Learning from adverse events through reporting and review:

A national framework for Scotland

April 2015 (2nd Edition)
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“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 to embrace wholeheartedly a culture of learning.”

Foreword

Our care system in Scotland is amongst the best in the world, but sometimes things will go wrong. Care will never be risk-free, but we can minimise these risks in order to provide high quality care for the people of Scotland.

Learning from adverse events is crucial to continually improve person-centred, safe and effective delivery of care. In turn, this contributes to achieving Scotland’s 2020 vision of sustainable, world-leading and high quality health and care services.

We published the first version of this framework in September 2013 following extensive consultation and engagement across Scotland. It aimed to support NHS boards to standardise processes for managing and learning from adverse events. We acknowledged that the framework did not have all the answers, and committed to review and update the framework as the programme developed.

Over the past two years, we have developed a number of tools to support implementation of the framework, and these are available on our Community of Practice website\(^1\). Best practice continually evolves and we will add supporting tools as and when they are developed.

The principles and approach outlined in the original framework remain the same in this refreshed version. However, we have taken the opportunity to refine and clarify areas based on feedback from key stakeholders. We always intended that the framework could be applied to any care setting, but we have ensured the language used supports this aim, although we recognise we need to engage fully with social care providers on making this a reality.

Supporting cultural change is at the heart of this framework. We all want to achieve a positive safety culture that is open, just and informed, in which reporting and learning from error is the norm. Achieving cultural change is challenging and will take time, but this approach and the tools developed will support the behavioural changes we want to see across Scotland.

David Farquharson

Robbie Pearson

Co-chairs of the Adverse Events Programme Board

\(^1\) [www.knowledge.scot.nhs.uk/adverse-events.aspx](http://www.knowledge.scot.nhs.uk/adverse-events.aspx)
Introduction

Health and social care services in Scotland aim to provide high quality care that is safe, effective and person-centred. This is a complex system and adverse events 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 care system for everyone.

This framework is intended to provide an overarching approach developed from best practice to support care providers effectively manage adverse events.

Over the past two years we have developed a number of tools to support consistent implementation of the framework, such as
- guidance on implementing the Being Open principles
- data redaction and standardised adverse event review reports guidance, and
- learning summary templates.

These are available on our Community of Practice website. Best practice continually evolves and we will add supporting tools as and when they are developed.

Aims

The aims of the national approach to learning from adverse events are to:
- learn locally and nationally to make service improvements that enhance the safety of our care system for everyone
- support adverse event management in a timely and effective manner
- support a consistent national approach to the identification, reporting and review of adverse events, and allow best practice to be actively promoted across Scotland
- present an approach that allows reflective review of events which 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 Scotland.

The national approach seeks to ensure that no matter where an adverse event occurs in Scotland:
- 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 more widely to improve the quality of services.

2 www.knowledge.scot.nhs.uk/adverse-events.aspx
**Scope**

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

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

The scope includes all events that could have contributed or did result in, harm to people or groups of people. This includes harm to patients and service users, as well as harm to staff.

A phased approach has been taken towards supporting implementation, with an initial focus to date on acute care, although the principles encompass all care settings. Our focus now will be in considering how we can support implementation within primary care and community services and how we can support working towards integration of arrangements across health and social care.

**Overarching principles**

The principles of the national approach to learning from adverse events support and build on the key values of care and compassion; dignity and respect; openness, honesty and responsibility; quality; and teamwork.

- **Emphasis on learning and promoting best practice across Scotland** – 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 care 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, service users 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 organisation’s 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 care providers is to patients, service users, their families and carers.

• **Teamwork** – everyone who works for Scotland’s care system 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.

Supporting cultural change is at the heart of this framework. We all want to achieve a positive safety culture that is open, just and informed, in which reporting and learning from error is the norm. Achieving cultural change is challenging and will take time, but the approach outlined in this framework and the tools developed will support the behavioural changes we want to see across Scotland.

**Implementation**

In collaboration with NHS boards, Healthcare Improvement Scotland has led in the development of the national approach to learning from adverse events and is driving implementation through an improvement support programme. However, individual care providers are responsible and accountable for effectively managing adverse events.

All organisations should have a management system for reporting, reviewing and learning from all types of adverse events. This includes clinical events involving patients, families, staff and carers (including health and safety, accidents or incidents) and non-clinical events (including including information governance, health and safety at work and finance).

Adverse event reviews are not about apportioning blame. The aim is to review the care provided to determine whether there are learning points for the organisation or organisations to improve the service. Organisations then need to implement those improvements identified to support a greater level of safety for all people involved in its care systems.

Leaders should make a clear, public commitment to staff that the organisation fully supports an open and fair culture. When things go wrong, staff need to feel able to be open, that they will be treated fairly and they are supported to identify the failures in the system and improve service delivery.

The process must be transparent and include all those involved in the adverse event: patients, service users, families and carers, and staff. To support this, significant adverse event review reports should be shared with everyone involved in the event, and a one-page learning summary completed and published in order to share key learning points more widely.
Definitions

What is an adverse event?

An **adverse event** is defined as an event that could have caused (a near miss), 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 unexpected worsening of a medical condition, the inherent risk of an investigation or treatment, violence and aggression, 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. However, it is often not possible to determine if the harm caused was avoidable until a review is carried out and often areas for improvement are identified even when harm is not avoidable.

**People** are defined as:

- service users
- patients
- members of staff
- carers
- family members, and
- visitors.

**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.
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.

Therefore, the response to each adverse event should be proportionate to its scale, scope, complexity and opportunity for learning. 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. Assessment and categorisation
5. Review and analysis
6. Improvement planning and monitoring

Organisations 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 (see Appendix 1).
Stage 1: Risk assessment and prevention

Organisations should be striving to embed a positive safety culture, and creating an environment that is open, just and informed, in which reporting and learning from error is the norm.

The organisation should promote and support the elements of a safety culture\(^3\) outlined in Table 1 below.

<table>
<thead>
<tr>
<th>Table 1: Elements of a safety culture</th>
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</thead>
<tbody>
<tr>
<td><strong>Open culture</strong></td>
</tr>
<tr>
<td>Staff feel comfortable discussing adverse events and raising safety issues with both colleagues and senior managers</td>
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<tr>
<td><strong>Just culture</strong></td>
</tr>
<tr>
<td>Staff, patients, service users and carers are treated fairly, with empathy and consideration when they have been involved in an adverse event or have raised a safety issue</td>
</tr>
<tr>
<td><strong>Reporting culture</strong></td>
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<tr>
<td>Staff have confidence in the local adverse event reporting system and use it to notify managers of adverse events that are occurring, including near misses.</td>
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<tr>
<td>Barriers to adverse event reporting have been identified and removed:</td>
</tr>
<tr>
<td>• staff are not blamed and punished when they report adverse events</td>
</tr>
<tr>
<td>• staff receive constructive timely communication and feedback after submitting an adverse event report, and</td>
</tr>
<tr>
<td>• the reporting process is easy</td>
</tr>
<tr>
<td>• staff will be directly involved in reviews</td>
</tr>
<tr>
<td><strong>Learning culture</strong></td>
</tr>
<tr>
<td>The organisation:</td>
</tr>
<tr>
<td>• is committed to learn safety lessons</td>
</tr>
<tr>
<td>• communicates learning outcomes to colleagues</td>
</tr>
<tr>
<td>• remembers them over time</td>
</tr>
<tr>
<td>• shares key learning points more widely</td>
</tr>
<tr>
<td><strong>Informed culture</strong></td>
</tr>
<tr>
<td>The organisation has learned from past experience and has the ability to identify and mitigate future adverse events because it:</td>
</tr>
<tr>
<td>• learns from events that have already happened (for example, adverse event reviews, and</td>
</tr>
<tr>
<td>• shares key learning points)</td>
</tr>
<tr>
<td>• undertakes trend analysis and develops appropriate action plans</td>
</tr>
<tr>
<td>• uses learning from adverse events to promote a positive safety culture</td>
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</tbody>
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\(^3\) Adapted from ‘Implementing Human Factors in Healthcare: How to guide’, Patient Safety First
Adverse event management is one part of an effective risk management strategy. Avoidance, prevention and reduction of risks should be the primary defence to prevent adverse events occurring. Care will never be risk free, but we can minimise these risks in order to provide high quality care for the people of Scotland.

Risk assessments will assist in the identification of the hazards present in the care system, evaluate the likelihood of potential harm, the potential severity of that harm and the number of people that might be affected. Hazard identification checklists and sector specific guidance can also help to identify hazards prior to risk assessment. Mitigating actions should then be put in place that are proportionate to the risk to prevent it occurring, or if this is not possible, minimise the likelihood and impact.

Acting on key learning points from adverse event reviews and other safety lessons, such as safety alerts, is an essential part of risk prevention. Safety alerts are a mechanism that can be used to rapidly alert the care system to risks and provide guidance on preventing potential events that may lead to harm. Effective structures should be in place to generate, receive and act upon these alerts throughout the organisation.

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

Managing and learning from when things go wrong is an integral component of risk management processes and supports risk prevention. These data can act as an early indicator that a system is not functioning effectively, and analysing trends can provide valuable insight into where improvements may be required.

### Summary of risk assessment and prevention actions

- The chair and chief executive should make a clear, public commitment to staff that the organisation fully supports an open and fair culture.
- Hazard identification exercises and risk assessments should take place and be reviewed regularly to evaluate potential harm and mitigating actions should be put in place to minimise these risks.
- Effective structures should be in place to generate, receive and act upon safety alerts and other key safety lessons throughout the organisation.
- Systems for managing complaints, concerns, claims, adverse events (including health and safety and information governance) and safety alerts should be aligned as part of an integrated risk management approach.
- Staff involvement in inspections, audits, risk assessment and development of preventative actions will contribute to the development of a positive safety culture.

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4 Examples include Medical Device Alerts, Drug Alerts and Dear Healthcare Professional Letters issued by MHRA, Patient Safety Alerts issued by NHS England, and Estates and Facilities Alerts issued by IRIC, the Scottish Incident Reporting and Investigation Centre for equipment and medical devices.
Stage 2: Identification and immediate actions following an adverse event

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.

The person must be cared for, theirs and other people’s health and welfare secured and further risk mitigated. The person’s family or carers must be similarly cared for and involved where a person has been harmed. Compassion and understanding should be shown at all times even if simply making regular contact to keep people involved and informed.

The Institute for Healthcare Improvement (IHI) publication *Respectful Management of Serious Clinical Adverse Events (Second Edition)*\(^5\) suggests that an adverse event does not necessarily break down the trust between people involved. However the way in which the organisation responds after such events often does. The IHI publication provides a number of ways in which organisations should keep people at the centre of the process when responding to an event. Communicating effectively with people is a vital part of dealing with errors or problems in the delivery of care. Saying sorry, providing an explanation and keeping them informed will help people cope when things have gone wrong.

The organisation should give early consideration to the provision of information and support to patients, service users, families, carers and staff involved in the adverse event, including details on available support systems. We have developed a suite of national leaflets which can be used as a support tool. We have also published a reference document for Scotland that builds on the principles within the National Patient Safety Agency’s (NPSA) *Being Open Framework* (2009) to support care providers develop their approach to communicating and engaging with people who have suffered harm following an adverse event. These tools are available on our Community of Practice website\(^6\).

This approach aligns with the Scottish Government’s proposal to introduce a Statutory Duty of Candour for Health and Social Care Services\(^7\). The duty of candour will require all organisations providing care in Scotland to tell people if there has been an event involving them where the organisation has recognised that there has been physical or psychological harm as a result of their care or treatment.

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\(^6\) www.knowledge.scot.nhs.uk/adverse-events.aspx

\(^7\) www.scotland.gov.uk/Publications/2014/10/9897
Summary of identification and 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, service users, families, carers and staff should be met and supported.
- Colleagues should be informed and support secured from other professionals.
- Faulty medicine or equipment should be removed and labeled to prevent future use.
- A timely and objective entry should be made in the patient or service user’s care records.
- Any actions to reduce the risk of recurrence should be taken immediately.

Stage 3: Initial reporting and notification

When an adverse event (including near misses) occurs, the organisation’s electronic adverse event reporting system must be used. An organisation-wide approach should be in place for training staff in adverse event reporting. The types of information to be reported in the first instance include:

- the location of where the adverse event occurred
- the date and time of the adverse event
- personal details relating to the person or people involved in the adverse event
- description of the adverse event
- the outcome of the person/people involved (if known at this stage)
- the immediate treatment given to the person or people involved
- any immediate action taken
- any remedial action taken to minimise risk of recurrence of the event, and
- others who were involved in observing or reporting the adverse event.

It is essential that the person or people reporting the adverse event provide a comprehensive factual overview. There is no place for any opinion or assumptions. It is important that details are accurate and factual for any future review.

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 whenever they have been identified, even if some time has passed since the event occurred. The electronic adverse event reporting system should be set up to automatically notify relevant senior managers and staff that an adverse event has been reported.

Local policies will define the notification and escalation procedures that should be followed following an adverse event. Organisations may wish to develop a flow chart to outline the notification and communication process distinguishing the out-of-hours and in working hours arrangements.
This framework does not provide a core list of events that must be reported. Although there is some evidence to suggest that this could support reporting, it could also discourage reporting of events that are not included, and the list would need to be continually reviewed and updated.

**Reporting to external agencies**

Specific events must be reported to external organisations. This includes:

- deaths and injuries due to a work related accident to the Health and Safety Executive as set out in the Reporting of Injuries, Diseases and Dangerous Occurrences Regulations 1995 (RIDDOR)\(^8\)
- 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)\(^9\)
- events relating to blood 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\(^10\)
- adverse drug reactions, defective medicines and counterfeit medicines via the Yellow Card Scheme to the MHRA\(^11\)
- suicides of individuals in contact with mental health services to Healthcare Improvement Scotland\(^12\)
- deaths associated with medical or dental care to the Procurator Fiscal\(^13\)
- relevant information to UK-wide national audits and enquiries managed by the Healthcare Quality Improvement Partnership (HQIP)\(^14\)
- information governance events to the eHealth Division within Scottish Government and the Information Commissioners Office\(^15\)
- Ionising Radiation adverse events to the Warranted Inspector for IR(ME)R\(^16\), and
- serious crimes (homicides, serious assault, serious sexual assault) by an individual who is receiving care from mental health or learning disability services to the Mental Welfare Commission for Scotland\(^17\).

The organisation should ensure there are appropriate arrangements in place to enable both local reporting and reporting to external agencies so individuals can easily meet the reporting requirements. For example, onward reporting to external agencies could be managed centrally by specialist teams.

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8. [www.hse.gov.uk/riddor/reportable-incidents.htm](http://www.hse.gov.uk/riddor/reportable-incidents.htm)
Summary of initial reporting and notification actions

- All adverse events should be recorded on local electronic adverse event reporting systems as soon as possible after the event has occurred.
- The adverse event should also be reported to the relevant external organisation where required.

Stage 4: Assessment and categorisation

Following initial reporting of an adverse event or near miss, the relevant manager will assess the reporting form to consider the organisation’s response to the event.

All adverse events are subject to review. The level of the review will be dependent on the event in terms of its complexity and potential for learning.

Adverse events should be categorised to support decision-making processes to determine the level of review required. However, the level of review should not only be mandated by the categorisation of the event as other factors also impact this decision, such as the characteristics of the event, the patient or service user, the service, the outcome and the potential for learning.

Information, communications and outcomes should be centrally recorded and stored, ideally on the electronic adverse event reporting system, so that an audit trail is evident. The decision to proceed, or not, to a significant adverse event review should be clearly documented.

Organisations 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.

Categorisation of adverse events

Every event should be reviewed, but the level of review will be determined from the category of the event and other factors, such as the potential for learning. 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 unexpected 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 on National Coordinating Council for Medical Error Reporting and Prevention (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 on NCC MERP index).

- **Category III** – events that had the potential to cause harm but no harm occurred, for example near miss events (by either chance or intervention) or low impact events where an error occurred, but no harm resulted (likely to be
graded as minor or negligible on NHSScotland risk matrix or Category A, B, C or D on NCC MERP index).

This categorisation is based on impact of harm and could support the measurement of reported events that resulted in harm compared to 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 our care system 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. This will provide opportunity to review and inform system improvements to avoid the potential for harm being realised.

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 4 and 5).

**Levels of review**

All events are subject to review. The basic process of adverse event review and analysis should be essentially the same. However, some events due to the complexity or the potential for learning require a more formal, extensive review making full use of all associated techniques to comprehensively examine the chronology, care delivery problems and contributory factors.

The category of the event will support the decision-making process for the level of review required, however it must be stressed that a severe or tragic outcome is not the only determining factor. Near miss events with no adverse outcome and complex lower severity adverse events (Category III) can also warrant high level review if there is potential for learning.

Considering the potential for learning from the event aims to ensure that responses are not overly focused on the impact or outcome. This aims to gain an insight on underlying weaknesses of the system or areas where the system could be improved. The following decision-making prompts may help to determine the potential for learning:

- Is the outcome a known complication of the disease, treatment or process?
- Has there been any known 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 the patient, service user, family or management concerned about the event?

An event being subject to a significant review does not automatically indicate a causal link between care or service delivery and the outcome, or that the event was avoidable. It reflects the perceived need to review the event in detail to establish the facts of what happened to determine any links between the care delivery and the outcome or that there is potential for learning to inform system/service improvement.
Table 2 below provides a guide on the levels of review for each category to promote a consistent national response. However, organisations are ultimately responsible for determining, through their own governance and decision-making arrangements, the action that should be taken following an event occurring. Within this it is acknowledged that there may be circumstances where a decision is made to apply a different level of review to that suggested below. For example, a Level 1 (significant) review process may be applied to a Category II or III event or a Level 2 review to a Category I event. Organisations should clearly document the decisions for the level of review undertaken.

Table 2: Guide to levels of review

<table>
<thead>
<tr>
<th>Adverse event category</th>
<th>Suggested minimum level of review</th>
<th>Review team</th>
<th>Reporting of findings and learning</th>
<th>Guidance timescale</th>
</tr>
</thead>
<tbody>
<tr>
<td>Category I</td>
<td>Level 1: significant adverse event analysis and review. Use of validated analysis tools or evidence of screening and clear rationale for any not progressing to analysis.</td>
<td>Full review team: commissioning manager to agree review lead and Terms of Reference (the review team should be sufficiently removed from the event, and have no conflict of interest, to be able to provide an objective view).</td>
<td>Via division/service governance structures with evidence of improvement plans as required. The development of the improvement plan should sit within the team/department where the adverse event took place.</td>
<td>Commence review within 2 weeks and complete within 3 months.</td>
</tr>
<tr>
<td>Category II</td>
<td>Level 2: local management team review.</td>
<td>Service manager with multidisciplinary team input.</td>
<td>Via local governance structures with evidence of improvement plans as required.</td>
<td>Commence review within 2 weeks and complete within 6 weeks.</td>
</tr>
<tr>
<td>Category III</td>
<td>Level 3: local review by line manager in discussion with staff. If further review required then local management review process.</td>
<td>Managers/staff locally.</td>
<td>Via aggregated reports and learning points to management and governance structures.</td>
<td>Adverse event approved and closed within 2 weeks of being reported.</td>
</tr>
</tbody>
</table>
Summary of assessment and categorisation actions

- The organisation will have clear criteria and processes that allow transparent decision-making to decide on the level of review required.
- 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 follow-up of significant adverse event reviews within given timescales. They should also be responsible for ensuring relevant internal staff are informed of the event and engaged in the process.
- Decision-making should be recorded.

Stage 5: Review and analysis

The purpose of the review is to determine what happened, how it happened, why it happened, and whether there are learning points for the service, wider organisation, or nationally. It should follow the principles of a just culture and take a systems approach. The review aims to examine the processes of care delivery to identify if any system failures occurred which contributed to the adverse event and the outcome. The review process can also identify good practice that should be shared, or learning points that are not directly related to the adverse event, but can have an impact on improving the system.

Multi-agency review

There will be occasions where an adverse event review has the potential to involve more than one organisation. At the outset of the review process, consideration should be given to whether a collaborative approach is needed. The lead organisation (where the adverse event was reported) should contact the other organisation(s) and agree the scale of the involvement (from providing information or documentation to being part of the review team). A single point of contact for the patient, service user, family or carer should be clearly defined at the outset. A multidisciplinary review team with experience relevant to the different components of the care system being reviewed should also be agreed at the outset. We are developing guidance to support a consistent approach to collaborative reviews and this will shortly be published on the Community of Practice website.

Methodology

As part of a robust review process, the following should be established.

- A lead director or senior manager should be assigned to ensure a thorough and appropriate review is undertaken.
- Terms of Reference for the review should be defined.
- For Level 1 significant reviews, a 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, service users or their representatives should be clarified by 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. We have produced standardised text for organisations to use in the letter they send to staff to notify them of the review process and their involvement\(^\text{18}\).
• The support needs of staff involved in the adverse event must be considered and information leaflets should be provided\(^\text{19}\).
• Electronic information management systems should be established to ensure a significant, 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 written recollections of events submitted as part of the review
  - all contact and communication with the patient, family or carer
  - any reports and documented information provided to support the review
  - details of any equipment involved in the adverse event including location, and
  - final report and improvement plan (including sign-off sheet).

Adverse event reviews should use ensure a structured and consistent approach by using defined tools and techniques to identify the contributory factors, details of the care provided and any lessons that could inform service improvement or reduce the risk of recurrence. A variety of tools, such as cause and effect charts, fishbone diagrams and contributory factor frameworks 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.

A human factors approach is critical to undertaking a review\(^\text{20}\). Awareness of human factors can help to\(^\text{21}\):

• understand why staff make errors and, in particular, which ‘systems factors’ threaten safety
• improve the safety culture of teams and organisations
• enhance teamwork and improve communication between care staff
• improve the design of care systems and equipment
• identify ‘what went wrong’ and predict ‘what could go wrong’, and
• appreciate how certain tools can help to lessen the likelihood of harm.

The following diagram outlines how a human factors framework can help to understand how possible contributory factors can combine to cause an adverse event\(^\text{22}\).

\(^{18}\) [www.knowledge.scot.nhs.uk/adverse-events.aspx](http://www.knowledge.scot.nhs.uk/adverse-events.aspx)
\(^{19}\) [www.knowledge.scot.nhs.uk/adverse-events.aspx](http://www.knowledge.scot.nhs.uk/adverse-events.aspx)
\(^{21}\) Health and Safety Executive and human factors [www.hse.gov.uk/humanfactors](http://www.hse.gov.uk/humanfactors)
Making recommendations

After analysis of the adverse event and agreement on the contributory causes, the review team should make recommendations to improve future care delivery. The recommendations are actions that the review team want the lead director/senior manager and the involved services to consider. A recommendation must make clear what it aims to improve or how it will minimise risk. The review team should consider how the recommendations will support changes in practice and quality improvement. For example, if interventions are recommended that design out as far as possible the human component in the process or if they rely on changing the behaviour of people. High reliability is rarely achievable with interventions that rely on people behaving consistently. The recommendations should indicate the timescale for making a decision about whether the recommendations will be accepted and for developing the improvement plan but it is not the responsibility of the review team to produce the improvement plan.

Reporting

A report presenting the findings, conclusions and recommendations of the review should be produced and shared with everyone involved in the event. The organisation should ensure engagement and involvement with all people involved in the adverse event during the review process and as the report is finalised.

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22 Adapted from enhanced Significant Event Analysis, A tool for the individual practitioner and primary care team. NHS Education for Scotland. www.nes.scot.nhs.uk/media/2407430/enhanced_sea_personal_booklet.pdf

It is advised that anonymised reports are produced so that staff members, patients or service users cannot be identified from the report. As such, specific information such as ‘direct lifts’ from patient records or staff statements should not be included within the report. We have developed national guidance \(^{24}\) to support a standard approach to writing adverse event review reports to enable appropriate learning to be shared, whilst safeguarding patient, service user, family, carer, donor and staff confidentiality. This includes writing review reports in a format that minimises the need to redact person-identifiable information (for example patient, service user, family, carer, blood donor, or staff) so that information can be more freely shared.

**Sharing reports**

Organisations will have local processes for the review of reports and recommendations either through clinical governance structures and/or management team structures. It is expected that the lead director or manager who 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 organisation should also share this with the patient, service user, family and carer. A one-page learning summary should be completed and published in order to share key learning points. We have developed templates to support a consistent approach to capturing learning points \(^{25}\).

**Review outcomes**

Not all adverse events reviews will identify system failures and may find appropriate care was delivered. A review may conclude that the care delivered was appropriate and an event was unavoidable. The potential for learning in these cases should still be recognised and areas of good practice shared appropriately. An outcome code can be applied to adverse event reviews to indicate the findings of the review in relation to the link between care and outcome which will allow identification of those events where improvements are required. The following codes can be used:

1. **Appropriate care** - The adverse event review concluded that the care and/or service was well planned and appropriately delivered; no care or service delivery problems were identified; and the adverse event outcome was ultimately unavoidable. However, it is likely there are still learning points (especially good practice points).

2. **Indirect system of care issues** - The adverse event review identified indirect or incidental sub-optimal care or service issues and lessons that could be learned (and good practice points), however, these were unlikely to have affected the final outcome. For example, a protocol was not strictly followed or there was a delay in accessing the patient notes, but these were unlikely to have affected the final outcome.

3. **Minor system of care issues** - The adverse event review identified minor or sub-optimal care or service provision and that a different plan or delivery of care/service may have resulted in a different outcome. For example, system or management factors were identified (such as incomplete records or a delay

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\(^{24}\) [www.knowledge.scot.nhs.uk/adverse-events.aspx](www.knowledge.scot.nhs.uk/adverse-events.aspx)

\(^{25}\) [www.knowledge.scot.nhs.uk/adverse-events.aspx](www.knowledge.scot.nhs.uk/adverse-events.aspx)
in transferring the patient or service user), but there was uncertainty regarding their impact on the final outcome. Learning points have been identified and improvement plans developed.

4. **Major system of care issues** - The adverse event review identified that a different plan and/or delivery of care or service would, on the balance of probability, have been expected to result in a more favourable outcome. Factors were identified which negatively influenced or contributed to the adverse event outcome. For example, how the case was managed had a significant impact on the level of harm. Learning points have been identified and improvement plans developed.

**Links with disciplinary process**

Whilst it is extremely rare, there may be an occasion where there is evidence that a member of staff has committed a punitive or criminal act. In such situations, organisations should invoke their disciplinary/conduct process. The NPSA’s Decision Incident Tree can be used to support the decision-making process to move to disciplinary procedures (see Appendix 6). If at any stage in the adverse event review process it is deemed that disciplinary/conduct processes are required, the HR department should be informed so that the disciplinary process can begin; this should not be part of the adverse event review.
Summary of review and analysis 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 professionals with experience relevant to the event being reviewed.

- For Level 1 significant reviews, 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. This includes asking them if they have any questions that they would like to be explored during 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, how and why it happened and recommend what systems or processes should be put in place to prevent future occurrence using a human factors approach.

- Reviews should be quality assured to ensure they are robust and demonstrate the use of appropriate tools and techniques.

- Electronic information management systems should be established to ensure a comprehensive, accessible file of review documentation is maintained.

- Outcome codes could be used to indicate the findings of the review in relation to the link between care delivery and outcome which will allow identification of those events where improvements are required.
Stage 6: Improvement planning and monitoring

Level 1 (significant) and Level 2 adverse event reviews should, as required, have an improvement plan developed in response to the findings and recommendations. The outputs from the review should focus on service improvements and ideally each review should have an improvement aim established at the end of the review (an overarching ‘how much by when’ in terms of service improvement).

Improvement plans should be developed by those with the responsibility for making the agreed changes and who therefore have control and responsibility for implementation. This may be the team or department where the adverse event took place or it may be a corporate management team if a consistent corporate response is required. The organisation 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.

Improvement plans should be owned locally and reviewed and updated regularly. If a recommendation is not being progressed, the reason for this should be recorded. Organisations’ local policies will outline which groups or committees have responsibility for monitoring implementation of improvement plans, ensuring completion within the agreed timescales, documenting rationale for exceptions and ensuring sustainable improvements have resulted following the changes made.

The organisation should ensure arrangements are in place to share learning and improvements from adverse event reviews across services, the wider organisation and nationally as appropriate. Although it is our aim for adverse event review reports to be written in a way that can be shared and others can learn from the event, a brief learning summary is likely to be a better way to share key learning points. We have developed a one-page template to summarise what happened, what went well, what if anything could be improved and what has been learned.

Reports relating to thematic learning should be collated over specific timeframes to assist and inform wider service and organisation improvement programmes. The organisation should also identify and share nationally any learning that could inform improvements to the process of managing adverse events.

The local infrastructure that supports safety should link with the systems managing adverse events and complaints so that learning and improvement activity are integrated and co-ordinated. Learning from all sources of data provides an organisation with a true reflection of where things are going wrong and what is needed to prevent minor events from becoming more major and significant adverse events.

Systems should be in place to effectively and efficiently capture, analyse and report data. Organisations should scrutinise adverse event data alongside data from complaints and claims to assure themselves that their organisation learns, takes action and monitors the impact. A checklist has been developed for non-executive directors as one mechanism to support them in their role of challenging executives.

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26 www.knowledge.scot.nhs.uk/adverse-events.aspx
and providing assurance to the Board that adverse events are being managed effectively\textsuperscript{27}.

### Summary of improvement planning and monitoring actions

- An overarching service improvement aim should be established where possible. The improvement plan should set out how each recommendation from the review will be actioned, monitored, implemented, measured and resultant learning 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.

- Organisations 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.

- Evaluation should take place to evidence that changes made have led to sustainable improvements, and if this cannot be demonstrated, that other actions have been taken to achieve improvements in care.

\textsuperscript{27} [www.knowledge.scot.nhs.uk/adverse-events.aspx](http://www.knowledge.scot.nhs.uk/adverse-events.aspx)
Learning at a national level; sharing learning points from adverse event reviews for improvement

We have developed the national approach to learning from adverse events to support organisations standardise processes for managing and learning from adverse events across all care settings within Scotland. This aims to maximise opportunities to share and actively learn from each other to put improvements into practice. We are working on developing the type of information that would add most value to share, and the mechanisms to enable this.

The focus is on sharing any learning that could inform service improvement and any learning that could inform organisations’ adverse event management processes to improve the quality of care delivered. This learning could come from a Category 1 significant adverse event review, or a near miss that was deemed as requiring a significant adverse event review. We have developed a risk awareness notice template to share recently identified risks which apply across the care system and the improvement interventions implemented to mitigate against the risks.

The Adverse Events Community of Practice website has been set up to support care providers to share learning for improvement following adverse events reviews. The longer term aim is to widen the scope to sharing learning from other patient safety sources, such as complaints and claims, across both health and social care. To begin with we are testing the approach with the Learning from Adverse Events Network which has agreed to start using a learning summary template, based on an approach already being used by some NHS boards.

We are asking organisations to use the learning summary template to share learning about:

- service improvements following recommendations and actions that have come from reviews with potential national application
- improvements in the management of adverse events, for example in relation to the process of reporting, reviewing and learning from adverse events, and
- risk awareness notices.

To provide clarity, we have developed a learning summary guidance document which outlines criteria on the sort of national learning points that we are aiming to share on the Adverse Events Community of Practice website.

Review teams can also use our local learning summary template to summarise individual events and the learning points identified during the review. We recommend that the local learning summaries are shared with staff, patients, service users, families and carers and are published on the organisation’s intranet and website.

More information can be found at on the Adverse Events Community of Practice website: [www.knowledge.scot.nhs.uk/adverse-events.aspx](http://www.knowledge.scot.nhs.uk/adverse-events.aspx)
Roles and responsibilities

Care providers 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. Organisations need to ensure that an infrastructure exists to support reporting, recording, managing, reviewing and monitoring 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.

There should be an integrated approach to data collection and reporting, and systems in place to effectively and efficiently capture, assure, analyse and report data. Patient, service user and staff stories can be used to put a ‘human face’ on the numbers and actively seeks accounts of patient, service user and staff experience wherever possible.

The Health Foundation’s report: The measurement and monitoring of safety proposes a framework for safety measurement and monitoring. The framework highlights the key dimensions that any healthcare organisation should consider in its safety measurement plans.

The five dimensions are:

- **Past harm**: this encompasses both psychological and physical measures.
- **Reliability**: this is defined as ‘failure free operation over time’ and applies to measures of behaviour, processes and systems.
- **Sensitivity to operations**: the information and capacity to monitor safety on an hourly or daily basis.
- **Anticipation and preparedness**: the ability to anticipate, and be prepared for, problems.
- **Integration and learning**: the ability to respond to, and improve from, safety information.

The report notes that there is not one measure of safety. What is required is a suite of qualitative and quantitative measures covering these dimensions. In Appendix 3 we provide examples of local measures that organisations can consider when developing their measurement and monitoring strategies.

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The organisation’s adverse event management arrangements should set out the roles and responsibilities of management and committees with details as follows.

**The Board**
Three core roles in relation to safety:

- **Formulating strategy**: clear vision and purpose that puts quality and safety at its heart including strategic aims for safety – ‘Will care be safe in the future?’
- **Ensuring accountability**: for delivering the strategy, for seeking assurance that systems are robust, and for the organisation operating with openness, transparency and candour.
- **Shaping culture**: modelling and promoting values and standards of conduct for everyone.

The Board will wish to seek assurance that the systems in place support the effective management of adverse events as outlined in this framework by monitoring locally developed measures. The Board should be kept informed of serious and ongoing issues and recognise the links between staffing, quality outcomes and safety.

**Governance committees**

- Demonstrate leadership behaviours and actions that support a positive safety culture and commitment to being open.
- Responsible for assuring the Board that there are robust measures in place to record and manage adverse events and that learning and improvement have taken place to reduce the risk of recurrence.
- Preventative measures and processes are in place to effectively undertake risk assessment, identify potential harm and manage risks to an acceptable level. The aim being to minimise the likelihood of an event occurring and/or the level of harm.
- Actions contained within improvement plans have been completed and contribute to organisational learning by sharing and adopting key learning points.

**Non-executive directors**

- Demonstrate leadership behaviours and actions that support a positive safety culture and commitment to being open.
- Challenge executives and seek assurance that effective systems for reporting, managing, reviewing, learning and improving from adverse events are in place and working well within the organisation.
- To ask:
  - Has care been safe in the past?
  - Is care safe today?
  - Are our systems and processes reliable?
  - Are we responding and improving?
  - Will care be safe in the future?

See checklist for additional information for non-executives.29

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29 [www.knowledge.scot.nhs.uk/adverse-events.aspx](http://www.knowledge.scot.nhs.uk/adverse-events.aspx)
Chief executive
- Demonstrate leadership behaviours and actions that support a positive safety culture and commitment to being open.
- Create a culture to support staff to safely express concerns and for these to be listened to, discussed and acted on as appropriate.
- Ensure robust and effective policies and procedures for adverse event management.
- Ensure effective systems are in place for reporting, learning and improvement.
- Any delegation of roles and responsibilities to executive team members.

Executive team
- Demonstrate leadership behaviours and actions that support a positive safety culture and commitment to being open.
- Delegated responsibilities from the chief executive.
- Role in determining the level of review of adverse events.
- Ensure compliance with adverse event policies and procedures.
- Engagement with patients, service users and families.
- Ensure staff support and training.
- Ensure actions are implemented and improvements are made.

Directorate management teams
- Demonstrate leadership behaviours and actions that support a positive safety culture and commitment to being open.
- Senior clinicians have a responsibility to set an example and encourage openness and honest in reporting adverse events. Clinical leaders should actively foster a culture of learning and improvement.
- Ensuring compliance with adverse event policies and procedures.
- Reviewing and managing adverse events.
- Progression of improvement plans and follow-up.
- Dissemination of learning points and support to turn learning into action.
- Engagement with patients, service users and families.
- Supporting staff.

Managers
- Demonstrate leadership behaviours and actions that support a positive safety culture and commitment to being open.
- Ensuring staff awareness and compliance with policies and procedures.
- Managing adverse events including review, progress of actions, dissemination of learning points and implementation of improvement actions.
- Engagement with patients, service users and families.
- Engaging with and supporting staff.

Staff
- Demonstrate leadership behaviours and actions that support a positive safety culture and commitment to being open.
- Attending training.
- Reporting adverse events.
- Following policy and procedures including adhering to timescales.
- Participating in reviews.
• Understanding learning points and implementing recommended improvement actions.
• Engaging with patients, service users, families and carers.
Appendix 1: 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 clinical needs
     - Hot debriefs with staff involved
   - 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
   - Structured debrief with staff involved

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

5. Review and analysis
   - Establish appropriate review
   - Undertake review involving patient/service user, their family and staff

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
   - Share learning and implement key learning points
   - Implement action plan
   - Review of implementation of actions
Appendix 2: Governance principles

All organisations are accountable for effective governance and learning following an adverse event. The following principles build on the clinical and care governance framework. Organisations should:

- work in an open and transparent manner.
- ensure a Board director is formally designated to lead on and be responsible for 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, service users and staff in a timely manner, and to understand the impact on individual patients, service users and staff.
- ensure that the contribution of patients, service users and frontline staff remains central to improving standards of care, including involving patients, service users 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 the Procurator Fiscal.
- apply relevant information governance principles (including the Caldicott principles) to all information representing potentially sensitive data.

Appendix 3: Measuring and monitoring

Examples of local measures are listed below for organisations to consider as part of measurement and monitoring of their processes for managing adverse events for governance purposes and for learning and improvement.

The Scottish Patient Safety Programme also has a number of measures of harm for each of its programmes of work which should be collected and contribute valuable information to support improvement.

Measures supporting implementation of the national framework and local organisational adverse event policies

- Compliance with timescales for completion of reviews
- Documentation of engagement with patient, service user and family/carer
- Development of improvement plans following reviews
- Compliance with dates set in improvement plans for completion of actions
- Production of learning summaries from review reports for sharing locally
- Sharing of learning summaries nationally via the community of practice
- Percentage of how many adverse events have caused harm to patients, service users or staff (such as events graded as Category 1 and 2) out of the total number of adverse events

Measures supporting learning and improvement from adverse events

- Patient safety walk-rounds
- Top themes and trends in adverse events
  - By number
  - By harm/impact (as per definitions for Category 1, 2 and 3 events)
- Safety culture and climate surveys
- Surveys of patient, service user and family or carer involvement and engagement with adverse event review processes
- Evaluation of effectiveness of actions implemented following reviews
### 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). 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. 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 “knock on” 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 level (&gt;1 day), where there is no disruption to patient care.</td>
<td>Ongoing low staffing level reduces service quality. <strong>Minor error</strong> due to ineffective training/implementation of training.</td>
<td>Late delivery of key objective / service due to lack of staff. <strong>Moderate error</strong> due to ineffective training/implementation of training. Ongoing problems with staffing levels.</td>
<td>Uncertain delivery of key objective/service due to lack of staff. <strong>Major error</strong> due to ineffective training/implementation of training.</td>
<td>Non-delivery of key objective/service due to lack of staff. Loss of key staff. <strong>Critical error</strong> 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). <strong>(NB. Please adjust for context)</strong></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 by appropriate action plan.</td>
<td>Enforcement action. Low rating. <strong>Critical report.</strong></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. <strong>Minor effect on staff morale/public attitudes.</strong></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/MP 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>Impact/Consequences</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Negligible</td>
</tr>
<tr>
<td>Almost Certain</td>
<td>Medium</td>
</tr>
<tr>
<td>Likely</td>
<td>Medium</td>
</tr>
<tr>
<td>Possible</td>
<td>Low</td>
</tr>
<tr>
<td>Unlikely</td>
<td>Low</td>
</tr>
<tr>
<td>Rare</td>
<td>Low</td>
</tr>
</tbody>
</table>
Appendix 5: National Coordinating Council for Medication Error Reporting and Prevention - Index for Categorizing Medication Errors

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.)
Appendix 6: National Patient Safety Agency Incident Decision Tree

Incident Decision Tree

Based on James Reason's Culpability Model. © National Patient Safety Agency 2005

http://www.nrls.npsa.nhs.uk/resources/?EntryId45=59900