Healthcare Improvement Scotland

A National Framework for Reviewing and Learning from Adverse Events in NHS Scotland

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> It is essential that all health workers, managers and leaders understand patient safety. In particular, they must be clear about the nature and importance of risk and how harm is generated, the core concepts of patient safety science, the ways in which the causes of unsafe care are investigated and understood, and the actions necessary to ensure that care, and its constituent individual processes, is as safe as is possible.
>
> World Health Organization (2021)

Contents

Significant Adverse Events: The Role of HIS

Healthcare Improvement Scotland (HIS) has worked collaboratively with NHS boards in recent years to:

- produce this revised national framework,
- develop learning networks for adverse events, and
- standardise the reporting of adverse events.

Building on this work, HIS will seek to ensure greater transparency about adverse events. We will use data and intelligence about adverse events to inform priorities for improving the safety and quality of care in NHS Scotland. This will mean a shift in our focus to the key priorities set out below:

- use the data from the national reporting to inform a range of interventions and initiatives undertaken across Healthcare Improvement Scotland to maintain and improve quality.
- undertake thematic and qualitative analysis of data (including learning from AE reviews) that we receive to improve quality.
- maintain and plan for quality by publicly reporting on the performance of significant adverse event reviews and adherence to the guidance in this framework, including the engagement of patients and families and completion within the specified timescales.
- continue to work closely with the Crown Office/Procurator Fiscal Service and other key stakeholders to develop and share learning from adverse events and Fatal Accident Inquiries.

Aligning to our Quality Management System

Effective quality management should lead to a variety of benefits for those who access services as well as those who deliver services

HIS promote an approach which is inclusive of all the key components of our quality management system (QMS). Further information on our QMS can be found on our website.

In line with our QMS, this framework recognises the complexity of healthcare systems within the NHS, and promotes a culture of psychological safety for staff. The framework recognises the importance of a no-blame, transparent and honest culture when adverse events occur, to enable improvement.

Our aims for the next two years are:

- consistent and coordinated identification and notification of significant adverse events for maintaining quality and improvement,
- consistency in how NHS boards commission and undertake significant adverse event reviews to improve quality, and
- developing the community of practice - our national learning system.

Our aims for the future also align to our intention to adopt a consistent and coordinated approach to maintaining and improving quality across NHS boards. To initiate these aims requires strong relationships with NHS boards which will enable us to support the boards in maintaining and planning for high quality care.

This will include developing our national learning system with a view to HIS providing quality assurance on the identification, reviewing and learning from significant adverse events. Quality assurance is vital in ensuring a positive safety culture is embedded.

To support the positive safety culture HIS will provide quality assurance by:

- Monitoring compliance of adherence to the principles in this framework, including meaningful engagement of patients/families.
- Monitoring compliance for timescales for completion of reviews of significant adverse events.
- Analysing themes and trends from the learning from significant adverse event reviews.
- Utilising the intelligence to inform our work on improvement, evidence and inspection.
- Publishing and analysing significant adverse events data.

Consistent and coordinated identification and notification of Significant Adverse Events for maintaining quality and improvement

> A culture of learning and accountability enable healthcare providers to embrace change for quality
>
> Chiponda et al (2023)

Aim

To establish a national approach for the consistent identification of significant adverse events by 2026. We will work in collaboration with NHS boards to agree a national defined list of what constitutes a significant adverse event. We will then amend the current significant adverse event review (SAER) notification process to allow all boards to report these events. We will use this to detect variations to give feedback to the boards. This will provide knowledge to facilitate national monitoring of trends and actions to maintain quality to inform quality planning and improvement.

Reasoning

Whilst some progress has been made towards national standardisation of significant adverse event reporting, there remains significant variation in the logging, reviewing, and reporting of adverse events. A more systematic approach is required to ensure the accuracy of reporting and trends of adverse events across all NHS boards. Ensuring consistent and reliable data will enable improvements in safety.

What will this involve

As is explained in this revised framework, the current categories for identifying significant adverse events will be replaced with agreed guidance on what constitutes a significant adverse event. They will also be provided with accompanying guidance on the revised notification system.

HIS will collate and analyse the data, identifying any trends. This will enable us to identify, monitor, maintain and support improvements in the delivery of safe and effective care nationally. This will form an important part of our learning system in maintaining, planning and improving quality.

HIS will work in collaboration with the NHS boards to update and develop the current significant adverse event data set. The notification system will evolve to include details of reviews, contributory factors and learning. This information will be used by HIS to drive improvements in patient safety.

Consistency in how NHS boards commission and undertake significant adverse event reviews to improve quality

> The true measure of cultural change and organizational development towards patient safety lies precisely in the effective integration of the analysis of adverse events into clinical and care practices.
>
> Bellandi et al (2020)

Aim

Undertaking the right review after each significant adverse event is an essential aspect of the learning system. Therefore, HIS will lead in developing a consistent and coordinated approach to the commissioning in Scotland by NHS boards of adverse event reviews. This will promote robust, meaningful analysis of the contributory factors and system wide learning.

Reasoning

Involvement in a significant adverse event can be traumatic. A consistent national approach to reviewing significant adverse events will help support patients, families and staff to understand the process and be clear about what they can expect, including how they will be kept informed and involved.

What will this involve

In 2025 we will work in collaboration with the NHS boards to agree a consistent and coordinated approach to reviewing all significant adverse events. To support decision making on whether or not a SAER should be commissioned there will be a clear systematic decision-making protocol for NHS boards. This will ensure robust, meaningful analysis and learning every time there is a significant adverse event. The purpose is to identify which contributory factors led to the adverse event and share this learning with the aim of reducing the potential for future harm. This ensures the maintenance of safety and quality and potentially reduces the risk of harm occurring in the future. Additionally, the outcome of all significant adverse events reviews will lead to actions which drive quality improvement.

Community of Practice

> Communities of Practice in particular offer a method for improving outcomes and sharing vital information across an ever more complex healthcare landscape.
>
> (Noar AP, Jeffery HE, et al, 2023)

Aim

To have a collaborative network of healthcare professionals across NHS Scotland, committed to sharing the learning from adverse events.

The online community has been developed and boards have now been trained in its use. In 2025 we will promote and support use of the community to share learning, and as a repository for tools and documents. The Community of Practice (CoP) is an example of an online national learning system.

Reasoning

Communities of practice are an important component of an effective learning system which is at the centre of good quality management. A learning system enables a group of people to come together to share and learn about a particular topic, to build knowledge and be empowered to improve outcomes. It connects and influences people and develops their understanding.

What's involved

Adverse events are complex and multifactorial. Communities of practice offer a sense of community for sharing information and shared problem solving. This will require individuals to commit to developing trusting and collaborative relationships.

Our community of practice will contribute to overall improvement in fostering and promoting a culture of learning and improvement to reduce the potential of future harm occurring. It is based on the ethos; everyone has something to share, everyone has something to learn and the opportunity to contribute.

HIS will facilitate the community of practice platform. NHS boards will upload learning summaries to the platform using the template provided in the toolkit. HIS will analyse the learning and identify any trends and emerging themes. This information will be shared with NHS Boards and colleagues across HIS at a national level to support the delivery and improvement of safe and effective care.

Introduction

An **adverse event** is defined as *an event that could have caused, or did result in, harm to people including death, disability, injury, disease or suffering and/or immediate or delayed emotional reaction or psychological harm.*

Health services in Scotland aim to provide high quality care that is safe, effective and person-centred. The delivery of healthcare takes place in complex environments and uses processes and procedures that may not always be straightforward. When an adverse event occurs the focus must be on learning from what happened and increasing the safety of the healthcare system.

This revised national framework is intended to provide an overarching approach developed from best practice to support healthcare providers effectively manage adverse events. This guidance may also be appropriate for use in social care and social work settings.

Tools have been developed to promote consistent implementation of the framework. These can be found in the toolkit on the HIS website. The tools in this framework include:

- SAER template.
- A learning summary template.
- A quality assurance checklist for completing reviews
- A risk matrix.

Harm may result from (but not limited to):

- the unexpected worsening of a medical condition.
- the inherent risk of an investigation or treatment.
- violence and aggression.
- system failure.
- provider performance issues.
- service disruption, and
- financial loss or adverse publicity.

An adverse event review will help to identify whether the potential harm, or actual harm, associated with the adverse event was avoidable. Some harms are not avoidable, for example the worsening of a medical condition or the inherent risk of treatment. It may not be possible to determine if the harm caused was avoidable until a review is carried out. Areas for improvement are often identified even where harm was not avoidable.

Throughout the framework the term patient/family is used. This includes the person who experienced the adverse event and/or whoever is representing them. This may be a family member, a representative, an advocate or a personal contact of the patient who has been asked to attend with or for them.

Background

> Learning from adverse events is important to facilitate continuous improvement to the safe and effective delivery of healthcare. In turn, this contributes to achieving the Scottish Governments vision of high-quality healthcare which meets the needs of the population.
>
> (Gray 2024).

This framework has been developed by HIS in collaboration with the NHS Scotland health boards and key partner organisations. It provides guidance and templates for reviewing and learning from adverse events. The aim is to improve the review process for patients, families and staff affected by a significant adverse event. This is underpinned by a strong focus on adopting a consistent approach to learning from significant adverse events.

Adverse event reviews should not be about apportioning blame. The purpose is to identify what went wrong, why it happened and what can be done to reduce the potential of future harm or reoccurrence. The review process also promotes openness and honesty with people when things go wrong. It promotes the offer of an apology as soon as an adverse event has been identified. The review process must be transparent and include patients, families and staff who were involved in the adverse event. The NHS board needs to identify the learning and develop action plans to implement identified changes.

On completion of the review, the findings and learning should be shared with everyone involved in the event and all who can implement learning actions.

Learning summaries should be uploaded onto the Community of Practice portal. This is a website where all Scottish NHS boards can share learning summaries to facilitate national learning. This portal is available to all NHS boards and is hosted by HIS.

Aims

The Adverse Events Framework provides guidance to allow NHS boards to:

- Apply a consistent national approach to the identification, reporting and review of significant adverse events.
- Ensure the affected person is given the same response regardless of where in Scotland the significant adverse event occurs.
- Involve and support patients and families throughout the adverse events review process.
- Support staff in a consistent manner.
- Promote adverse event reviews being undertaken in a timely and effective manner.
- Share and implement learning to improve the quality of services.
- Share learning across NHS Scotland to drive improvement in patient safety.

Principles

The review process outlined in this framework is underpinned by the following principles:

- **Care and compassion:** The review process should be person centred with patients, families and staff feeling safe throughout.
- **Openness and respect:** A transparent approach is taken with everyone involved treated with openness, honesty and respect.
- **Learning:** Identifying, sharing and disseminating learning is a primary focus of the review process.
- **Empowerment:** Patients, families and staff are supported to ask questions during the review process. Staff are empowered to speak up and raise concerns without the fear of negative repercussions.

Disciplinary processes and complaints

Whilst it is rare, there may be occasions where it is appropriate to invoke your organisations suite of disciplinary processes.

If a concern arises that there is a possibility that a criminal act may have been committed, then the NHS board should involve the Police.

In the circumstances where a complaint is submitted to the NHS board then this should be dealt with separately through the usual complaint processes.

Legislation

The Patient Rights (Scotland) Act 2011 sets out what patients in Scotland have a right to expect of their health services and places a duty on healthcare providers to uphold the principles in the Act. These principles include that patients should be supported to participate in decisions relating to their care and treatment and be provided with appropriate information to enable that. The principles also include that no avoidable harm or injury is to be caused to patients by the health care provider, that patients should be cared for in an appropriate environment that is as clean and safe as reasonably possible. The principles are reflected in the approach set out in this framework.

This framework incorporates the Health and Care (Staffing) Scotland Act 2019 which was passed into law in June 2019 and came into effect in April 2024. This provides a statutory basis for the provision of appropriate staffing in health and care settings. The act seeks to enable safe, high-quality care, and improved outcomes for service users and people experiencing care. It builds on arrangements already in place for local, regional and national workforce planning. It promotes transparency and an open and honest culture. The provision of appropriate staffing is a key element in reducing the risk of serious adverse events.

The Carers (Scotland) Act 2016 emphasises the importance of involving carers in decisions affecting the individuals they care for. The principle within the act of carer involvement is an important aspect of the SAER process. This is reflected in the framework by involving patients and their families/carers and recognising the valuable insights they can provide. Involving carers in the SAER process supports alignment with the principles of the carers (Scotland) Act 2016 ensuring carers insights contribute to learning from adverse events and support the effective delivery of care.

The Duty of Candour legislation also seeks to promote an open and transparent approach to apologising when an unintended or unexpected event occurs which results in harm. Both pieces of legislation and this revised version of the framework seek to form a coherent approach to support NHS boards. This will enable the fostering of a culture that prioritises improving transparency, accountability and quality in the delivery of safe and effective care.

The Adults with Incapacity (Scotland) Act 2000 provides a framework for decision making on behalf of the individual who lacks the capacity to make decisions for themselves. Where an adverse event has occurred, it is important to consider the rights, needs and wellbeing of individuals with incapacity. The legislation emphasises the need for appropriate decision making in the best interests of people who lack capacity. This will ensure legal safeguards are respected and that any incidents involving such individuals are investigated with consideration of their legal and personal rights. The integration of these considerations ensures that NHS practices remain compliant with the law and protect the vulnerable.

Reviewing an adverse event

> The review has taken 18 months. I've been living and reliving his death every day.
>
> Relative of a patient involved in a SAER (2023)

Introduction

The framework describes the six stages of review following an adverse event. This approach to reviews of significant adverse events ensures systems and processes are in place to disseminate safety-related alerts and recognises the importance of complaint reports in identifying areas of concern. Following an adverse event, the needs of the patient/family and staff must be considered and managed. A human factors approach should be used to undertake the review and analysis of an adverse event.

Standardisation of approach across NHS Scotland is required to allow learning to be shared and improvements to be made for all patients in Scotland. To support this, an adverse event must be recorded on the NHS board's electronic reporting system to ensure data is shared in a systematic way. Information is provided for the categorisation of an adverse event and to determine the level of review required. The use of a SAER reporting template promotes a consistent approach to the reporting of reviews across NHS Scotland. The recommendations made at the end of the review will promote learning and improvement within the NHS board. By recording the learning onto the standard learning template, lessons can be shared within and beyond the organisation by being uploaded to the Community of Practice portal.

Aim

The aim of reviewing adverse events is to maximise learning, improve systems and processes and reduce the potential of future harm. This will contribute to the safe and effective delivery of high-quality care.

Reasoning

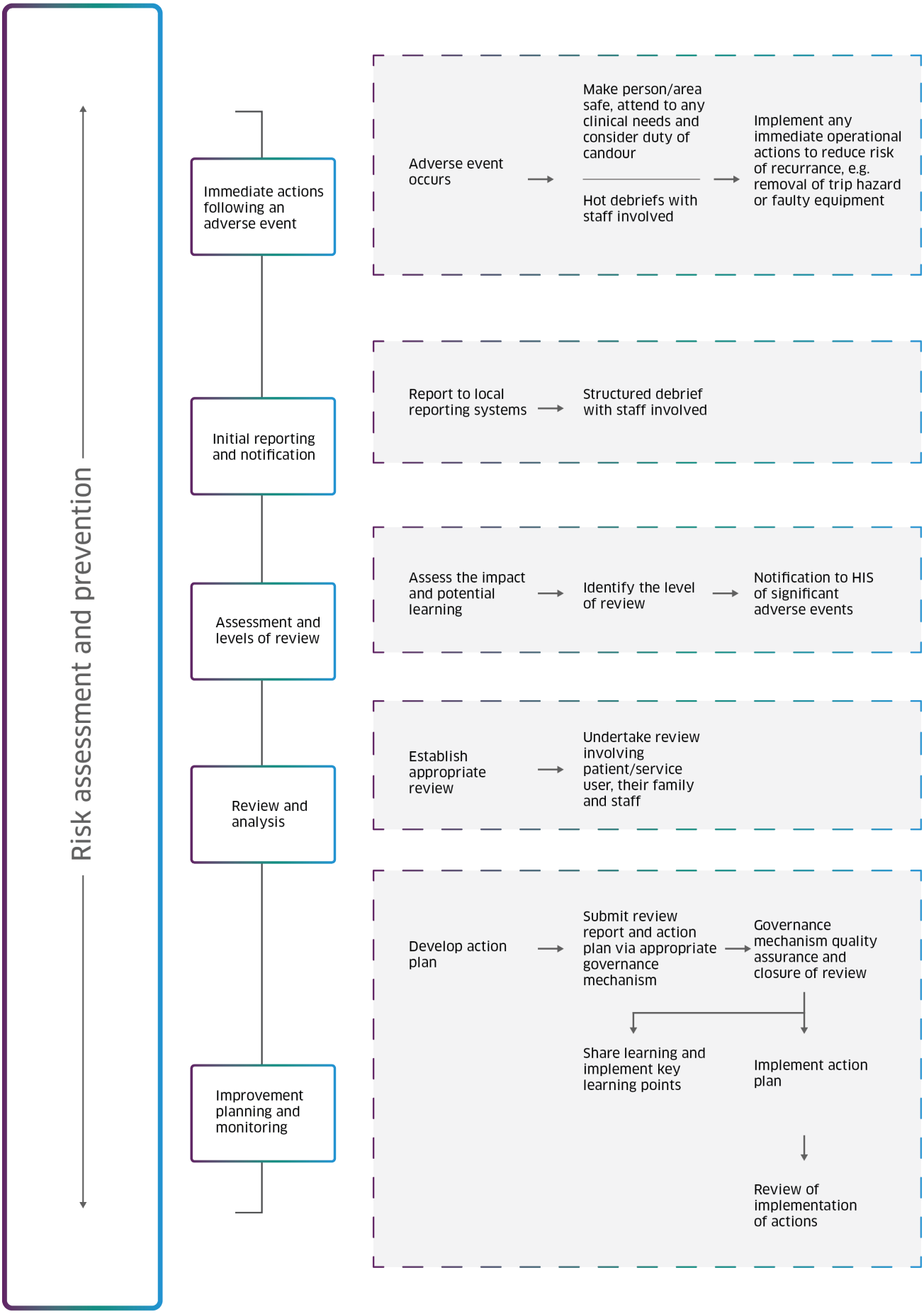
Learning from adverse events supports the creation of a safety culture. This also helps drive improvement in the delivery of safe, person centred and effective care.

What is involved

An effective approach to reviewing adverse events helps to understand what went wrong, why it happened and to reduce the potential of future harm. The review process can help identify system failures that may have caused the adverse event. It can also highlight training or support requirements. However, it is important to remember adverse event reviews should not be about apportioning blame.

This guidance, summarised in Figure 1, describes the six stages of a review, and the three levels of review (1-3). A level 1 review is required for all significant adverse events. In addition, a SAER should be commissioned for events where staff, clinicians or managers believe there is significant learning to prevent potential harm. The response to each adverse event should be proportionate to its scale, scope, complexity and opportunity for learning.

Figure 1: Actions to effectively review an adverse event.



Actions to effectively review an adverse event.

Stage 1 - Risk assessment and prevention

Adverse event management is an important part of an effective risk management strategy. For further information about assessing risk refer to the 'Risk' chapter.

Key points:

- Use risk assessments to identify and mitigate against potential hazards.
- Use hazard identification checklists and sector-specific guidance to identify hazards prior to risk assessment

Key learning from adverse event reviews and other safety lessons, such as safety alerts, is an essential part of risk prevention. Safety alerts can be used to rapidly alert the healthcare system to risks. They also provide guidance on preventing potential events that may lead to harm. Effective structures should be in place to generate, receive and act upon safety alerts throughout the NHS board.

Governance principles for the management of adverse events should be integrated with the organisation's risk management strategy and governance processes. This includes 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 more effective governance of the process by providing the necessary support and oversight.

Stage 2 - identification and immediate actions following an adverse event

Addressing the needs of the patient/family affected by the adverse event is a priority. This may include urgent clinical care to reduce any harmful impact.

Key points:

- Identify an appropriate named contact to work with the patient/family who will:
  - establish whether or not the patient/family wish to be involved in the review
  - their preferred method of communication and involvement
  - explain the scope of the review and likely timelines
  - keep the family informed and up to date, and
  - make sure questions or concerns raised by the patient/family are shared with the review team.
- Identify a representative to apologise to the patient/family on behalf of the board.
- Establish a Terms of Reference (ToR) document for the review.

For detail on engaging patients/families please see the 'Patient/family involvement in a Significant Adverse Events Review' chapter.

Following the adverse event the staff involved may require support. This support should be provided throughout and after the review and in a way that meets their needs.

Key points:

- NHS boards should ensure immediate access to support for staff involved in adverse events. A hot debrief or discussion that takes place immediately following the event is an important part of staff support.
- Staff are offered psychological first aid and access to debriefing and support during the review process
- The impact on staff involved in an adverse event must be recognised and they must be provided with ongoing support.
- NHS board policies should consider the principles of psychological safety

For detail on support for staff please see the 'Staff involved in an Adverse Event' chapter.

Stage 3 - Initial reporting and notification

When an adverse event (or near miss) is identified, it should be recorded using the NHS board's local reporting system as soon as possible after the event, ideally within one day. In some circumstances there may be an exceptional reason for the delay for example, retrospective identification of events that could cause harm. All staff should receive training on the electronic reporting of an adverse event.

The information to be reported should include:

- An honest and factually accurate account of the adverse event.
- A detailed description and outcome of the event.
- Any remedial actions and treatment provided.
- The details of any other staff involved or aware of the event.
- Dates, times, locations?
- Any patient related details? Anonymised?

Following an adverse event, local policies will define the notification and escalation procedures. NHS boards may wish to develop a flow chart to outline the notification and communication process. This will distinguish between the out-of-hours and in working hours arrangements.

When external agencies are involved, NHS boards should ensure there are appropriate arrangements in place to support both local reporting and external agency reporting.

Stage 4 - Assessment and levels of review

The focus on learning from the adverse event aims to ensure that responses are not purely focussed on the impact or outcome. A near miss with no adverse outcome may warrant a higher-level review where there is potential for learning. This may provide an insight into potential underlying weaknesses in the system or areas which 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?

Levels of Review

All adverse events should be subject to some level of review and analysis. There are three levels of review:

Level 1: significant adverse event analysis and review or equivalent

Level 2: local management team review

Level 3: local review by line manager in discussion with staff

The level of review will be decided based upon:

- The national list of significant adverse events[1]
- The severity of the harm or potential harm,
- The potential for learning, both national and local.

Events which cause significant harm or where staff or clinicians identify significant learning require a level 1 or SAER. This requires a range of techniques to thoroughly consider the contributory factors.

On any occasion when staff, clinicians or managers believe the near miss or adverse event could occur again and result in a more significant or harmful outcome, a level one review should be completed.

The national list of significant adverse events is compiled and administered by HIS and helps local governance teams identify events with the highest levels of harm, or where a specific national focus has been identified.

Where a significant adverse event occurs, but local governance teams decide that a level 1 review is not required, this, and the reasons for coming to that decision, must be clearly documented.

[1] Guidance on categories of event are included in appendix 1, this will be replaced by the list of significant adverse events in 2025.

Table 1: Guide to the three levels of reviews

Level	Review Type	Review Team	Stages	Timeline	Total
1	Significant Adverse Event Review or equivalent	Full review team using validated analysis tools or evidence of screening and clear rationale for any not progressing to analysis. 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.	Review commissioned following logging of adverse event on local electronic adverse event reporting system	<10 working days	<140 working days
			Review completed, and report submitted for approval from commissioning date	<90 working days	
			Final approval and local sign-off as soon as possible	<30 working days	
			Develop improvement plan within 10 working days from report being approved	<10 working days	
2	Local management team review	Service manager with multidisciplinary team input.	Review completed, and report submitted for approval following logging of adverse event on local electronic adverse event reporting system	<30 working days	<70 working days
			Final approval following report submission	<30 working days	
			Develop improvement plan following approval	<10 working days	
3	Local review	Line Manager in discussion with local staff.	Adverse event approved and closed following being logged onto the local electronic adverse event reporting system	<10 working days	<10 working days

To create an audit trail, information, communications and outcomes should be recorded on the local reporting system. The decision to proceed, or not, to a SAER should also be clearly documented.

Stage 5 - Review and analysis

The purpose of the review is to determine what happened, how it happened and why it happened. Details for undertaking a review and a template are described in the Significant Adverse Event Review (SAER) Report Writing Guidance section.

Taking a human factors approach is critical to undertaking a review. This can help reviewers understand how interactions between people and systems can combine to cause a significant adverse event.

Stage 6 -Improvement planning and monitoring

Following analysis of the adverse event and agreement on the contributing factors, the review team should make recommendations to drive forward the improvements. Details for identification of recommendations, development of improvement plans and implementation and monitoring of these can be found in the 'Identifying learning and improvement' chapter.

Managing adverse events should link with safety and quality improvement systems. Links should also exist with managing complaints to ensure learning and improvement activity are integrated and co-ordinated. Learning from all sources of data provides the NHS board with a true reflection of where things are going wrong.

Learning should then be fed back into risk assessments to highlight the controls these improvements provide in minimising risks to Health boards.

Review Outcomes

A review may conclude that the care delivered was appropriate and an event was unavoidable. Not all adverse event reviews will identify system failures. The potential for learning in these cases should still be recognised and areas of good practice shared appropriately. The following outcome codes should be applied to adverse event reviews to indicate the findings. Linking the healthcare provided with the outcome allows identification of the events where the improvements are required.

1. **Appropriate care** - The adverse event review concluded that the healthcare and/or service was well planned and appropriately delivered. No care or service delivery problems were identified, and the adverse event outcome was unavoidable. However, it is likely there are still learning points for example highlighting areas of good practice.

2. **Indirect system of care issues** - The adverse event review identified indirect or incidental sub-optimal care or service issues. Lessons could be learned and any good practice points identified. For example, a protocol was not strictly followed or there was a delay in accessing case notes. However, these are examples of areas of improvement that were unlikely to have affected the final outcome.
3. **Minor system of care issues** - The adverse event review identified minor or suboptimal care or service provision. A different plan or delivery of care/service may have resulted in a different outcome. Factors were identified such as incomplete records or a delay in transferring the patient or service user. However, there was uncertainty regarding their impact on the 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 would 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.

Timescales

The following guidance refers to SAERS, but it is anticipated that all reviews of significant adverse events would be completed in 140 working days, or less. The timescales below are for guidance only, and NHS boards should allocate timescales locally, but always adhering to the 140 working days for completion. It is essential that the timescales outlined below are followed. Any delay may pose an unavoidable risk of recurrence of the adverse event before learning has been identified. Delays may also add additional distress caused by the review process to the patient/family and staff.

The following timescales are guidance:

- Commission a SAER within 10 working days of the adverse event being reported on the local reporting system.
- Commence and close a SAER, including writing the report in 90 working days.
- Final approval should take place as soon as possible and no later than 30 working days from the submission of the SAER report.

- Finalise the learning summary and improvement plan within 10 working days from SAER report being approved.
- Working days are defined as weekdays which are not designated public holidays.
- The learning outcomes of the completed and signed off review, should then be used in the development of an improvement plan to be shared locally and nationally, as appropriate within 10 working days.

The SAER process should only be paused or delayed in the exceptional circumstances of legal proceedings. These should be documented in the SAER report and the patient/family and staff involved should be informed regularly of the reason for the delay and the projected timescales. Any delay may have a detrimental effect on the:

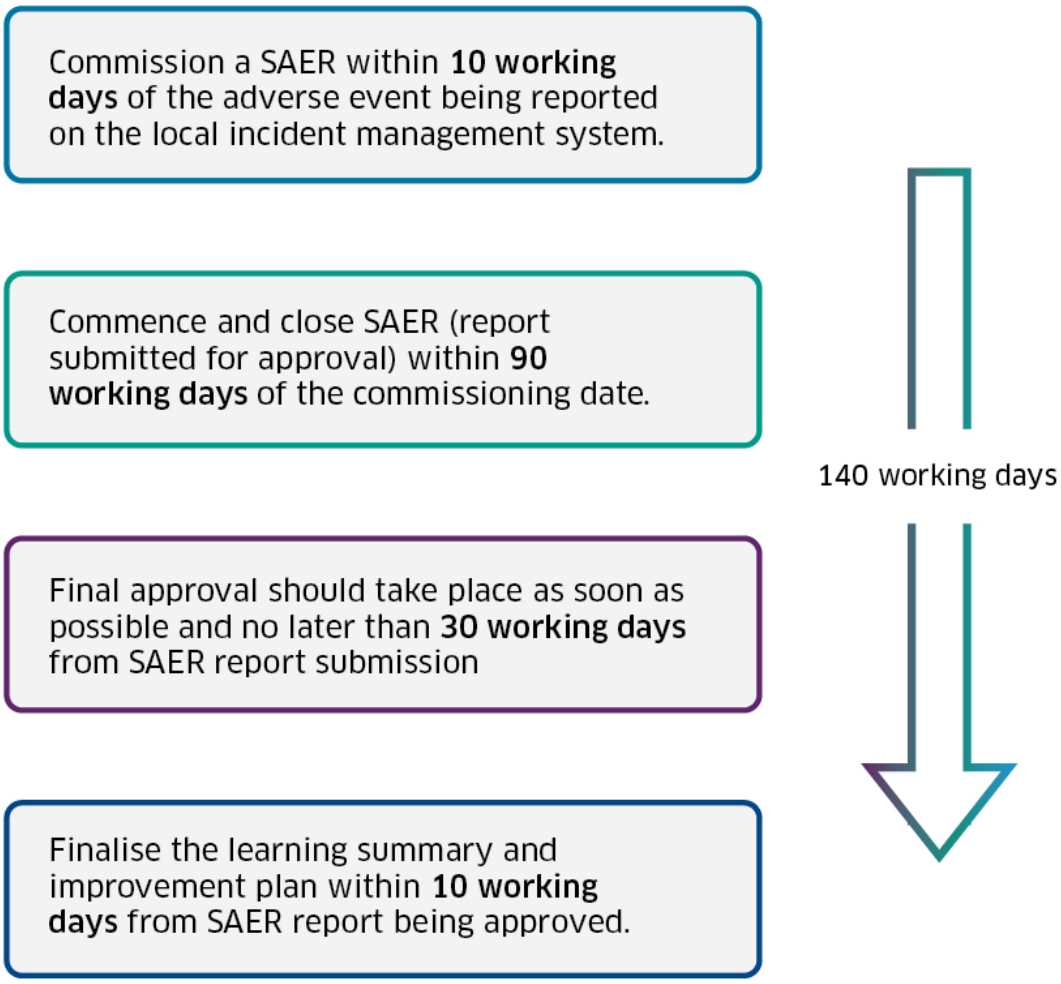
- patient and family
- staff, and
- the work of partner organisation reviews such as the Procurator Fiscal Service.

The SAER aims to identify and share learning to prevent recurrence. Additionally, it could minimise the consequence and impact of any recurrence of the event. Learning gathered from the completion of the SAER should be included in the learning summary and an updated improvement plan. Any delays in the SAER could adversely impact learning being shared in a timely manner.

If any timescale cannot be met, the patient/family and staff involved should be informed of the reason why. They should also be advised of the anticipated length of delay.

Figure 2 provides a guide on completing the SAER.

Figure 2: Guide to complete a SAER



Significant Adverse Event Review (SAER) Report Writing Guidance

National template for Scotland

A national approach for reviewing SAERs aims to ensure consistency across the country. The key findings section, which includes learning provides information from which the learning summary can be written and shared locally and nationally.

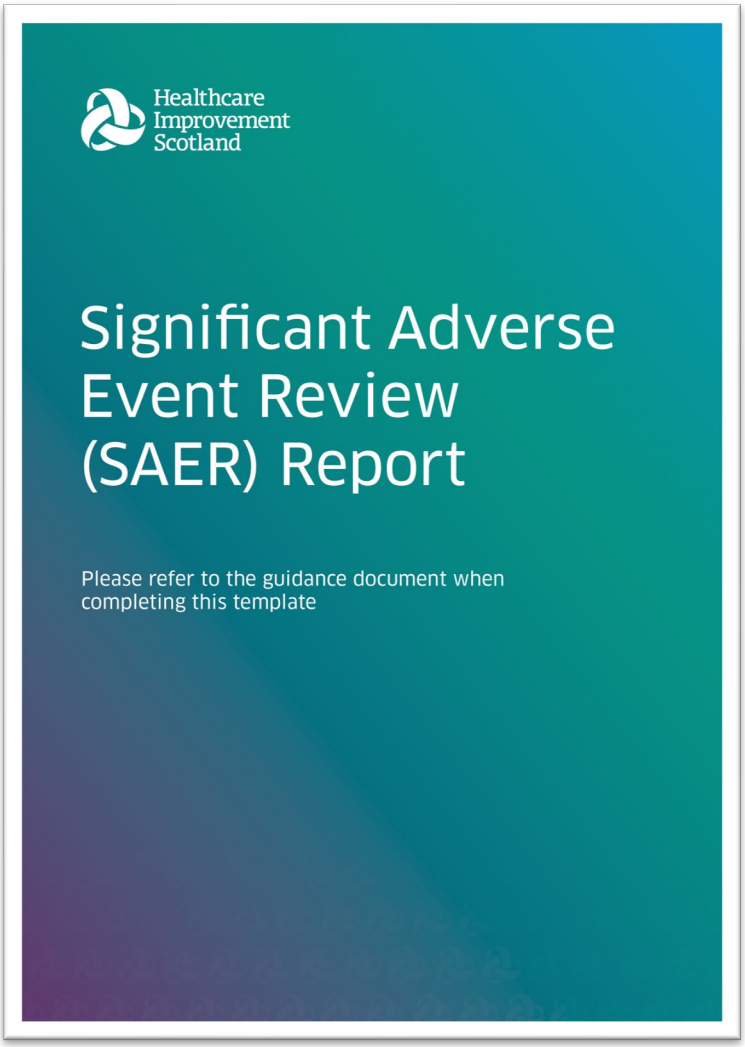
Purpose of a SAER

- The SAER report will include information about the significant adverse event and what happened. The review methodology, findings and conclusions should be clearly described and any recommendations documented. Recommendations will be designed to reduce the potential of future harm.

- The recommendations will inform the development of an action plan to address the findings of the SAER in a timely manner.

Significant Adverse Event Review (SAER) Report

The SAER Report template can be found on the HIS Adverse Event website.



How to complete the template

- The content of the report must be factual and clear, avoiding additional distress to those involved. It is important to remember that patient/family and staff involved in the adverse event are part of the target audience. There must not be an indication of blame.
- Write in plain English using short sentences for ease of reading and understanding.
- Where possible avoid using technical terminology and abbreviations. If these are required, provide explanations in the useful information section.
- The SAER report should identify improvement actions to be taken forward whilst avoiding the term ‘lessons learned’.
- To support accessibility, use font Calibri 12 when completing the SAER report.

Executive summary

- This should be completed after the main report has been written. It provides an overview of the main report, including the event, key findings and recommendations. This summary details only the most important aspects of the SAER. The detailed description of the event must not be repeated here.
- A drop-down list is provided to allow selection of the correct outcome.

Acknowledgements

- Add information into this section to acknowledge the people you wish to thank for their input into the SAER.
- Suggested wording could be: 'We would like to thank everyone who has participated in this SAER. This includes the patient/family, staff and others who have provided information which has identified the areas of learning and improvement.'

Useful information

- The naming convention of the patient/family used in the SAER report should be agreed with them, where possible and should also be recorded here. Patients and their families should be advised that as the agreed name will not be redacted before the report is published and shared, they may wish to anonymise the details.
- Consideration must be given to how staff are described in the SAER report. For example, staff should be typically described as Dr A, B or Dr 1, 2.
- The SAER report should be written in a way that minimises the need to redact person-identifiable information of those involved including the patient/family, staff and SAER panel.
- Include a concise list of definitions, acronyms and descriptions of medical terminology which will help with the reading and understanding of the report. A full list can be included in the appendix which should then be referenced under the concise list in the report.
- Diagrams, process flow charts or other relevant information can also be included in the appendix.

Terms of reference and review process

Every SAER requires a ToR to be developed. Please note that these may be subject to change throughout the duration of the review.

Method/approach used

- Briefly describe the approach to be used to uncover the cause of the significant adverse event, for example, root cause analysis or human factors.

- Include the role and designation of team members including the named contact for the patient/family.

Key considerations and questions

- This section should record points to be reviewed by the team.
- Any questions and/or concerns raised by the staff involved (patient/family queries are in the next section) should be documented in the ToR.
- Consider the role of the environment and impact from this in the adverse event.
- Include information about staffing levels, for example staff shortages, inappropriate skill-mix, sickness absence.
- Consider any relevant legislation.

Period covered by the review

- A review may cover a specific event that took place on a single day or relate to a review of healthcare provided over a specified time. Specific dates should be included where possible.

Staff

- The engagement process with staff should be described in a sensitive manner being mindful that they may have required support throughout the SAER process.

Recording of discussion and review of paperwork

- Following discussions with staff, and any required review of patient records, provide a summary of relevant information used to inform the SAER.
- If the case was reviewed at a Morbidity and Mortality Review or Team-Based Quality Review, describe any learning that was shared with the review team.
- Describe any policies, processes and procedures that were reviewed. Documents can be added as an appendix. Any important points from the policy should be highlighted here along with an explanation of their relevance to the SAER.

Involvement in the significant adverse event review process

- Include areas of importance to the patient/family (including scope, contact and what matters to them).
- Include the patient/family's preferred level of engagement in the review process, including any questions and concerns.
- When there have been challenges in engaging with them or contact has been unsuccessful, this should be described sensitively in the SAER report.

Summary of information from discussions with the patient/family

- Describe the agreed process for contact, for example, weekly telephone calls.
- Write a summary of all relevant information following discussions with them.
- List any outstanding questions and concerns made by the patient/family and describe the plan to address them.
- Questions and concerns raised by the patient/family which do not relate directly to the review, should be forwarded to an identified person who is able to answer them. Document this in the report as evidence for the patient/family that the review team have heard and responded to all their questions and concerns.

Description of event

- Describe the event including the timelines, rationale for decisions taken at the time and relevant background information. It is important to avoid language which would indicate any blame.
- Include questions and/or areas of concern raised with the responses.
- This section should not include any analysis of the event or key findings.

Key findings

Analysis of findings

- Write in a direct way such as the 'review found' and not from the perspective of those involved.
- Focus on why the event happened, avoid describing what happened again.
- Link back to the questions identified in the terms of reference.
- Identify the situational and contextual factors associated with the event and how they have been understood.
- Identify the contributory factors, including human and system failures which led to the event. Use open questions (such as those below) to help identify the key issues. This includes whether each action, inaction and decision was reasonable including consideration of environment, people and activities. Explain the rationale and evidence used to reach any conclusions.
- Identify learning and corrective actions and clearly link them to the highlighted contributory factors.
- Throughout the report avoid to the use of language that indicates blame.

Example questions to identify contributory factors (this is not an exhaustive list):

- Was the initial patient assessment reasonable?
- Did the safety brief include all the essential information?
- Was the medication prescribed appropriate?

- Was information provided to the patient/family appropriate?
- Was patient supervision as directed?
- Were the staffing levels and skill mix adequate for the acuity and dependency of the ward at the time of the event?
- Were there any other known safety concerns?
- Were there staff shortages?
- Were there any equipment issues, for example malfunctioning equipment or training and education issues?
- Was all required equipment available at the right time?
- Were there any challenges with the physical environment that may have contributed?
- Were standard operating procedures followed correctly? Were these up to date?

Areas of good practice

- Include things that went well.

Learning identified

- Summarise the main learning points which will be explored in more detail in the learning summary.

Conclusions

- Summarise the findings from the SAER and use to provide a closing statement.

Duty of candour

- If a decision as to whether the duty of candour threshold has been met, please record by selecting either yes or no. If this decision has not yet been taken or is unknown select decision pending.

Recommendations

Recommendations should be presented in order of importance to address the main contributory factors and key system changes. They must:

- Relate directly to the key findings of the SAER report.
- Be clear and stand alone.
- Fully describe the rationale behind each recommendation.

Quality of Review

> Quality is never an accident. It is always the result of intelligent effort.
>
> John Ruskin (1849)

Aim

A good quality adverse event review seeks to reach outcomes that will improve the safe and effective delivery of healthcare, practices and processes where needed and support a culture of continuous improvement.

Reasoning

A good quality review will seek to identify root causes, enhance patient safety and improve processes and systems within the healthcare environment. This will support a learning culture and support compliance with national standards, regulations and legislation.

A good quality adverse event review will align with NHS Scotland's commitment to continuous improvement and should takes a systems-based healthcare quality improvement approach which is person centred, safe, effective, efficient, equitable and timely.

What is involved?

The quality of an adverse event review will be evidenced by both immediate and longer-term outcomes. Indicators of these outcomes will include the implementation of action plans that are effective and measured. Through ongoing monitoring improvements in the following may be observed:

- Reduction in similar adverse events
- Improvement in patient safety
- Changes to policies, procedures, training or systems that address the root causes identified through the review, and
- Improved workflows or updated clinical guidance.

There should be evidence of organisational learning, observation of reports, presentations, training and staff able to demonstrate an increased awareness of risks and mitigations to manage them and these learnings included in the organisation's risk register where appropriate

Stakeholder feedback will support evidence of patients, families, and staff involvement and seeking to understand concerns have been addressed.

Audit activity and scrutiny activity should provide assurance that standards, regulations, guidance and legislation are being adhered to and followed.

A culture of increased reporting of incidents and/near misses will indicate that staff feel safe and supported to report without fear of blame and further support a culture of transparency and continuous improvement.

Quality checklist

The following checklist provides a systematic approach to verifying all necessary steps are taken in the six stages of an adverse event review. Thus, ensuring a quality-based approach.

Stage 1: Risk assessment and prevention

What learning can be identified from the following:

- Inspections, audits, risk assessments and hazard identification. What mitigating actions have been put in place to minimise these risks?
- Complaints, compliments, concerns, claims, duty of candour events and adverse events.
- Lessons learned from previous adverse event reviews

Stage 2: Identification and immediate actions following an adverse event.

- What steps were taken to meet the needs of individuals affected by the event?
- Describe the steps taken to re-establish a safe environment.
- How long after the event occurred were the records updated?

Stage 3: Initial reporting and notification

- What training has been provided for staff involved in using the event reporting system?
- How are you assured that all relevant information is recorded and accurately describes the event?
- Following the adverse event which local policies are in place to define the notification and escalation procedures?

Stage 4: Assessment and categorisation

- How are you assured that the relevant manager has accurately assessed the reporting system form to consider the organisations response following the adverse event?
- How do you know that the adverse event was accurately categorised to determine the level of review required?
- What local mechanisms are in place to quality assure the categorisation of events?
- What actions were taken if the original categorisation was inappropriate?
- Was the decision whether to proceed, or not, to a SAER clearly documented?

Stage 5: Review and analysis

The NHS boards should self-evaluate the SAER process to establish:

- That the SAER process accurately identifies what happened. How are you assured that this has accurately identified what happened?
- Learning points for the service, wider organisation, or nationally have been identified. How are you assured that these learning points have been identified?

Stage 6: Improvement planning and monitoring

The NHS boards should self-evaluate the SAER process to establish:

- The action plan developed accurately reflects the findings and recommendations. How are you assured that the action plan does accurately reflect the findings and recommendations?
- The steps taken to ensure effective implementation of the actions. What steps have been taken to ensure effective implementation of the actions?
- That good governance arrangements are in place regarding timeframes, using a consistent approach and monitoring of any work. How are you assured that there is good governance and monitoring arrangements in place in regarding timeframes?
- The level of learning was decided upon including the reasons why and whether this has been efficient and effective. How are you assured that the level of learning has been efficient and effective?
- The steps taken to measure and evidence any improvements. What steps are you taking to measure and evidence improvements?
- Evidence of any reduction in adverse events.

Patient/family involvement in a Significant Adverse Events Review

> I was heard, and it made me feel safe going forward in the future because I'm likely to have this (medical issue) again, and I'm likely to be seen (by that healthcare professional) again…. So, it made me feel incredibly safe, it made me feel heard. And it was like, actually that's all I want, that's all I need to feel safe going forward.
>
> McQueen et al (2023)

Introduction

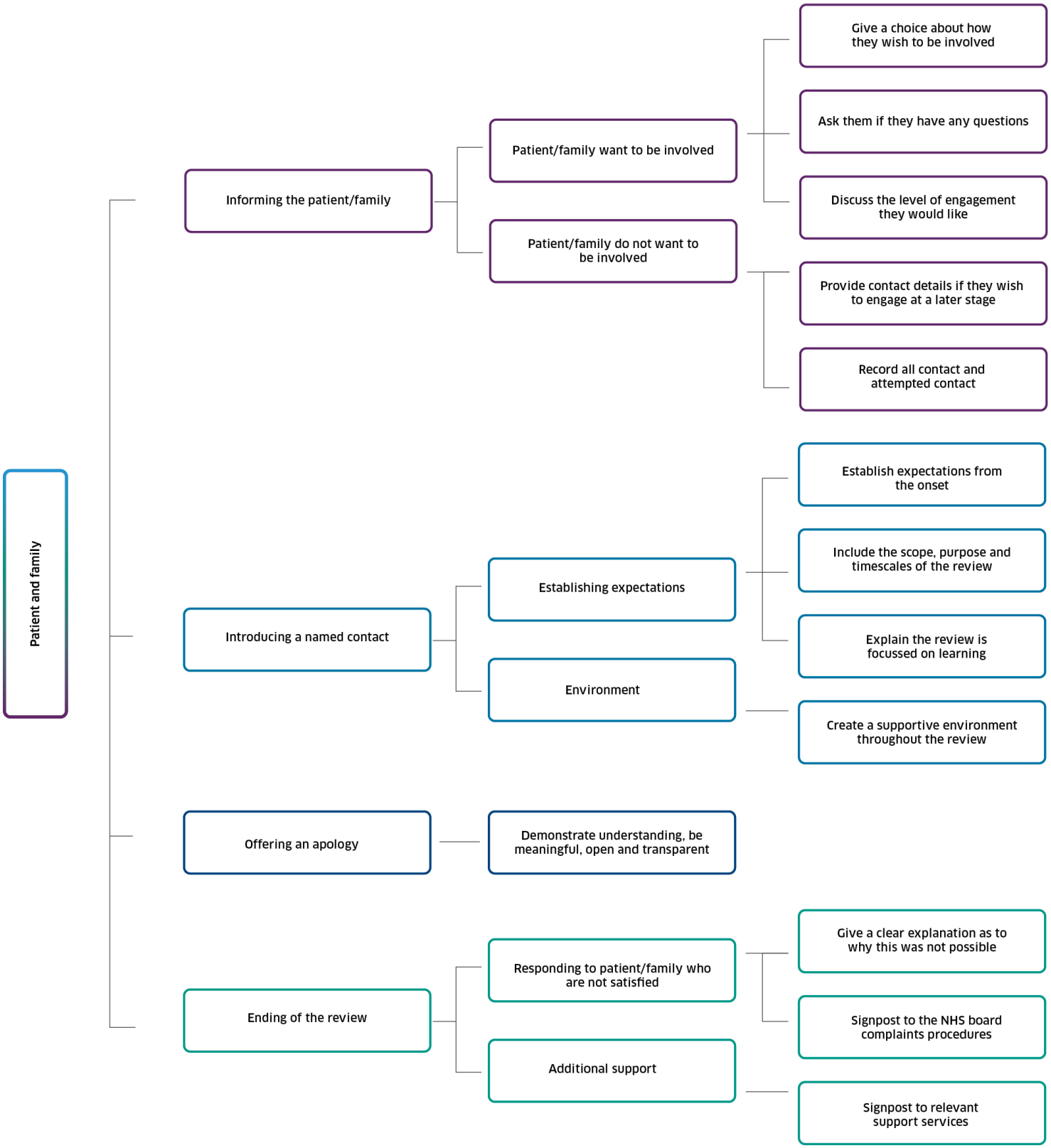
This chapter focuses on the requirement for the patient/family to be involved in a supported manner throughout the review of the significant adverse event.

This chapter provides guidance on how to prepare staff to engage with the patient/family during the review. There is a specific focus on:

- informing of the review
- the patient/family who do not want to be involved in the review
- introducing a named contact
- establishing expectations.
- the environment.
- importance of offering an apology
- completion of the review
- responding to family who are not satisfied, and
- additional support required.

This is outlined in Figure 3.

Figure 3: Engaging with patient/family flowchart



Informing the patient/family of the review

Aim

When a significant adverse event has occurred, the patient/family should be informed at the first opportunity. They must also be invited to contribute to and be informed throughout the review process. They must be given a choice about whether and how they wish to be involved. This includes asking if they have any questions/concerns that they would like to be explored during the review process.

Reasoning

The patient/family has a unique understanding of what happened to them. As such they can add a different perspective, provide context, and add additional information which may assist the review process. They may be the only people with insight into what has occurred at every stage of the journey through the healthcare system.

From the onset, it is important to advise that the primary objective of the review is to identify learning and to ensure that any observations or recommendations are implemented. Assessing the needs, expectations and concerns of the patient/family is important. This ensures the appropriate information and advice is given to them in a way that meets their needs.

What is involved?

When contacting a patient/family who have experienced an adverse event, it is important to be mindful of the potential psychological impact and distress they are experiencing. All interactions should be person-centred, open, honest and transparent. The member of staff should demonstrate care and compassion in all communications and consider the wishes of the patient/family when discussing the review. The member of staff should be skilled in relevant topics, such as communication and trauma informed practice.

It is important to discuss with the patient/family, the level of engagement that they wish to have in the review. They must also be advised that this can be changed if they wish throughout the process. It is also important to ask if they have any questions/concerns they would like to be explored during the review process.

Patient/family who do not want to be involved in the review

Aim

The patient/family may not wish to engage at the initial stages of the review process. They should be given the details of the named contact should they wish to engage at a later stage or receive occasional updates.

Reasoning

The patient/family have been through an experience which may have been traumatic and distressing. The consequence of this can impact on their decision to be involved in the review, but they can engage with the process later, should they wish. Having the opportunity to request the findings and recommendations of the review also gives them the opportunity to be informed.

What is involved?

If the patient/family do not wish to participate in the review, then consideration should be given to any information they could be provided with as the review progresses. This should include contact details for a named contact who they could liaise with directly if they wish. The named contact could provide details about the report and discuss the expectation that the review protects the anonymity of all of those involved. The named contact should also check if they would like the opportunity to review the report for factual accuracy.

A record of all contacts with the patient/family, attempted contacts or a rationale for deciding not to make any further contact should be documented in the review records. Where the patient/family decide not to engage this also should be documented.

Introducing a named contact for the patient/family involved in the review.

Aim

The person who is the NHS board named contact should liaise with the patient/family once they have confirmed that they wish to engage in the review and should be available to the patient/family throughout the review process. They will provide a route for the patient/family to identify what matters to them. The named contact will ensure that all questions or concerns put forward are included in the review. If it is not possible to address these this should be explained and be documented.

It is important that the named contact shows sensitivity from the first engagement, for example, being sensitive about the patient/family preference around any known anniversaries. The patient/family should be involved in deciding how the patient will be referred to in the report, for example as ‘the patient’, or by name.

Reasoning

Establishing a relationship with the named contact, and effective management of processes by the named contact can help the patient/family understand what has happened to them. Developing a relationship which facilitates open, honest and meaningful discussions will help to provide a consistent approach throughout the review process.

Who should undertake this role?

A named contact should be able to build effective relationships with the patient/family and the review team enabling the team to provide timely and accurate feedback. The named contact should be someone who was not involved in the delivery of the patient's care and who can remain impartial and professional.

The named contact should have excellent communication skills with an understanding of trauma informed practice. They should be able to address the needs of the patient/family, answer any questions/concerns and manage their expectations.

What is involved?

The named contact will provide updates to the family and ensure the patient/family feel supported and have their voices heard. They will be able to provide re-assurance that their questions/concerns are shared with the review team and share responses.

Clear written information should be shared, such as information on the review process and associated guidance documents. It is important to consider the communication methods preferred by the patient/family and use these whenever possible.

The named contact should provide their contact details to the patient/family. The boundaries of the relationship should be discussed along with information about the role. The named contact, rather than a member of the patient's clinical team, will also answer any questions/concerns raised by the family.

The named contact needs to create a supportive environment throughout the review process. They need to demonstrate openness and honesty with the patient/family and provide opportunities for them to talk about their experience. They will need a good understanding of key pieces of legislation including the Patient Rights (Scotland) Act 2011, Adults with Incapacity (Scotland) Act 2000, Health and Care Staffing (Scotland) Act 2019 and Duty of Candour. The named contact should also share information about the review findings which can help with the restoration of faith or trust in the NHS board.

It is important to check that the patient/family remain comfortable with their initial decision on their preferred style of communication throughout the process. The named contact should advise them that they can change this at any point during the review process and will be supported to do so. The named contact should be supported by the NHS board to ensure they are not being adversely affected by the event.

Establishing expectations

Aim

At the start of the review process, it is important to be transparent with the patient/family about the expected scope, purpose and timescales of the review, in order to establish realistic expectations. This should include the anticipated frequency of contact with the named

contact. The named contact should revisit the purpose and scope of the review to ensure a continuing shared understanding.

Reasoning

This can help provide realistic expectations and can help to ensure that any misconceptions can be identified and resolved as early as possible.

What is involved?

The named contact will explain to the patient/family that the review is primarily focussed on identifying learning from the serious adverse event and not about apportioning blame. It is hoped that doing this will reduce the potential of future harm of a similar adverse event occurring. The named contact will be aware of any processes relating to disciplinary or legal action and can inform the patient/family, if relevant.

The patient/family should be given a choice about their preferred method of communication, for example email, text, face-to-face meetings or written communication. The preferred method of communication should be noted at the start of the review. This approach should be used throughout unless they specify a change. Any additional support needs, such as advocacy or translation services, should be provided.

The named contact must agree with the patient/family members how they wish to be addressed. At the end of every contact, arrangements for the next contact should be made. The named contact should ensure the patient/family are aware that all timescales for completion of reviews are working days. For example, 90 working days for the completion of the review is 126 calendar days or 18 weeks.

Involvement in the review can include participation in establishing the ToR and being included and informed at each stage of the review. The review team may ask the patient/family to attend an interview in addition to meetings with their named contact. In addition, it could include being consulted on the factual accuracy of the final report.

The patient/family should be given clear guidance on the role of the named contact, that is, to gather relevant information and to answer questions/concerns raised. The named contact should ensure the patient/family are clear of anything they raise which is outside the scope of the review. If this happens, the named contact will signpost them to where answers are available. All questions/concerns within the scope of the review will be recorded in the report. It should be explained that the named contact cannot provide clinical care or updates on the delivery of healthcare.

It is important the patient/family are aware that their relationship with the named contact will end on completion of the review. Any further updates about the implementation of improvements following the review will be shared as appropriate. Ongoing support for the patient/family is covered later in this chapter.

The named contact should also ensure that the patient/family are advised of any changes in the projected timescales. A transparent reason for these should be given, and a realistic timescale offered.

The environment

Aim

A supportive environment that is suited to the needs of the patient/family must be available for all face-to-face meetings.

Reasoning

A supportive physical environment will create the conditions for the sharing of information which is relevant to the review. This may also facilitate the asking of questions that are important.

What is involved?

If the patient/family wish to have face-to-face meetings, sensitivity should be shown around the selection of the venue. For example, not returning to the venue associated with the adverse event. A neutral and accessible venue should be considered. It is important to consider the safety and comfort of both the patient/family and the named contact. The venue must be appropriate for these sensitive and confidential discussions.

The patient/family may elect to meet the named contact using remote communication. It is important to ensure that phone calls or video calls are held in a private space will not be interrupted by background noise or other people being present.

The importance of offering an apology

Aim

An apology should be given for the harm caused to the patient/family. This can help them to come to terms with what has happened. The power of an apology comes from the acknowledgement something could have gone better. It is the first step to learning from the adverse event and reducing the risk of it reoccurring. Apologising that a serious adverse event occurred does not mean the staff member is accepting liability for what has happened.

The apology needs to demonstrate an understanding of the potential impact of the adverse event. It must be meaningful, open and transparent. The apology must be delivered in a sensitive and person-centred manner. The apology must be delivered in an environment that the patient/family determines is acceptable.

Reasoning

The patient/family may have placed considerable trust in their NHS board so their reaction to a representative explaining what happened may be powerful. The representative needs to

facilitate an open and truthful discussion. This should include a factual explanation of what happened and any anticipated consequences. The representative should be on the lookout for any non-verbal signs that the patient/family is exhibiting that may indicate anxiety or distress.

Receiving an apology can be particularly important to the patient/family as it provides recognition of their anxiety and distress. Getting the apology right is important, as it can help enhance relationships and deal with concerns and complaints. It also sets the tone for everything that follows.

What is involved?

The staff member undertaking this role should be a representative of the NHS board who understands what happened. They should be able to give the apology in an objective and supportive manner. Consideration should be given to the timing and location of the apology. The person delivering the apology should have excellent communication skills and knowledge of trauma informed practice. This will ensure the apology is meaningful and tailored to each individual circumstance. Additional useful information can be found in the Adverse Events toolkit included on the HIS website.

Conclusion of the review

Aim

The completion of the review and the conclusion of the relationship with the named contact should be communicated in a planned and sensitive manner.

Reasoning

The patient/family may be distressed by what has happened and may be suffering from trauma. A sudden and unexpected end to the review and the relationship can cause additional emotional distress.

What is involved?

The outcome of the review should be shared with the patient/family. The method for this should be agreed in advance of the completion of the review and clearly documented.

The patient/family should be advised when the review is nearing completion. If the patient/family choose to review the report for accuracy this should be shared with them. The named contact should explain about the scope of the factual accuracy review. They should also explain what will happen if they have any queries. The named contact should explain any terms that the patient/family do not understand, for example, medical or technical language and abbreviations.

The named contact should revisit the boundaries of the relationship as explained at the start. This includes the ending of the relationship once the review is complete. The named contact should also confirm how the action plan will be shared.

At the end of the review process, the patient/family should be reminded of the support options available to them.

Responding to patient/family who are not satisfied with the review

Aim

Patients/family need to feel that their voice is heard, and concerns addressed even when they are not satisfied with the review process.

Reasoning

There must be a meaningful, truthful and clear discussion even if the patient/family feel that their expectations are not being met. It may be helpful to reflect on the information shared at the start of the review. This includes the process, timescales and established expectations.

This will help promote trust and support a culture of learning as well as provide a willingness to a commitment to improving effective and safe delivery of care.

For reviews involving multiple patients/families the named contact will aim to select an environment for meetings that balances the needs of the group as much as possible recognising that a single setting may not be achievable.

While a variety of communication methods may not be available specific requests can be shared with the named contacts who will carefully consider them.

What is involved?

If the relationship between the named contact and the patient/family breaks down, it is important to ensure that they can remain involved in the review should they wish. This could include the option of an alternative named contact being offered. It may be appropriate to signpost to advocacy or support services.

If the patient/family continue to be dissatisfied with the response, they can be signposted to the NHS board complaints procedures. If they are unhappy with this response, they can escalate their complaint to the Scottish Public Services Ombudsman.

Additional support for patient/family

Aim

Any patient/family who has experienced an adverse event may need additional support.

Reasoning

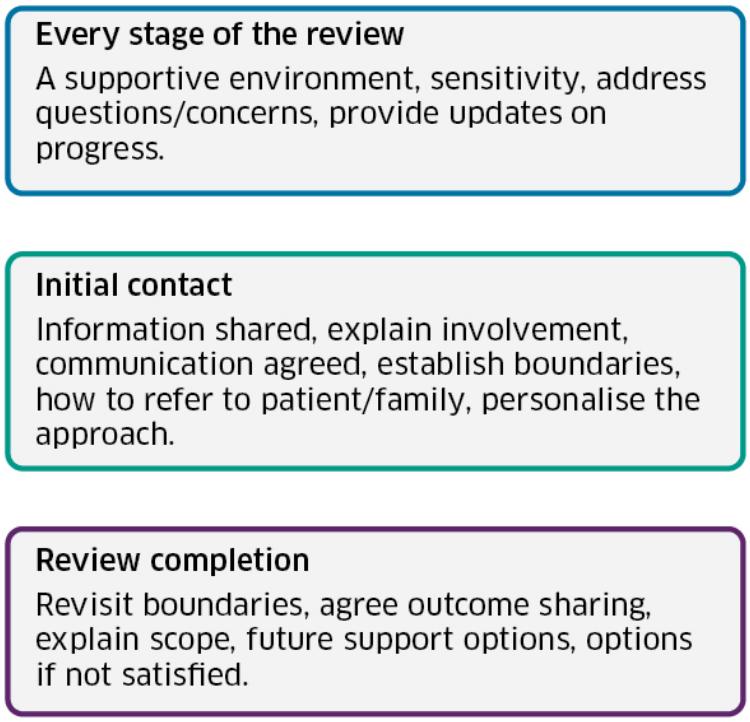
The emotional impact of an adverse event is well understood. Signposting to the appropriate resources to seek additional support can alleviate the impact on the patient/family.

What is involved?

Every NHS board should have a list of all the relevant support services that can be shared with the patient/family as appropriate.

The named contact should also advise the patient/family that spiritual care services can provide support and space for families. This can be accessed both through the hospital and, in many board areas, through the GP for community support.

Overview of the Named Contact Role



Overview of named contact 1

The named contact will:

At every stage of review

- Create a supportive environment throughout the review whilst demonstrating openness and honesty.
- Be sensitive when choosing a venue if the patient/family wish to meet in person.
- Show sensitivity, for example, avoiding any known anniversaries.
- Ensure that the patient/family are given the opportunity to identify what matters to them and any questions/concerns that they have are included in the review.
- Provide updates on the review progress.

At initial contact

- Share information with the patient/family, such as information about the review process, the named contact role and contact details
- Explain where the patient/family can be involved in the review: involvement can include participation in establishing the ToR, being included and informed at each stage of the review and being consulted on the factual accuracy of the final report.
- Establish the preferred communication method by the patient/family, and frequency of contact.
- Determine how the patient/family want the patient to be referred to in the report.
- Establish boundaries including: the scope, timescales and purpose of the review, establishing the boundaries of the named contact relationship and what will happen when the review is complete.
- Agree how to address the patient/family members, to personalise the approach.

At review completion

- Establish how the patient/family would like the outcome of the review/action plans to be shared with them.
- Revisit boundaries, explaining that the named contact will no longer have contact after the review is completed.
- Explain what the scope of the factual accuracy review is and their role in it.
- Remind the patient/family of the future support options available to them.
- Explain the process the patient/family can take if they are not satisfied with the review.

Reviews of Multiple Patient Significant Adverse Events

> Effective management of an adverse incident has many benefits. Most importantly, the patient will understand what happened and receive a much sought-after apology and recognition of the distress they feel. Learning can then ensue, in a blame-free manner, minimising the risk of the same error happening again.
>
> McDavid (2015)

Introduction

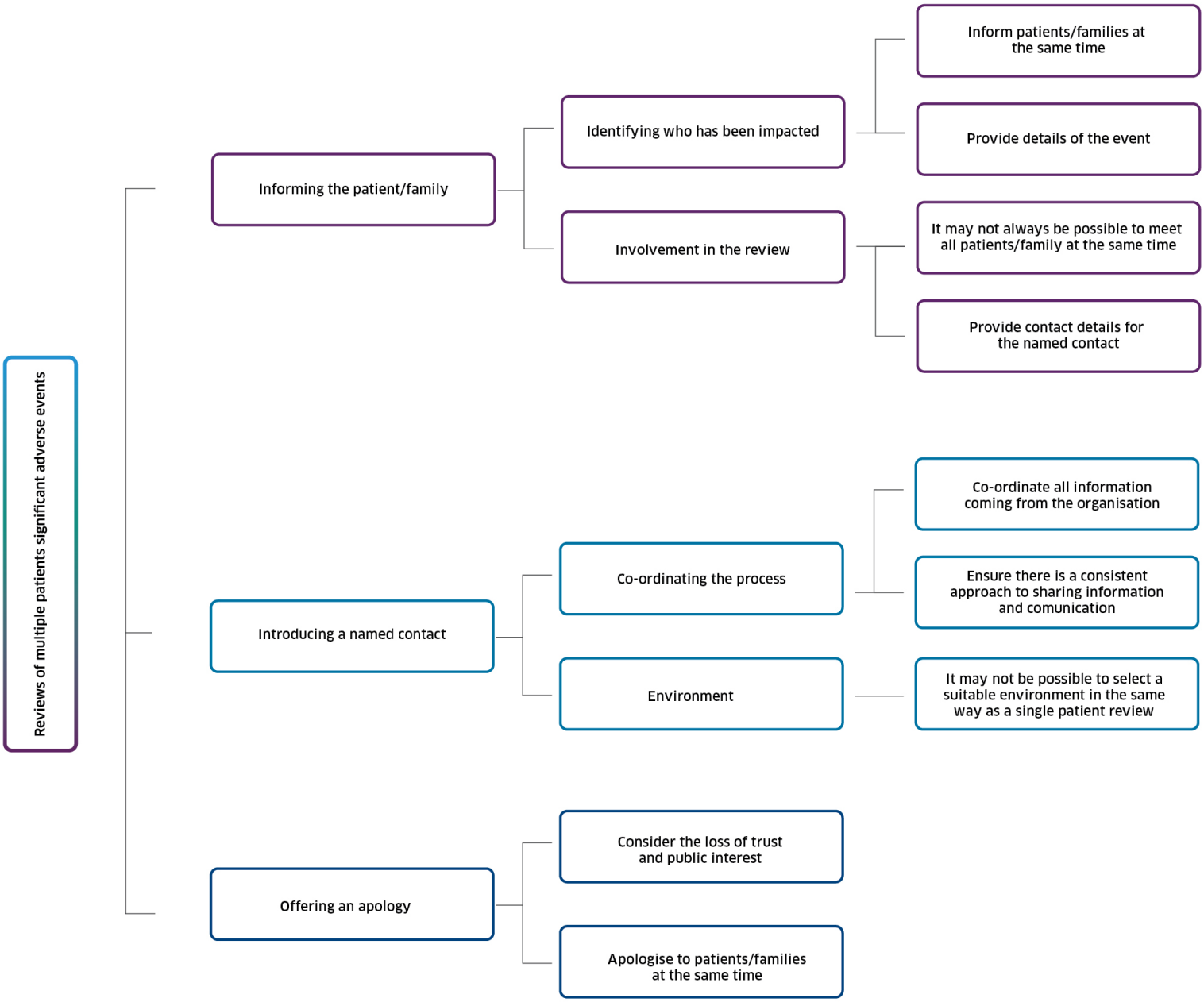
A significant adverse event may sometimes affect multiple patients/families. The principles of engaging with the patient/family, described throughout the framework, apply in multiple patient adverse event reviews. The expectations of staffs' skills in communication and trauma informed practice are the same. This chapter identifies the aspects which are different when multiple patients are involved.

Multiple patient review

Please note that references should also be made to the patient/family chapter where there may be overlap, for example the named person and apology section.

Figure 4 outlines the process for multiple patients SAERs.

Figure 4: Reviews of multiple patients significant adverse event flowchart



Informing the patient/family of the review

Aim

When multiple people have been impacted by an adverse event, all the potentially harmed patients should be informed at the same time. However, it may take some time to retrospectively identify all the people who have potentially been affected.

Reasoning

Some patients/families may not be aware they have been involved in the event and the first they become aware of it is when they are notified by the NHS board. Informing everyone who may have been harmed at the same time reduces the risk of speculation and anxiety.

What is involved

In situations such as this, sending a letter or email to all patients/families involved in the event is recommended. This ensures that they are informed at the same time and in the same way. The letter or e-mail should contain sufficient information relevant to the adverse event. This should include contact details for the named contact, should the patient/family wish to discuss anything or have any questions.

A key part of the review carried out for multiple patient adverse events is identifying all patients who are involved in the event. It may be best not to inform the patient/family until all affected patients have been identified. This will help reduce the speculation and anxiety from any rumours or third hand information.

NHS boards should have a process in place to support the patients/families who are involved in the multiple patient adverse events.

In case of multiple patient adverse events, it may not always be possible to meet and inform patients/families individually. Depending on how many patients are involved this could take weeks or even months. This could lead to patients/families not being informed at the same time.

The role of the named contact for patients/families involved in the review

Aim

If the patient/family agree to engage in the review, they should be contacted by a representative of their NHS board. This will be their named contact for the review who should be available throughout the review process.

Reasoning

It is recommended that a named contact within the NHS board is appointed who can oversee this process of working with families and coordinate the approach. It is important to

coordinate all information and messages coming from all areas of the NHS board to ensure there is a consistent approach.

Who should undertake this role?

The named contact(s) for a multiple patient adverse event should have all the same skills as one for a single patient event. The named contact(s) should be able to adapt their skills/methods of communication to suit different patients and families.

The named contact should be well informed regarding the adverse event and review, to answer any questions patients/families may have quickly and efficiently.

The named contact should be supported by the NHS board to ensure they are not being adversely affected by the event.

What is involved?

For reviews affecting multiple patients/families, it will not be possible for the named contact to select a single environment for meetings that is suitable for all. A variety of communication methods may not be offered, but specific requests to the named contacts will be considered. The named contact will be representing several patients/families and will adopt a consistent method of communication. This includes letters and e-mails being sent to all those affected at the same time. The named contact's information should be included in the letter or e-mail so that patients/families know who to go to with any questions or concerns.

It may be that face-to-face meetings are not possible for all patients/families and are only offered in exceptional circumstances.

The importance of offering an apology

Aim

An apology should be given for the harm caused to all patients/families involved.

Reasoning

The aim of the apology does not differ whether the adverse event affected one or several patients. Adverse events which affect multiple patients may attract media attention and may affect more than one person in a family or social group. Apart from the harm, or potential harm, there can be a loss of trust and negative perception of the NHS board. The apology should address both of these aspects.

What is involved?

Multiple adverse events may attract external stakeholder interest such as media, local and Scottish Government, patient advocacy groups and the wider public. It is important that the apology refers to the actual event and what the organisation is apologising for. If an apology is too vague, or does not include all aspects of what happened, this can affect the trust

patients/families, and the wider public, have of the NHS board. If the apology is sincere and identifies what happened and what improvements will be put in place, this can help to rebuild the trust with the patients/families involved and the wider public.

Staff involved in an Adverse Event

> Most staff choose their profession because they wish to improve the lives of others. When a patient is accidentally harmed in the care process, this can be a traumatic experience not only for the patient but also for the staff involved.
>
> Ullstrom et al (2014)

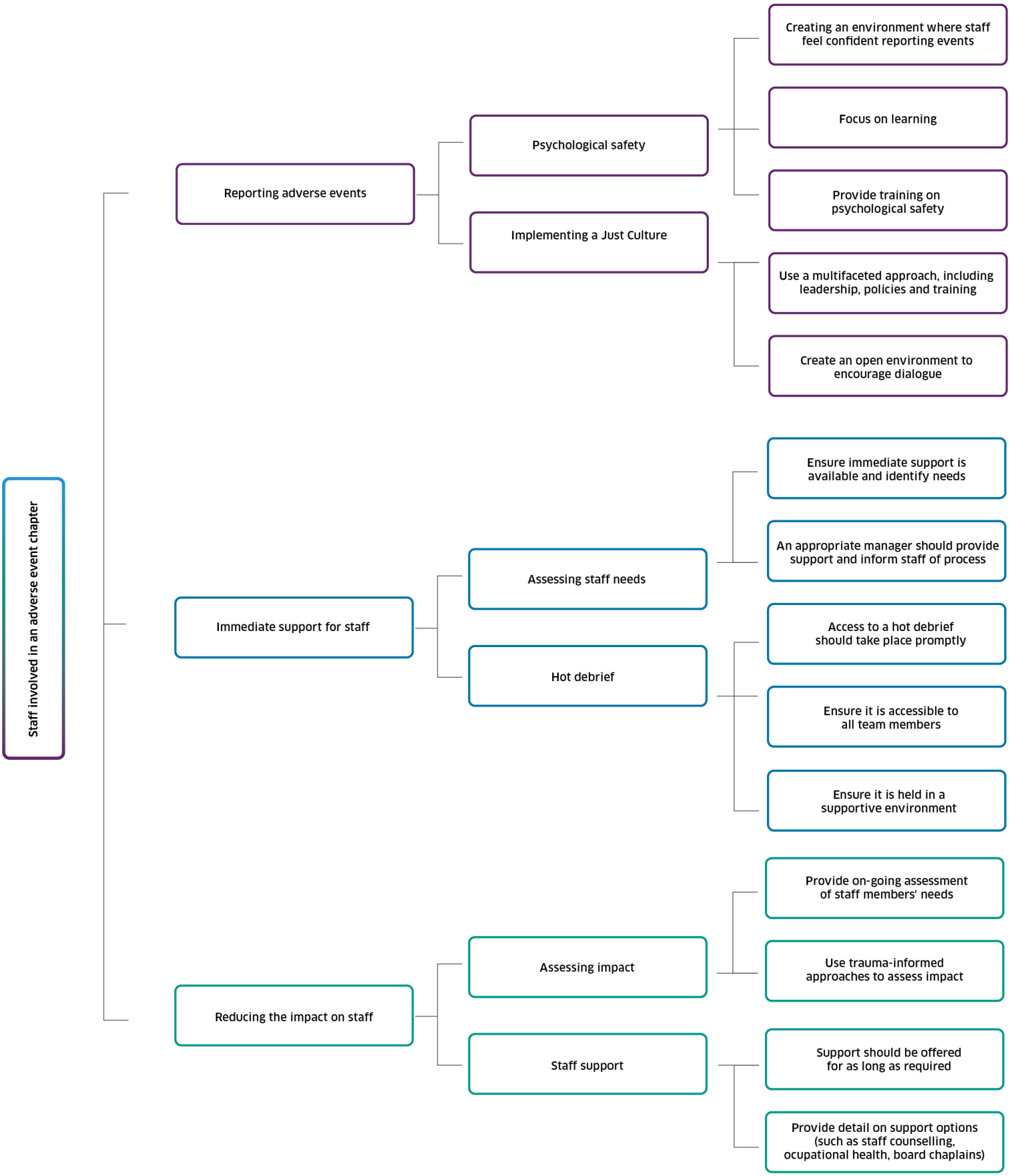
Introduction

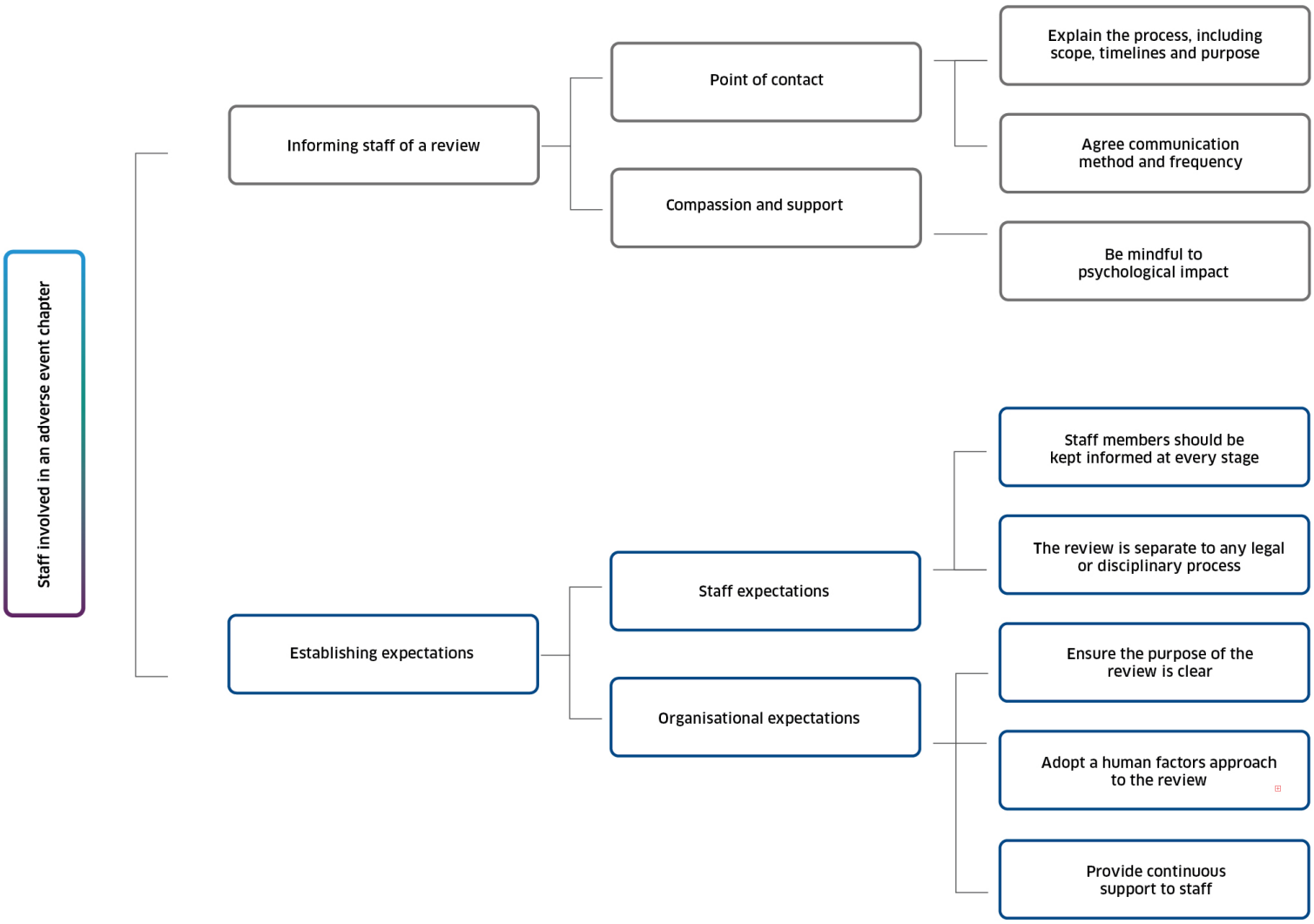
The delivery of modern healthcare is increasingly challenging and complex. On occasions adverse events happen which can be traumatic and have a negative effect on the health and wellbeing of staff.

This chapter focuses on the support for staff who are involved in an adverse event and subsequent review. It refers only to the review process and does not cover the impact of any other legal and/or disciplinary processes.

Figure 5 outlines the chapter contents.

Figure 5: Staff involvement in adverse events review flowchart





Psychological safety and reporting of adverse events

Aim

To create a psychologically safe environment where staff feel confident to report adverse events.

Reasoning

A psychologically safe environment facilitates staff reporting and allows the event to be documented in a clear and honest way. A safe environment with a focus on learning, provides the opportunity for all involved to process what has happened.

What is involved?

Developing a psychologically safe environment requires a multifaceted approach. This includes leadership, policies and training.

Leaders and managers have a vital role in creating a supportive and psychologically safe workplace. Discussions can take place in an open environment. This can be achieved through compassionate and inclusive leadership and a modelling of desired behaviours by senior staff. This leadership style promotes learning and places the principles of quality assurance at the core of the NHS board.

A psychologically safe approach encourages and supports staff to report errors and near misses without a fear of blame. To achieve this, trust and openness must be fostered. NHS board policies should consider the principles of psychological safety. The focus should be on learning from adverse events and reducing the potential of future harm. Providing training in psychological safety can also help to create a safe culture. The training should emphasise that speaking up and reporting harm is an effective way of improving patient safety.

Support for staff immediately following the event

Aim

The NHS board should ensure immediate access to support for staff involved in adverse events. This will reduce the impact of any trauma and help with their health, wellbeing and recovery. Support offered should remain confidential.

Reasoning

Taking action, in the time immediately following an adverse event is important to help staff to understand what happened and to reduce the feeling of isolation. NHS boards have a duty of care to assess their needs and offer them the right support. It is important that staff are offered psychological first aid and access to debriefing and support during the review process. Providing support for staff can reduce sickness absence levels and prevent additional pressure on their team.

What is involved?

When staff are involved in an adverse event, immediate support should be provided by their line manager. If the line manager is unable to provide this, they should ensure that an appropriately skilled alternative manager is appointed to do so. This should include understanding any immediate and ongoing emotional and psychological support required. Staff should be informed of the relevant processes including what will happen next.

A hot debrief or discussion that takes place immediately following the event is an important part of staff support. This is a short meeting following a particularly stressful adverse or critical event. It is usually led by a senior nurse, doctor or manager and should be available to all members of the team involved. It is important that the person conducting the hot debrief was not involved in the event.

The aim of a hot debrief is to pause, acknowledge what has happened and to check in with staff. It is important this is offered in a supportive environment to allow staff to process their emotions. A hot debrief can help the team gain a clearer sense of what has happened and to reduce stress levels immediately after a difficult event. This should be a psychologically safe space for staff where attendance is voluntary. Staff should not feel the need to talk about what has happened, or how they feel, unless they wish to do so.

The hot debrief should avoid discussing performance, opinion or analysis. A clinical, technical or other professional based discussion of the adverse event should be held on another occasion. This should be arranged by the senior clinician, or for non-patient related events, the senior line manager involved. Hot debriefs should not be used in any way as part of an adverse event review or investigation. No record of discussion should be kept, other than immediate action points for example, a malfunctioning piece of equipment or identified training needs.

Understanding and reducing the impact of adverse events

Aim

The impact on staff involved in an adverse event must be recognised and they must be provided with ongoing support. This should be available to all staff who may have been directly involved with, or indirectly affected by, an adverse event.

Reasoning

The impact of an adverse event can affect the physical and mental health of staff. Staff may feel that they have let the patient/family, their team, the organisation or themselves down. They may start second-guessing their skills and knowledge base. It is not uncommon for staff to feel personally responsible for the outcome. Providing on-going support for them could help to reduce this negative impact.

The term ‘second victim’ refers to staff who experience emotional distress following an adverse event. They are the second victim in the sense that they are traumatised by the event. The impact can include symptoms of mental ill-health and a loss of confidence or motivation at work. If left unaddressed this can have a negative impact on their health and wellbeing.

The reaction of individuals to an adverse event can vary as will staff attitudes to accessing support networks and to seeking help. Trauma can be associated with minor adverse events and near misses, as well as with death and major events. Trauma can also result from personal circumstances or prior life experience. This can result in an adverse event being traumatic for one staff member, whilst not for another. It can also be a cumulative effect of a series of events which can lead to trauma.

Ongoing assessment of the needs, and support of staff, could reduce the psychological impact, helping to increase their motivation and morale at work.

What is involved?

Using trauma-informed approaches to risk assess the impact on staff should help identify the right level of support. This can be complex and may be identified over several discussions with staff. This approach can also help identify the need for additional support and ongoing monitoring for staff. It involves considering any additional stress that the staff are experiencing. Any publicity relating to the adverse event in the media may also have an impact. There are several models which can support trauma involved management following an adverse event.

A staff member may not wish to return to the area where the adverse event occurred and consideration should be given to any opportunities to work in a different team or environment.

Staff must be advised that they can access professional advice from their relevant professional body or union. Information about accessing employee assistance programmes, staff counselling services or occupational health should also be provided. Information on relevant external health and support agencies may also be beneficial. This could include organisations such as Breathing Space, The Mental Health Foundation, Maternity and Neonatal Psychological Interventions Service and Living Life.

NHS boards have health and social care chaplains who are available to discuss emotional, spiritual, religious and wellbeing issues. This includes support following an adverse event. This should be person-centred and can include confidential one-to-one or group support and crisis intervention. It can also include group sessions or training in using Values Based Reflective Practice tools in your day-to-day work. This support can be accessed from spiritual care teams who can be contacted via hospital switchboards.

Staff who have experienced an adverse event may also need ongoing support. This may be practical or emotional support, or both.

Informing staff of a review into the adverse event

Aim

When an adverse event review takes place, staff who were involved should have a single point of contact throughout the review process. It is important for staff to understand the process from the start. Any information should be provided in a sensitive and compassionate manner.

Reasoning

Staff may be anxious or frightened about an impending review. Organisations should be aware that fear of the unknown can cause additional stress. The organisation should also be

aware of the potential psychological impact and distress staff could be experiencing after an adverse event.

What is involved?

At the start of the review, the point of contact should provide the staff member with detailed information about the process. They should be aware of how anxious and stressed the staff member may be. To minimise distress, the discussion to share the information should be carried out in a respectful, compassionate and supportive manner. The information shared should include the scope, purpose, timescale of the review and how they will be involved. Staff should be advised that the primary objective is to identify learning and to ensure that any observations or recommendations are implemented. Agreement should be reached with staff about how often up-dates will be provided.

Establishing expectations for a review

Aim

An adverse event review can be a lengthy process. It is important that the expectation of both staff and the NHS board are clear.

Staff involved in the review process should be given the right on-going support throughout the review.

Reasoning

To identify learning it is important to understand why an adverse event has occurred. This can reduce the potential of future harm.

The purpose of the review should be clear and the point of contact should then discuss this with the staff member. This can reduce the level of anxiety for the staff member before and during the review process. In turn, this allows them to be involved in the review in a more effective way. This clarity can help set realistic expectations to ensure that any misconceptions can be identified and resolved at the earliest opportunity.

What is involved?

Staff must be informed that the purpose of the review is to take a constructive approach to learning, not to apportion blame. Additionally, it is separate from any other legal and/or disciplinary processes. The review team should create an environment in which the staff member feels psychologically safe. This will allow the staff member to be involved in constructive learning.

Without applying the principles described in this framework, members of staff can find contributing to an adverse event review equally, if not more stressful, than being involved in the actual adverse event. To avoid this, NHS boards should adopt a culture of no blame and use a human factors systems approach to adverse event reviews.

A human factors approach focuses on the system. It considers human error to be a symptom of a problem in the system, rather than the cause. A human factors system approach seeks to understand the multiple, interacting contributory factors from across the healthcare system.

Staff should be informed about the format of the review meetings and when they may be invited to attend. They should also be informed of any delays.

When the review is complete and the report is drafted, the staff member will benefit from having the opportunity to check it for factual accuracy. Sharing of learning and any actions identified are important parts of the process.

Those providing support for the staff member should have regular supervision and access to peer support. They should be provided with learning opportunities to develop self-awareness, self-compassion and emotional intelligence. This will help them look after their own wellbeing at the same time as they provide support for their staff member.

Following an adverse event, an evaluation of the NHS board's support for staff should be carried out. This will help identify where things are working well and where there is room for improvement. A combination of outcome and process evaluations can provide a comprehensive understanding of the effectiveness of an NHS board's processes.

Identifying learning and improvement

> The best way to reduce harm... is to embrace wholeheartedly a culture of learning.
>
> The National Advisory Group on the Safety of Patients in England (2013)

Introduction

When an adverse event occurs in healthcare it is imperative that there is a focus on learning from what has happened. Learning in a psychologically safe environment and using a human factors approach will facilitate the identification of recommendations and actions. These actions will drive improvement. Identifying and embedding learning following an adverse event is one of the most challenging, yet most important parts of the adverse events review process. It is imperative that learning from adverse events informs the boards proactive approach to risk management.

Learning from adverse events

Aim

To maximise learning following an adverse event and to increase safety for everyone involved in healthcare.

Reasoning

Learning from adverse events and near misses is one of the most effective ways to reduce the potential of future harm.

What is involved?

There are many opportunities to identify learning following an adverse event and the review process allows recommendations to be formed that will drive improvement. The list of recommendations included in the adverse event review report can be updated after a full improvement cycle.

Recommendations for improvement and improvement plans

Aim

Adverse events reviews in healthcare require the identification of recommendations for systematic and organisational improvements, to facilitate continual improvement, increasing quality and patient safety. An improvement plan ensures that the recommendations identified following the adverse event are translated into achievable and actionable steps.

Reasoning

Identifying recommendations, following an adverse events review, provides a focus on specific areas for improvement which address factors found to have contributed to the event. The improvement plan facilitates learning (the recommendations) from the adverse event being translated into improvement. All actions within the improvement plan should consider the need for education and training.

What is involved?

The review team develops recommendations based on findings from the adverse event review. They should consider all contributory factors identified and make recommendations that seek to address these.

Recommendations should be made without consideration of cost, staff resources or the requirement of external support. They should be based on best practice and should aim to reduce the potential of further harm from reoccurrence. Recommendations from adverse event reviews should be shared with the senior staff responsible for the area where the event occurred.

The improvement plan must be achievable and consider realistic cost, resource and requirement for external assistance. Any recommendations that cannot be translated into achievable actions should be escalated upward through the seniority of management.

Improvement plans should follow a SMART (specific, measurable, achievable, relevant and time-bound) approach. All actions in the plan should be detailed and include how the changes will be implemented with clear and realistic timescales. Every action must have an identified person who is accountable for its implementation. It is also important that it is clear how and when to measure if the action, once implemented, has been successful.

Progress against actions in the improvement plan must be recorded by the senior staff. Relevant policies, risk assessments, standard operating procedures or other system processes must be reviewed and updated by senior staff.

Implementation of the improvement plan governance and monitoring

Aim

To ensure that appropriate governance and monitoring is in place for implementation of learning following adverse events.

Reasoning

To support a culture of continual learning within the NHS board, governance structures must support the implementation of identified improvements following an adverse event. Having appropriate systems and processes in place for the implementation of improvement plans will ensure that learning is effective.

What is involved?

A member of the executive team must be assigned to the improvement plan. They will be accountable for the implementation and sharing of improvements at all levels of the organisation. This will include the management of risk, engaging staff and stakeholders to promote a just and safety culture.

The responsible executive must have oversight of the governance arrangements, timescales and implementation of actions in addition to ensuring any escalations or changes to the process are managed.

The governance arrangements must include plans to ensure learning from adverse events. These should be shared in a timely manner by all staff, including frontline staff, accountable for delivering healthcare.

An effective governance structure will ensure ongoing analysis of learning, support continual monitoring and measurement of improvement. This should support recurring reviews to identify themes, trends and prioritisation of areas for further learning.

Timescales and implementation of all actions should be regularly monitored and reviewed. Any delay in implementation of learning must be escalated to the responsible executive.

To provide assurance that steps taken for improvement and learning have been effective, monitoring should be undertaken which could include the use of audit cycles. The results of this monitoring should support knowledge on whether changes made have led to sustainable improvements. Where identified actions are not effective, or delivering the required improvement, a clear escalation process must be in place to inform the allocated executive.

Following escalation an ongoing review must be undertaken to achieve the desired outcome.

Documented evidence of implementation of the improvement plan should be captured throughout the process.

Sharing learning

> Improving the quality of health services requires attention to knowledge generation and learning. Lessons on delivery of quality care should be systematically captured, documented and shared.
>
> World Health Organization (WHO)

Aim

To create a culture of learning and encourage improvement in the delivery of care by learning from adverse events locally and by sharing this learning nationally.

Reasoning

A focus on sharing learning will inform organisations' adverse event management processes to improve the quality of care delivered.

What is involved?

A learning summary template has been developed as a useful tool for sharing learning both locally and nationally. It will standardise the information that is captured and align how NHS boards complete learning summaries. The purpose is to put the focus on the learning gained from adverse event reviews and widen the reach of improvements throughout Scotland.

To promote national learning, organisations are expected to share:

- Improvements in the delivery of care which have the potential for national application.
- Improvements in the management of adverse events, for example in relation to the process of reporting, reviewing and learning from adverse events.
- Good practice that can be adopted by other NHS boards.

The new adverse events Community of Practice portal has been launched to support Scottish NHS boards to share learning. This interactive platform encourages national learning from shared learning summaries, policies and other relevant documentation. The website has the functionality to:

- allow searches of adverse event categories
- to create and share events, and
- to promote news items

The success of the adverse events Community of Practice portal relies on NHS boards continuing to share learning resources to promote national learning.

Guidance for shareable learning template

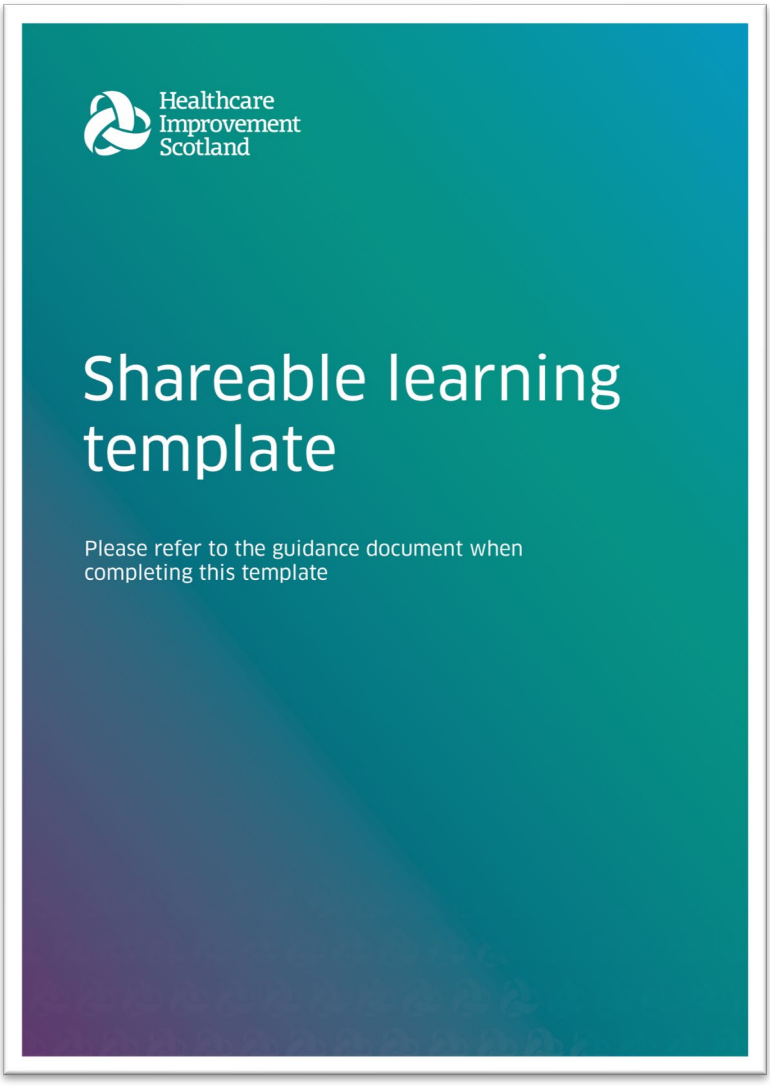
This guidance is to help complete the sharable learning template. For each section, we have suggested information that should be included but there may be further information you wish to detail. The completed document should be brief and focus on sharing learning with colleagues and other NHS boards.

What is the purpose of this template

This template is a tool to share learning for improvement both locally and nationally. The template can also be a useful tool to evidence learning outcomes.

Shareable learning template

The learning template can be found on the HIS Adverse Event website.



When to complete this template

The sharable learning template can be completed at different stages of a SAER:

- Immediately after the adverse event, if the service has identified any learning prior to the review process.
- Immediately after the conclusion of the adverse event review process, to share any identified learning promptly.
- Once a full improvement cycle has taken place, this can help identify if the recommendations have led to improvement.

This template should also be completed when any learning has been identified from SAERs or other means, for example:

- Complaints.
- Audit cycles (for example infection control audits).
- Following an inspection.
- Following a local review for example, mortality and morbidity reviews, team-based quality reviews.

Please note, this list is not exhaustive.

After completion

This template can be shared on the adverse events Community of Practice portal to facilitate national learning.

The learning template can also be used as a tool for sharing learning locally, examples include:

- Added to TURAS.
- Added to educational materials.
- Shared on the intranet.
- Discussed at huddles.
- Workshops can be undertaken where the completed template is discussed.

Who should complete the template?

This varies across NHS boards but can include:

- the clinical risk management facilitator
- the clinical governance team or report author
- a member of the review team with input from the directorate management team
- the lead reviewer
- the central risk and patient safety teams, and
- the directorate/corporate function team at the conclusion of the investigation.

How to complete the template

Event category

The **speciality** refers to the event category. There may be more than one.

Key words will be used when uploading learning summaries onto the Community of Practice portal. These words will be used to support searches which colleagues make and ensure the summary is easy to find.

Date of publication refers to the date that the sharable learning template was signed off for approval.

What happened?

This section should detail the key moments of the event, where possible in a chronological order. It is important that the relevant information is captured to give context to any learning points suggested later in the template. It should be brief and not be a summary of the report.

The learning summary must be written without any person identifiable information relating to anyone involved, both patients and staff.

Consider the following:

- Initial communication/presentation.
- Factors that may have contributed both during and prior to the event.
- Did the patient have previous contact with healthcare services?

What went well?

This section should include any good practice followed prior to, or during the event.

Consider the following:

- Good communication between staff/patient/family.
- Examples of policies and procedures being followed.
- Timely response to the event.

What have we learned?

This section should focus on all learning that can be taken from the review and shared. This does not have to include every point made in the report and action plan, but these documents can be referenced to support learning.

Focus on any improvements which have already been implemented and those which are planned.

Consider the following:

- What changes have been immediately implemented following the event?
- Improvements to be implemented from the recommendations and learning points noted in the SAER report and action plan. Can changes be made to current practices/procedures?
- Is there any learning for wider sharing across the board and nationally?
- How is learning being shared?

Distribution of completed learning summary

To ensure learning is shared appropriately within the organisation, consider which teams and individuals should receive this summary to promote learning in order to reduce the potential of future harm or reoccurrence.

Where the learning summary has been shared out with the organisation, who and when the document was shared should also be recorded here.

Risk

Management of risk

Aim

The identification, avoidance, prevention and reduction of risks should be the primary defence to prevent adverse events occurring.

Reasoning

Delivering healthcare will never be risk free, but risks can be minimised to provide high quality care for the people of Scotland. Risk is the potential for harm. It is a prediction of a probable outcome, based on evidence from previous experience. The nature of risk and harm can vary greatly in healthcare.

What is involved?

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

Learning from adverse events to minimise risk

Aim

Using learning from reviews as a key driver to minimise risk within health boards.

Reasoning

Ensuring that improvements made are informing risk controls and are fed into organisational risk governance structures.

What is involved?

Reports from lessons learned from adverse event reviews can be added as risk controls, evidencing improvements made to minimise risk and reducing the recurrence of adverse events.

The use of adverse event reviews identifies where improvements are required and incorporates both proactive and reactive risk management processes, and through the use of adverse event reviews identifies where improvements are required. To ensure these improvements are impacting positively on the risks faced by NHS boards these need to be reflected in the risk assessment.

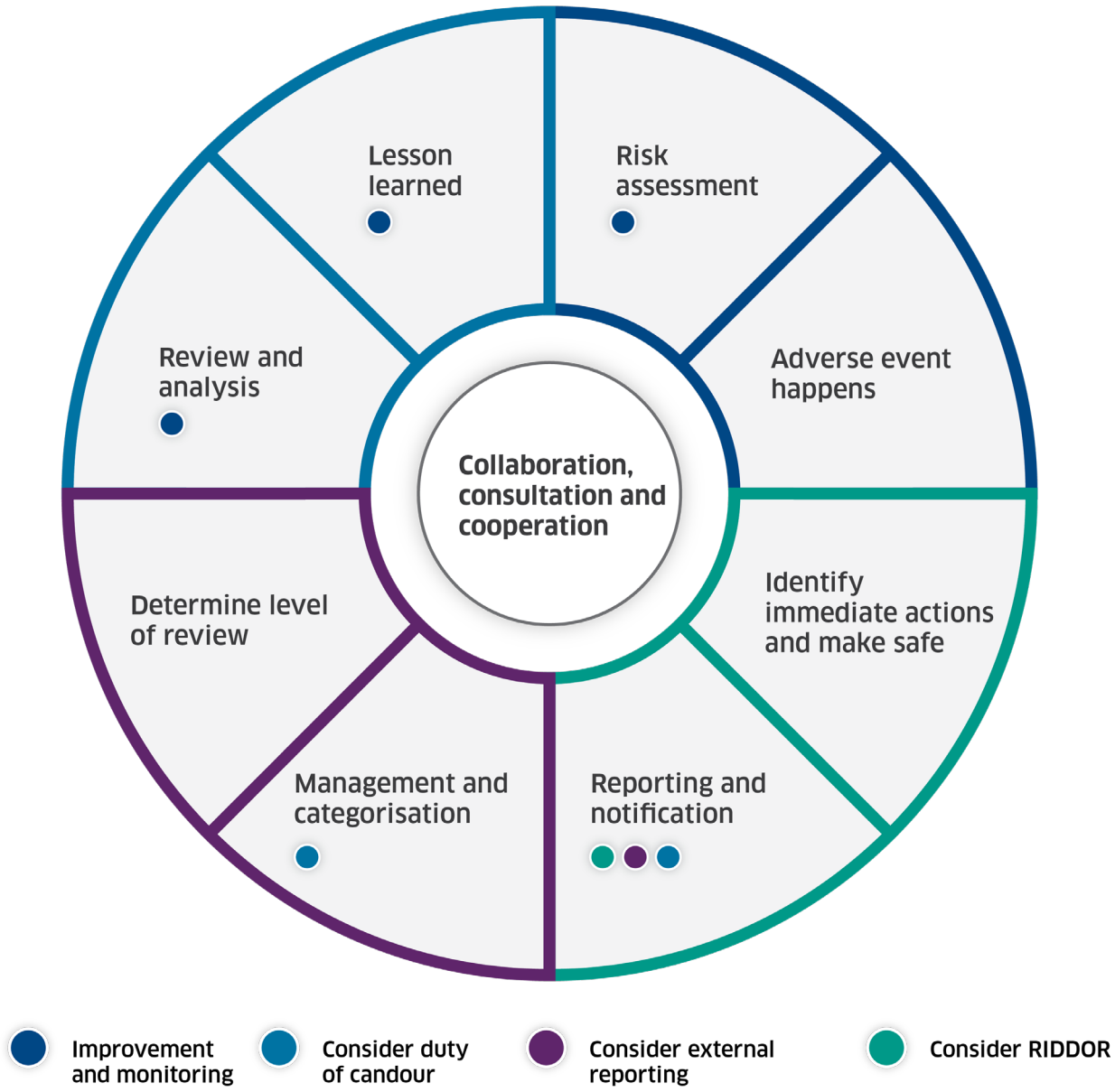


Table 3 below is the risk matrix to support NHS boards to assess risks

Table 3: Impact and Likelihood Assessment Matrix

Category	Negligible (1)	Minor (2)	Moderate (3)	Major ()	Extreme (5)
Injury/Illness **(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.	Injury requiring medical treatment. Injury (RIDDOR reportable) that results in >7 days incapacitation for routine work. Consideration of Organisational Duty of Candour.	Long term incapacity/disability requiring medical treatment. Specified RIDDOR injury; occupational disease or dangerous occurrences with/without a ≥ 7-day incapacitation for routine work. E.g. – Fractures, amputation, crush, serious burns. Consideration of Organisational Duty of Candour.	Any adverse event leading to death(s). Major permanent physical incapacity. RIDDOR reportable work-related fatality. Consideration of Organisational Duty of Candour.

Category	Negligible (1)	Minor (2)	Moderate (3)	Major ()	Extreme (5)
	Psychological impact with no wellbeing support required.	Psychological impact with signposting to wellbeing support.	Psychological impact requiring short term wellbeing support.	Psychological impact requiring medium-term wellbeing support.	Long-term psychological impact. Critical impact on wellbeing, co-ordinated response, and referral to support services.
Healthcare Experience (Impact on how our stakeholders experience our organisation)	Reduced quality experience.	Unsatisfactory experience – readily resolvable.	Unsatisfactory experience/clinical outcome with potential for short term effects.	Unsatisfactory experience /clinical outcome with potential for long-term effects.	Unsatisfactory experience/clinical outcome continued permanent effects.
	Locally resolved verbal complaint or observations.	Justified written complaint.	Multiple justified written complaints.	Multiple justified complaints with problem themes emerging, informed from more than one source.	Complex justified complaints with serious problem themes from more than one source.

Category	Negligible (1)	Minor (2)	Moderate (3)	Major ()	Extreme (5)
Transformation & Innovation (Impact on our ability to deliver change & innovation across our organisation)	Barely noticeable reduction in scope, quality or schedule of change programme or project.	Minor reduction in scope, quality or schedule of change programme or project.	Moderate reduction in scope, quality or schedule of change programme or project.	Significant change to scope, quality or schedule of change programme or project, resulting in significant changes to projected outcomes.	Inability to meet scope, quality or schedule of change programme or project.
Service Delivery / Business Interruption (Impact on our ability to deliver efficient & effective services)	Interruption to service/process that does not impact on delivery of services.	Short term disruption to service/process with minor impact on services.	Medium term disruption to service/process with unacceptable impact services, impacting on departmental business continuity plans being enacted.	Long-term/sustained loss of service/process which has serious impact on delivery of services, resulting in major service wide continuity plans being enacted.	Permanent loss of core service/facility/process resulting in a significant knock-on effect to other services. Major organisation wide contingency planning enacted.
Workforce (Impact on our staff wellbeing, competency & levels)	Temporary reduction in staffing levels/skills mix or any escalations fully mitigated with no impact on service delivery or care quality.	Short-term reduction in staffing levels/skills mix (1 week) or escalations mitigated with no impact on service delivery or care quality due to work prioritisation/delay.	Medium term reduction in staffing levels/skills mix (1 month), or escalations unable to mitigate resulting in missed care.	Long term reduction in staffing levels/skills mix (>1month) or, multiple escalations unable to mitigate resulting in missed care and patient harm.	Loss of key/high volumes of staff or, system wide escalations unable to mitigate resulting in patient harm and impacting care standards.
	Staff unable to network with other professionals.	Staff unable to carry out complementary / non-essential training.	Staff unable to carry out training required by the organisation (including training that improves function of the organisation).	Staff unable to carry out statutory / mandatory/role specific training or maintain competency levels.	Staff are unable to carry out any training / maintain competency levels which impact on the function of the organisation.
	No use of supplementary staffing.	Increased usage of supplementary staff.	Reliance of supplementary staff in a few areas.	Reliance on supplementary staff in multiple areas.	Unsustainable reliance on supplementary staff across the organisation.

Category	Negligible (1)	Minor (2)	Moderate (3)	Major ()	Extreme (5)
	Negligible impact on staff wellbeing.	Minor impact on staff wellbeing, requiring peer support.	Moderate impact on staff wellbeing, requiring line manager support in a few areas.	Major impact on staff wellbeing, requiring referral to support services in multiple areas.	Extreme impact on staff wellbeing, requiring co-ordinated response and referral to support service across the organisation.
Financial (Impact through unplanned cost/reduction of available finances) *%'s used may vary depending on size of Board and are to act as a guide.	Some adverse financial impact but not sufficient to affect the ability of the service /department to operate within its annual budget. Scale of impact experienced is ≤1% of Directorate Impact OR 0.1% of Board Annual Budget.	Adverse financial impact affecting the ability of one or more services/ departments to achieve their annual financial balance. Scale of impact experienced is 2-5% of Directorate Impact and or multiple Directorates OR 0.2 – 0.5% of Board Annual Budget.	Significant adverse financial impact affecting the ability of one or more directorates to achieve financial balance. Scale of impact experienced is 6-10% of Directorate impact and or multiple Directorates OR 0.6 -1% of Board Annual Budget.	Unable to achieve annual financial balance given scale of funding gap and savings requirements across the full Board. Scale of impact experienced is 11 -20% of Directorate Impact and or multiple Directorates OR 1.1 to 2% of Board Annual Budget across Full Board Impact in year. Potential for Scottish Government involvement/escalation.	Significant aggregated financial impact affecting the long-term financial sustainability of the organisation. Scale of impact experienced is >2% of Board Annual Budget Potential for Scottish Government escalation.
Compliance (Impact on business controls to comply with industry rules, regulations and sustainability)	Report/ Audit that identifies minor compliance/quality issues. No change to level of Board Assurance.	Report/Audit that identifies a small number of compliance/quality issues. No change to level of Board Assurance.	Report/Audit that identifies a challenging number of compliance/quality issues. Minimal reduction on Board Assurance.	Report/ Audit that identifies a significant number of compliance/quality issues stating a low compliance rating/critical rating. Reduced level of Board Assurance.	Report/Audit that identifies a Zero/ Severely critical rating in relation to Compliance/Quality. Significant reduction in level of Board Assurance.
	No compliance/permit impact. No	Minor non-compliance/permit impact (Regulatory advisory letter).	Moderate non-compliance/ permit impact that results in Regulator Involvement.	Major non-compliance/ permit impact that results in Regulator Enforcement action	Extreme non-compliance/ permit impact that results in Regulator Enforcement action and /or Fines (Prohibition

Category	Negligible (1)	Minor (2)	Moderate (3)	Major ()	Extreme (5)
	Regulatory involvement.		(Notice of Contravention issued)	and /or Fines (Improvement Notice)	Notice/Prosecution/Public Register)
Public Confidence (Impact on public confidence of the organisation)	Some concerns from individuals, local community groups and media (including social media)– short-term (< 1 day).	Ongoing concerns raised by individuals, local media, social media, local communities, and their representatives – long-term (≤1 week).	Ongoing concerns raised by individuals, local media, social media, local communities, and their representative – long-term (>1 week).	Significant impact on public confidence in the organisation that either results in a decline in uptake/use of services, or from concerns raised by national organisations / scrutiny bodies and short-term (< 1 week) national media coverage.	Critical impact on staff, public and stakeholder confidence in the organisation resulting from an external investigation/ public enquiry or through prolonged (>1 week) national / international concerns and media coverage or being scrutinised by parliament.
Health Inequalities (Impact could create/increase Health Inequalities across the Population)	Negligible impact on health inequalities as measured by patient access and patient outcomes.	Minor impact on health inequalities as measured by patient access and patient outcomes.	Moderate impact on health inequalities as measured by patient access and patient outcomes.	Serious exacerbation of health inequalities as measured by patient access and patient outcomes.	Critical exacerbation of health inequalities as measured by patient access and patient outcomes.
	No issues with access to service or differential/inequitable outcomes across the population.	Some differences in service access and / or outcomes for different population groups identified.	Restricted access and / or different outcomes for different population groups identified.	Significant access and / or differential health outcomes for different population groups identified.	Extensive barriers to services and /or inequity in outcomes for different population groups.
	Compliance with equalities legislation.	Unlikely to result in inequity of access/ outcomes.	May result in inequity of outcome or legislation non –compliance.	Likely to result in impact on equity of outcome and/or legislation non –compliance.	Will result in failure to comply with equalities legislation.

Likelihood – What is the likelihood of the risk occurring? *

*There is no need to use all sections of each descriptor below, these are for a guide only.

Rare (1)	Unlikely (2)	Possible (3)	Likely (4)	Almost Certain (5)
It is assessed that the risk is very unlikely to happen. Will only occur in exceptional circumstances.	It is assessed that the risk is not likely to happen. Unlikely to occur but potential exists.	It is assessed that the risk may happen. Reasonable chance of occurring - has happened before on occasions.	It is assessed that the risk is likely to happen. Likely to occur - strong possibility.	It is assessed that the risk is very likely to happen. The event will occur in most circumstances.
≤10% chance that the risk may occur.	11-37% chance that the risk may occur.	38-64% chance that the risk may occur.	65-89% chance that the risk may occur.	>90% chance that the risk may occur.
A potential 5–10-year event.	A potential for a 2–5-year event.	A potential for an annual event.	A potential for a quarterly event.	A potential for frequent occurrence e.g., daily/weekly/monthly.

LIKELIHOOD						
	5	Medium 5	High 10	High 15	Very High 20	Very High 25
	4	Medium 4	Medium 8	High 12	High 16	Very High 20
	3	Low 3	Medium 6	Medium 9	High 12	High 15
	2	Low 2	Medium 4	Medium 6	Medium 8	High 10
	1	Low 1	Low 2	Low 3	Medium 4	Medium 5
		1	2	3	4	5
IMPACT						

Appendices

Appendix 1

Categorisation of adverse events

The level of review will be determined by the category of the event and other factors such as the potential for learning. This may require some initial assessment which can be supported by a decision tool. The categories in Table 2 should be used to categorise adverse events.

Table 2: Categorisation of adverse events

Category 1	Category 2	Category 3
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. This is likely to be graded as major or extreme impact on NHS Scotland risk assessment matrix.	**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. This is likely to be graded as minor or moderate impact on NHS Scotland risk assessment matrix.	**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. This is likely to be graded as minor or negligible on NHS Scotland risk matrix.

This categorisation is based on the impact of harm and supports the measurement of reported events that resulted in harm and allows comparison with those which did not result in harm. NHS boards should take a preventative rather than a reactive approach. As NHS boards improve, the focus will move to the analysis and review of events that did not result in harm. This will provide the opportunity to review and inform system improvements to avoid the potential for harm.

NHS boards should ensure local mechanisms are in place to quality assure the categorisation of events. Appropriate actions should be taken should the original categorisation be inappropriate.

Appendix 2

Multiple board reviews

There will be occasions where an adverse event review, of any level, has the potential to involve more than one NHS board. At the start of the review process, consideration should be given to whether a collaborative approach is required. The board where the adverse event was reported is considered the lead organisation. It should contact the other organisation(s) and agree the scale of their involvement. This could include providing information or documentation to being part of the review team. A single point of contact for the patient/family should be clearly defined at the outset. It is the responsibility of the lead organisation to notify HIS of the commissioning of any such multiple board reviews. Separate guidance has been developed to support a consistent approach to collaborative multiple board reviews and is available from the HIS website.

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