

NHS Greater Glasgow and Clyde	Paper No. 25/164
Meeting:	NHSGGC Board Meeting
Meeting Date:	18 December 2025
Title:	NHSGGC Policy and Procedure for Managing Significant Adverse Events
Sponsoring Director:	Dr Scott Davidson, Board Medical Director
Report Author:	Ms Paula Spaven, Director of Clinical and Care Governance Professor Colin Mckay, Deputy Medical Director, Corporate

1. Purpose

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

2. Executive Summary

The Interim NHSGGC Policy and Procedure for Managing Significant Adverse Events (SAEs) was approved at the Board in June 2025 and effective from 1st July 2025. An Interim Policy was 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.

The main aims of the 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

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compliance with the statutory organisational Duty of Candour requirements where applicable

The full policy and procedure have been consulted on across NHSGGC, with extensive testing of the interim approach; as well as ongoing work to improve SAER performance with enhanced oversight and monitoring, and to review and streamline the SAER process.

The policy and procedure have been endorsed through clinical governance arrangements, the Boardwide Clinical Governance Forum, Corporate Management team (CMT), and Clinical and Care Governance Committee.

Members are asked to note:

- A minor change to the policy to include the role of the Board
- Minor wording changes to the procedure which are outlined in the document
- An extensive SAER toolkit is in place to support the policy and procedure. An index is attached as Appendix 1. This is subject to ongoing review, evaluation and update in response to feedback and learning.
- The SAER policy section of the Clinical Governance Support Unit (CGSU) Staffnet pages is being redesigned to enhance access to key documents and guidance, including a specific section on staff support. This is available at the following link: [Significant Adverse Events Policy and Toolkit](#)
- The completed Policy Development Assurance Framework Checklist, in line with the NHSGGC Policy Development Framework, which is attached as Appendix 2.

3. Recommendations

Board members are asked to approve the policy and procedure.

4. Response Required

This paper is presented for **approval**

5. Impact Assessment

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

6. Engagement & Communications

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

- NHSGGC Consultation
- Area Partnership Forum
- Divisional Clinical Governance Forums (Acute, Mental Health and Primary Care)

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- Boardwide Clinical Governance Forum
- Corporate management team
- Clinical and Care Governance Committee

7. Governance Route

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

- Divisional Clinical Governance Forums – electronic endorsement
- Boardwide Clinical Governance Forum – 20 October 2025
- Corporate Management Team – 3 November 2025
- Clinical and Care Governance Committee – 4 December 2025

8. Date Prepared & Issued

Prepared on: 8 December 2025

Issued on: 10 December 2025

Appendix 1: Significant Adverse Events Toolkit: Index

[Significant Adverse Events Policy and Toolkit](#)



Briefing Note, Commissioner and AEOG Resources

Resource
Action Plan Guidance
AEOG Terms of Reference Template
Communication and External Reporting
Complaint to SAERs Process Map
Datix Quick Guide to Updating Review Fields
Level of Adverse Event Review - Guidance and Pathway
LAE Review Commissioner Checklist
Approach to Multi Board Reviews of Adverse Events
Multi Service Review Diagram
Request to contribute to multi-board significant adverse event review
NHSGGC Significant Adverse Event Briefing Note Template
NHS Scotland Risk Assessment Matrix
Recommendations Actions and Learning Flowchart
Adverse Event Review: Decision Making Flowchart
SAE Review Commissioner Checklist
Significant Adverse Event (SAE) - Red Flag Process
Significant Falls Investigation Process

Adverse Event Reporting Templates

Resource
SAER Report Template
LAE Report Template
Timeline Template
Staff Key Template
GGC Learning Summary Template
SAER Quality Assurance Checklist
LAER Quality Assurance Checklist

Lead Reviewer Guidance

Resource
SAER Report Guidance
LAER Report Guidance
SAER Lead Reviewer Checklist
LAER Lead Reviewer Checklist
Contributory Factors List
Data Redaction and Standardised Guidance
Developing Recommendations from a Significant Adverse Events Investigation
Error Analysis
Introduction to Human Factors Guidance
Reporting Deaths to the Procurator Fiscal
Role of Lead Reviewer
Role of Review Team Member Guidance

Patient and Family Engagement and Support

Resource

Duty of Candour Policy and Guidance
Guidance to support communication with families
Adverse Event Leaflet for Patients and Families

Letter templates

Resource

Initial Letter to a Patient
Report Cover Letter to Patient
Initial Letter to Family of a Deceased Patient
Initial Letter to Family of a Living Patient
Report Cover Letter to Family

Staff engagement and support

Resource

Brief SAER Guide for Staff
Manager's Guide for supporting staff involved in a SAE review
Interview Introduction for SAE Reviews
Reflective Exercise Example
Writing a Recollection of Events
Sample Letter Inviting Staff to Interview

Review Investigation tools

Resource

7 Minute Briefing Overview
7 Minute Briefing Template
Cause and Effect Model Guidance
Questions to Ask in Investigations and Learning Reviews
Fishbone Diagram
Reactive Barrier Analysis
Systems Engineering Initiative for Patient Safety (SEIPS) Worksheet
Time Person Analysis
Yorkshire Contributory Factors Framework

Local SAER processes

Resource

MHS 25 - Significant Adverse Event (SAE) Guidance
SAE Protocol (GPs)
SAE Protocol (HSCPs)
SAER Process for Clyde Sector
SAER Process for North Sector
SAER Process for RSD
SAER Process for South Sector

NHS Greater Glasgow and Clyde Equality Impact Assessment Tool

Equality Impact Assessment is a legal requirement as set out in the Equality Act (2010) and the Equality Act 2010 (Specific Duties)(Scotland) regulations 2012 and may be used as evidence for cases referred for further investigation for compliance issues. Please refer to the EQIA Guidance Document while completing this form. Please note that prior to starting an EQIA all Lead Reviewers are required to attend a Lead Reviewer training session or arrange to meet with a member of the Equality and Human Rights Team to discuss the process. Please contact CITAdminTeam@ggc.scot.nhs.uk for further details or call 0141 2014560.

Name of Policy/Service Review/Service Development/Service Redesign/New Service:

Policy for Managing Significant Adverse Events (clinical)

Is this a: Current Service ☐ Service Development ☐ Service Redesign ☐ New Service ☐ New Policy ☐ Policy Review ☒

Description of the service & rationale for selection for EQIA: (Please state if this is part of a Board-wide service or is locally driven).

What does the service or policy do/aim to achieve? Please give as much information as you can, remembering that this document will be published in the public domain and should promote transparency.

The NHSGGC Policy for Managing Significant Adverse Events (clinical) is a key organizational policy, which aims to ensure 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.; and that learning from reviews is identified, shared and used to inform improvements to services. The main aims of this policy are:

- 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

Why was this service or policy selected for EQIA? Where does it link to organisational priorities? (If no link, please provide evidence of proportionality, relevance, potential legal risk etc.)

The NHSGGC Policy for Managing Significant Adverse Events (clinical) is written at a strategic level, recognising that implementation and practice will be supplemented by supporting guidance and other relevant policies.

It is proportionate that the policy is robustly assessed for consideration of any potential negative impact on protected characteristics, which aligns to our commitment to eliminate discrimination, harassment and victimisation, promote equality of opportunity and foster good relations between groups that share a protected characteristic and those who do not.

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Who is the lead reviewer and when did they attend Lead reviewer Training? (Please note the lead reviewer must be someone in a position to authorise any actions identified as a result of the EQIA)

Name: Paula Spaven Director of Clinical and Care Governance	Date of Lead Reviewer Training:
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Please list the staff involved in carrying out this EQIA

(Where non-NHS staff are involved e.g. third sector reps or patients, please record their organisation or reason for inclusion):

Director of Clinical and Care Governance Clinical Risk Managers
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		<i>Example</i>	Service Evidence Provided	Possible negative impact and Additional Mitigating Action Required
1.	What equalities information is routinely collected from people currently using the service or affected by the policy? If this is a new service proposal what data do you have on proposed service user groups. Please note any barriers to collecting this data in your submitted evidence and an explanation for any protected characteristic data omitted.	<i>A sexual health service collects service user data covering all 9 protected characteristics to enable them to monitor patterns of use.</i>	<p>A Significant Adverse Event (SAE) investigation collects a range of relevant information through the reporting system and review process.</p> <p>The SAE report template includes a question on whether an Equality Factor Contributed to the Event, which will enhance the collection of equalities information on people affected by the policy.</p>	
		<i>Example</i>	Service Evidence Provided	Possible negative impact and Additional Mitigating Action Required

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2.	<p>Please provide details of how data captured has been/will be used to inform policy content or service design.</p> <p>Your evidence should show which of the 3 parts of the General Duty have been considered (tick relevant boxes).</p> <p>1) Remove discrimination, harassment and victimisation <input checked="" type="checkbox"/></p> <p>2) Promote equality of opportunity <input checked="" type="checkbox"/></p> <p>3) Foster good relations between protected characteristics. <input type="checkbox"/></p> <p>4) Not applicable <input type="checkbox"/></p>	<p><i>A physical activity programme for people with long term conditions reviewed service user data and found very low uptake by BME (Black and Minority Ethnic) people. Engagement activity found promotional material for the interventions was not representative. As a result an adapted range of materials were introduced with ongoing monitoring of uptake. (Due regard promoting equality of opportunity)</i></p>	<p>Review of patient data is an important aspect of understanding how policy implementation may be patterned by protected characteristic groups. To this end, capture of population demographic data when reporting and reviewing adverse events, and potential consideration of the data through an 'equality lens' will help define any areas for improvement.</p> <p>The policy specifically states that 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</p>	
		Example	Service Evidence Provided	Possible negative impact and Additional Mitigating Action Required
3.	<p>How have you applied learning from research evidence about the experience of equality groups to the service or Policy?</p> <p>Your evidence should show which of the 3 parts of the General Duty have been</p>	<p><i>Looked after and accommodated care services reviewed a range of research evidence to help promote a more inclusive care environment. Research suggested that young LGBT+ people had a disproportionately</i></p>	<p>The NHSGGC Policy for Managing Significant Adverse Events relies on the effective use of supporting NHSGGC policies in areas where there may be a need to actively consider potential detriment experienced by protected characteristic groups.</p> <p>These supporting policies have been extensively consulted on with equality groups. For instance, informing and involving patients and families is a core element of policy and will be directed by effective use of the Clear to All Policy and Interpreting Policy.</p>	

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	<p>considered (tick relevant boxes).</p> <p>1) Remove discrimination, harassment and victimisation <input checked="" type="checkbox"/></p> <p>2) Promote equality of opportunity <input checked="" type="checkbox"/></p> <p>3) Foster good relations between protected characteristics <input type="checkbox"/></p> <p>4) Not applicable <input type="checkbox"/></p>	<p><i>difficult time through exposure to bullying and harassment. As a result staff were trained in LGBT+ issues and were more confident in asking related questions to young people. (Due regard to removing discrimination, harassment and victimisation and fostering good relations).</i></p>		
		<p><i>Example</i></p>	<p>Service Evidence Provided</p>	<p>Possible negative impact and Additional Mitigating Action Required</p>
4.	<p>Can you give details of how you have engaged with equality groups with regard to the service review or policy development? What did this engagement tell you about user experience and how was this information used?</p> <p>Your evidence should show which of the 3 parts of the General Duty have been considered (tick relevant boxes).</p>	<p><i>A money advice service spoke to lone parents (predominantly women) to better understand barriers to accessing the service. Feedback included concerns about waiting times at the drop in service, made more difficult due to child care issues. As a result the service introduced a home visit and telephone service which significantly increased uptake.</i></p>	<p>The Policy is not a patient-facing document , but will be implemented in services that are required to show due regard to meeting the Public Sector Equality Duty and respond to local evidence of possible variations in service uptake by protected characteristic groups (Specific Outcomes), or in the process of reviewing adverse events.</p> <p>The policy has been consulted on across NHSGGC for comment, bringing into consideration past experience and best practice.</p>	

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	<p>1) Remove discrimination, harassment and victimisation <input type="checkbox"/></p> <p>2) Promote equality of opportunity <input type="checkbox"/></p> <p>3) Foster good relations between protected characteristics <input type="checkbox"/></p> <p>4) Not applicable x</p>	<p><i>(Due regard to promoting equality of opportunity)</i></p> <p><i>* The Child Poverty (Scotland) Act 2017 requires organisations to take actions to reduce poverty for children in households at risk of low incomes.</i></p>		
		<i>Example</i>	Service Evidence Provided	Possible negative impact and Additional Mitigating Action Required
5.	<p>Is your service physically accessible to everyone? If this is a policy that impacts on movement of service users through areas are there potential barriers that need to be addressed?</p> <p>Your evidence should show which of the 3 parts of the General Duty have been considered (tick relevant boxes).</p>	<p><i>An access audit of an outpatient physiotherapy department found that users were required to negotiate 2 sets of heavy manual pull doors to access the service. A request was placed to have the doors retained by magnets that could deactivate in the event of a fire.</i></p> <p><i>(Due regard to remove discrimination, harassment and victimisation).</i></p>	Not applicable	

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	1) Remove discrimination, harassment and victimisation <input type="checkbox"/> 2) Promote equality of opportunity <input type="checkbox"/> 3) Foster good relations between protected characteristics. <input type="checkbox"/> 4) Not applicable <input type="checkbox"/>			
	<i>Example</i>	Service Evidence Provided	Possible negative impact and Additional Mitigating Action Required	
6.	<p>How will the service change or policy development ensure it does not discriminate in the way it communicates with service users and staff?</p> <p>Your evidence should show which of the 3 parts of the General Duty have been considered (tick relevant boxes).</p> <p>1) Remove discrimination, harassment and victimisation x</p> <p>2) Promote equality of opportunity x</p>	<p><i>Following a service review, an information video to explain new procedures was hosted on the organisation's YouTube site. This was accompanied by a BSL signer to explain service changes to Deaf service users.</i></p> <p><i>Written materials were offered in other languages and formats.</i></p> <p><i>(Due regard to remove discrimination, harassment and victimisation and promote equality of</i></p>	<p>Communicating effectively with patients and/or their families is an essential part of the process when dealing with a clinical adverse event. The process will utilise existing NHSGGC policies to ensure proportionate steps are taken to remove any barriers to full and meaningful engagement, such as the need for interpreter service and advocacy services, and consideration of special cultural needs</p>	

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	<p>3) Foster good relations between protected characteristics <input type="checkbox"/></p> <p>4) Not applicable <input type="checkbox"/></p> <p>The British Sign Language (Scotland) Act 2017 aims to raise awareness of British Sign Language and improve access to services for those using the language. Specific attention should be paid in your evidence to show how the service review or policy has taken note of this.</p>	<i>opportunity).</i>		
7	Protected Characteristic	Service Evidence Provided	Possible negative impact and Additional Mitigating Action Required	
(a)	<p>Age</p> <p>Could the service design or policy content have a disproportionate impact on people due to differences in age? (Consider any age cut-offs that exist in the service design or policy content. You will need to objectively justify in the evidence section any segregation on the grounds of age promoted by the policy or included in the service design).</p>	<p>Given the high level and strategic nature of the policy, it is unlikely to have an impact on the protected characteristic of age. Any relevance to age will be captured within the review process and considered alongside any relevant organisational policies.</p>		

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	<p>Your evidence should show which of the 3 parts of the General Duty have been considered (tick relevant boxes).</p> <p>1) Remove discrimination, harassment and victimisation</p> <p>2) Promote equality of opportunity <input type="checkbox"/></p> <p>3) Foster good relations between protected characteristics. <input type="checkbox"/></p>		
(b)	<p>Disability</p> <p>Could the service design or policy content have a disproportionate impact on people due to the protected characteristic of disability?</p> <p>Your evidence should show which of the 3 parts of the General Duty have been considered (tick relevant boxes).</p> <p>1) Remove discrimination, harassment and victimisation x</p> <p>2) Promote equality of opportunity</p> <p>3) Foster good relations between protected characteristics. <input type="checkbox"/></p> <p>4) Not applicable <input type="checkbox"/></p>	<p>Given the high level and strategic nature of the policy, it is unlikely to have an impact on the protected characteristic of disability. Any relevance to disability will be captured within the review process and considered alongside any relevant organisational policies.</p>	
	Protected Characteristic	Service Evidence Provided	Possible negative impact and Additional Mitigating Action Required

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(c)	<p>Gender Identity</p> <p>Could the service change or policy have a disproportionate impact on people with the protected characteristic of gender identity?</p> <p>Your evidence should show which of the 3 parts of the General Duty have been considered (tick relevant boxes).</p> <p>1) Remove discrimination, harassment and victimisation <input checked="" type="checkbox"/></p> <p>2) Promote equality of opportunity <input type="checkbox"/></p> <p>3) Foster good relations between protected characteristics <input type="checkbox"/></p> <p>4) Not applicable <input type="checkbox"/></p>	<p>Given the high level and strategic nature of the policy, it is unlikely to have an impact on the protected characteristic of gender identity. Any relevance to gender identity will be captured within the review process and considered alongside any relevant organisational policies, and legal protections afforded to transsexual people.</p>	
	Protected Characteristic	Service Evidence Provided	Possible negative impact and Additional Mitigating Action Required
(d)	<p>Marriage and Civil Partnership</p> <p>Could the service change or policy have a disproportionate impact on the people with the protected characteristics of Marriage and Civil Partnership?</p> <p>Your evidence should show which of the 3 parts of the General Duty have been considered (tick relevant boxes).</p>	<p>Given the high level and strategic nature of the policy, it is unlikely to have an impact on the protected characteristic of marriage and civil partnership. Any relevance to marriage and civil partnership will be captured within the review process and considered alongside any relevant organisational policies</p>	

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	<p>1) Remove discrimination, harassment and victimisation <input checked="" type="checkbox"/></p> <p>2) Promote equality of opportunity <input type="checkbox"/></p> <p>3) Foster good relations between protected characteristics <input type="checkbox"/></p> <p>4) Not applicable <input type="checkbox"/></p>		
(e)	<p>Pregnancy and Maternity</p> <p>Could the service change or policy have a disproportionate impact on the people with the protected characteristics of Pregnancy and Maternity?</p> <p>Your evidence should show which of the 3 parts of the General Duty have been considered (tick relevant boxes).</p> <p>1) Remove discrimination, harassment and victimisation <input checked="" type="checkbox"/></p> <p>2) Promote equality of opportunity <input type="checkbox"/></p> <p>3) Foster good relations between protected characteristics. <input type="checkbox"/></p> <p>4) Not applicable <input type="checkbox"/></p>	<p>Given the high level and strategic nature of the policy, it is unlikely to have an impact on the protected characteristic of pregnancy and maternity. Any relevance to pregnancy and maternity will be captured within the review process and considered alongside any relevant organisational policies</p>	
	Protected Characteristic	Service Evidence Provided	Possible negative impact and Additional Mitigating Action Required

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(f)	<p>Race</p> <p>Could the service change or policy have a disproportionate impact on people with the protected characteristics of Race?</p> <p>Your evidence should show which of the 3 parts of the General Duty have been considered (tick relevant boxes).</p> <p>1) Remove discrimination, harassment and victimisation x</p> <p>2) Promote equality of opportunity x</p> <p>3) Foster good relations between protected characteristics <input type="checkbox"/></p> <p>4) Not applicable <input type="checkbox"/></p>	<p>Given the high level and strategic nature of the policy, it is unlikely to have an impact on the protected characteristic of race. Any relevance to race will be captured within the review process and considered alongside any relevant organisational policies</p> <p>The policy aims to ensure effective involvement of patients, family and carers who may require communication support to engage fully with the review process. This would extend to use of spoken language interpreters and timely translation of all relevant documentation into appropriate languages.</p>	
(g)	<p>Religion and Belief</p> <p>Could the service change or policy have a disproportionate impact on the people with the protected characteristic of Religion and Belief?</p> <p>Your evidence should show which of the 3 parts of the General Duty have been considered (tick relevant boxes).</p> <p>1) Remove discrimination, harassment and victimisation x</p> <p>2) Promote equality of opportunity <input type="checkbox"/></p> <p>3) Foster good relations between protected characteristics. <input type="checkbox"/></p>	<p>Given the high level and strategic nature of the policy, it is unlikely to have an impact on the protected characteristic of religion and belief. Any relevance to religion and belief will be captured within the review process and considered alongside any relevant organisational policies</p>	

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	4) Not applicable <input type="checkbox"/>		
	Protected Characteristic	Service Evidence Provided	Possible negative impact and Additional Mitigating Action Required
(h)	<p>Sex</p> <p>Could the service change or policy have a disproportionate impact on the people with the protected characteristic of Sex?</p> <p>Your evidence should show which of the 3 parts of the General Duty have been considered (tick relevant boxes).</p> <p>1) Remove discrimination, harassment and victimisation <input checked="" type="checkbox"/></p> <p>2) Promote equality of opportunity <input type="checkbox"/></p> <p>3) Foster good relations between protected characteristics. <input type="checkbox"/></p> <p>4) Not applicable <input type="checkbox"/></p>	<p>Given the high level and strategic nature of the policy, it is unlikely to have an impact on the protected characteristic of sex. Any relevance to sex will be captured within the review process and considered alongside any relevant organisational policies</p>	
(i)	<p>Sexual Orientation</p> <p>Could the service change or policy have a disproportionate impact on the people with the protected characteristic of Sexual Orientation?</p> <p>Your evidence should show which of the 3 parts of the General Duty have been considered (tick relevant boxes).</p>	<p>Given the high level and strategic nature of the policy, it is unlikely to have an impact on the protected characteristic of sexual orientation. Any relevance to sexual orientation will be captured within the review process and considered alongside any relevant organisational policies</p>	

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	<p>1) Remove discrimination, harassment and victimisation <input checked="" type="checkbox"/></p> <p>2) Promote equality of opportunity <input type="checkbox"/></p> <p>3) Foster good relations between protected characteristics. <input type="checkbox"/></p> <p>4) Not applicable <input type="checkbox"/></p>		
	Protected Characteristic	Service Evidence Provided	Possible negative impact and Additional Mitigating Action Required
(j)	<p>Socio – Economic Status & Social Class</p> <p>Could the proposed service change or policy have a disproportionate impact on the people because of their social class or experience of poverty and what mitigating action have you taken/planned?</p> <p>The Fairer Scotland Duty (2018) places a duty on public bodies in Scotland to actively consider how they can reduce inequalities of outcome caused by socioeconomic disadvantage in strategic planning. You should evidence here steps taken to assess and mitigate risk of exacerbating inequality on the ground of socio-economic status.</p>	<p>Given the high level and strategic nature of the policy, it is unlikely to have an impact on the protected characteristic of socio-economic status and social class. Any relevance to socio-economic status and social class will be captured within the review process and considered alongside any relevant organisational policies</p>	
(k)	<p>Other marginalised groups</p> <p>How have you considered the specific impact on other groups including homeless people, prisoners and ex-offenders, ex-service personnel, people with</p>	<p>Given the high level and strategic nature of the policy, it is unlikely to have an impact on marginalised groups. Any relevance to marginalised groups will be captured within the review process and considered alongside any relevant organisational policies</p>	

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	addictions, people involved in prostitution, asylum seekers & refugees and travellers?		
8.	<p>Does the service change or policy development include an element of cost savings? How have you managed this in a way that will not disproportionately impact on protected characteristic groups?</p> <p>Your evidence should show which of the 3 parts of the General Duty have been considered (tick relevant boxes).</p> <p>1) Remove discrimination, harassment and victimisation <input type="checkbox"/></p> <p>2) Promote equality of opportunity <input type="checkbox"/></p> <p>3) Foster good relations between protected characteristics. <input type="checkbox"/></p> <p>4) Not applicable x</p>	Not applicable.	
		Service Evidence Provided	Possible negative impact and Additional Mitigating Action Required
9.	What investment in learning has been made to prevent discrimination, promote equality of opportunity and foster good relations between protected characteristic groups? As a minimum include recorded completion rates of statutory and mandatory learning programmes (or local equivalent) covering equality, diversity and human rights.	All NHSGGC staff are expected to complete their statutory and mandatory Equality and Human Rights e-learning module and any role specific learning and education.	

10. In addition to understanding and responding to legal responsibilities set out in Equality Act (2010), services must pay due regard to ensure a person's human rights are protected in all aspects of health and social care provision. This may be more obvious in some areas than others. For instance, mental health inpatient care or older people's residential care may be considered higher risk in terms of potential human rights breach due to potential removal of liberty, seclusion or application of restraint. However risk may also involve fundamental gaps like not providing access to communication support, not involving patients/service

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users in decisions relating to their care, making decisions that infringe the rights of carers to participate in society or not respecting someone's right to dignity or privacy.

The Human Rights Act sets out rights in a series of articles – right to Life, right to freedom from torture and inhumane and degrading treatment, freedom from slavery and forced labour, right to liberty and security, right to a fair trial, no punishment without law, right to respect for private and family life, right to freedom of thought, belief and religion, right to freedom of expression, right to freedom of assembly and association, right to marry, right to protection from discrimination.

Please explain in the field below if any risks in relation to the service design or policy were identified which could impact on the human rights of patients, service users or staff.

The Policy sets out a robust process to review clinical adverse events. Any review process will be cognisant of the need to consider if and how an individual's rights might have been affected, and will include detailed assessment in the resulting reports.

Please explain in the field below any human rights based approaches undertaken to better understand rights and responsibilities resulting from the service or policy development and what measures have been taken as a result e.g. applying the PANEL Principles to maximise Participation, Accountability, Non-discrimination and Equality, Empowerment and Legality or FAIR* .

While the policy has not explicitly considered application of the PANEL principles, the basis of the policy is to ensure everyone connected to a Significant Adverse Event is afforded a fair and transparent process.

- **Facts:** What is the experience of the individuals involved and what are the important facts to understand?
- **Analyse rights:** Develop an analysis of the human rights at stake
- **Identify responsibilities:** Identify what needs to be done and who is responsible for doing it
- **Review actions:** Make recommendations for action and later recall and evaluate what has happened as a result.

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Having completed the EQIA template, please tick which option you (Lead Reviewer) perceive best reflects the findings of the assessment. This can be cross-checked via the Quality Assurance process:

- X Option 1: No major change (where no impact or potential for improvement is found, no action is required)
- ☐ Option 2: Adjust (where a potential or actual negative impact or potential for a more positive impact is found, make changes to mitigate risks or make improvements)
- ☐ Option 3: Continue (where a potential or actual negative impact or potential for a more positive impact is found but a decision not to make a change can be objectively justified, continue without making changes)
- ☐ Option 4: Stop and remove (where a serious risk of negative impact is found, the plans, policies etc. being assessed should be halted until these issues can be addressed)

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11. If you believe your service is doing something that 'stands out' as an example of good practice - for instance you are routinely collecting patient data on sexual orientation, faith etc. - please use the box below to describe the activity and the benefits this has brought to the service. This information will help others consider opportunities for developments in their own services.

Not applicable

Actions – from the additional mitigating action requirements boxes completed above, please summarise the actions this service will be taking forward.

Date for completion

Who is responsible?(initials)

Ongoing 6 Monthly Review please write your 6 monthly EQIA review date:

--

Lead Reviewer:

EQIA Sign Off:

Name

Job Title

Signature

Date

Paula Spaven

Director of Clinical and Care Governance

3rd December 2025

Quality Assurance Sign Off:

Name

Job Title

Signature

Date

Alistair Low

Planning and Development Manager, Equality and Human Rights Team

**NHS GREATER GLASGOW AND CLYDE EQUALITY IMPACT ASSESSMENT TOOL
MEETING THE NEEDS OF DIVERSE COMMUNITIES
6 MONTHLY REVIEW SHEET**

Name of Policy/Current Service/Service Development/Service Redesign:

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Please detail activity undertaken with regard to actions highlighted in the original EQIA for this Service/Policy

		Completed	
		Date	Initials
Action:			
Status:			
Action:			
Status:			
Action:			
Status:			
Action:			
Status:			

Please detail any outstanding activity with regard to required actions highlighted in the original EQIA process for this Service/Policy and reason for non-completion

		To be Completed by	
		Date	Initials
Action:			
Reason:			
Action:			
Reason:			

BOARD OFFICIAL

Please detail any new actions required since completing the original EQIA and reasons:

		To be completed by	
		Date	Initials
Action:			
Reason:			
Action:			
Reason:			

Please detail any discontinued actions that were originally planned and reasons:

Action:	
Reason:	
Action:	
Reason:	

Please write your next 6-month review date

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Name of completing officer:

Date submitted:

If you would like to have your 6 month report reviewed by a Quality Assuror please e-mail to: alastair.low@ggc.scot.nhs.uk

Policy for Managing Significant Adverse Events (Clinical)

Lead Manager:	Director of Clinical and Care Governance
Responsible Director:	Executive Medical Director
Approved by:	NHSGGC Board
Date approved:	
Date for Review:	3 years
Replaces previous version: [if applicable]	Policy: V6 Replaces Version 5: Interim NHSGGC Policy for Managing Significant Adverse Events (June 2025)

DOCUMENT CONTROL SHEET: KEY INFORMATION

Title	NHSGGC Policy for Managing Significant Adverse Events (Clinical): Interim
Author(s)	Policy Lead: 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	Policy
Status	Draft
Version	V6
Effective From	

REVISION HISTORY

Version	Date	Summary of Changes
V6	September 2025	No changes to Interim Policy
Interim (v5)	June 2025	<p>The interim policy aligns NHSGGC with the HIS National Framework for Reviewing and Learning from Adverse Events, to formalize 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 and NHS Board• 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 (CAEOG) will be set up to maintain oversight of the implementation of this policy on behalf of the Executive Medical Director. The CAEOG 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 Groups 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 Groups (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 and 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: NHSGGC Board

In addition to the Clinical and Care Governance Committee, The NHS Board provides oversight and scrutiny on the effectiveness of NHSGGC's Significant Adverse Event Reviews (SAERs) to seek assurance that timely, high-quality reviews are undertaken and learning is applied.

3:11 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

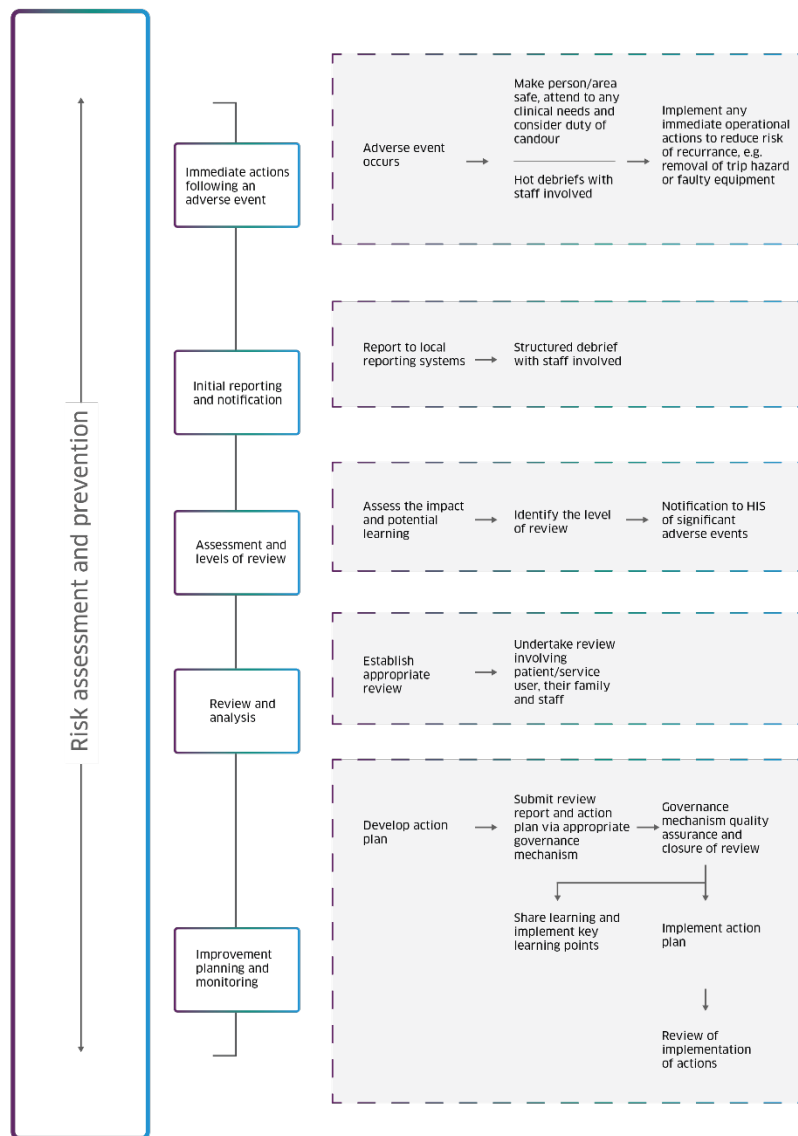
- Adverse event - an adverse event is defined as “an event that could have caused, or did result in harm to people, including death, disability, injury, disease or suffering, and/or immediate or delayed emotional reactions or psychological harm”.
- Harm – harm is defined as “an outcome with a negative 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
<https://www.nhsggc.scot/downloads/incident-management-and-recording-policy-nov2024/>
- Significant Adverse Events Policy and Toolkit
<https://scottish.sharepoint.com/sites/GGC-ClinicalGovernance/SitePages/Significant-Adverse-Event-Policy.aspx>
- NHS Ayrshire and Arran,
<https://www.nhsaaa.net/wp-content/uploads/Adverse-Event-Policy-v3.pdf>
- NHS Lothian Adverse Event Management
https://policyonline.nhslothian.scot/policy_page/adverse-event-management-policy/#:~:text=NHS%20Lothian%20policy%20requires%20that,to%20inform%20improvements%20to%20services.
- NHS Lanarkshire Adverse Event Management Policy
<https://www.nhslanarkshire.scot.nhs.uk/download/adverse-event-management-policy/>

Procedure for Managing Significant Adverse Events (Clinical)

Lead Manager:	Director of Clinical and Care Governance
Responsible Director:	Executive Medical Director
Approved by:	NHSGGC Board
Date approved:	Draft
Date for Review:	3 years
Replaces previous version: [if applicable]	Version 2 Replaces Interim Procedure v1: June 2025

DOCUMENT CONTROL SHEET

KEY INFORMATION

Title	Procedure for Managing Significant Adverse events
Policy Lead	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	2
Effective From	

REVISION HISTORY

Version	Date	Summary of Changes
V2		The following changes have been made: <ul style="list-style-type: none">• Minor wording changes to description of a red flag SAE• Minor wording changes to categorisation of SAEs
V1	June 2025	Not applicable.

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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 details 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 [Significant Adverse Events Policy and Toolkit](#).

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 details 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 defense 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

A “red flag” Significant Adverse Event (SAE) SAEs is a high-profile event which has the potential to result in risk exposure, financial loss, or adverse publicity.

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 arrangements for notification and communication, oversight and monitoring, and sharing learning.

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 that are 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). Decisions not to inform and involve patients/ families should not be made due to 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 ensure that the event is communicated as widely as is needed throughout the organisation 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 flow chart 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 HIS National Framework defines 3 categories of adverse event, based on the level of harm. This may require some initial assessment which can be supported by a decision tool. 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.nhs.gov.uk/scotland/downloads/incident-management-and-recording-policy-nov2024/>
- NHSGGC Security Policy
<https://www.nhs.gov.uk/scotland/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.

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

Appendix 1

Assurance Checklist

Name of Policy ... **Policy and Procedure for Managing Significant Adverse Events**

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Approving Body or Bodies: **NHSGGC Board**

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Date of Approval **18th December 2025**

.....

Director/Policy Lead **Dr Scott Davidson, Executive Medical Director**

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The main aims of the 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

	Requirement	Comment
Scope	The scope is clearly defined. There is clear evidence that it does not duplicate existing policy. Recognition is given where it overlaps with or supplements existing policy.	The scope of the policy is outlined in section 2
Consultation	There has been sufficient consultation with those affected by the policy, including those with responsibility for implementation.	NHSGGC wide consultation for Interim Policy and Procedure in April 2025, and for full Policy and Procedure in September 2025. Feedback received, reviewed and incorporated.
Staff Partnership	The policy development requires collaboration with, and agreement of, Staff Partnership.	<p>There are unlikely to be additional workforce implications associated with this policy as it describes arrangements that are already considered to be in place.</p> <p>APF Staff side representative nominated to support collaboration for the interim policy. As only minor changes have been made no further agreement of collaboration was required.</p>
Communications Plan	There is a comprehensive communication and implementation plan in place.	<p>The policy and procedure have been endorsed through clinical governance arrangements, the Boardwide Clinical Governance Forum, Corporate Management team (CMT), and Clinical and Care Governance Committee</p> <p>The policy will be promoted through core brief, email</p>

		<p>dissemination and tabling at key clinical governance groups and forums to support awareness and implementation.</p> <p>An extensive SAER toolkit is in place to support the policy and procedure. This is subject to ongoing review, evaluation and update in response to feedback and learning.</p>
Finance	<p>Cost implications are fully understood and agreed by budget holders, or additional resource Secured.</p>	<p>There are unlikely to be any additional cost implications associated with this policy as it describes arrangements that are already considered to be in place.</p>
Equalities	<p>The policy has been subject to EQIA assessment and shared with the Corporate Inequalities Team.</p>	<p>EQIA completed for Interim Policy. This has been updated for full policy, and will be shared with Corporate Inequalities Team on approval of policy.</p>
Human Resources	<p>Implications for staff are fully understood and agreed.</p> <p>Where appropriate, the policy has taken into account the Health and Care (Staffing) (Scotland) Act 2019 (legislation.gov.uk)</p>	<p>There are unlikely to be any additional workforce implications associated with this policy as it describes arrangements that are already considered to be in place.</p>
Sustainability	<p>Impact on the environment (e.g. carbon emissions; travel) is understood and agreed.</p>	<p>N/A to this policy</p>

Risk	Any risks to the organisation are fully understood and agreed as a result of this Policy.	A risk assessment was completed for the Interim Policy. This is reviewed by the Corporate Adverse Events oversight Group in line with the NHSGGC Risk Register Policy and Procedure
Service Delivery	Implications for service delivery including achievement of performance targets are fully understood and agreed.	Roles/ responsibilities are outlined within the policy.
Review	A review has been carried out to evaluate the effectiveness of the current policy.	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.

The completed Assurance Checklist should be submitted to Iain Paterson, Corporate Services Manager (iain.paterson2@ggc.scot.nhs.uk) following approval of the Policy.