and that encourages reporting of adverse events, in order that we can learn from these events and make improvements.

The national approach is built on the views of patients, clinicians, NHS boards and others involved in delivering high quality healthcare. Healthcare Improvement Scotland is leading the development of the national approach; however, individual NHS boards are responsible and accountable for managing their clinical governance processes. I commend this approach to all NHS boards and encourage you to work with Healthcare Improvement Scotland so as to continue to improve the safety of our healthcare system.

Alex Neil, Cabinet Secretary for Health and Wellbeing
Introduction

NHSScotland aims to provide high quality care that is safe, effective and person-centred. However, NHSScotland is a complex system and adverse events can occur that do, or could have, a major effect on the people involved. Each of these events should be regarded as an opportunity to learn and to improve in order to increase the safety of our healthcare system for everyone.

The national approach to learning from adverse events has been produced following consultation and engagement with NHS boards, clinicians, patients and a number of national groups and organisations¹. It has also been informed by policies, procedures and practice in place across NHSScotland and international evidence.

The principles outlined in this document are not new. However, improvement comes from the application of knowledge and this approach draws on existing evidence and good practice to provide a national framework for making long-lasting and successful improvements across NHSScotland.

The national approach is not intended to prescribe a management system, but provides a framework to support NHS boards standardise processes of managing adverse events across all care settings within NHSScotland. A phased approach will be taken, with an initial focus on acute care and managed community services, although the principles are intended to encompass all care settings with an intention to integrate across health and social care in due course.

Although the principles are not new, implementation of this framework, which is applicable to clinical and non-clinical events, across specialties and services, at a national level is new for NHSScotland. Consistent definitions and a standardised approach to adverse event management across NHSScotland will maximise the opportunities for NHS boards to share and actively learn from each other in order to put improvements into practice.

Implementation of the national approach to learning from adverse events is a quality improvement programme, and as such local ownership is essential to test and implement improvements at a local level, recognising that each service, specialty or NHS board has different needs and a greater understanding of how the change will work locally.

As implementation of the national approach is aimed at improving a complex system, Healthcare Improvement Scotland has established a Programme Board co-chaired by Robbie Pearson, Director of Scrutiny and Assurance, and David Farquharson, Medical Director, NHS Lothian, and four working groups to take work forward that would add most value at a national level². These groups are made up of individuals with appropriate skills and expertise from across Scotland.

² http://www.knowledge.scot.nhs.uk/adverse-events/programme-board.aspx
However, the national approach to learning from adverse events does not yet have all the answers. Throughout this document, the initial actions the working groups will deliver are highlighted, and throughout the programme we will develop, test, implement and spread changes working with NHS boards. Healthcare Improvement Scotland is committed to reviewing and updating this framework in 2014 as the programme develops and the rolling programme of adverse event reviews across NHS boards is completed.

**Aims**

The aims of the national approach to learning from adverse events are to:

- learn from adverse events locally and nationally to make service improvements that enhance the safety of our healthcare system for everyone
- support NHS boards to manage adverse events in a timely and effective manner
- establish a standardised approach to adverse event management across NHSScotland, including consistent definitions and the establishment of measures to monitor implementation
- ensure a consistent and co-ordinated approach to the identification, reporting and review of adverse events and allow best practice to be actively promoted across NHSScotland
- present an approach that allows reflective review of events and can be adapted to different settings, and
- provide national resources to develop the skills, culture and systems required to effectively learn from adverse events to improve services across NHSScotland.

The national approach seeks to ensure that no matter where an adverse event occurs in NHSScotland:

- the affected person receives the same high quality response
- any staff involved are treated in a consistent manner
- the event is reviewed in a similar way, and
- learning is shared and implemented across the organisation and NHSScotland to improve the quality of services.

**Scope**

The national approach is intended to cover all care provided throughout NHSScotland including:

- acute care and managed community services
- primary care (GP practices, dental practices, community pharmacies and optometrists)
- NHSScotland employees and independent contractors, and
- clinical and non-clinical events (including information governance, health and safety at work).

The scope will include all events that could have caused, or did result in, harm to people or groups of people.
National Framework – Part 1: Definitions

What is an adverse event?

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

1.2 **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.

1.3 All harm is not avoidable, for example the worsening of a medical condition or the inherent risk of treatment. However, it is often not possible to determine if the harm caused was avoidable until a review is carried out.

1.4 **People** are defined as:
   - service users
   - patients
   - members of staff
   - carers
   - family members, and
   - visitors.

1.5 **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.

Categorisation of adverse events

1.6 The following categories should be used to group adverse events.

- **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).

- **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.
National Framework – Part 2: Overarching principles

2.1 The 2020 Workforce Vision\(^3\) re-affirms NHSScotland’s key values, which are care and compassion; dignity and respect; openness, honesty and responsibility; quality and teamwork. The principles of the national approach to learning from adverse events support and build on these values.

- **Emphasis on learning and promoting best practice across NHSScotland** – the system is focused on learning, locally and nationally, and makes extensive use of improvement methodology to test and implement the necessary changes. Near misses are reviewed regularly to promote learning and system improvements.

- **System approach** – adverse events act as a ‘window’ on the healthcare system allowing a systems analysis. This is important to allow a reflection on the weaknesses of the system, or in the case of near misses, the strengths, and prevent future events.

- **Openness about failures** – errors are identified, reported and managed in a timely manner, and patients and their families are told what went wrong and why. Reviews of events happen frequently and quickly following their occurrence. We expect adverse event reporting to increase as we move to a more open culture.

- **Just culture** – individuals are treated fairly. Organisational culture is based upon the values of trust, openness, equality and diversity which encourages and supports staff to recognise, report and learn from adverse events.

- **Positive safety culture** – avoidance, prevention and mitigation of risks is part of the organisation’s approach and attitude to all its activities and is recognised at all levels of the organisation. Decisions relating to the management of adverse events are risk-based, informed and transparent to allow an appropriate level of scrutiny.

- **Personal, professional and organisational accountability** – everyone is responsible for taking action to prevent adverse events, including speaking up when they see practice that endangers safety, in line with the whistle-blowing policy. Roles and responsibilities will be explicit and clearly accepted with individuals understanding when they may be held accountable for their actions. The principal accountability of all NHS care providers is to patients, their families and carers.

- **Teamwork** – everyone who works for Scotland’s health service is an essential and equal member of the team and needs to be valued, treated well and empowered to work to the best of their ability. Teamwork is recognised as the best defence of system failures and is explicitly encouraged and fostered within a culture of trust, mutual respect and open communication.

\(^3\) Everyone Matters: 2020 Workforce Vision, June 2013 (http://www.scotland.gov.uk/Publications/2013/06/5943)
National Framework Part 3: Managing an adverse event

3.1 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.

3.2 Therefore, the response to each adverse event should be proportionate to its scale, scope and complexity. This section outlines steps to manage adverse events.

Six stages of adverse event management

1. Risk assessment and prevention
2. Identification and immediate actions following an adverse event
3. Initial reporting and notification
4. Analysis and categorisation
5. Review
6. Improvement planning and monitoring

3.3 NHS boards will build their own local procedures to support implementation of this process and may wish to develop a flow chart to guide staff, with clear timescales outlined for each stage of the process.
Flow chart of 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

6. Improvement planning and monitoring
   - Develop action plan
   - Submit review report and action plan via the appropriate governance mechanism
   - Governance mechanism quality assurance and closure of review
   - Implement action plan
   - Review of implementation of actions

Share learning and implement key learning points
Stage 1: Risk assessment and prevention

3.4 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 therefore important that risk assessment and prevention is seen as the first step in effective adverse event management.

3.5 Risk assessments should identify the hazards present in the healthcare system, evaluate the likelihood of potential harm from that hazard occurring, evaluate the potential severity of that harm and evaluate the number of people that might be affected. Mitigating actions should then be put in place that are proportionate to the risk to prevent it occurring.

3.6 As part of an integrated risk management approach, the governance structures for the management of adverse events should also be aligned with the organisation’s risk management strategy and governance processes, including complaints and claims.

Stage 2: Identification and immediate actions following an adverse event

3.7 In all instances, the first priority is to ensure the needs of individuals affected by the adverse event are attended to, including any urgent clinical care which may reduce the harmful impact. A safe environment should be re-established, all equipment or medication retained and isolated, and relevant documentation copied and secured to preserve evidence and facilitate review and learning.

3.8 The first consideration following an adverse event is that the patient must be cared for, their, and other patients’, health and welfare secured and further risk mitigated. The patient’s family or carers must be similarly cared for and involved where a patient has died or suffered serious harm. Consideration must be given to their needs first. That means prioritising further treatment they may require, at all times showing compassion and understanding even if simply making regular contact to keep them informed of the progress of reviews or improvement plan implementation.

3.9 The Institute for Healthcare Improvement (IHI) within their publication the 
Respectful Management of Serious Clinical Adverse Events (Second Edition)⁴ suggests that an adverse event does not necessarily break down the trust between patient and staff, however the way in which the organisation responds after such events often does. The document provides a number of ways in which organisations should never lose sight of the patient and family when responding to an event.

3.10 The organisation should give early consideration to the provision of information and support to patients, relatives and carers and staff involved in the adverse event, including information on support systems which are available to patients, relatives,

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visitors and contractors. The organisation should follow guidance provided in the local Being Open policy. The needs and involvement of staff in the adverse event should also be considered.

Summary of immediate actions

- Ensure a safe environment is re-established as soon as possible.
- Any urgent clinical care that may reduce the harmful impact of the event must be given immediately.
- The needs of patients and their families and carers should be met and support provided.
- Colleagues should be informed and support secured from other professionals.
- Any faulty medicine or equipment should be removed and labeled so as to prevent future use.
- A timely and objective entry should be made in the patient’s clinical records.
- Any actions to reduce the risk of recurrence should be taken immediately.

Working group action point

Action 1
The leadership and culture working group will support NHS boards in the application of the ‘Being Open’ principles which includes guidance for how and when to disclose adverse events, and how to involve those affected in the review process.

Stage 3: Initial reporting and notification

3.11 When an adverse event (including near misses) occurs, the NHS board electronic adverse event reporting system must be used. The NHS board should ensure an organisation-wide approach is in place for training staff in adverse event reporting. The types of information to be reported in the first instance includes:

- the location of where the adverse event occurred (Where)
- the date and time of the adverse event (When)
- personal details relating to the person/people involved in the adverse event (victim/injured party)
- description of the adverse event (What, Why and How)
- the outcome of the person/people involved (injury/result)
- the immediate treatment given to the person/people involved
- any immediate action taken
- any remedial action taken to minimise risk of recurrence, and
- others who were involved in observing or reporting the adverse event.

5 Being Open: Communicating patient safety incidents with patients, their families and carers. National Patient Safety Agency; 2009 (http://www.nrls.npsa.nhs.uk/alerts/?entryid45=65077)
3.12 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.

3.13 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. The electronic adverse event reporting system should be automatically setup to notify relevant senior managers and clinical staff that an adverse event has been reported.

3.14 Local policies will define the notification and escalation procedures that should be followed following an adverse event. NHS boards may wish to develop a flow chart to outline the notification and communication process distinguishing the out-of-hours and in working hours arrangements.

**Reporting to external agencies**

3.15 Specific events must be reported to external regulators at a national or UK level. This includes:

- reporting to the Health and Safety Executive as set out in the Reporting of Injuries, Diseases and Dangerous Occurrences Regulations 1995 (RIDDOR)\(^6\)
- reporting all adverse events involving health, social care, estates and facilities equipment to the Incident Reporting and Investigation Centre (IRIC) within Health Facilities Scotland as set out in CEL 43 (2009)\(^7\)
- reporting of serious adverse events relating to blood transfusion to the Medicines and Healthcare Products Regulatory Agency (MHRA) as required by the UK Blood Safety and Quality Regulations 2005 and the EU Blood Safety Directive\(^8\)
- reporting suicides of individuals in contact with mental health services to Healthcare Improvement Scotland\(^9\)
- reporting of deaths associated with medical or dental care to the Procurator Fiscal\(^10\)
- reporting to the UK wide national audits and enquiries\(^11\)
- reporting information governance incidents to the Information Commissioners Office\(^12\)
- reporting of Adverse Drug Reactions via the Yellow Card Scheme to the MHRA\(^13\). This system has been expanded since July 2012 to include medication errors due to a change in the European Transposition of Pharmacovigilance legislation, and

\(^{6}\) [http://www.hse.gov.uk/riddor/what-must-i-report.htm](http://www.hse.gov.uk/riddor/what-must-i-report.htm)
\(^{8}\) [http://www.mhra.gov.uk/Safetyinformation/Reportingsafetyproblems/Blood/index.htm#1](http://www.mhra.gov.uk/Safetyinformation/Reportingsafetyproblems/Blood/index.htm#1)
\(^{13}\) [https://yellowcard.mhra.gov.uk/the-yellow-card-scheme/](https://yellowcard.mhra.gov.uk/the-yellow-card-scheme/)
• reporting of Ionising Radiation adverse events to the Warranted Inspector for IR(ME)R\textsuperscript{14}.

Summary of reporting actions

• All adverse events should be recorded on local adverse event reporting systems as soon as possible after the event has occurred.

• The adverse event should be reported to any external agencies as appropriate.

Working group action point

Action 2

The infrastructure working group will build upon existing good practice in Scotland to develop a consistent approach and set of tools that encourages all groups of staff to report adverse events.

Stage 4: Analysis and categorisation

3.16 Following initial reporting of an adverse event or near miss, the relevant manager will assess the adverse event reporting form to consider whether a more in-depth review of the event is required.

3.17 It is important the level of review is proportionate to the severity of the adverse event. Adverse event reviews aim to establish the contributing factors of an adverse event, with a view to reducing the likelihood and/or impact of similar future events.

3.18 The NHS board will have clear criteria and processes that allow transparent decision-making to decide on the level of review required. The decision to proceed, or not, to an adverse event review should be clearly documented. The decision as to whether a full review should take place will depend on the characteristics of the event, the patient or the clinical service, the outcome and the potential for learning. If an initial review of a near miss suggests that there could be defects or failures in systems and processes then this could trigger a more extensive review.

3.19 Information, communications, outcomes and associated actions should be centrally recorded and stored, ideally within the electronic adverse event reporting system, so that an audit trail is evident.

3.20 Every event should be reviewed, but the level of review will be determined from the category of the event and the potential for learning (see below). NHS boards should ensure local mechanisms are in place to quality assure the categorisation of events and appropriate actions should be taken should the original categorisation be inappropriate.

\textsuperscript{14} http://www.legislation.gov.uk/uksi/2000/1059/contents/made
Categorisation of adverse events

3.21 Adverse events should be categorised to support decision-making processes to determine the level of review required, although as described above, the level of review should not only be mandated by the categorisation of the event as other factors also impact this decision.

3.22 The following categories should be used to group adverse events.

- **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).

- **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.

3.23 This categorisation is based on impact of harm and could support the measurement of reported events that resulted in harm versus those which did not result in harm. It is acknowledged that we should be aiming to take a preventative rather than reactive approach and we should not wait for harm to occur before making improvements to the system. Therefore, as NHSScotland exhibits more qualities and behaviours of a high reliability organisation, we will increasingly focus our efforts on the analysis and review of events that did not result in harm, as these provide the most important learning and improvement opportunities.

3.24 This categorisation requires some initial assessment of the event, which can be supported by a decision tool, such as the NHSScotland risk matrices or the NCC MERP index of harm (see appendices 3 and 4).

Levels of review

3.25 The basic process of adverse event review and analysis should be essentially the same. However, the review team can choose whether to quickly run through the main issues in a short meeting or to carry out a full, detailed review over several weeks making full use of all associated techniques to comprehensively examine the chronology, care delivery problems and contributory factors.

3.26 The category of the event will largely determine the level of review required, i.e. category I events that result in permanent harm are likely to require a more extensive review than category II events that result in temporary harm. Trend and thematic
analysis of events will identify if more detailed review of category II or III events are required.

3.27 However, consideration of the potential for learning from the event should also determine the level of review required. This aims to ensure that responses are not overly focused on the impact or outcome of that particular event but are used to gain an insight on underlying weaknesses of the system. The following decision-making prompts may help to determine the potential for learning:

- Is the outcome a known complication of the disease/treatment/process?
- Has there been any breach or deviation in policy or procedure?
- Are there unknowns surrounding the event?
- Is there learning to be gained/would you do anything differently next time?
- Is there concern regarding the event from the patient or family, or from management?

3.28 The table below provides a guide to promote a consistent national response. However, NHS boards are ultimately responsible for determining through their own governance and decision-making arrangements, the action that should be taken following an event occurring. NHS boards should clearly document the decisions for the level of review undertaken.

<table>
<thead>
<tr>
<th>Adverse event category</th>
<th>Level of review</th>
<th>Review team</th>
<th>Improvement plan</th>
<th>Guidance timescale</th>
</tr>
</thead>
<tbody>
<tr>
<td>Category I</td>
<td>Level 1</td>
<td>Full review team – commissioning manager to agree review lead and Terms of Reference</td>
<td>Improvement plan to be developed and put through governance structures</td>
<td>Commence local review within 10 working days and complete within 3 months</td>
</tr>
<tr>
<td></td>
<td>Comprehensive adverse event analysis and review</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Category II</td>
<td>Level 2</td>
<td>Manager in charge of the department or area in consultation with staff</td>
<td>Improvement/ action plan to be developed and reported through service management structures</td>
<td>Commence local review within 10 working days and complete within 4-6 weeks</td>
</tr>
<tr>
<td></td>
<td>Local management review in consultation with Associate Medical Director/Nurse Director or General Manager</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Category III</td>
<td>Level 3</td>
<td>Managers/staff locally</td>
<td>Not applicable unless trends require a review then a plan should be developed to address the outcomes</td>
<td>Adverse event approved and closed within 10 working days of being reported</td>
</tr>
<tr>
<td></td>
<td>Further inquiries/questions</td>
<td>If further review required then local management review process</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Trends should be considered for further review</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Summary of categorisation actions

- A discussion with appropriate individuals should take place about the categorisation of the adverse event and what level of review is required.
- A senior member of staff should be designated as responsible for reporting and follow-up of category I adverse events within given timescales. They should also be responsible for ensuring relevant internal staff are informed of the event.
- Decision-making should be recorded.

Stage 5: Review

3.29 The purpose of the review is to determine what happened, how it happened, why it happened, and whether there are learning points for service or wider organisation. It should follow the principles of a just culture and take a systems approach. If the review team considers that there are any issues about the performance of an individual member of staff, this should be referred to the appropriate line manager and should not be part of the review.

3.30 A lead director or senior manager should be assigned to ensure a thorough and appropriate review is undertaken. The following should be established.

- Terms of reference for the review should be defined.
- Review team should be identified with a lead reviewer appointed and roles within the team clearly defined (the review team should be sufficiently removed from the event, and have no conflict of interest, to be able to provide an objective view).
- The lead responsibility for establishing and meeting the communication requirements of patients, or their representatives, should be clarified with the lead reviewer.
- Staff and managers involved should be informed of the review and invited to contribute to the review process. Staff should be kept informed of progress throughout the review.
- The support needs of staff involved in the adverse event must be considered.
- Electronic information management systems should be established to ensure a comprehensive, accessible file of review documentation is maintained which should include (but 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/documentated 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).
3.31 Adverse event reviews should use defined methodologies to ensure a structured and consistent approach to identifying the contributory factors, details of the care provided and if any lessons about that care could inform service improvement or reduce recurrence. A variety of tools such as cause and effect charts, fishbone diagrams and the ‘Five Whys’ Model can be used. At least one member of the review team should be trained in review methodologies and their application. Where this is not possible, support from central clinical governance and risk management teams should be sought.

3.32 A report presenting the findings, conclusions and recommendations of the review should be produced. It is advised that anonymised reports are produced so that no staff members or patients can be identified from the report. The NHS board should ensure engagement with staff involved in the adverse event as the report is finalised.

3.33 NHS boards will have local processes for the review of reports and recommendations either through clinical governance structures and/or the management team structures. It is expected that the lead director or manager that commissioned the review will be responsible for approving the report. The review team and all staff involved in the adverse event should receive a copy of the final report. The NHS board should also share this with the patient, family and carer.

**Summary of review actions**

- Adverse events should be reviewed using best practice investigative techniques and methodologies. Methodologies should be briefly, but clearly set out in the review report.

- Staff leading adverse event reviews should have up to date training and be competent in investigative methodologies, techniques and analysis, including human factors, and report writing.

- The review team must be multidisciplinary and should include a professional with experience relevant to the event being reviewed.

- The review team should be sufficiently removed from the event, have no conflict of interest (real or perceived) to be able to provide an objective view.

- The roles and responsibilities of each member of the review team must be clear, including identifying a lead reviewer, and should be documented.

- Individuals involved in the adverse event (for example patients, family, carers, staff) must be involved and informed throughout the review process.

- The scale, scope and timescale for the review must be agreed at the outset of the review process and documented in the terms of reference.

- Reviews should seek to understand what happened, why it happened and recommend what systems or processes should be put in place to prevent future occurrence.

- Reviews should be quality assured to ensure they are robust and demonstrate the use of investigative methodologies.
• Electronic information management systems should be established to ensure a comprehensive, accessible file of review documentation is maintained.

Working group action points

Action 3
The infrastructure working group will develop standardised processes of producing adverse event review reports which minimises the need for redaction and allows information to be freely shared within, across and outwith NHS boards.

Action 4
The leadership and culture working group will identify areas of good practice and relevant leadership training, education and guidance materials with a focus on adverse event management, and promote these across NHSScotland.

Action 5
The learning and improvement working group will build on capability and capacity across NHSScotland to perform adverse event reviews. They will do this by building on the model being developed by the Suicide Reporting System to pilot a wider adverse events reviewer network that can be used to review cases outside their host boards.

Stage 6: Improvement planning and monitoring

3.34 Level 1 and level 2 adverse event reviews must have an improvement plan developed in response to the findings and recommendations. The NHS board should clearly define who is responsible for developing the plan and who should be involved in the process. All actions should identify owners and timescales for completion. Final plans should be shared with those who reported and were involved in the original adverse event.

3.35 Improvement plans should be owned locally and reviewed and updated regularly. If a recommendation is not being progressed, there should be a reason why recorded. NHS board local policies will outline which groups or committees have responsibility for monitoring implementation of improvement plans, ensuring completion within the agreed timescales and documenting rationale for exceptions.

3.36 The NHS board should ensure arrangements are in place to share learning and improvements from adverse event reviews across services and the wider organisation. Reports relating to thematic learning should be collated over specific timeframes to assist and inform wider service and organisation improvement programmes.
Summary of improvement planning and monitoring actions

- An agreed improvement plan should set out how each recommendation from the review will be monitored, implemented, measured and shared. The plan should include responsible owners, timescales for delivery and review dates.
- The outcome of the review and improvement plan should be shared with those who reported and were involved in the adverse event.
- NHS boards should monitor and review all adverse event reviews and seek assurances about learning and the embedding of improvement plans through regular thematic reviews.
- Learning, improvements and best practice should be actively promoted and implemented locally and nationally.

Working group action points

**Action 6**
The learning and improvement working group will support NHS boards to improve the identification of local learning through adverse event reviews by scoping the requirement for, and developing, guidance and tools.

**Action 7**
The learning and improvement working group will support NHS boards to translate learning into service improvement by reviewing current challenges to inform guidance.

**Action 8**
The learning and improvement working group will scope and develop mechanisms for sharing learning locally and nationally.

**Action 9**
The infrastructure working group will explore the technical requirements of a national system to collate and share learning as well as integrate data from adverse events, complaints and claims.
National Framework Part 4: Roles and responsibilities

4.1 NHS boards are responsible for ensuring governance systems are in place with clear lines of accountability and clearly defined roles and responsibilities to support the effective management of adverse events.

4.2 Organisations need to ensure that effective arrangements are in place for reporting, recording, management, review and monitoring of all adverse events. They should also ensure robust systems are in place to learn from adverse event reports, review actions and identify themes or trends in order to make improvements to address risks. This will require regular, reliable and ongoing monitoring and review of adverse event reports.

4.3 The NHS board’s adverse event management arrangements should set out the roles and responsibilities of the various levels of management and committees. The roles and responsibilities should provide detail on:

- **Board**
  - assurance on risk and adverse event management, and
  - any delegation of responsibility to governance committees.

- **Chief Executive**
  - policies and procedures for adverse event management
  - systems for reporting and learning, and
  - any delegation of roles and responsibilities to executive team members.

- **Executive team**
  - any delegated responsibilities from chief executive
  - any role in determining the level of review of adverse events
  - ensuring compliance with adverse event policies and procedures
  - engagement with patient and families
  - staff support and training, and
  - ensuring actions are implemented.

- **Governance committees**
  - any delegated responsibility from the Board for assurance on risk and adverse event management.

- **Directorate management teams**
  - ensuring compliance with adverse event policies and procedures
  - reviewing and managing adverse events
  - progression of action plans and follow-up
  - dissemination of learning
  - engagement with patient and families, and
  - staff support.
- Managers
  - engagement with patient and families
  - ensuring staff awareness and compliance with adverse event policies and procedures
  - staff support, and
  - managing adverse events including review, progress of actions, dissemination and implementation of learning.

- Staff
  - engagement with patient and families
  - attending training
  - reporting adverse events
  - following policy and procedures including adhering to timescales
  - participating in reviews, and
  - implementing recommended actions and learning points.

4.4 The Board will wish to seek assurance that the systems in place are supporting the effective management of adverse events. This can be supported by monitoring and compliance of process measures for implementation of the national approach, complemented by locally developed measures.

### Working group action points

**Action 10**
The leadership and culture working group will review the role of the non-executive director in adverse event management. They will scope the potential outcomes a non-executive director’s network would have in supporting their role in building a reporting and learning culture and assuring the process.

**Action 11**
The measurement working group will develop and test mechanisms that can be used at local and national level to provide assurance that NHS boards are managing adverse events effectively, for example indicators or criteria for future reviews or self-evaluation.

**Action 12**
The measurement working group will develop and embed key national performance/quality indicators to support measurement of the implementation of the national approach.
Reviewing and updating the framework

Healthcare Improvement Scotland is committed to reviewing and updating this framework in 2014 as the programme develops and the rolling programme of adverse event reviews across NHS boards is completed.

The revised version will contain further details building on the following actions being taken forward by the working groups:

**Action 1**
The leadership and culture working group will support NHS boards in the application of the ‘Being Open’ principles which includes guidance for how and when to disclose adverse events, and how to involve those affected in the review process.

**Action 2**
The infrastructure working group will build upon existing good practice in Scotland to develop a consistent approach and set of tools that encourages all groups of staff to report adverse events.

**Action 3**
The infrastructure working group will develop standardised processes of producing adverse event review reports which minimises the need for redaction and allows information to be freely shared within, across and outwith NHS boards.

**Action 4**
The leadership and culture working group will identify areas of good practice and relevant leadership training, education and guidance materials with a focus on adverse event management, and promote these across NHSScotland.

**Action 5**
The learning and improvement working group will build on capability and capacity across NHSScotland to perform adverse event reviews. They will do this by building on the model being developed by the Suicide Reporting System to pilot a wider adverse events reviewer network that can be used to review cases outside their host boards.

**Action 6**
The learning and improvement working group will support NHS boards to improve the identification of local learning through adverse event reviews by scoping the requirement for, and developing, guidance and tools.

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**Action 12**
The measurement working group will develop and embed key national performance/quality indicators to support measurement of the implementation of the national approach.
Learning from adverse events: A national framework

Actions for NHS boards

All NHS boards have taken steps to review and consider their adverse event management processes following publication of our report ‘The management of significant adverse events in NHS Ayrshire & Arran’\(^{15}\). This improvement activity is continuing, supported by the rolling programme of NHS board adverse event reviews.

Although Healthcare Improvement Scotland has led in the development of the national approach to learning from adverse events and is driving improvement through the activities of the four working groups, individual NHS boards are responsible and accountable for effectively managing adverse events.

We expect that all NHS boards will build upon ongoing development and improvement work and review their policies and processes to reflect the definitions and principles outlined in this national approach. We also expect that all NHS boards will continue to work with Healthcare Improvement Scotland and contribute to the continuous development of a consistent national approach to learning from adverse events, which supports services improvements and enhances the safety of our healthcare system for everyone.

NHS board action points

**Action 1**
NHS boards should continue to implement recommendations 18-23 from ‘The management of significant adverse events in NHS Ayrshire and Arran’ report and the associated recommendations following their board adverse event review.

**Action 2**
NHS boards should review their policies and processes to reflect the definitions and principles outlined in this national approach by April 2014.

**Action 3**
NHS boards should continue to contribute to continuous development of the framework by working with Healthcare Improvement Scotland, colleagues across NHSSScotand and beyond.

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Concluding comments

We know that the NHS in Scotland already provides excellent care, and good practice is occurring across Scotland relating to the management of adverse events. However, we also know that sometimes things go wrong. There are a number of challenges faced when implementing a consistent national approach to learning from adverse events that improves the safety of our healthcare system for everyone that interacts with it and places the person at the centre of all decisions.

These challenges include the following.

- How and when to disclose information to patients, families and carers, and how to involve them in the review process.
- How to encourage staff to openly report adverse events without fear of personal consequence (although this does not mean that individuals should never be held to account for their actions).
- How we ensure adverse event reviews are proportionate and make best use of our resources.
- How to translate learning into service improvements and actively promote this at a national level.
- How we collate, analyse and learn from adverse events at a national level, and how we look to integrate other data, such as from complaints and claims, in order to inform improvements.
- How we truly take a systems approach to analyse and learn from adverse events, and move towards a preventative rather than reactive approach.
- How we will know if the national approach to learning from adverse events results in changes that are improvements, as there is often a delay between making changes and seeing an effect.

The action points throughout this document aim to support improvement work to try to address these challenges, and work is already ongoing locally within NHS boards. However, this whole approach is underpinned by a just and positive safety culture. Much work has taken place in recent years to foster this culture and the national approach to learning from adverse events will further contribute, although it is recognised that transforming the culture is a long-term goal.

However, the impact of this work cannot be understated. The national approach provides for the first time a national definition of an adverse event, and a framework that is applicable to clinical and non-clinical events, across specialties and services. The national approach provides focus and momentum to improve how we learn and make changes in practice following adverse events, so we can deliver the highest quality healthcare services to the people of Scotland.
Appendix 1: Policy context

1. NHSScotland’s Healthcare Quality Strategy\(^{16}\) sets out the aims of delivering the highest quality healthcare services to the people of Scotland and for NHSScotland to be recognised as world-leading in the quality of healthcare it provides. The Quality Strategy articulates three ambitions based on what people have said they want from their NHS.

- **Person-centred**: Mutually beneficial partnerships between patients, their families and those delivering healthcare services. Partnerships which respect individual needs and values and which demonstrate compassion, continuity, clear communication and shared decision-making.

- **Safe**: No avoidable injury or harm from the healthcare they receive, and that they are cared for in an appropriate, clean and safe environment at all times.

- **Effective**: The most appropriate treatments, interventions, support and services will be provided at the right time to everyone who will benefit, with no wasteful or harmful variation.

2. The 2020 Vision for health and social care\(^{17}\) provides the strategic narrative for taking forward the implementation of the Quality Strategy and the required actions to achieve sustainable quality in the delivery of healthcare services across Scotland:

   “Our vision is that by 2020 everyone is able to live longer and healthier lives at home, or in a homely setting. We will have a healthcare system where we have integrated health and social care, a focus on prevention, anticipation and supported self-management. When hospital treatment is required, and cannot be provided in a community setting, care will be provided to the highest standards of quality and safety, with the person at the centre of all decisions. There will be a focus on ensuring that people get back into their home or community environment as soon as appropriate, with minimal risk of re-admission.”

3. The route map to the 2020 Vision\(^{18}\) describes 12 priority areas for action for pursuing our 2020 Vision for high quality sustainable health and social care services in Scotland in three domains:

   - quality of care
   - health of the population, and
   - value and financial sustainability.

4. Safe care is a priority area for improvement within the quality of care domain, with a key deliverable for 2013/2014 to further increase safety in Scottish hospitals. The national approach to learning from adverse events will contribute to further improving the safety of care.

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5. The Patient Rights (Scotland) Act 2011 and the Person-Centred Health and Care Collaborative build on the person-centred quality ambition to improve patients’ experience of using NHS services in Scotland and support them to become more involved and engaged in their healthcare.

6. The Patient Rights (Scotland) Act 2011, together with supporting legislation, introduces the right to give feedback, make comments, raise concerns and to make complaints about NHS services. It also places a responsibility on the NHS to encourage, monitor, take action and share learning from the views they receive. The Act introduces the Healthcare Principles to be upheld by NHS bodies (see Appendix 2).

7. All NHS boards have local policies and processes in place to handle and learn from feedback, comments, concerns and complaints which have been advised by national guidance19.

8. NHSScotland benefits enormously from having a dedicated, committed and highly skilled workforce, focusing on offering quality care for patients. The 2020 Workforce Vision20 has been developed in recognition of the vital role of the workforce:

   “We will respond to the needs of the people we care for, adapt to new, improved ways of working, and work seamlessly with colleagues and partner organisations. We will continue to modernise the way we work and embrace technology. We will do this in a way that lives up to our core values.

   “Together, we will create a great place to work and deliver a high quality healthcare service which is amongst the best in the world.”

9. The 2020 Workforce Vision sets out how the vision will be achieved in order to improve patient care and overall performance. However, sometimes things will go wrong and a healthcare professional may find their practice called into question. The over-riding concern is patient safety but practitioners must also be treated fairly and sensitively. Each NHS board have policies and procedures in place to handle performance concerns and concerns can be reported to the regulators of health practitioners.

10. The national approach to learning from adverse events supports the healthcare principles and is complementary to the comments, concerns and complaints and performance management processes in place at a local and national level. All are focused on developing a positive safety culture that learns from experience and implements service improvements in order to continually improve the quality of care.

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19 Guidance on Handling and Learning from Feedback, Comments, Concerns and Complaints about NHS healthcare Services, March 2012 (http://www.sehd.scot.nhs.uk/mels/CEL2012_08.pdf)
Governance principles

11. All NHS boards are accountable for effective governance and learning following an adverse event. The following principles build on the governance for quality healthcare in Scotland agreement\(^{21}\). NHS boards should:

- work in an open and transparent manner.
- ensure an NHS board director is formally designated to lead on and be responsible for patient safety and the management of adverse events, including responsibility for appropriate closure of adverse event reviews.
- have a relevant mechanism and governance in place to consider and monitor adverse event reviews. Such mechanisms should be responsible for ensuring that regular thematic reviews are undertaken to extract learning and support the development of organisational memory and continuous improvement with regard to safety.
- have systems for their senior leadership team to receive regular briefings on the detail of significant issues, trends and other analysis on adverse events. This includes consideration of adverse events and associated information during Board meetings.
- ensure their senior leadership team receive summary information, including the number of adverse event reviews open beyond recommended timescales, to help gain assurance that appropriate action has been, or is being, taken to safeguard patients and staff in a timely manner, and to understand the impact on individual patients and on staff.
- ensure that the contribution of patients and frontline staff remains central to improving standards of care, including involving patients, or their representatives, and staff in all reviews.
- monitor the implementation of action plans including the effectiveness of any changes implemented following a review and that these are embedded across all relevant areas.
- support the need for effective learning and improvement to drive quality, including proactively sharing emerging risks and learning with peers in an open, transparent and timely way.
- have robust processes to ensure that learning from adverse events is shared and improvements embedded locally and at national level as appropriate.
- ensure that all adverse events are disclosed to those affected in a timely manner, appropriately reported and reviewed, with the findings being shared with those involved.
- manage any staff related issues identified during the course of an adverse event review within the principles of an open and just culture.
- understand and apply reporting and liaison requirements with regard to agencies such as the Health and Safety Executive, Health Facilities Scotland, MHRA, Healthcare Improvement Scotland and Procurator Fiscal.
- apply relevant information governance principles to all information representing potentially sensitive data.

Appendix 2: Healthcare principles

Healthcare principles to be upheld by relevant NHS bodies and relevant service providers (as introduced by the Patient Rights (Scotland) Act 2011)\(^\text{22}\).

**Patient focus**

1. Anything done in relation to the patient takes into account the patient’s needs.
2. Patients are treated with dignity and respect.
3. Privacy and confidentiality are respected.
4. Healthcare is provided in a caring and compassionate manner.
5. Support necessary to receive or access health care is available.
6. The patient’s abilities, characteristics and circumstances are considered.

**Quality care and treatment**

7. Regard is had to the importance of providing the optimum benefit to the patient’s health and wellbeing.
8. The range of options available in the patient's case is considered.
9. Healthcare is based on current recognised clinical guidance.
10. No avoidable harm or injury is to be caused to the patient by the healthcare provided.
11. Patients are cared for in an appropriate environment which is as clean and safe as is reasonably possible.

**Patient participation**

12. Patients participate as fully as possible in decisions relating to the patient’s health and wellbeing.
13. Patients are provided with such information and support as is necessary to enable them to participate in accordance with paragraph 12 and in relation to any related processes (general or specific).
14. Patients are encouraged to treat any person involved in the delivery of healthcare with dignity and respect.

**Communication**

15. Communication about a patient’s health and wellbeing is clear, accessible and understood.

Complaints

16. Communication about general services and processes and decisions is clear, accessible and understood.

17. Issues of concern are dealt with reasonably, promptly and in accordance with proper procedures.

Other

18. Waste of resources in the provision of healthcare is avoided.
## Appendix 3: NHSScotland risk assessment matrices (produced by NHS QIS)

### Table 1 - Impact/Consequence Definitions

<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, e.g. Police (violent and aggressive acts).</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. Justified complaint involving lack of appropriate care.</td>
<td>Claim above excess level. Multiple justified complaints.</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).</td>
<td>Ongoing low staffing level reduces service quality.</td>
<td>Late delivery of key objective / service due to lack of staff.</td>
<td>Uncertain delivery of key objective/service due to lack of staff.</td>
<td>Non-delivery of key objective/service due to lack of staff. Loss of key staff. Critical error due to ineffective training/implementation of training.</td>
</tr>
<tr>
<td><strong>Financial (including damage / loss / fraud)</strong></td>
<td>Negligible organisational/personal financial loss. (£&lt;1k). (NB. Please adjust for context)</td>
<td>Minor organisational/personal financial loss (£1-10k).</td>
<td>Significant organisational/personal financial loss (£10-100k).</td>
<td>Major organisational/personal financial loss (£100k-1m).</td>
<td>Severe organisational/personal financial loss (£&gt;1m)</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 of management action.</td>
<td>Challenging recommendations that can be addressed with appropriate action plan.</td>
<td>Enforcement action. Low rating. Critical report.</td>
<td>Prosecution. Zero rating. Severely critical report.</td>
</tr>
<tr>
<td><strong>Adverse Publicity / Reputation</strong></td>
<td>Rumours, no media coverage. Little effect on staff morale.</td>
<td>Local media coverage – short term. Some public embarrassment. Minor effect on staff morale/public attitudes.</td>
<td>Local media – long-term adverse publicity. Significant effect on staff morale and public perception of the organisation.</td>
<td>National media/ adverse publicity, less than 3 days. Public confidence in the organisation undermined. Use of services affected.</td>
<td>National/international media/adverse publicity, more than 3 days. MSP/MIP concern (Questions in Parliament). Court Enforcement. Public Inquiry/FAI.</td>
</tr>
</tbody>
</table>
Table 2 – Likelihood Definitions

<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>

Table 3 - Risk Matrix

<table>
<thead>
<tr>
<th>Likelihood</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>V High</td>
<td>V High</td>
</tr>
<tr>
<td>Likely</td>
<td>Medium</td>
<td>Medium</td>
<td>High</td>
<td>High</td>
<td>V High</td>
</tr>
<tr>
<td>Possible</td>
<td>Low</td>
<td>Medium</td>
<td>Medium</td>
<td>High</td>
<td>High</td>
</tr>
<tr>
<td>Unlikely</td>
<td>Low</td>
<td>Medium</td>
<td>Medium</td>
<td>Medium</td>
<td>High</td>
</tr>
<tr>
<td>Rare</td>
<td>Low</td>
<td>Low</td>
<td>Low</td>
<td>Medium</td>
<td>Medium</td>
</tr>
</tbody>
</table>
Appendix 4: NCC MERP Index for Categorizing Medication Errors

NCC MERP Index for Categorizing Medication Errors

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

Category J: 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 and required monitoring to confirm 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 5: Resources


Canadian Incident Analysis Framework. Canadian Patient Safety Institute; 2012. (http://www.patientsafetyinstitute.ca/English/toolsResources/IncidentAnalysis/Pages/default.aspx)


