

Learning from adverse events through reporting and review

A national framework for Scotland

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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.”

A promise to learn – a commitment to act, The National Advisory Group on the Safety of Patients in England, chaired by Don Berwick, August 2013

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 has a very important contribution to make to improve the quality and safety of care. To get the most benefit from this, adverse events need to be considered alongside other sources of data and intelligence including information about anticipating and preventing future safety problems. Integrating and responding to the learning from these different sources is key.

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.

The first version of this framework was published in September 2013 following an 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.

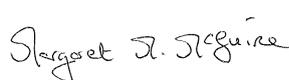
A revised second edition was published in April 2015 following the development of a number of tools to support implementation of the framework. These are available on the Adverse Events Community of Practice website¹.

The third edition of the framework was produced following the implementation of the statutory organisational duty of candour legislation in Scotland on 1 April 2018². The requirements of this legislation were incorporated into the revised third edition of the framework.

This fourth edition reflects the [direction](#) provided by the Cabinet Secretary for Health and Sport on 10 September 2019³. This instructed Healthcare Improvement Scotland (HIS) to work with all NHS boards to ensure that they notify HIS when a category I Significant Adverse Event Review (SAER) is commissioned, and to move towards standardising terminology and definitions, including the implementation across all NHS boards of the consistent use of 'Significant Adverse Event Review'.

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. Practice continually evolves and we will add supporting tools as and when they are developed.

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.



Margaret McGuire



Helen Munro

Co-chairs of the Adverse Events Programme Board

¹ www.knowledge.scot.nhs.uk/adverse-events.aspx

² <http://www.gov.scot/Topics/Health/Policy/Duty-of-Candour>

³ <https://www.gov.scot/publications/adverse-events-management-nhs-scotland/>

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.

The question 'How safe is our care?' is clearly of fundamental importance, yet those teams and organisations that provide care typically report that the answer to this remains somewhat elusive. Approaches to measuring and monitoring the safety of care often put the greatest emphasis on measuring harms that have occurred in this past. This is necessary, but not sufficient for understanding safety. Another common theme observed in healthcare systems is that there are no mechanisms to routinely draw together, and respond to, various sources of data and intelligence about safety.

To attempt to answer the question 'How safe is our care?' The Health Foundation published a framework⁴ that brings together critical aspects of safety, and for which it is suggested that the following five questions need to be considered:

1. Has care been safe in the past?
2. Are our clinical systems and processes reliable?
3. Is care safe today?
4. Will care be safe in the future?
5. Are we responding and improving?

Work has been carried out in parts of Scotland and England to test the practical application of The Health Foundation framework. Key findings include a reported benefit from shifting away from a narrow focus on past incidents and risk assessments and moving towards a more holistic and thorough enquiry about safety.

The Health Foundation framework is directly relevant to learning from adverse events.

- Adverse events are a key source of intelligence about how safe care has been in the past and so have a clear place in understanding and improving safety.
- As well as learning from when things do go wrong, there needs to be a clear focus on anticipating future risks and preventing safety problems occurring in the first place.
- Learning from when things go well should also be considered.
- To get the most benefit, adverse events should be considered alongside rather than separately from other sources of data/intelligence. To illustrate, this could include information on/from: feedback; safety huddles; staffing levels; reliability of key clinical processes; team/organisation scorecards; local quality improvement work, and: mortality and morbidity reviews.
- It is important to have mechanisms in place to ensure that the learning from these different sources is integrated and acted upon.

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

A number of tools have been developed to support consistent implementation of the framework such as:

- guidance on implementing the Being Open principles

⁴ <https://www.health.org.uk/publication/framework-measuring-and-monitoring-safety>

- data redaction and standardised adverse event review reports guidance, and
- learning summary templates.

These are available on the Community of Practice website⁵. Practice continually evolves and supporting tools will be added as and when they are developed.

The statutory organisational duty of candour legislation came into force on 1 April 2018. The purpose of the new duty of candour provisions is to support the implementation of consistent responses across health and social care providers when there has been an unexpected event or incident that has resulted in death or harm that is not related to the course of the condition for which the person is receiving care. The requirements of this new legislation have been incorporated into this update of the framework.

In September 2019 Healthcare Improvement Scotland (HIS) published [Adverse Event Management: NHS boards self-evaluation report](#)⁶.

The report highlighted areas of good practice in adverse event management within the NHS boards but also identified variations and inconsistencies between the boards

In response to the self–evaluation report the Cabinet Secretary [instructed](#) Healthcare Improvement Scotland (HIS) to work with all NHS boards to ensure that they notify HIS when a category I Significant Adverse Event Review (SAER) is commissioned, and to move towards standardising terminology and definitions, including the implementation across all NHS boards of the consistent use of ‘Significant Adverse Event Review’. The new national notification system was to be in operational by end of December 2019.

From 1st January 2020 all NHS boards will inform HIS of any Significant Adverse Event Reviews commissioned for category 1 events. HIS has produced a supplementary guidance document for the notification process. This is available on the HIS website and is titled [Adverse Events – guidance on national notification data](#)⁷. This supplementary guidance will be updated periodically.

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 the 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 health and care 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

⁵ www.knowledge.scot.nhs.uk/adverse-events.aspx

⁶ http://www.healthcareimprovementscotland.org/our_work/governance_and_assurance/learning_from_adverse_events/self-evaluation_report.aspx

⁷ http://www.healthcareimprovementscotland.org/our_work/governance_and_assurance/learning_from_adverse_events/national_framework.aspx

- organisations are open, honest and supportive towards the affected person, apologising for any harm that occurred
- any staff involved are supported in a consistent manner
- events are reviewed in a consistent way, and
- learning is shared and implemented across the organisation and more widely to improve the quality of services.

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. Duty of candour will apply to specific events or incidents that have resulted in death or harm. The Scottish Government has published guidance⁸ to assist organisations in the development of their local policies and procedures for duty of candour events.

A phased approach has been taken towards supporting implementation of learning from adverse events with an initial focus to date on acute care, although the principles encompass all care settings. The focus now will be in considering how implementation within primary care and community services can be supported as well as working towards integration of arrangements across health and social care. It should be noted that the statutory duty of candour applies to all organisations who provide health and social care services.

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 good 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 prevention of future events.
- **Openness about failures** – events are identified, reported and managed in a timely manner. Patients, service users and their families are told what went wrong and why, and receive an apology for any harm that has occurred. Reviews of events happen frequently and quickly following their occurrence. Adverse event reporting increases as the organisation moves 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

⁸ <http://www.gov.scot/Publications/2018/03/1321>

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. Everyone wishes to achieve a positive safety culture that is open, just and informed, in which reporting and learning from error is the norm. A key principle of duty of candour is being honest with people when things do go wrong and offering an apology as soon as an event has been identified. 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 required for Scotland.

Implementation

In collaboration with NHS boards, Healthcare Improvement Scotland has led 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 (as well as including information governance, health and safety at work and finance).

Adverse event reviews are not about apportioning blame. The aim is to be open and honest with people when things do go wrong and offering an apology as soon as an event has been identified. A review of the care provided determines whether there are learning points for the organisation or organisations to improve the service. Organisations then need to implement the 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, organisations must consider activation of duty of candour procedures if an unexpected or unintended event has led to death or harm. Significant adverse event review reports should also 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.

There are some harms which are 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, including consideration of duty of candour
Initial reporting and notification
3. Assessment and categorisation, including consideration of duty of candour
4. Review and analysis
5. 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 culture⁹ outlined in Table 1 below.

Table 1: Elements of a safety culture

Open culture	Staff feel comfortable discussing adverse events and raising safety issues with both colleagues and senior managers
Just culture	Staff, patients, service users, their families and carers are treated fairly, with empathy and consideration when they have been involved in an adverse event or have raised a safety issue. Duty of candour procedures are followed, and organisations are open about adverse events, apologising to the affected person.
Reporting culture	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. Barriers to adverse event reporting have been identified and removed: <ul style="list-style-type: none"> • staff are not blamed and punished when they report adverse events • staff receive constructive timely communication and feedback after submitting an adverse event report • the reporting process is easy, and • staff will be directly involved in reviews.
Learning culture	The organisation: <ul style="list-style-type: none"> • is committed to learning safety lessons • communicates learning outcomes to colleagues • remembers them over time, and • shares key learning points more widely.
Informed culture	The organisation has learned from past experience and has the ability to identify and mitigate future adverse events because it: <ul style="list-style-type: none"> • learns from events that have already happened (for example, adverse event reviews) • shares key learning points • undertakes trend analysis and develops appropriate action plans, and • uses learning from adverse events to promote a positive safety culture.

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 risks can be minimised in order to provide high quality care for the people of Scotland.

⁹ Adapted from 'Implementing Human Factors in Healthcare: How to guide', Patient Safety First
www.patientsafetyfirst.nhs.uk/ashx/Asset.ashx?path=/Intervention-support/Human+Factors+How-to+Guide+v1.2.pdf

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 alerts¹⁰, 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 principles (see [Appendix 2](#)) for the management of adverse events should be integrated with the organisation's risk management strategy and governance processes, including complaints, claims and duty of candour procedures.

A clear link with structured departmental Mortality and Morbidity Meetings/Team Based Quality Reviews) facilitates a positive reporting and learning culture across all levels in the organisation. This also ensures a more effective governance of the process by providing the necessary support and oversight.

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, compliments, concerns, feedback, claims, duty of candour events, 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.

Stage 2: Identification and immediate actions following an adverse event, including consideration of duty of candour

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.

¹⁰ 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.

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)*¹¹ 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. A suite of national leaflets have been developed which can be used as a support tool. A [reference document](#)¹² has been published 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 the Community of Practice website¹³.

This approach aligns with the Scottish Government's introduction of a statutory organisational duty of candour for health and social care services. Since 1 April 2018, the duty of candour legislation has required all organisations providing care in Scotland to be open, honest and supportive towards anyone affected by an unexpected or unintended event which results in death or harm. Organisations must notify the person affected, apologise and offer a meeting to explain what happened. They must also review the event, and publish an annual report outlining the learning and improvements put in place as a result of these procedures.

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, taking into account the statutory duty of candour.
- Colleagues should be informed and support secured from other professionals.
- Faulty medicine or equipment should be removed and labelled 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.

¹¹ *Respectful Management of Serious Clinical Adverse Events (Second Edition)*. Conway J, Federico F, Stewart K, Campbell MJ. IHI Innovation Series white paper. Cambridge, Massachusetts: Institute for Healthcare Improvement; 2011 (www.ihl.org/knowledge/Pages/IHIWhitePapers/RespectfulManagementSeriousClinicalAEsWhitePaper.aspx)

¹² http://www.healthcareimprovementscotland.org/our_work/governance_and_assurance/learning_from_adverse_events/being_open_guidance.aspx

¹³ www.knowledge.scot.nhs.uk/adverse-events.aspx

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 actions taken under duty of candour processes
- 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.

Reporting to external agencies

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

- from 01 January 2020, all significant adverse event reviews commissioned by the NHS boards for a category 1 adverse event should be reported to **Healthcare Improvement Scotland (HIS)** in alignment with the new national notification system. See supplementary [Adverse Events – guidance on national notification data](#)¹⁴.
- 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)¹⁵
- 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)¹⁶
- 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 Directive¹⁷

¹⁴http://www.healthcareimprovementscotland.org/our_work/governance_and_assurance/learning_from_adverse_events/national_framework.aspx

¹⁵ www.hse.gov.uk/riddor/reportable-incidents.htm

¹⁶ www.hfs.scot.nhs.uk/services/incident-reporting-and-investigation-centre-iric/adverse-incident-reporting/

¹⁷ www.gov.uk/blood-authorisations-and-safety-reporting#report-a-serious-adverse-event-or-reaction-related-to-blood

- adverse drug reactions, defective medicines and counterfeit medicines via the Yellow Card Scheme to the **MHRA**¹⁸
- suicides of individuals in contact with mental health services to **Healthcare Improvement Scotland**¹⁹
- sudden deaths associated with medical or dental care to the **Procurator Fiscal**²⁰
- relevant information to UK-wide national audits and enquiries managed by the **Healthcare Quality Improvement Partnership (HQIP)**²¹
- information governance events to the eHealth Division within **Scottish Government** and the **Information Commissioners Office**²²
- Ionising Radiation adverse events to Healthcare Improvement Scotland via hcis.irmer@nhs.net²³, and
- All deaths of patients subject to mental health detention or a community based order under the Mental Health (Care and Treatment)(Scotland) Act 2003 or the Criminal Procedure (Scotland) Act 1995; all homicides committed by people with recent contact with mental health services; and serious crimes (serious assault, serious sexual assault) by an individual who is receiving care from mental health or learning disability services are notified to the **Mental Welfare Commission for Scotland**²⁴.

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.

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, including consideration of duty of candour

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.

¹⁸ yellowcard.mhra.gov.uk/the-yellow-card-scheme/ Note: the Yellow Card Scheme now also collects information on events involving medical devices, however, this information should in the first instance be reported to IRIC who collect the information for Scotland and are responsible for onward transmission to the MHRA.)

¹⁹ http://www.healthcareimprovementscotland.org/our_work/mental_health/suicide_reviews.aspx

²⁰ <http://www.copfs.gov.uk/images/Documents/Deaths/Reporting%20Deaths%20to%20the%20Procurator%20Fiscal%202015.pdf>

²¹ www.hqip.org.uk/clinical-outcome-review-programmes-2/

²² www.ico.org.uk/for_organisations/sector_guides/health

²³ <http://www.legislation.gov.uk/uksi/2017/1322/introduction/made>

²⁴ <https://www.mwscot.org.uk/good-practice/notifying-commission>

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 organisations should be aiming to take a preventative rather than reactive approach and should not wait for harm to occur before making improvements to the system. Therefore, as the care system exhibits more qualities and behaviours of a high reliability organisation, it will increasingly focus its 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?
- Does the event activate duty of candour procedures?
- 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 adverse event 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 adverse event review process may be applied to a Category II or Category III event Organisations should clearly document the decisions for the level of review undertaken.

Table 2: Guide to levels of review

Adverse event category	Suggested minimum level of review	Review team	Reporting of findings and learning	Guidance timescale
Category I	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.	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).	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.	Commission review within 10 working days of the adverse event being reported on incident management system. Commence and close review (report submitted for approval) within 90 working days of the commissioning date. Final approval should take place as soon as possible and no later than 30 working days from report submission. Develop improvement plan within 10 working days from report being approved.
Category II	Level 2: local management team review.	Service manager with multidisciplinary team input.	Via local governance structures with evidence of improvement plans as required.	Commence and close review (report submitted for approval) within 30 working days of the adverse event being reported on incident management system. Final approval should take place as soon as possible and no later than 30 working days from report submission. Develop improvement plan within 10 working days from report being approved.
Category III	Level 3: local review by line manager in discussion with staff.	Managers/staff locally. If further review required then local management review process.	Via aggregated reports and learning points to management and governance structures.	Adverse event approved and closed within 10 working days of adverse event being reported on incident management system.

Links with duty of candour

In most cases, an event falling under duty of candour requirements will be identified before an adverse event review takes place and appropriate procedures will have been followed. However, if an adverse event review identifies an instance where the organisation has not yet met the requirements of duty of candour, this should be undertaken as soon as possible.

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. This should take into account the potential for learning from the event.
- 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 or sector. 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 and should ensure that all organisational duty of candour responsibilities are met. A multidisciplinary review team with experience relevant to the different components of the care system being reviewed should also be agreed at the outset. Guidance²⁵ has been developed to support a consistent approach to collaborative reviews and is available on the Community of Practice website.

The lead organisation should also notify HIS of the commissioning of any multi-agency category I Significant Adverse Event Reviews.

Methodology

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

- A lead director or senior manager (band 7 and above) 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 adverse event reviews, a review team (member(s) with knowledge of specialty) should be identified with a lead reviewer appointed and roles

²⁵[Multi-board approach to significant adverse event reviews](#)

- 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, taking into account the duty of candour.
 - 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. Standardised text has been produced for organisations to use in the letter they send to staff to notify them of the review process and their involvement²⁶.
 - The support needs of staff involved in the adverse event must be considered and information leaflets should be provided²⁷.
 - 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 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 review²⁸. Awareness of human factors can help to²⁹:

- understand why events happen 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' (in the future)
- help to identify events which went well, 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 event³⁰.

²⁶ www.knowledge.scot.nhs.uk/adverse-events.aspx

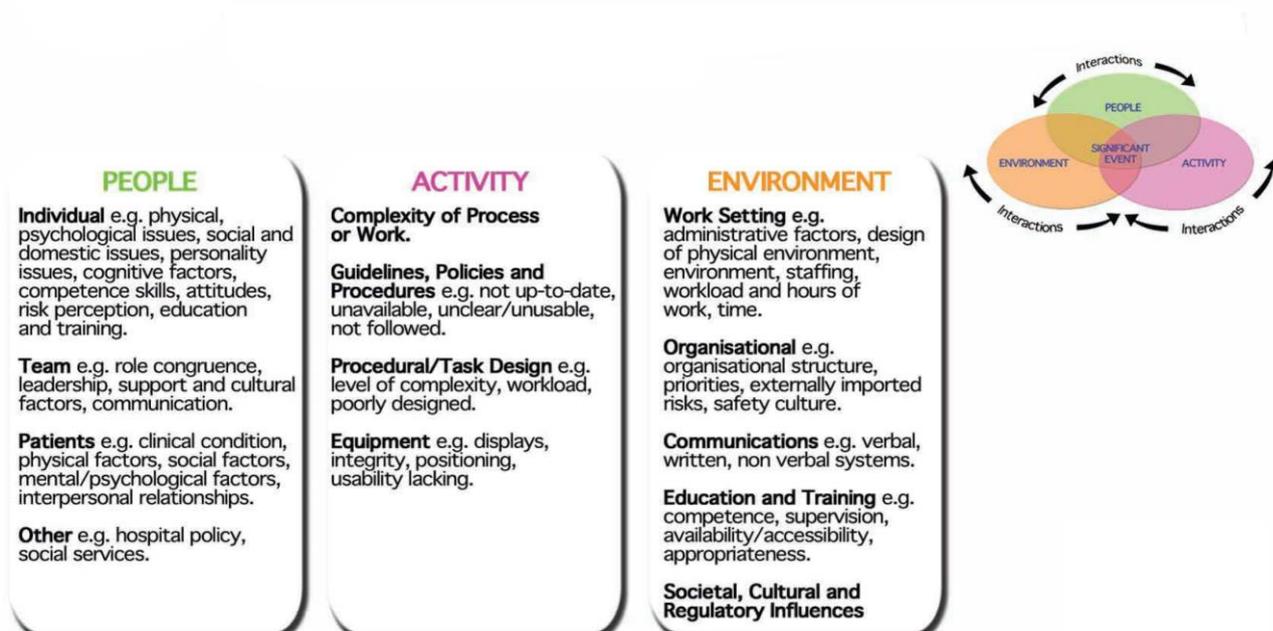
²⁷ www.knowledge.scot.nhs.uk/adverse-events.aspx

²⁸ Clinical Human Factors Group <http://chfg.org/>

²⁹ Health and Safety Executive and human factors www.hse.gov.uk/humanfactors

³⁰ 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

Applying a Human Factors Framework



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, recommendations for interventions that design out as far as possible the human component in the process achieve more than recommendations that rely on changing the behaviour of people. High reliability is rarely achievable with interventions that rely on people behaving consistently³¹. 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.

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 case notes or staff statements should not be included within the report. National guidance³² has been developed 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, donor, or staff) so that information can be more freely shared.

³¹ Dineen M. Six steps to Root Cause Analysis, 3rd edition. Oxford: Consequence; 2002

³² www.knowledge.scot.nhs.uk/adverse-events.aspx

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. Templates have been developed to support a consistent approach to capturing learning points³³.

Since 1 April 2018, organisations have had a duty to produce an annual report³⁴ setting out:

- the number of times duty of candour processes have been used
- how the organisation has complied with the duty of candour legislation, and
- what learning and improvements have been put in place as a result.

Review outcomes

Not all adverse event reviews will identify system failures. 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 case 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 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, and in appropriate cases, involve the police. In such situations, organisations should invoke their disciplinary/conduct process. The NHS

³³ www.knowledge.scot.nhs.uk/adverse-events.aspx

³⁴ http://www.careinspectorate.com/images/Professionals/DoC_M_R_GROUP_FINAL_REPORT.pdf

Improvement – A just culture guide 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 adverse event 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 invited to contribute 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.
- If an adverse event review identifies previously unrecognised duty of candour requirements, these should be addressed as soon as possible.
- 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 the 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. A one-page template has been developed to summarise what happened, what went well, what if anything could be improved and what has been learned³⁵.

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 and quality improvement 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 and providing assurance to the Board that adverse events are being managed effectively³⁶.

Evaluation of the effectiveness of adverse events processes, including seeking feedback from patients, carers, families and staff that have been involved, should be undertaken regularly to support continuous improvement.

³⁵ www.knowledge.scot.nhs.uk/adverse-events.aspx

³⁶ www.knowledge.scot.nhs.uk/adverse-events.aspx

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.
- Evaluation of the effectiveness of adverse events processes, including obtaining feedback from those involved, should be undertaken regularly.

Learning at a national level – sharing learning points from adverse event reviews for improvement

The national approach to learning from adverse events has been developed 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. Development of 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 I significant adverse event review, or a near miss that was deemed as requiring a significant adverse event review. A risk awareness notice template³⁷ has been developed 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. The approach has been tested 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.

Organisations are expected to use the learning summary template³⁸ 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, a learning summary guidance document³⁹ has been developed which outlines criteria on the sort of national learning points to be shared and published on the Community of Practice website.

Review teams can also use the local learning summary template to summarise individual events and the learning points identified during the review. It is recommended that organisations share the local learning summaries with staff, patients, service users, families and carers and publish them on their intranet and website.

More information can be found on the Community of Practice website:

www.knowledge.scot.nhs.uk/adverse-events.aspx

³⁷ <http://www.knowledge.scot.nhs.uk>

³⁸ www.knowledge.scot.nhs.uk/adverse-events.aspx

³⁹ 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, including duty of candour procedures. This includes providing appropriate opportunities for staff at all levels, and Board members, to take part in appropriate learning and development, in addition to recognising the time required for people to participate in adverse events reporting and reviews. They should also ensure robust and integrated 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 demonstrate the human impact behind the numbers and care providers should seek accounts of patient, service user and staff experience for this purpose

The Health Foundation's report: *The measurement and monitoring of safety*⁴⁰ 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 single measure of safety. What is required is a suite of qualitative and quantitative measures covering these dimensions. Examples of local measures that organisations can consider when developing their measurement and monitoring strategies can be found in [Appendix 3](#).

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

The Board

The Board has 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.

⁴⁰ *The Measurement and Monitoring of Safety*. Charles Vincent; Susan Burnett; Jane Carthey. Health Foundation; April 2013
www.health.org.uk/publications/the-measurement-and-monitoring-of-safety/

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, including meeting duty of candour requirements, and that learning and improvement have taken place to reduce the risk of recurrence.
- Ensure 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.
- Ensure 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 and duty of candour procedures 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-executives⁴¹.

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 and meeting duty of candour requirements.
- Ensure effective systems are in place for reporting, learning and improvement.
- Delegate 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.
- Have a role in determining the level of review of adverse events.
- Ensure compliance with adverse event policies and procedures, including duty of candour requirements.
- Engagement with patients, service users and families, including through duty of candour processes.
- Ensure staff support and training.
- Ensure actions are implemented and improvements are made.

⁴¹ www.knowledge.scot.nhs.uk/adverse-events.aspx

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 honesty in reporting adverse events. Clinical leaders should actively foster a culture of learning and improvement.
- Ensure compliance with adverse event and duty of candour policies and procedures.
- Review and manage adverse events.
- Progress improvement plans and follow-up.
- Disseminate learning points and provide support to turn learning into action.
- Engage with patients, service users and families, including through duty of candour processes.
- Support staff.

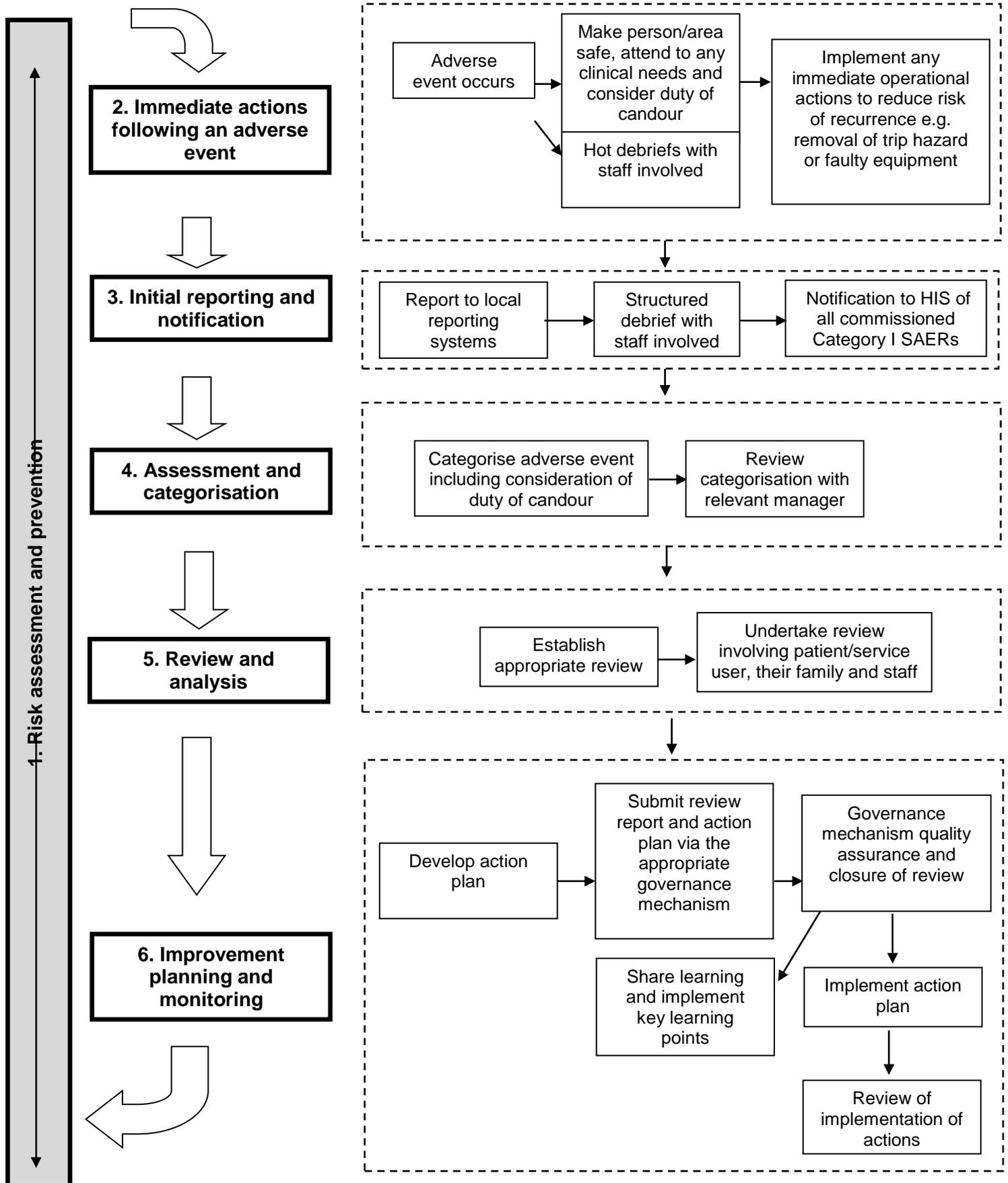
Managers

- Demonstrate leadership behaviours and actions that support a positive safety culture and commitment to being open.
- Ensure staff awareness and compliance with policies and procedures.
- Manage adverse events including duty of candour processes, review, progress of actions, dissemination of learning points and implementation of improvement actions.
- Engage with patients, service users and families, including through duty of candour processes.
- Engage with and support staff.

Other staff

- Demonstrate leadership behaviours and actions that support a positive safety culture and commitment to being open.
- Attend training.
- Report adverse events.
- Follow policy and procedures, including adhering to timescales.
- Participate in reviews and duty of candour processes.
- Understand learning points and implement recommended improvement actions.
- Engage with patients, service users, families and carers.

Appendix 1: Actions to be taken to effectively manage adverse events



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 framework⁴².

Organisations should:

- work in an open and transparent manner, meeting duty of candour requirements.
- 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 and duty of candour procedures. 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 and duty of candour processes. This includes consideration of adverse events, duty of candour processes 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 in accordance with duty of candour requirements, and are 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.

⁴² Clinical and Care Governance Framework, December 2014 www.gov.scot/Topics/Health/Policy/Adult-Health-SocialCare-Integration/Implementation/working_Groups/CCGG/ClinCareGovFwork

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 completion of duty of candour processes and any other 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 I and Category II) 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 I, Category II and Category III 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.

Appendix 4: NHSScotland risk assessment matrices⁴³

Table 1 – Impact/Consequence definitions

Descriptor	Negligible	Minor	Moderate	Major	Extreme
Patient Experience	Reduced quality of patient experience/clinical outcome not directly related to delivery of clinical care.	Unsatisfactory patient experience/ clinical outcome directly related to care provision – readily resolvable.	Unsatisfactory patient experience/ clinical outcome; short term effects – expect recovery <1wk.	Unsatisfactory patient experience/ clinical outcome; long term effects – expect recovery >1wk.	Unsatisfactory patient experience/ clinical outcome; continued ongoing long term effects
Objectives / Project	Barely noticeable reduction in scope, quality or schedule.	Minor reduction in scope, quality or schedule.	Reduction in scope or quality of project; project objectives or schedule.	Significant project over-run.	Inability to meet project objectives; reputation of the organisation seriously damaged.
Injury (physical and psychological) to patient/visitor/ staff	Adverse event leading to minor injury not requiring first aid.	Minor injury or illness, first aid treatment required.	Agency reportable, e.g. Police (violent and aggressive acts). Significant injury requiring medical treatment and/or counselling.	Major injuries/long term incapacity or disability (loss of limb) requiring medical treatment and/or counselling.	Incident leading to death or major permanent incapacity.
Complaints / Claims	Locally resolved verbal complaint.	Justified written complaint peripheral to clinical care.	Below excess claim. Justified complaint involving lack of appropriate care.	Claim above excess level. Multiple justified complaints.	Multiple claims or single major claim Complex justified complaint
Service / Business Interruption	Interruption in a service which does not impact on the delivery of patient care or the ability to continue to provide service.	Short term disruption to service with minor impact on patient care.	Some disruption in service with unacceptable impact on patient care. Temporary loss of ability to provide service.	Sustained loss of service which has serious impact on delivery of patient care resulting in major contingency plans being invoked.	Permanent loss of core service or facility. Disruption to facility leading to significant “knock on” effect
Staffing and Competence	Short term low staffing level temporarily reduces service quality (< 1 day). Short term low staffing level (>1 day), where there is no disruption to patient care.	Ongoing low staffing level reduces service quality. Minor error due to ineffective training/implementation of training.	Late delivery of key objective / service due to lack of staff. Moderate error due to ineffective training/implementation of training. Ongoing problems with staffing levels.	Uncertain delivery of key objective/ service due to lack of staff. Major error due to ineffective training/ implementation of training.	Non-delivery of key objective/service due to lack of staff. Loss of key staff. Critical error due to ineffective training/ implementation of training.
Financial (including damage / loss / fraud)	Negligible organisational/ personal financial loss. (£<1k). (NB. Please adjust for context)	Minor organisational/personal financial loss (£1-10k).	Significant organisational/personal financial loss (£10-100k).	Major organisational/personal financial loss (£100k-1m).	Severe organisational/personal financial loss (£>1m).
Inspection / Audit	Small number of recommendations which focus on minor quality improvement issues.	Recommendations made which can be addressed by low level of management action.	Challenging recommendations that can be addressed with appropriate action plan.	Enforcement action. Low rating. Critical report.	Prosecution. Zero rating. Severely critical report.
Adverse Publicity / Reputation	Rumours, no media coverage. Little effect on staff morale.	Local media coverage – short term. Some public embarrassment. Minor effect on staff morale/public attitudes.	Local media – long-term adverse publicity. Significant effect on staff morale and public perception of the organisation.	National media/adverse publicity, less than 3 days. Public confidence in the organisation undermined. Use of services affected.	National/international media/adverse publicity, more than 3 days. MSP/MP concern (Questions in Parliament). Court Enforcement. Public Inquiry/ FAI.

⁴³ NHS Quality Improvement Scotland (February 2008) sourced AS/NZS 4360:2004 'Making it Work' (2004)

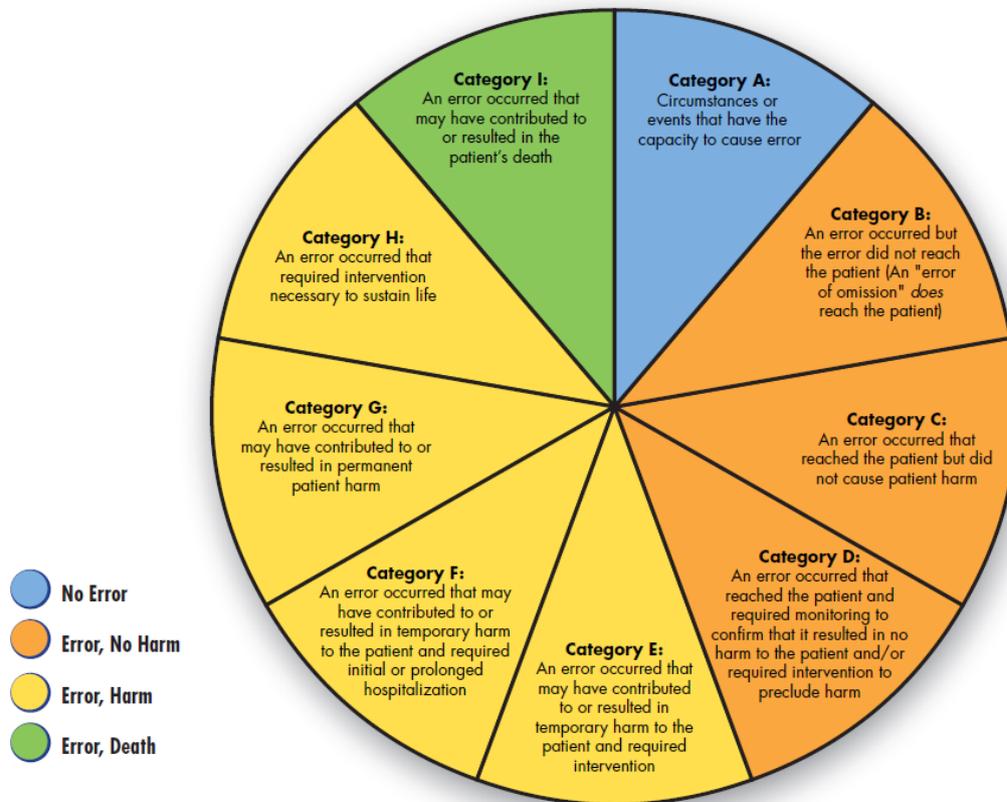
Table 2 – Likelihood Definitions

Descriptor	Rare	Unlikely	Possible	Likely	Almost Certain
Probability	Can't believe this event would happen – will only happen in exceptional circumstances.	Not expected to happen, but definite potential exists – unlikely to occur.	May occur occasionally, has happened before on occasions – reasonable chance of occurring.	Strong possibility that this could occur – likely to occur.	This is expected to occur frequently / in most circumstances – more likely to occur than not.

Table 3 - Risk Matrix

Likelihood	Impact/Consequences				
	Negligible	Minor	Moderate	Major	Extreme
Almost Certain	Medium	High	High	V High	V High
Likely	Medium	Medium	High	High	V High
Possible	Low	Medium	Medium	High	High
Unlikely	Low	Medium	Medium	Medium	High
Rare	Low	Low	Low	Medium	Medium

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.)

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Appendix 6: NHS Improvement – A just culture guide⁴⁴



A just culture guide

Supporting consistent, constructive and fair evaluation of the actions of staff involved in patient safety incidents

This guide supports a conversation between managers about whether a staff member involved in a patient safety incident requires specific individual support or intervention to work safely. Action singling out an individual is rarely appropriate - most patient safety issues have deeper causes and require wider action.

The actions of staff involved in an incident should not automatically be examined using this just culture guide, but it can be useful if the investigation of an incident begins to suggest a concern about an individual action. The guide highlights important principles that need to be considered before formal management action is directed at an individual staff member.

An important part of a just culture is being able to explain the approach that will be taken if an incident occurs. A just culture guide can be used by all parties to explain how they will respond to incidents, as a reference point for organisational HR and incident reporting policies, and as a communication tool to help staff, patients and families understand how the appropriate response to a member of staff involved in an incident can and should differ according to the circumstances in which an error was made. As well as protecting staff from unfair targeting, using the guide helps protect patients by removing the tendency to treat wider patient safety issues as individual issues.

Please note:

- A just culture guide is not a replacement for an investigation of a patient safety incident. Only a full investigation can identify the underlying causes that need to be acted on to reduce the risk of future incidents.
- A just culture guide can be used at any point of an investigation, but the guide may need to be revisited as more information becomes available.
- A just culture guide does not replace HR advice and should be used in conjunction with organisational policy.
- The guide can only be used to take one action (or failure to act) through the guide at a time. If multiple actions are involved in an incident they must be considered separately.

Start here - Q1. deliberate harm test

1a. Was there any intention to cause harm?



Yes

Recommendation: Follow organisational guidance for appropriate management action. This could involve: contact relevant regulatory bodies, suspension of staff, and referral to police and disciplinary processes. Wider investigation is still needed to understand how and why patients were not protected from the actions of the individual.

END HERE

No go to next question - Q2. health test

2a. Are there indications of substance abuse?



Yes

Recommendation: Follow organisational substance abuse at work guidance. Wider investigation is still needed to understand if substance abuse could have been recognised and addressed earlier.

END HERE

2b. Are there indications of physical ill health?



Yes

Recommendation: Follow organisational guidance for health issues affecting work, which is likely to include occupational health referral. Wider investigation is still needed to understand if health issues could have been recognised and addressed earlier.

END HERE

2c. Are there indications of mental ill health?

if No to all go to next question - Q3. foresight test

3a. Are there agreed protocols/accepted practice in place that apply to the action/omission in question?



If No to any

Recommendation: Action singling out the individual is unlikely to be appropriate; the patient safety incident investigation should indicate the wider actions needed to improve safety for future patients. These actions may include, but not be limited to, the individual.

END HERE

3b. Were the protocols/accepted practice workable and in routine use?

3c. Did the individual knowingly depart from these protocols?

if Yes to all go to next question - Q4. substitution test

4a. Are there indications that other individuals from the same peer group, with comparable experience and qualifications, would behave in the same way in similar circumstances?



If Yes to any

Recommendation: Action singling out the individual is unlikely to be appropriate; the patient safety incident investigation should indicate the wider actions needed to improve safety for future patients. These actions may include, but not be limited to, the individual.

END HERE

4b. Was the individual missed out when relevant training was provided to their peer group?

4c. Did more senior members of the team fail to provide supervision that normally should be provided?

if No to all go to next question - Q5. mitigating circumstances

5a. Were there any significant mitigating circumstances?



Yes

Recommendation: Action directed at the individual may not be appropriate; follow organisational guidance, which is likely to include senior HR advice on what degree of mitigation applies. The patient safety incident investigation should indicate the wider actions needed to improve safety for future patients.

END HERE

if No

Recommendation: Follow organisational guidance for appropriate management action. This could involve individual training, performance management, competency assessments, changes to role or increased supervision, and may require relevant regulatory bodies to be contacted, staff suspension and disciplinary processes. The patient safety incident investigation should indicate the wider actions needed to improve safety for future patients.

END HERE

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Based on the work of Professor James Reason and the National Patient Safety Agency's Incident Decision Tree



collaboration trust respect innovation courage compassion

⁴⁴ https://improvement.nhs.uk/documents/2490/NHSi_just_culture_guide_A3.pdf

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