

NHS Greater Glasgow and Clyde	Paper No. 25/84
Meeting:	NHSGGC Board
Meeting Date:	24th June 2025
Title	Interim NHSGGC Policy and Procedure for Managing Significant Adverse Events
Sponsoring Director/Manager	Scott Davidson, Board Medical Director
Report Author:	Paula Spaven, Director of Clinical and Care Governance Professor Colin Mckay, Deputy Medical Director, Corporate Clinical Risk Team

1. Purpose

The purpose of this paper is to present an Interim NHSGGC Policy and Procedure for Managing Significant Adverse Events (SAEs) to the NHSGGC Board for approval.

An Interim Policy is required to align NHSGGC with the updated Healthcare Improvement Scotland (HIS) national framework for reviewing and learning from adverse events, which was published in February 2025. A fuller review of the policy will be undertaken in line with any changes at a national level to create consistency across NHS Scotland in how NHS boards commission and undertake significant adverse event reviews.

2. Executive Summary

Healthcare Improvement Scotland (HIS) published an updated national framework for reviewing and learning from adverse events in February 2025.

An update is required to the current NHSGGC Policy for Managing Significant Adverse Events to align with the framework, which would formalise 3 levels of adverse event review within NHSGGC.

Adverse Event Oversight Groups (AEOGs) will be formed to support the interim policy. They will provide enhanced evaluation and monitoring mechanisms, by endorsing decision making for an appropriate level of review, and overseeing SAE reviews within their area.

A general refresh of the links and language within the policy has been undertaken, along with a review of roles and responsibilities, and addition of a red flag process to address urgent issues of escalation and oversight. A procedure document has also been created to remove some of the process detail from the overarching policy.

The following documents are provided for Board consideration and approval:

- Interim Policy for Managing Significant Adverse Events
- Interim Procedure for Managing Significant Adverse Events
- Key guidance/ templates to support formalisation of 3 levels of adverse event review
 - Adverse Event Review Flow Chart
 - Guidance on level of review
 - Terms of Reference for Sector/Directorate/Partnership AEOGs

3: Recommendations

The NHSGGC Board are asked to approve the interim policy, which would be in place for 1st July 2025.

A fuller review of the policy will be undertaken in line with any changes at a national level to create consistency across NHS Scotland in how NHS boards commission and undertake significant adverse event reviews.

3. Response Required

This paper is presented for approval

4. Impact Assessment

- | | |
|------------------------|-----------------|
| • Better Health | <u>Positive</u> |
| • Better Care | <u>Positive</u> |
| • Better Value | <u>Neutral</u> |
| • Better Workplace | <u>Neutral</u> |
| • Equality & Diversity | <u>Neutral</u> |
| • Environment | <u>Neutral</u> |

5. Engagement & Communications

The issues addressed in this paper were subject to the following engagement and communications activity:

- NHSGGC SAER Implementation Group meetings: 27th September, 25th October 2025, 8th November 2024, 22nd November 2024, 24th January 2025
- Board Clinical Governance Forum – 18th November 2024, 10th February 2025, 28th April 2025

- NHSGGC Chiefs of Medicine meeting – 22nd November 2024

6. Governance Route

The issues addressed in this paper have been considered by the following groups as part of its development:

- Updates to CMT on 5th September 2024, 7th November 2024, 5th December 2025 and 1st May 2025
- Board Clinical Governance Forum – 18th November 2024, 10th February 2025, 28th April 2025, 16th June 2025
- Clinical and Care Governance Committee – 4th March 2025, 3rd June 2025
- Divisional Clinical Governance Forums - Acute, Primary Care and Community, and Mental Health – during May 2025

7. Date Prepared & Issued

16th June 2025

Policy for Managing Significant Adverse Events (Clinical) INTERIM POLICY

Lead Manager:	Director of Clinical and Care Governance
Responsible Director:	Executive Medical Director
Approved by:	NHSGGC Board
Date approved:	<<date>>
Date for Review:	<<date>>
Replaces previous version: [if applicable]	Interim Policy: V5 Version 4: NHSGGC Policy for Managing Significant Adverse Events (August 2023)

DOCUMENT CONTROL SHEET

KEY INFORMATION

Title	NHSGGC Policy for Managing Significant Adverse Events (Clinical): Interim
Author(s)	Policy Lead: Dr Scott Davidson, Executive Medical Director Policy Owner: Paula Spaven, Director of Clinical and Care Governance
Key Contact(s)	Lynnette Cameron, Clinical Risk Manager Catherine Brown, Clinical Risk Manager Clinical Governance Support Unit - Clinical Risk Team
Approval	NHSGGC Board
Type	Interim Policy
Status	Draft
Version	V5
Effective From	Proposed 1 st July 2025

REVISION HISTORY

Version	Date	Summary of Changes
Interim	June 2025	<p>The interim policy aligns NHSGGC with the HIS National Framework for Reviewing and Learning from Adverse Events, to formalise 3 levels of adverse event review within NHSGGC.</p> <p>Addition of Adverse Event Oversight Groups (AEOGs) to support the interim policy, providing enhanced evaluation and monitoring mechanisms</p> <p>The following changes have also been made to refresh and update the existing policy.</p> <ul style="list-style-type: none"> • Review of roles and responsibilities in line with updated approach, including addition of role for the Clinical and Care Governance Committee • Links to source documents/ references updated, where source has been changed or updated • Updates to reflect changes to HIS National Framework for Adverse Events 2025 document, and NHS Scotland Risk Matrix • Addition of red flag process to address issue of escalation and oversight • Creation of a procedure document to remove process detail from the overarching policy. •

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1: Introduction

1:1 Purpose of the policy

NHS Greater Glasgow and Clyde (NHSGGC) aims to provide high quality care, which is person-centred, effective and safe. For most patients requiring healthcare this aim is satisfied, but, it is acknowledged that things can and do go wrong. It is important that we learn from these events, share that learning, and make improvements, to minimise the risk of recurrence and improve the safety and quality of our services.

It is the policy of NHSGGC that:

- Clinical adverse events and near-misses are reported and reviewed in a timely and effective way, in partnership with patients, carers, families and staff.
- learning from review is identified, shared and used to inform improvements to services.

The purpose of this policy is to ensure that a consistent approach is taken to the management and review of clinical adverse events, when they do or could have occurred.

NHSGGC is committed to carrying out timely and high-quality reviews:

Timely: Any delay may have a detrimental effect on the patient and family, staff, or the work of partner organisation reviews such as the Procurator Fiscal Service. A timely SAER is important to identify and share learning, and to minimise the consequence and impact of any recurrence of the event.

High-quality: 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 compliance with national standards, regulations and legislation.

The approach to learning builds upon our core values, which are reflected in the principles and requirements of this policy, and associated procedure and toolkit. These are:

- Care and compassion
- Dignity and respect
- Openness, honesty and responsibility
- Quality and teamwork

This policy reflects the principles and requirements set out in Healthcare Improvement Scotland '[A-national-framework-for-reviewing-and-learning-from-adverse-events-in-NHS-Scotland march 2025](#)', which has been developed drawing on international evidence and best practice relating to the management of adverse events.

1:2 Procedure and Toolkit

An operational procedure complements this policy and informs implementation, by providing further detail of the standard methodology and specific processes which should be followed. The key processes included in the procedure must be followed including completion of standard documentation.

The SAER Toolkit contains templates for all documents referred to in the policy, guides for local procedures, guidance on tools and processes, as well as key information links. The toolkit is reviewed, evaluated and updated on an ongoing basis, based on feedback and learning. The procedure, toolkit and associated materials are available here: [Significant Adverse Events Policy and Toolkit](#)

2: Scope

2:1 Who does this policy apply to?

This policy applies to all staff in NHSGGC, in all services and in all settings. All staff can become aware of harm, and have a responsibility for reporting adverse events, and implementing this policy and associated procedure as appropriate to their role.

This policy does not cover non-clinical adverse events. These should be managed in line with the [NHSGGC Incident Management and Recording Policy](#)

2:2 Aims of the Policy

The main aims of this policy are that:

- Clinical adverse events and near-misses are reported and managed in a timely and effective manner in partnership with patients, carers, families and staff

- All people, including staff who are involved in an adverse event are offered support, at a time and in a way which meets their needs
- Feedback is given to staff and will inform decision-making
- Learning from adverse events is identified and used to inform service improvements, that enhance the safety and quality of healthcare provided
- Learning is shared both within and out with NHSGGC to provide opportunities for improvement
- NHSGGC complies with its legal duties in respect of adverse events, including compliance with the statutory organisational Duty of Candour requirements where applicable

2:3 Principles

There are a number of key principles which underpin implementation, these are:

- Openness about failures – adverse events are identified, reported and managed in a timely manner, and patients and their families are told what went wrong and why.
- A systems approach – adverse events act as a ‘window’ on the healthcare system, allowing a systems analysis. This is important to allow a reflection on the weaknesses of the system, or in the case of near-misses, the strengths which prevent future adverse events
- Personal, professional and organisational accountability – everyone is responsible for taking action to prevent adverse events, including speaking up when they see practice that endangers safety.
- Reviews of events happen quickly following their occurrence. Adverse event reporting is expected to increase as we move to a more open culture
- A just culture – individuals are treated fairly. Organisational culture is based upon the values of trust, openness, equality and diversity, which encourage and support staff to recognise, report and learn from adverse events
- Teamwork – everyone is an essential and equal member of the team and needs to be valued, treated well and empowered to work to the best of their ability. Teamwork is recognised as the best defence of system failures and is explicitly encouraged and fostered within a culture of trust, mutual respect and open communication.
- An emphasis on learning and promoting best practice – the system is focused on learning at all levels - local team, service, NHSGGC and, where appropriate, nationally, and makes extensive use of improvement methodology to test and implement the necessary changes.

3: Roles and responsibilities

3:1 All Staff

All staff can become aware of harm, and have a responsibility for reporting adverse events, and implementing this policy and associated procedure as appropriate to their role.

3:2 The Chief Executive

The Chief Executive is the accountable officer and has overall responsibility for the quality of care. This is delegated through the line of general management; and complemented by the Board's governance arrangements including Executive leadership, clinical governance structures and professional leadership frameworks for clinical disciplines.

3:3 The Executive Medical Director

The Executive Medical Director has lead executive responsibility for the management of significant adverse events, and for ensuring that an effective policy is in place for reporting, managing and learning from adverse events; and for meeting the statutory and national requirements that support a safe, learning, just and open culture.

3:4 Directors and Chief Officers

The Chief Operating Officer within Acute Services Division (ASD), Chief Officers in Health and Social Care Partnership (HSCP), and Directors of clinical services, are responsible for ensuring this policy is implemented in their services, and for ensuring that effective processes and systems are in place.

3:5 Operational Management

General/Service Managers and Heads of Service, in line with operational management structures, are responsible for overall implementation, management and compliance with this policy within their area of responsibility

Individual services must establish their own local procedures to support implementation of this policy. A generic procedure document is available in the toolkit.

3:6 Clinical Leadership Frameworks

Clinical leadership arrangements (Clinical Directors, Chief Nurses, Lead Nurse/Senior Nurse) are designed to augment the professional and corporate assurance mechanisms in place, to ensure the delivery of safe, high quality patient care, and the application of this policy.

3:7 Adverse Event Oversight Groups (AEOG)

Corporate Adverse Event Oversight Group

A Corporate Adverse Event Oversight Group will be set up to maintain oversight of the implementation of this policy on behalf of the Board Medical Director. The Corporate AEOG will ensure NHSGGC is meeting the statutory and national requirements that support a safe, learning, just and open culture, and that NHSGGC is working in line with the HIS National Framework for Reviewing and Learning from Adverse Events. The group will also seek assurance from Directorate/Sector/ Partnerships Adverse Event Oversight Group(s) that timely and high-quality SAERS are being carried out.

Directorate/ Sector/ Partnership Adverse Event Oversight Group(s)

Directorate/Sector/ Partnerships will form Adverse Event Oversight Group(s) (AEOG), who will have oversight of significant adverse events occurring within its service. The AEOG will endorse decision making for an appropriate level of review, and will have a key role in overseeing adverse event reviews in their service, ensuring these are effectively project managed and that timely and high-quality reviews are undertaken.

3:8 The Director of Clinical and Care Governance

The Director of Clinical and Care Governance is the lead manager for this policy, and is responsible overall for the development and maintenance of systems and processes that support the policy; and for the associated procedure and toolkit.

The Clinical Governance Support Unit provide guidance and expert support to NHSGGC in managing significant adverse events, as well as providing assurance to Board that the policy and arrangements are functioning effectively.

The Director of Clinical and Care Governance, along with the Deputy Medical Director (Corporate) will act as an arbitrator if there are any disagreements regarding the application of this policy.

3:9 Clinical and Care Governance Committee

The overall purpose of the Clinical & Care Governance Committee is to provide assurance across the whole system regarding clinical and care governance ensuring escalation to the NHS Board. The NHSGGC Clinical and Care Governance Committee has a key duty to ensure that appropriate action is taken in response to adverse clinical incidents, and that lessons are applied to provide for sustainable improvement in the quality of care. Regular reports will be presented to the committee in line with the agreed annual cycle of business.

3:10 Corporate oversight

Corporate oversight of policy implementation will be maintained by the Executive Medical Director, via regular reports to the NHSGGC Clinical and Care Governance Committee, and the Boardwide Clinical Governance Forum, in line with their agreed annual cycle of business

4: Managing Adverse Events

4:1 Definitions

- Adverse event - 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 reactions or psychological harm”.
- Harm – harm is defined as “an outcome with a negative effect”. *Harm to a person* includes unexpected worsening of a medical condition and the inherent risk of an investigation or treatment. It is often not possible to determine whether or not the harm could have been avoided until a review is carried out.
- A clinical near miss - A clinical near-miss is an adverse event where a harmful outcome was avoided either by chance or by intervention.

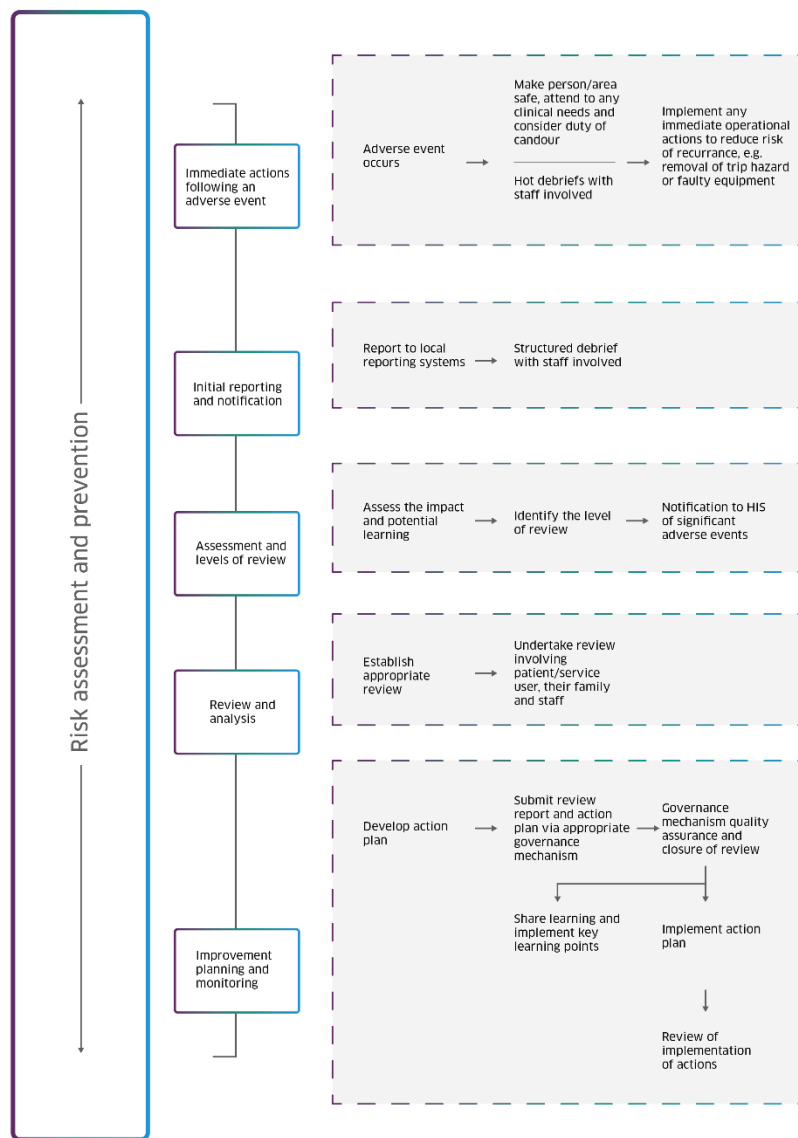
4:2 Actions to effectively manage an adverse event

Figure 1, taken from the National HIS AE Framework, outlines the key actions to effectively manage an adverse event.

- Risk Assessment and prevention
- Identification and immediate actions following an adverse event

- Initial reporting and notification
- Assessment and categorisation
- Review and analysis
- Improvement planning and monitoring

Figure 1: Actions to effectively manage adverse events



4:3 Adverse event review

The circumstances surrounding each adverse event will vary in terms of

- Level of harm
- Numbers of people involved
- Risk exposure
- Financial loss
- Media interest
- Level of concern raised by patient or family members
- The need to involve other stakeholders
- Interest/Potential interest from an external agency, such as the Procurator Fiscal

Therefore, the response to each adverse event should be proportionate to its scale, scope, complexity and opportunity for learning.

The level of review will be determined by the category of the event (i.e. the severity of harm) and other factors such as the potential for learning, both within the organisation and nationally. In line with the HIS Adverse Event Framework, NHSGGC defines 3 levels of adverse event review. The levels are:

- Level 1 – Significant Adverse Event Review (SAER).
- Level 2 – Local Adverse Event Review (LAER)
- Level 3- Local Management Review – these events will be investigated in line with the [NHSGGC Incident Management and Recording Policy](#)

4:4 Bespoke review process

Where this policy is not suitable for a specific clinical event, then a bespoke review process will be commissioned. This includes instances where there are concerns of technical expertise and independence of perspective, or where the events involve significant non-clinical elements, or there is an extant investigation agency/process that has precedence over the significant adverse event policy.

There may also be instances where the Board Executive Directors will commission a review.

5: Review

This policy will be formally reviewed every three years. The Medical Director as the Executive Lead will continuously review implementation of the policy and procedure, and prompt earlier review if required.

6: References

- A National Framework for Reviewing and Learning from Adverse Events in NHS Scotland
- <https://www.healthcareimprovementscotland.scot/wp-content/uploads/2025/02/A-national-framework-for-reviewing-and-learning-from-adverse-events-in-NHS-Scotland.pdf>
- NHSGGC Incident Management and Recording Policy 2024
- Significant Adverse Events Policy and Toolkit
- <https://scottish.sharepoint.com/sites/GGC-ClinicalGovernance/SitePages/Significant-Adverse-Event-Policy.aspx>
- Other NHS Scotland Board Adverse Event Policies – NHS Lothian, NHS Ayrshire and Arran, NHS Lanarkshire

Procedure for Managing Significant Adverse Events (Clinical) INTERIM

Lead Manager:	Director of Clinical and Care Governance
Responsible Director:	Executive Medical Director
Approved by:	NHSGGC Board
Date approved:	<<date>>
Date for Review:	1 year initially, or in line with any changes to policy
Replaces previous version: [if applicable]	Draft v0.07 – for endorsement

DOCUMENT CONTROL SHEET

KEY INFORMATION

Title	Procedure for Managing Significant Adverse events: Interim
Policy Owner:	Dr Scott Davidson, Executive Medical Director
Policy Leads	Paula Spaven, Director of Clinical and Care Governance
Key Contact(s)	Lynnette Cameron, Clinical Risk Manager Catherine Brown, Clinical Risk Manager Clinical Governance Support Unit - Clinical Risk Team
Approval	NHSGGC Board
Type	Procedure
Status	Draft
Version	V0.07
Effective From	

REVISION HISTORY

Version	Date	Summary of Changes
V1		Not applicable. Draft version for endorsement

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1: Introduction

The purpose of the NHSGGC Policy for Managing Significant Adverse Events (SAEs) is to ensure that a consistent approach is taken to the management and review of clinical adverse events, when they do or could have occurred. This is important so that NHSGGC can learn from these events, share that learning, and make improvements, to minimise the risk of recurrence and improve the safety and quality of our services.

This procedure complements the policy and informs implementation, by providing further detail of the standard methodology and specific processes which should be followed. The key processes included in the procedure must be followed, including completion of standard documentation.

The SAER Toolkit contains templates for all documents referred to in the policy, guides for local procedures, guidance on tools and processes, as well as key information links. The toolkit is reviewed, evaluated and updated on an ongoing basis, based on feedback and learning. The toolkit is available here [\[INSERT LINK\]](#).

2: Actions to effectively manage an adverse event

As outlined in the Policy, there are a number of actions to effectively manage an adverse event

- Risk Assessment and prevention
- Identification and immediate actions following an adverse event
- Initial reporting and notification
- Assessment and categorisation
- Review and analysis
- Improvement planning and monitoring

Further detail on the principles and process for each stage is provided below

2:1 Risk assessment and prevention

It is recognised that adverse event management is one part of effective risk management. Avoidance, prevention and reduction of risks should be the primary defence to prevent adverse events occurring. It is therefore important that risk assessment and prevention is seen as the first step in effective adverse event management.

The management of a SAE forms part of the current Clinical Risk Management arrangements and should be recognised as an important means of improving the quality of patient care and identifying and minimising risk.

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

2:2:1 Identification of an adverse event

From the full range of clinical events reported in NHSGGC there is a smaller set of instances where there is a risk of significant harm to patients. Such events have been traditionally referred to as Significant Adverse Events (SAE), or significant near misses.

We have a responsibility to ensure these events are appropriately reviewed to minimise the risk of recurrence by applying lessons learned. This opportunity for learning exists at times without a significant adverse outcome for the patient, e.g., a near miss or a lower impact event which exposes potential clinical system weaknesses that could lead to further significant harm.

2:2:2 Red flag SAE

Significant Adverse Event (SAE) SAEs which meet any of the following criteria have the potential to be a “red flag” SAE:

- Highlights an ongoing clinical concern
- Is a “never event”/ Avoiding Serious Event Monitoring Event
- Is a high-profile event - due to potential impact of risk exposure, financial loss or ongoing national adverse publicity
- Has potential interest/ interest from an external agency e.g. Procurator Fiscal, FAI, GMC

A red flag SAE can be identified at any stage of the adverse event review process, and by any individual. Once a red flag has been applied, this will put in place enhanced mechanisms for notification and communication, to project manage and share the learning from these SAEs, and escalation stages if the review becomes overdue.

2:2:3 Immediate action

The person who discovers the event must:

- Take immediate action to ensure the safety and wellbeing of the patient involved, other patients and the public.
- Raise the alarm to secure support from other clinical professionals.
- Initiate communication by notifying their Line Manager.

Line managers must ensure that:

- Immediate corrective action has been taken to secure safety and that the potential for further harm has been reduced to tolerable levels or eliminated.
- Senior clinical staff and the service senior management team are informed including out of hours as appropriate.
- Patients, families and other persons who need to have details of the events receive timely, adequate explanations/apologies from appropriate senior members of staff.
- Personal support is given where necessary to staff who have been involved in a SAE.
- Any faulty medicine, equipment or device is removed from use immediately and labelled to prevent further use, and ensure it is reported via the appropriate route e.g. Defective Medicines Policy
- Records, materials, and equipment, including disposable equipment used in conjunction with any device, are retained.
- Other departments involved are notified as appropriate; please refer to Appendix B for guidance.
- If records are being sent externally to the Procurator Fiscal, ensure a copy is retained.
- An electronic event report is made (if more than one service is involved one event should be recorded and teams should discuss and agree who will record and lead the event review).

2:2:4 Being Open

Patients/Family Communication

NHSGGC maintains a policy of “being open” when patients are affected by significant adverse events. Communicating effectively with patients and/or their families is an essential part of the process when dealing with a clinical event. The need for interpreter service and advocacy services, and consideration of special cultural needs must be taken into account when

planning to discuss incident information. Strongly linked to this is the need to ensure that staff are adequately supported through this process.

As soon as a SAE has been identified it is essential that an appropriate person is identified to inform patients and families. Who this person is will depend on the individual circumstances but is likely to be a member of the team involved in the overall charge of the patient's care.

It is both natural and desirable for those involved in treatment which produces an adverse outcome, for whatever reason, to sympathise with the patient or the patient's family and to express sorrow or regret at that outcome. Such expressions of regret would not normally constitute an admission of liability, either in part or full, and where staff wish to do so NHSGGC encourage such expressions to patients and/or families.

Once the review has been commissioned, patients/families should also be advised a SAE review will be undertaken and where appropriate offered the opportunity to input to this process. A 2021 study ([*Adverse event reviews in healthcare: what matters to patients and their family? A qualitative study exploring the perspective of patients and family*](#)) identified that patients and families preferred the opportunity to discuss their individual circumstances rather than a procedural approach such as being sent a letter or leaflet.

It is good practice for initial communication with families to be held face to face, by telephone or virtually, which can be followed up by letter or emails depending on the patient/family preference. All interactions should be documented in the SAE central file including any queries the patient or family may have.

It is important that the process and remit of a review is carefully explained to the patients/ families. It may be that there are issues/concerns they have out with the scope of the SAE review and if this is the case then support should be given to ensure these are addressed via the appropriate channels such as the complaints process. At this stage agreement should also be made on the level of contact the patient/family wish during the process and on the type of feedback. It is acknowledged that not all patients/families will wish to be involved in the process and this should also be respected.

In all instances those decisions relating to the involvement of patients and families must be recorded by the review team and made visible in the report. The electronic event record should also be updated to allow the service to log whether the patient was informed. This will allow the Board to monitor patient involvement.

In principle all patients/families should be informed if they are involved in a SAE.

It is acknowledged that there may be rare occasions where it is felt appropriate to deviate from this position due to assessment of the risks/benefits to the individual patient/family; in these cases agreement must be reached with the review commissioner and rationale reflected in the final report. These decisions must be agreed at the earliest opportunity by the Adverse Event Oversight Group (AEOG). These occasions do not include delays in the SAE process or any fiscal enquiries. Please see further guidance on the SAE toolkit.

If the SAE review is not completed within the agreed timescale, then the lead investigator should discuss and agree with the commissioner the requirement to contact patients/families to inform them of the delay and offer an expected completion date using a holding letter.

Organisational Duty of Candour

The Duty of Candour Procedure (Scotland) Regulations 2018, came into force on 1 April 2018. The overall purpose of the organisational duty of candour is to ensure that organisations are open, honest and supportive when there is an unexpected or unintended incident resulting in death or harm, as defined in The Act. The procedure applies to incidents that the responsible person becomes aware of after 1 April 2018, and should be activated as soon as the incident is identified. The NHSGGC Duty of Candour Policy can be found at: [Duty of Candour Policy and Guidance](#)

Informing and Involving Staff

Local Management Teams should inform staff of any incidents escalated under the Management of Significant Adverse Event Policy and detail the review process. (Supporting information is available within the toolkit).

It is important that any staff involved in a SAE are fully supported both in terms of dealing with the incident and throughout the review process. Being involved in such an event can have an impact on an individual and it is important they are offered a full opportunity to immediately debrief and discuss any concerns.

The Occupational Health service is available to support staff and should always be offered as an option to staff involved in a SAE.

Any staff engaged in a SAE review process are entitled to seek advice and be accompanied by a colleague or friend where they are not a member of a trade union or a professional

organisation. Where they are a member, they have a right to be represented by that trade union or professional organisation. Further guidance is available in the toolkit.

Colleagues can be a very useful support mechanism to staff and local managers should consider appointing a designated colleague to discuss matters in a supportive manner and provide ongoing support to an individual.

Local Management Teams should ensure staff are kept updated on the SAE process and take the opportunity to offer further support. If the need for an individual debrief is identified through the review, the line manager will be informed and can make arrangements to progress.

It is also important that once a review has concluded a general debrief is held for staff involved in the event to advise them of the findings and outcomes. This should be arranged by local management teams. Local procedures will set out how the final outcome is communicated to management and senior clinicians to ensure wider discussion takes place.

2:3 Initial reporting and notification

2:3:1 Event reporting

Routine adverse event reporting for both clinical and non-clinical events should be managed in line with the NHSGGC Incident Management and Recording Policy. Any clinical adverse events or near misses should be reported on the NHSGGC Incident Reporting System as soon as possible after the incident.

The system is used to support monitoring and reporting of SAEs and it is therefore imperative the information within here is up to date and accurate.

Local SAE procedures should outline how the electronic event record will be subsequently managed.

2:3:2 Communication and notification

As noted, services should have a briefing note system in place to ensure that the event is communicated as widely as is needed throughout the organization, and to support rapid communication to senior staff. This is separate to recording the incident on the NHSGGC Incident Reporting System.

This should be done as soon as is practicable after the event has occurred by the Local Management Team referred to above. The briefing note must be reviewed by the commissioner and must be confirmed as a SAE, which will trigger the review process within the service.

Within local procedures, services will wish to define a list of events that should automatically be escalated. All areas must develop their own briefing note distribution list as part of their local procedures which should include appropriate members of the Senior Management Team and may have to be amended in light of the specific event (e.g. to include pharmacy for medication events).

In implementing this briefing note distribution list services can refer to the template within the SAE toolkit which contains the core information that should be included, services can amend to include additions specific to local requirements. Services must ensure that the information contained within a briefing note meets the requirements of the [Data Protection Act \(2018\)](#) and the [Board Information Security Policy](#).

Directors/Chief Officers must consider arrangements for immediate communication/escalation of events to Division/Board level within their process. Escalation to senior staff is intended to create transparency and to generate support around the ongoing management of SAEs.

Corporate Communications should be consulted before any public/external communication is made: [NHSGGC Press Team](#)

2:3:3 Links to other Formal Proceedings

Staff should be aware that incidents of this nature can at times be involved in other formal proceedings linked to the incident, specific reviews, HR reviews and legal claims (Appendix B) and the Procurator Fiscal (Appendix C). Where a SAE highlights the need for potential disciplinary action the report should include a recommendation to local management that other HR policies will be utilised. In these named examples copies of the core file may be shared if requested.

In cases where there is a formal complaint linked to an incident a final copy of the SAE report can be used to support the complaint response. A complaints and SAE flowchart can be found in the toolkit.

The spirit of the review into a clinical event will be characterised by a *just* culture. 'Just culture' in this context means that the purpose of the review is to identify contributory

factors or clinical system failures. Staff will not be 'blamed' for such failures or their consequences; however, they retain individual responsibility for their own actions or inactions in accordance with the professional codes that apply to them and their professional practice. It is recognised that staff are expected to follow policies and procedures and that if there is willful knowing departure from that which cannot be justified or explained in terms of contributory factors, then this is likely to be addressed through the established disciplinary procedures.

Any review of a SAE will not, and cannot, preclude use of the code of conduct process where there has been an obvious significant breach of professional practice or organisational policy. If a disciplinary procedure is invoked, the lead investigator will be made aware.

In all other cases the appropriate HR processes should not be instigated until a SAE review has been completed and causal factors identified unless there is a presenting or ongoing risk to patients, staff and the public.

Information gathered as part of a review may be shared if the incident is subject to further review, this includes a staff recollection of events document. All staff should be advised at the time of submitting a staff recollection of events document that this may be the case. This is a supportive action to prevent staff being asked to submit multiple recollections of events.

Relationship to the [Freedom of Information \(Scotland\) Act 2002 \(FOISA\)](#)

SAE information is within the remit of the Freedom of Information (FOI) legislation, and we may be required to disclose if requested under the Act information relating to SAEs, either as high-level information or in relation to specific incidents. This could include key documents such as:

- SAE Final report
- Action Plan
- Review Timeline (if used)
- Other information created during the course of the review, for example email correspondence and their attachments/ review template

The position in relation to information that must be released under FOI legislation is constantly evolving in line with decisions made by the Information Commissioner and all requests will be reviewed and considered on an individual basis; full redaction principles will be applied to any information released. The final SAE report contains the findings of the review and all relevant information gathered through that process therefore would be regarded as the key information source for any requests. It is acknowledged that action plans and timelines can provide additional factual information in relation to the review process and

conclusion. Any change to the position as to what information we are required to disclose will be communicated and guidance amended to reflect.

2:4 Assessment and categorisation

The National Framework defines 3 event categories based on the level of harm the event may have contributed to or resulted in. These are:

- Category 1 - Events which may have contributed to or resulted in permanent harm. These events meet the definition of Major or Extreme Events on the National Risk Matrix and align to Severity 4 and 5 events on the Board's Risk Management System (Datix).
- Category 2 – Events which may have contributed or resulted in temporary harm. These events meet the definition of Minor or Moderate Events on the National Risk Matrix and align to Severity 2 and 3 events on the Board's Risk Management System (Datix).
- Category 3 – Events which had the potential to cause harm but no harm occurred. These events meet the definition of Minor or Negligible Events on the National Risk Matrix and align to Severity 1 and 2 events on the Board's Risk Management System (Datix).
- If there is any uncertainty as to whether an event falls in the scope of the policy, or the category of the event, the Adverse Event Oversight Group should be involved in the decision. Advice can also be sought from Clinical Risk.

The Director of Clinical and Care Governance, along with the Deputy Medical Director (Corporate) will act as an arbitrator if there are any disagreements regarding the application of this policy.

2:5 Review and analysis

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

- Level of harm
- Numbers of people involved
- Risk exposure
- Financial loss
- Media interest
- Level of concern raised by patient or family members
- The need to involve other stakeholders
- Interest/Potential interest from an external agency, such as the Procurator Fiscal

Therefore, the response to each adverse event should be proportionate to its scale, scope, complexity and opportunity for learning.

The level of review will be determined by the category of the event (i.e. the severity of harm) and other factors such as the potential for learning within the organisation and nationally. In line with the HIS Adverse Event Framework, NHSGGC defines 3 levels of adverse event review.

The levels are:

- Level 1 – Significant Adverse Event Review (SAER).
- Level 2 – Local Adverse Event Review (LAER)
- Level 3- Local Management Review – these events will be investigated in line with the Incident Management Policy

Adverse Event Oversight Groups (AEOGs) will endorse decision making for an appropriate level of review and will have a key role in overseeing adverse event reviews in their service.

Although it is recognised that some events have a greater impact, are more complex, or require a more formal, in-depth review; all adverse event reviews should follow the same principles, and basic review and analysis process. The key difference between a SAER and a LAER is in the method of undertaking the review. Guidance to support decision making on the appropriate level of review, and on the differences between a SAER and a LAER are available in the toolkit.

2:5:1 Aim of Review

The review aims to examine the processes of care to identify if any clinical system failures occurred which contributed to the incident and the patient outcome. This understanding is vital if the learning from these incidents is to be realised.

Where clinical system failures are identified, causal analysis should be undertaken to further understand why and how these can be managed to prevent recurrence. A review should consider how significant this failure has been in the overall incident (i.e. if multiple failures how they relate to each other) and also how they impacted on the patient and subsequent outcome. This may be difficult at times depending on the circumstances of the event but should be considered and included within the final conclusions of the report.

It is recognised that not all events reviews will identify clinical system failures and may find appropriate care was delivered, the potential for learning in these cases should also be recognised and areas of good practice shared appropriately.

An event being declared a SAE does not indicate any causal link between the care and patient outcome but reflects the perceived need to investigate an event in detail to establish this and/or that there is potential for learning on a wider level. A review may conclude that the care delivered was appropriate and an event unavoidable; this is still logged as a SAE as the review process has been enacted to inform this conclusion.

Principles for commissioning/conducting reviews

All staff involved in must adhere to the following principles:

- The review is not about apportioning blame but establishing causality.
- The review is a transparent process and there must be evidence of appropriate staff/patient/family involvement.
- Staff members directly involved in the incident or patient care must not be involved in the review team but may contribute to the review.
- The Commissioner of the review should not form part of the review team.
- 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.
- There is a robust process in place to ensure reviews are appropriately supported from commissioning to conclusion.
- All staff who contribute to the review will have the opportunity to review draft reports for factual accuracy, a final report will then be agreed by the review team and submitted to the review commissioner.
- The commissioner will ensure that all staff receive feedback following publication of the final report.
- The review is to investigate the clinical care of the patient. The complaints process will run concurrently with the review process if there are other elements of the complaint to be answered
- If the incident involves more than one service a joint review is required involving both parties. There should not be two separate reviews for the same event.
- Local procedures must include an escalation process for resolution of disputes where appropriate.

A core team can be established, and specialist input sought to support this as required if particular issues are identified. For example, if the event concerns medication, then a pharmacist must be part of the review team, or if digital health systems are implicated a clinical e-health lead should advise. If the remit of the review includes multiple services a representative from the services should be on the review team.

The supporting toolkit provides guidance on tools and techniques that can be used to

support the review process, and also specialist support staff within the Board who should be notified of SAEs and may provide support.

The process generally involves gathering all relevant information.

Conclusion/ causation code

A review conclusion code is applied to all events to indicate the findings of the review in relation to the link between care and patient outcome, which will allow identification of those events where improvements are required. All reviews will conclude one of the following review causation codes:

1. Appropriate care: well planned and delivered
2. Indirect system of care issues: Issues identified but they did not contribute to the event
3. Minor System of Care Issue: Issues identified which may have caused or contributed to the event
4. Major System of Care Issue: Issues identified that directly related to the cause of the event

Core File

The Commissioner must ensure a core file must be kept separate to the electronic incident record which must include:

- Any staff recollection of events submitted as part of the review
- Any reports/documented information provided to support review
- Any photographs taken as part of the review
- Details of any equipment involved in the incident including location of equipment
- Tools used in the review timeline
- Key of names

Local procedures must define the process for ensuring this core file is maintained; this includes a log of file paths to where these are stored; all files must be kept in line with records retention guidelines. Scottish Government Records Management, Health and Social Care Code of Practice (Scotland) 2020

2:5:2 The Report

The final report of a review is a key document and presents the findings, conclusions and recommendations of the review team. Templates are available of the toolkit and the correct template should be submitted.

Reports may be shared with external agencies, for example the Procurator Fiscal, SGHD, NMC, GMC and with other NHS Scotland Boards. It must be confirmed that the report has been finalised prior to release and that a named lead is agreed to manage any ongoing contact. Any reports to be shared in the public domain (i.e. via an FOI request) must be redacted in line with Board procedures as outlined in an earlier section.

Staff should be aware that when investigating deaths, the Procurator Fiscal may consider all information gathered as part of a review to be relevant, including statements they provided as part of the process. Where statements have been requested, the relevant staff will be advised. There is an expectation that the Board as a public authority will support Crown investigations. NHSGGC have always encouraged staff to participate in investigations on a voluntary basis to potentially avoid the need for them to do so in a formal capacity in Court.

All reviews of events being considered as a SAE must be completed and documented using the defined template, which is then attached to the record on the NHSGGC Incident Management System.

Clinical Risk will attach the final SAE report at the conclusion of the review. The electronic event record is at this time the prescribed data store for SAEs and must be used as a single repository of all SAEs.

2:6 Improvement Planning and Monitoring

2:6:1 Action plan and recommendations

Following submission of the report, services have a responsibility to develop action plans considering any recommendations from the report. A completed action plan should be recorded on the NHSGGC Incident Management System by the service who own the actions. If actions have already been taken forward this should be reflected in the final report and recorded on the electronic reporting system.

Where a recommendation is not being progressed, there should be clear reasoning as to why and a record of this should be made using the progress field of the actions module in the electronic reporting system. It may be appropriate to transfer actions that are not able to be progressed at the time to the risk register.

Services must ensure a robust process is in place to monitor the completion of actions including updating of the electronic reporting system on completion of all actions. Further guidance on developing action plans can be found in the Toolkit.

As actions are being completed it is the responsibility of the service manager to ensure that the action plan is updated on the electronic reporting system.

2:6:2 Sharing Learning

NHSGGC expect that where there are system of care issues that contributed to the event a learning summary is developed (investigation outcome 3 and 4). NHSGGC uses the Healthcare Improvement Scotland (HIS) template for sharing learning nationally.

The learning summary should focus on what can be done to prevent recurrence rather than just highlighting the issue/problem. It is helpful if the last section gives an indication of what can be done to reduce the risk.

The template for the learning summary can be found on StaffNet as part of the toolkit, along with the national guidance.

Clinical Risk will support services to ensure SAE reviews are analysed to identify themes and solutions that can be shared across services. This and the aforementioned aggregate reports will support ongoing monitoring of the learning from these reviews.

The Board Annual Clinical Governance Report will also include consideration of learning.

3: Useful documents

- Adverse event reviews in healthcare: what matters to patients and their family? A qualitative study exploring the perspective of patients and family
<https://bmjopen.bmj.com/content/bmjopen/12/5/e060158.full.pdf>
- Clear to All Toolkit
<https://www.nhsggc.scot/hospitals-services/services-a-to-z/clear-to-all/>
- Data Protection Act
<https://www.gov.uk/data-protection>
- Duty of Candour Policy and Guidance
<https://scottish.sharepoint.com/sites/GGC-ClinicalGovernance/SitePages/Duty-Of-Candour-Policy.aspx>

- Freedom of Information (Scotland) Act 2002 (FOISA)
<https://www.legislation.gov.uk/asp/2002/13/contents>
- Health (Tobacco, Nicotine etc. and Care) (Scotland) Bill (2016)
<https://www.legislation.gov.uk/asp/2016/14>
- Health and Safety Policy
<https://www.nhsggc.org.uk/media/269268/health-safety-policy-april-2021.pdf>
- Maternity and neonatal (perinatal) adverse event review process for Scotland
<https://www.gov.scot/publications/maternity-neonatal-perinatal-adverse-event-review-process-scotland/pages/6/#:~:text=Health%20Boards%20should%20have%20a,and%20staff%20and%20sharing%20learning.>
- National Adverse Events Framework (2025)
<https://www.healthcareimprovementscotland.scot/wp-content/uploads/2025/02/A-national-framework-for-reviewing-and-learning-from-adverse-events-in-NHS-Scotland.pdf>
- NHSGGC Incident Management and Recording Policy 2024
<https://www.nhsggc.scot/downloads/incident-management-and-recording-policy-nov2024/>
- NHSGGC Security Policy
<https://www.nhsggc.org.uk/media/262942/information-security-policy-19-acceptable-use-v-n10docx.pdf>
- Pressure Ulcer Prevention and Management Policy 2023
<http://www.staffnet.ggc.scot.nhs.uk/Acute/Division%20Wide%20Services/TissueViabilityServiceAcuteDivision/Documents/NHSGGC%20Pressure%20Ulcer%20Policy%202022%20Final%2025.4.23.pdf>
- Scottish Government Records Management Code of Practice
<https://www.informationgovernance.scot.nhs.uk/wp-content/uploads/2020/06/SG-HSC-Scotland-Records-Management-Code-of-Practice-2020-v20200602.pdf>
- Significant Adverse Events Policy and Toolkit
<https://scottish.sharepoint.com/sites/GGC-ClinicalGovernance/SitePages/Significant-Adverse-Event-Policy.aspx>

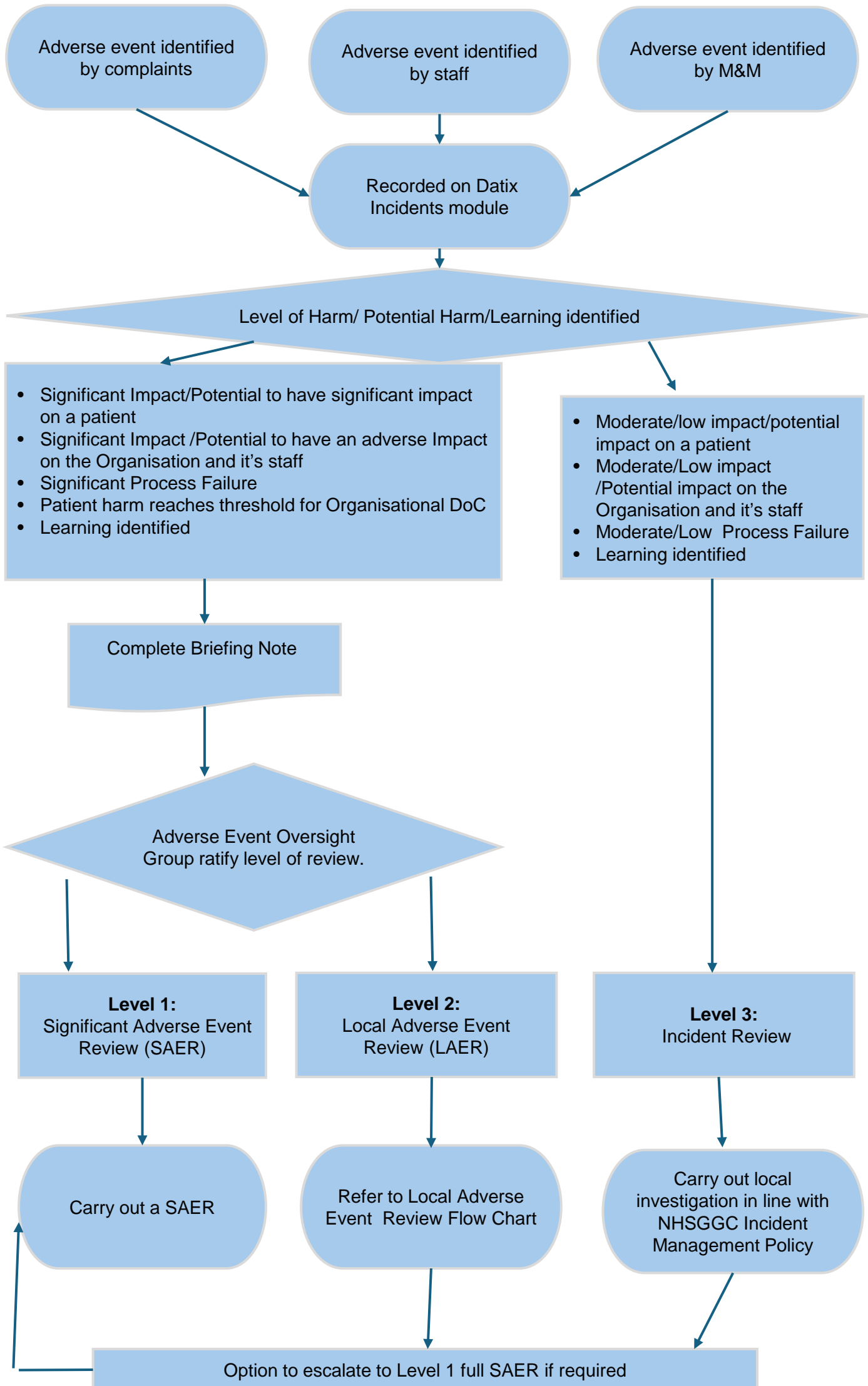
4: Review

This procedure will be formally reviewed on a 3 yearly basis, in conjunction with the NHSGGC Management of Significant Adverse Event Policy.

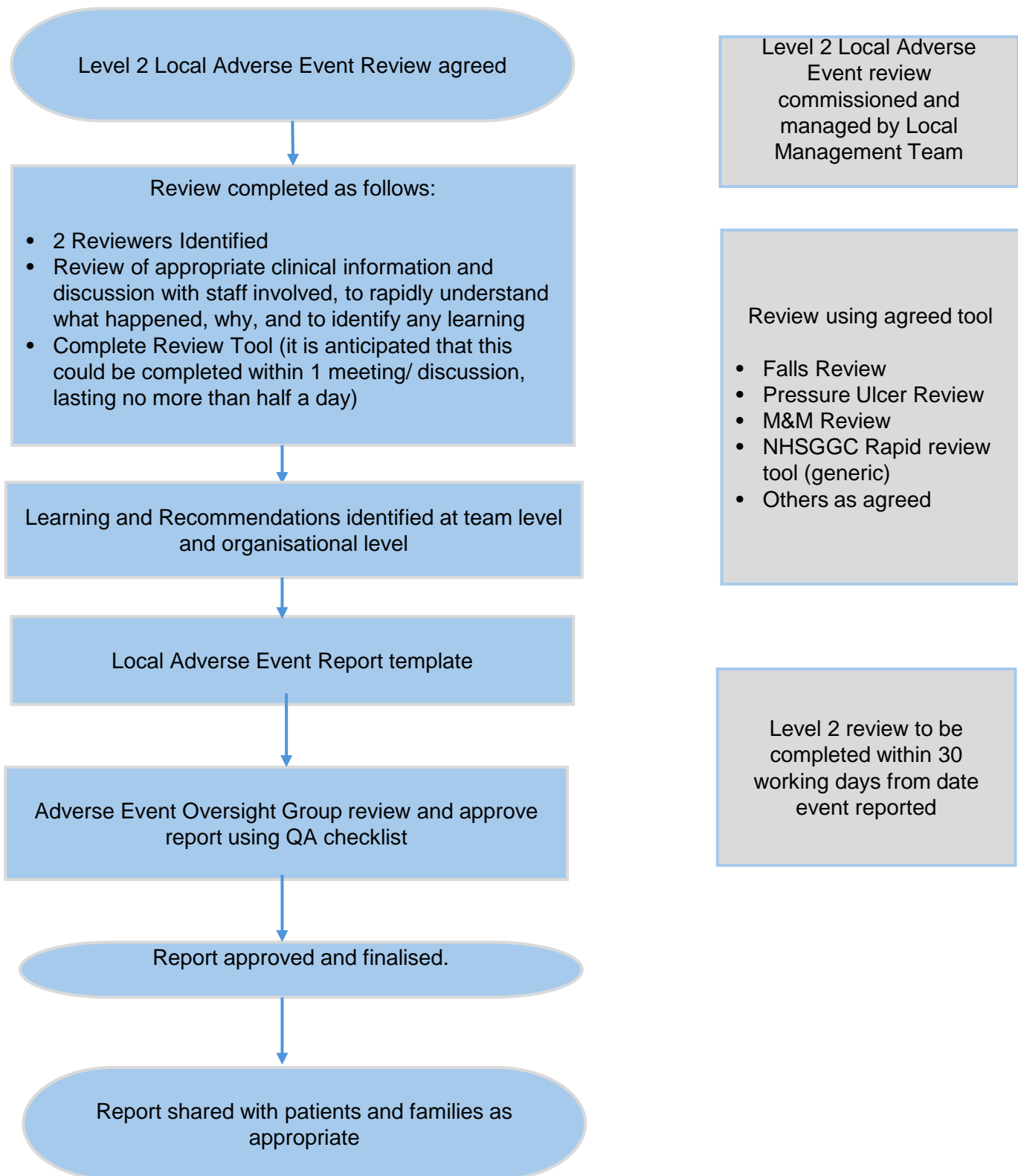
An initial review will be undertaken at 1 year, or in line with any changes to the Interim Policy.

Documents within the toolkit are reviewed, evaluated and updated on an ongoing basis, based on feedback and learning.

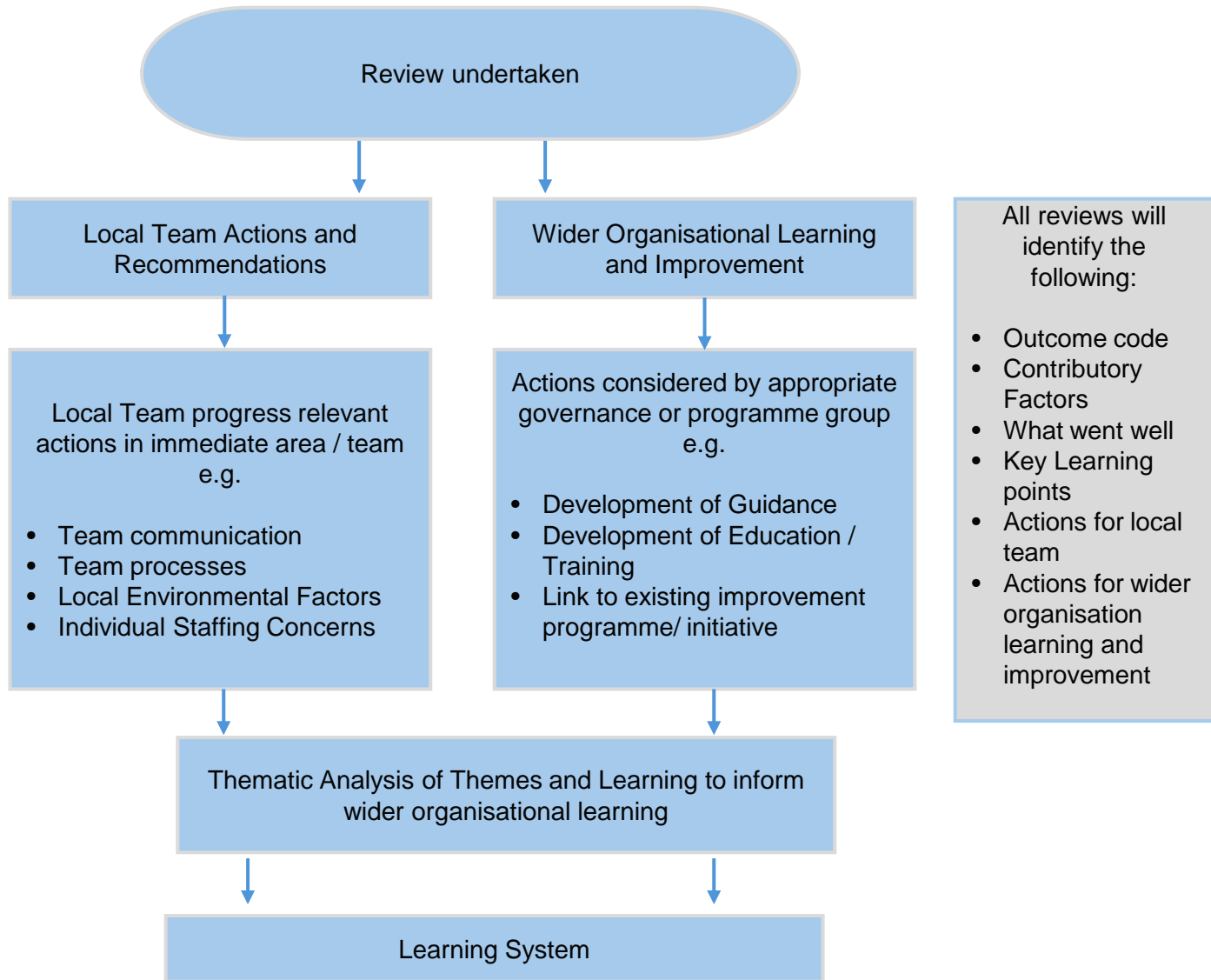
Decision Making



Level 2: Local Adverse Event Review



Learning and Recommendations



Level of Adverse Event Review – Guidance and Pathway

The response to each adverse event should be proportionate to its scale, scope, complexity and opportunity for learning.
The level of review will be endorsed by the Adverse Event Oversight Group based upon an assessment of:

- the national list of significant adverse events (when available*)
- the severity of harm or potential harm (impact in line with the NHS Scotland Risk Impact and Likelihood Assessment Matrix)
 - the potential for learning, both national and local

Level of Review	Significant Adverse Event Review	Local Adverse Event Review	Standard Incident Management Ward/Department Review by Line Manager
Type of Review	<p>The review team should be sufficiently removed from the event and have no conflict of interest to be able to provide an objective view.</p> <p>SAER Group uses Systems Based Approach.</p>	<p>Service/General/Clinical Manager with Multi-disciplinary Team input.</p> <p>Group uses a Systems Based Approach.</p>	<p>Ward/Department Reviewer or Deputy undertakes review of adverse event using appropriate tools and a Systems Based Approach.</p> <p>Directorate Review Groups may carry out multidisciplinary reviews and carry out trend analysis of all adverse events.</p>
Level of authority (Decision making)	<p>Adverse Event Oversight Group (AEOG) will:</p> <ul style="list-style-type: none"> Review AE briefing note; Propose review level as SAE; The AEOG sets the Terms of Reference The AEOG identifies a Lead Reviewer which is agreed by the Commissioner and sends the commissioning email informing the Lead Reviewer. 	<p>Adverse Event Oversight Group (AEOG) will:</p> <ul style="list-style-type: none"> Review AE briefing note; Authorise the Local Adverse Event Review The commissioner for the area the event took place appoints the Lead Reviewer. 	<p>Final Approver quality assures the review, confirming that a robust review has been undertaken and finally approves and closes the record.</p>
Review Team	<p>The review team will consist of:</p> <ul style="list-style-type: none"> A Lead Reviewer; Representative from Service; Subject Matter Experts; Patients/ Service User or family contact; and Staff contact <p>N.B. Some members may act in a dual capacity e.g. the Service Representative can be the staff contact. A member of the review team will have Systems Based Approach skill</p>	<p>Lead Reviewer enlists the support of other as felt necessary in order to complete the review. This includes:</p> <ul style="list-style-type: none"> Patient/Service User or family contact, Agreeing terms of reference/ scope ensuring the review is robust for sharing with others, identifying learning to form action plan, provide feedback to staff in area where the event occurred ensuring the learning is implemented <p>N.B. Some members may act in a dual capacity e.g. the Lead Reviewer can be the patient/service user or family contact. /service user named contact.</p>	<p>A Team is not necessary however; the review should not be undertaken in isolation where other services are involved.</p> <p>Specialist advice should be sought where appropriate.</p>

Level of Adverse Event Review – Guidance and Pathway

The response to each adverse event should be proportionate to its scale, scope, complexity and opportunity for learning.
The level of review will be endorsed by the Adverse Event Oversight Group based upon an assessment of:

- the national list of significant adverse events (when available*)
- the severity of harm or potential harm (impact in line with the NHS Scotland Risk Impact and Likelihood Assessment Matrix)
 - the potential for learning, both national and local

Level of Review	Significant Adverse Event Review	Local Adverse Event Review	Standard Incident Management Ward/Department Review by Line Manager
Key principles that must be followed	All reviews must have a: <ul style="list-style-type: none"> • Datix ID; • Terms of reference; • Tabular timeline of events; • Review Report on the Organisations' agreed format; • Action Plan if required; and • Organisational Learning Summary (excluding reviews with outcome code 1 and 2) • Completion of Duty of Candour procedure (if triggered) – this will be detailed in the report and will include to what extent the duty has been applied. 	All reviews must have <ul style="list-style-type: none"> • Datix ID • LAER/ bespoke template completed or Terms of reference and Tabular timeline of events; • Review Report on the Organisations' agreed format; • Action Plan if required; and • Organisational Learning Summary (excluding reviews with outcome code 1 and potentially 2) • Completion of Duty of Candour procedure (if triggered) – this will be detailed in the report and will include to what extent the duty has been applied 	The review must document <ul style="list-style-type: none"> • What led to the event happening? • When did the event happen? • How did the event happen? • Why did the event happen? • Impact of the event and learning.
Governance / Performance	Report and recommendations to be approved by the relevant AEOG. Completed action plan is presented to the AEOG for approval	Report and recommendations to be approved by the relevant AEOG. Completed action plan is presented to the AEOG for assurance.	Local monitoring by Ward/Department/Service Managers.
Time-scale	Review must be commissioned within 10 working days of the Adverse Event being reported on electronic risk management system. Commence and close review (report submitted for approval to AEOG within 90 working days of the commissioning date). Final approval and local sign off within 30 working days Action plan to be developed within 10 working days from report being approved. TOTAL = 140 working days	Commence and close review (report submitted for approval through AEOG) within 30 working days of the Adverse Event being reported on the electronic risk management system. Final approval should take place as soon as possible but no later than 30 working days from report. Develop action plan within 10 working days from report being approved. TOTAL = 70 working days	Adverse Event finally approved within 10 working days.

1. INTRODUCTION

1:1 The (*Directorate/Sector/ Partnership Name*) Adverse Event Oversight Group(s) (AEOGs) provide enhanced evaluation and monitoring mechanisms for Adverse event reviews occurring within its service.

The AEOG will endorse decision making for an appropriate level of review for Significant Adverse Events, ensuring the Briefing Note is completed. This could be: Level 1 Significant Adverse Event Review (SAER), Level 2 Local Adverse Event Review (LAER) or Level 3 Local Incident Review (in line with NHSGGC Incident Management Policy)

1:2 The AEOG will have a key role in overseeing SAERs and LAERs:

- To work with the Commissioner to establish robust adverse event review process, in line with agreed level of review
- Oversee progress of the AER, ensuring timescales are met
- Ensure quality of AER reports (SAERs will continue to go through formal QA process.
- Receive the final AER report and recommendations for approval.
- Agree actions as required,
- Monitor completion of actions and sharing of learning

2: ROLES AND RESPONSIBILITIES

- The group will ensure that the NHSGGC Policy on the Management of Significant Adverse Events and the NHSGGC Incident Management Policy are adhered to for all adverse events
- Have oversight of the Duty of Candour procedure, ensuring all legal requirements have been met in full for all significant adverse events.
- Evaluate improvements and actions that will support wider learning (including organisational and national learning where appropriate).
- Identify recurring themes that may warrant further exploration.

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3: CONDUCT OF BUSINESS

3:1 GROUP MEMBERSHIP

The Adverse Event Oversight Group will comprise of a core group, with other members to be confirmed locally. It is suggested that the core group should consist of the following:

- Directorate/ Sector/ Partnership Chief of Medicine/Clinical Director (Co-chair)
- Directorate/Sector/ Partnership Chief Nurse/ Lead Nurse/Assistant Director (Co-chair)
- General Manager for each service/area
- Clinical risk representative
- Administration Support

The group may invite other members to participate in discussions and reviews as appropriate, such as:

- Pharmacy
- Allied health Professionals

3:2 FREQUENCY OF MEETINGS

The frequency of meetings will be agreed by the Adverse Event Oversight Group, taking into consideration the number of adverse events and matters for consideration, although the group should meet a minimum of monthly. This will be reviewed by the group on an ongoing basis.

Meetings can be virtual in nature.

3:3 EFFECTIVE WORKING

To work effectively, the AEOG will:

- Ensure confidentiality of the individuals involved in any case is respected.
- Co-opt other clinical/operational advisors as required, dependent on the nature of the adverse events tabled for discussion.
- Ensure that one of the Co-chairs attends each meeting.
- Keep a record of adverse events discussed and outcomes for every meeting, which will be circulated to Group members prior to the next

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meeting. The Agenda for meetings of the Group will primarily derive from adverse events reported via the Incident Reporting System (Datix).

- Co-chairs will provide summary reports to the overarching Sector/ Directorate/ Partnership Clinical governance group for assurance, in line with agreed reporting schedule.

4: GOVERNANCE AND ASSURANCE

4:1 The AEOG is responsible for providing evidence and assurance to the respective Divisional Clinical Governance Group (Acute, mental Health, or Primary Care and Community) that significant adverse events are being managed in line with relevant policy, and that improvements are being implemented and learning shared.

4:2 Key performance indicators will be in place to support monitoring and assurance.

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