Adverse Event Policy

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V03.0	25/11/2024	Section 9.2 – Healthcare Governance Committee (HGC) Governance Assurance updated	Risk Team
V03.0	25/10/2024	Removed reference to “Datix” throughout and replaced with electronic risk management system	Risk Team
V03.0	25/10/2024	Updated reference to Root Cause Analysis to Systems Based Approach throughout	Risk Team
V03.0	25/10/2024	Section 2.4 - Reference to Being Open has been updated in one section and removed duplication throughout	Risk Team
V03.0	25/10/2024	Section 2.5 - Information relating to Internal Processes updated	Risk Team
V03.0	25/10/2024	Section 2.6 - Duty of Candour section updated to reference the standalone NHSAA Duty of Candour Policy	Risk Team
V03.0	25/10/2024	Section 4.0 - Definition of Terms table updated to include initial assessment of consequence 1 and 2 and trend analysis will be used to identify patterns and trends and areas for action. Significant Adverse Event Analysis and Review (SAER) section updated to reflect the AERG Terms of Reference.	Risk Team
V03.0	25/10/2024	Section 4.10 - Contractors section updated	Risk Team
V03.0	25/10/2024	Section 5.0 - Roles and Responsibilities section amended to update the Director for Clinical and Care Governance responsibilities	Risk Team

V03.0	25/10/2024	Section 5.2 - Commitments to those involved in Adverse Events has been updated and condensed in one section	Risk Team
V03.0	25/10/2024	Section 5.2.6 - Recollection of events updated to include timeframes	Risk Team
V03.0	25/10/2024	Reporting to External Agencies - Moved to Application Guidance Document and updated to reflect who's responsibility to report in a table format	Risk Team

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1.0 Introduction

1.1 NHS Ayrshire & Arran (NHSAA) is committed to the delivery of effective, safe, and person centred care ensuring there will be no avoidable injury or harm to people or adverse impact on the organisation resulting from the delivery of healthcare or work related activity. This Policy sets out the actions required to effectively identify, report, review and learn from adverse events across NHSAA Board and should be read in conjunction with NHSAA's Adverse Event Policy Application Guidance, Risk Management Strategy and Duty of Candour Policy (under development) where the principles are also outlined within this policy.

1.2 In line with the Scottish Government's Healthcare Quality Strategy for NHS Scotland[1], Staff Governance Standards[2] and The Management of Health and Safety at Work Regulations,[3] the personal health, safety and wellbeing of patient/service users, their family and carers, staff and members of the public will be achieved through the provision of an appropriate, clean and safe environment.

1.3 This Policy also reflects the Learning from adverse events through reporting and review: A national framework for Scotland 4th Edition (HIS December 2019) developed by Healthcare Improvement Scotland developed to improve local approaches to handling adverse events.

2.0 Purpose

2.1 NHSAA will take all reasonably practicable steps, to minimise and manage risk with the overall objective of protecting patient/service users, staff, visitors and members of the public. The NHS Board is committed to improving the quality of care to patient/service users, and ensuring the safety of patient/service users, staff and members of the public accessing its premises. This will be achieved through the consistent monitoring and review of adverse events that result, or had the potential to result in injury, damage or other loss in order to identify learning.

2.2 The review of an adverse event forms part of a wider strategy for risk management, which advocates the use of a systems based approach and human factors methodology/principles to understand why an adverse event has occurred. In accordance with the HIS national approach, the actions to be taken to effectively manage adverse events are described in Appendix 3 of the Adverse Event Policy Application Guidance.

2.3 NHSAA will fulfil its legal and moral duties in relation to the Management of Adverse events by:

- Encouraging all staff to report all adverse events, including near misses;
- Making electronic reporting of adverse events accessible to all;
- Ensuring all staff have the opportunity to complete an Adverse Event Report;

[1] The Healthcare Quality Strategy for NHS Scotland (May 2010)
[2] Staff Governance Standards 4th Edition (2012)
[3] The Management of Health and Safety at Work Regulations 1999. The Regulations were introduced to reinforce the Health and Safety at Work etc Act 1974. The MHSWR places duties on employers and employees including those who are clients, designers, principal contractors or other contractors

- Ensuring that where staff do not have access to the electronic risk management system, support will be in place to assist staff to report the event;
- Ensuring that there is a programme of training available to staff for reporting and review of adverse events;
- Providing advice of what should be reported to enable consistency;
- Take care of, make safe and/or support those involved at the time of the adverse event;
- Committing to providing opportunity for learning for all by ensuring feedback is provided both locally and organisationally through recognised processes taking cognisance of multi-agency sharing of learning where appropriate;
- Ensuring the requirements of The Health (Tobacco, Nicotine etc. And Care) (Scotland) Act 2016 'Duty of Candour' and 'Being Open in Scotland – Guidance on implementing the Being Open Principles' January 2015 guidance are applied where appropriate; and
- Reporting to the Health and Safety Executive specific events as determined by the Health and Safety at Work etc., Act 1974 and more specifically in accordance with the Reporting of Injuries, Diseases and Dangerous Occurrences Regulations (RIDDOR) 2013 are fulfilled.

2.4 Being Open and Fair

2.4.1 NHSAA will demonstrate transparency and openness to patient/service users, families, members of the public, staff and partner agencies affected by an adverse event. Reviews will be conducted openly, fairly and timeously.

2.4.2 Open and effective communication with people should begin at the start of their care and continue throughout all the care they receive. This should be no different when an adverse event happens. Being Open (2009) provides a suite of tools to support communication with those who have suffered harm from an adverse event.

2.4.3 Being open involves:

- acknowledging, apologising and explaining when things go wrong;
- if appropriate, conducting a thorough review into the adverse event which involves patients, families, carers and staff, and aims to identify lessons that will support;
- improvements and help prevent the adverse event being repeated, and providing support for those involved to address any physical and/or psychological consequences of what happened

2.4.4 NHSAA is committed to a "Just Culture" in creating "an environment where learning and accountability are fairly and constructively balanced" (Dekker, 2012)[4]. The organisation aims to ensure that the overall approach within NHSAA is one of help and support rather than blame and recrimination. Adverse events reporting is a tool with a main purpose of learning and to identify causes and/or weaknesses in systems, actions and inactions thus ensuring the highest standard of safety,

[4] Just Culture 'Balancing Safety and Accountability', 2nd Edition, Sidney Dekker 2012.

therefore staff must be encouraged and feel supported, safe and confident to report adverse events

2.5 Internal Processes

2.5.1 There are various different organisational process that may link to the adverse event process. The adverse event review process does not preclude the use of these and should be used to complement/dovetail with these

2.5.2 Organisational processes linked to the adverse event process include:

- Management of Employee Conduct
- Public Protection processes
- Child Death Review process
- Maternity process
- Mental Health Service process
- Feedback and Complaints process
- Infection Control Incident Management process
- Hospital Standardised Mortality Review process
- Morbidity and Mortality review process
- Cardiac Arrest process
- All Independent Contractor process

2.5.3 Further detail around the linkage to these organisational processes and responsibilities is detailed in the Adverse Event Policy Application Guidance.

2.6 Duty of Candour

2.6.1 The Health (Tobacco, Nicotine etc. And Care) (Scotland) Act 2016 introduced a new organisational duty of candour on health, care and social work services. The implementation date for the duty of candour provisions came into effect on 1st April 2018.

2.6.2 The overall purpose of the duty is to ensure that organisations are open, honest and supportive when there is an **unexpected or unintended incident resulting in death or harm** that is not related to the course of the condition for which the person is receiving care.

2.6.3 NHSAA has overall accountability for duty of candour, and the Nurse Director has delegated responsibility as the 'responsible person' to ensure the legislative requirements in relation to duty of candour are adhered to.

2.6.4 When an adverse event has been graded in agreement with the reviewer and final approver as a consequence score 4 or 5, this triggers the requirement for an Adverse Event Review Level Decision Making Form to be completed (Adverse Event Policy Application Guidance Appendix 7).

2.6.5 The Adverse Event Review Level Decision Making Form is then emailed to the relevant Directorate Adverse Event Review Group (AERG) who review the information presented and determine the level of review to be undertaken and if duty of candour is applicable.

This decision is based on:

- the adverse event
- the content of the Adverse Event Decision Making Form
- NHSAA's agreed 'never events' list (Adverse Event Policy Application Guidance Appendix 5)
- the flowchart for Maternal Death and Stillbirths (Adverse Event Policy Application Guidance Appendix 6), and;
- the specialist knowledge of the advisors of the group.

2.6.6 The duty of candour procedure must be carried out by the responsible person as soon as practicable after becoming aware that an individual who has received a health service has been the subject of an unintended or unexpected event, and in the reasonable opinion of a registered health professional, has resulted in or could result in:

- Death of the person;
- A permanent lessening of bodily, sensory, motor, physiologic or intellectual functions;
- An increase in the persons treatment;
- Changes to the structure of the person's body;
- The shortening life expectancy of the person;
- An impairment of the sensory, motor or intellectual functions of the person which has lasted, or is likely to last, for a continuous period of at least 28 days;
- The person experiencing pain or psychological harm which has been or is likely to be experienced by the person for a continuous period of at least 28 days; and
- The person requiring treatment by a registered health professional in order to prevent –
  (i) The death of the person; or
  (ii) Any injury to the person which, if left untreated, would lead to one or more of the outcomes mentioned above.

2.6.7 In the instance of an apology being a necessary action as a result of an adverse event, this will be done in accordance with the duty of candour procedure. The key stages of the procedure include:

- Notify the person affected (or family/relative where appropriate);
- Provide an apology;
- Carry out a review into the circumstances leading to the incident;
- Offer and arrange a meeting with the person affected and/or their family, where appropriate;
- Provide the person affected with an account of the incident;
- Provide information about further steps taken;
- Make available, or provide information about, support to persons affected by the incident; and
- Prepare and publish an annual report on duty of candour.

2.6.8 It is important that an apology is open, honest and supportive from the outset as this can reassure an individual/family and sets the tone for moving forward. NHSAA is committed to ensuring appropriate apologies are provided.

2.6.9 NHSAA will ensure that a minimum of a Local Management Team Review (LMTR) will be carried out where Duty of Candour applies and the Lead Reviewer of the LMTR will ensure that this Duty has been discharged.

3.0 Scope

3.1 The Policy applies to **all employees of NHSAA and those undertaking NHS healthcare activity within the Health and Social Care Partnerships,** this includes bank staff, agency staff, trainees (including students and work experience), volunteers, and contractors.

3.2 The Clinical and Care Governance Framework provides the key elements and principles that should be reflected in clinical and care governance processes within Health and Social Care Partnerships.

4.0 Definition of Terms

Definition	Meaning
Adverse event	is defined as **an event that did result in, harm**, loss or damage to a patient/service user, member of staff, visitor, contractor or to NHSAA property or reputation.
Near miss	is an event that **could result** in an adverse outcome or harm but due to action taken or a fortunate break in the chain of events, the adverse outcome or harm was averted.
Never events	are serious, largely preventable patient/service user safety events that should not occur if the available preventative measures have been implemented. A never event would result in a Significant Adverse Event Review. The NHSAA 'never events' list has been developed in conjunction with NHS Improvement Never Events List January 2018 and can be found in Appendix 5 of the Adverse Event Policy Application Guidance.
Harm	is defined as **an outcome with a negative effect**. Harm to a person or groups of people may result from worsening of a medical condition, the inherent risk of an investigation or treatment, violence and aggression, system failure, provider performance issues, service disruption, financial loss, environmental harm or adverse publicity/reputational harm. All harm is **not avoidable**, for example the worsening of a medical condition or the inherent risk of treatment. However, it is often not possible to determine if the harm caused was **avoidable** until a review is carried out and often areas for improvement are identified even when harm is **not avoidable**.
Duty of Candour	is a legal duty on all bodies delivering health and social care to be open honest and supportive when there is an

	unexpected or unintended incident resulting in death or harm. In such cases a legally prescribed procedure must be followed as detailed in section 2.6 and NHSAA Duty of Candour Policy (under development).
Legal requirement	is where a piece of legislation places specific duties on the Organisation such as reporting to external agencies. Specific requirements for reporting to these external agencies are detailed within Section 3.2 of the Adverse Event Application Policy Guidance.
Operations	are the day to day activities of a service that enable it to function, and an **operational matter** is an obstacle or issue which may affect or impact on the delivery of that service.
People	are defined as: • Patient/service users • Family members/NOK • Carers • Members of staff • Visitors /Public /External Partner Agency • Contractors
Groups of people	include any functional grouping of individuals such as an organisation. In this way, adverse events that result in, for example, reputational harm or financial harm are included within the scope of the national approach.
Partner Agencies	are other bodies that work with NHSAA to deliver healthcare such as Local Authority, Care/Residential homes, Scottish Ambulance Service, Hospice Services and Higher Education Institutions.
Independent Contractor Groups	General Medical Practice, General Dental Practice, Community Pharmacy, Community Optometry, Prison Services
Consequence Grading Matrix	a national tool used to grade the consequence impact of an adverse event.
Category I, II and III (Healthcare Improvement Scotland (HIS))	the HIS national approach categorises adverse events as follows: **Category I: Events that may have contributed to or resulted in permanent harm**, for example death, intervention required to sustain life, severe financial loss (> £1M), ongoing national adverse publicity (these are likely to be graded as major (4)/extreme (5)) **Category II: Events that may have contributed to or resulted in temporary harm**, for example initial or prolonged treatment, intervention or monitoring required, temporary loss of service, significant financial loss, adverse local publicity (these are likely to be graded moderate (3)) **Category III: Events that may have contributed to or resulted in minor or insignificant harm** (Likely to be graded as insignificant/minor). These events can be a **near miss**.

Adverse Event Review Group (AERG)	a governance group that provides a co-ordinated and integrated approach to managing all escalated adverse events and complaints linked to an adverse event occurring within the respective service. The groups are responsible for providing evidence and assurance to their Directorate Governance Group and Executive Sponsor that adverse events are being addressed, improvements implemented and learning shared. An example 'Terms of Reference' can be found at Appendix 13 of the Adverse Event Policy Application Guidance.
Initial Assessment	an initial assessment of Consequence levels 1 and 2 which is carried out by the service where the adverse event has occurred. Trend analysis will then be used to identify patterns and trends and areas for action.
Ward/Departmental Review by Line Manager	a review of Consequence level 3 which is led by the service where the adverse event has occurred and completed within the electronic risk management system.
Local Management Team Review	a review of Consequence level 4 or where appropriate Consequence level 3 in which the lead reviewer will be identified dependent on the adverse event from the service where the adverse event occurred. The Directorate AERG may nominate established groups to lead this review e.g. Morbidity and Mortality; Maternity Clinical Risk Management Group etc. RIDDOR reportable adverse events will be subject to this review level and carried out by Health and Safety in conjunction with the services.
Significant Adverse Event Analysis and Review (SAER)	a review of Consequence level 5 or where appropriate Consequence level 4. The relevant AERG will identify an appropriate lead reviewer, relevant subject experts and agree the terms of reference of the review within the meeting where the level of review is agreed.
Reviewer	is the named authorised person to undertake a review of an adverse event; this is normally the ward/department manager. The Reviewer will require specific access to the electronic risk management system.
Final Approver	is the named authorised person to undertake the quality assurance and closure of a review of an adverse event; this is normally the **Reviewer's** Manager. In some circumstances the Final Approver may be required to undertake the review and in these circumstances the adverse event would be finally approved by another nominated Final Approver. The Final Approver will require specific system access permissions to the electronic risk management system.
Systems Based Approach	is a method of problem solving focusing on the process and the system factors that facilitated the adverse event. 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, and prevent future events.

Executive Sponsor	the **Executive Sponsor** for commissioning a significant adverse event review is the Medical Director and/or the Nurse Director.

5.0 Roles & Responsibilities

5.1 The Chief Executive is the accountable officer and has overall responsibility to the NHSAA Board for ensuring that an effective policy is in place in relation to the reporting, management and learning from adverse events; and for meeting the statutory and national requirements that support a safe, learning, just and open culture. This includes healthcare provision within Health and Social Care Partnerships.

In addition, the Chief Executive will:

- Demonstrate leadership behaviours and actions that support a positive safety culture and commitment to being open;
- Create a culture to support staff to safely express concerns and for these to be listened to, discussed and acted on as appropriate;
- Ensure robust and effective policies and procedures for adverse events management and meeting duty of candour requirements;
- Ensure effective systems are in place for reporting, learning and improvement; and
- Delegate roles and responsibilities to executive team members.

5.2 Directors with delegated responsibility for adverse events

5.2.1 The **Medical Director**, as lead for all aspects of Risk Management within NHS Ayrshire & Arran, has delegated responsibility for ensuring that adverse event management processes including significant adverse events are effective and learning and improvement takes place. The Medical Director is responsible for developing quality measures to monitor and evaluate the implementation of the adverse event process.

5.2.2 The **Nurse Director** has delegated responsibility for ensuring that significant adverse event review processes are effective and learning and improvement takes place; and ensuring effective governance of the subsequent action plans. The **Nurse Director** has further delegated responsibility for ensuring that the requirements of duty of candour under the Health (Tobacco, Nicotine etc. and Care) (Scotland) Act 2016 are carried out.

5.2.3 The **Human Resources (HR) Director** has delegated responsibility for ensuring adverse events relating to Health and Safety legislation are reported to the Health and Safety Executive (HSE) in accordance with RIDDOR and other statutory instruments.

5.2.4 The **Director of Clinical and Care Governance** has delegated responsibility for the operational oversight of the Risk Management function within the organisation and will ensure that processes are in place to enable staff to report and review adverse events.

5.2.5 The **Risk Management Team** has responsibility for providing training and support to all staff members regarding reporting, reviewing and approving adverse events at the appropriate level.

5.2.6 **All Staff**

Role	Staff Groups	Responsibilities
Final Approver	Directors, Assistant and Associate Directors (including Associate Medical and Nurse Directors (AMD/AND)) which includes Health and Social Care Partnerships (H&SCP), Clinical Directors, Clinical Nurse Managers, Allied Health Professionals, General/Senior Managers, Heads of Service (HoS)	• Demonstrating leadership behaviours and actions that support a positive culture of safety which encourages adverse event reporting, management of such events and the subsequent learning and improvement; • Ensuring that NHSAA policies and procedures are implemented to enable effective reporting, recording, review and monitoring of all adverse events; • Ensuring that processes and procedures are implemented to foster a culture of learning from adverse events; • Implementation and supporting of AERG within their service; and participating in review level decision making; • Leading and/or participating in Significant Adverse Event Analysis and Reviews; and/or LMTRs as appropriate; • Performing the role of 'Final Approver' (electronic risk management system) where required, confirming that a robust and proportionate review has been undertaken following the adverse event, ensuring that a named Deputy is identified for periods of absence; • Ensuring staff within their remit have attended appropriate training to enable them to carry out their role in the adverse event process; • Engagement with patients, service users and families, including through duty of candour processes; • The management and analysis of information and implementation of relevant learning including working together to ensure learning from adverse events and their associated action plans are shared across the Organisation; • To ensure the legal requirements of Duty of Candour are met within; and • Ensure actions are implemented and improvements are made.

Role	Staff Groups	Responsibilities
Reviewer	Senior Charge Nurses, Specialty Consultants, Allied Health Professionals and Department Managers /Supervisors/Line Managers (including named Deputy)	• Demonstrate leadership behaviours and actions that support positive safety culture and commitment to being open; • Have attended training to enable robust review and final approval of adverse events; • Have assurance that their Deputies have attended training to enable robust review and final approval of adverse events; • Allow time for staff training on identification and reporting of adverse events; • Support and engage with staff; • Adhere to the timescales identified in the policy for the review of all adverse events using recognised root cause analysis principles and tools where appropriate to identify root causes and contributory factors; • Escalate adverse events of concern and those that meet the escalation level as detailed in the flowchart (figure 1); • Have an awareness and understanding of the legal requirements of Duty of Candour in conjunction with their Manager • Implement the agreed remedial actions for improvement, in conjunction with their manager; • Feedback to staff involved in the adverse event in a timeous manner; and • Feedback learning to their teams.
Reporter	All staff (including agency staff, trainees, students, work experience, volunteers, and contractors – via their nominated responsible person)	• Follow their duty of care to report adverse events arising out of, or in connection with work within 24 hours of the adverse event occurring or being identified; • Co-operate with any review being conducted and, if requested, provide a Recollection of Events using the organisational template. This should be made available within three working days of the request to enable timely review/investigation and adherence to the policy timelines. Staff should be mindful that a recollection of events may be requested by a legal authority such as Police Scotland or the Health and Safety Executive; • Adhere to any instruction, information or training on content, implementation and management of this policy document including duty of candour processes;

Role	Staff Groups	Responsibilities
		• Seek feedback of the review of an adverse event that they have been involved in when this has not been provided in a timeous manner by the reviewer; • Where an adverse event occurs arising from the activities of a Contractor commissioned by NHSAA, in addition to review/investigation undertaken by NHSAA, the Contractor will undertake an investigation and report their findings to NHSAA and, if appropriate, to the Health and Safety Executive.

6.0 Managing an Adverse Event

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

- Levels of harm;
- Numbers of people involved;
- Risk exposure;
- Financial loss;
- Media interest; and
- The need to involve other stakeholders.

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

6.2 There are six stages to adverse event management. Further information and detail on each stage can be found within section 3.3 of the Adverse Event Policy Application Guidance.

6.3 In order to meet the requirements of robust review and learning, the Adverse Event flowchart demonstrates the process to follow to determine the review level for adverse events. This flowchart can be found in Appendix 1 of the Adverse Event Policy Application Guidance.

6.4 Once the required level of review has been determined, the pathway for each review level as detailed Appendix 2 of the Adverse Event Policy Application Guidance. The organisation has identified three levels of review and descriptors which are consistent with those identified in the 'Learning from adverse events through reporting and review: A national framework for NHS Scotland 4th Edition (HIS December 2019)'

Level of Review	Significant Adverse Event Analysis & Review	Local Management Team Review	Ward/Department Review
Time scale	Review must be commissioned within 10 working days of the Adverse Event being reported on electronic risk management system. Commence and close review (report submitted for approval to LOG within 90 working days of the commissioning date).	Commence and close review (report submitted for approval through AERG) within 30 working days of the Adverse Event being reported on the electronic risk management system.	Adverse Event finally approved within 10 working days.

	Action plan to be developed within 10 working days from report being approved.	Final approval should take place as soon as possible but no later than 30 working days from report. Develop action plan within 10 working days from report being approved.	

7.0 Reporting to External Agencies, Bodies and Partner Agencies

7.1 Specific adverse events must be reported to external agencies/bodies within prescribed timescales. Managers must ensure that there are appropriate arrangements in place to enable both local reporting and reporting to external agencies so individuals can easily meet the reporting requirements. Further guidance can be found in section 3.2 of the Adverse Event Policy Application Guidance.

8.0 Learning from Adverse Events

8.1 Learning from experience entails analysing and evaluating adverse events. This process is critical to the delivery of safe and effective services. We can also learn from analysis of trends or patterns from adverse event reporting as a key element of an integrated approach to assessing 'quality' and informing improvement priorities.

8.2 There are four stages to learning from adverse events:

1. Identifying learning and improvement issues through review and analysis of adverse events, near misses and analysis of adverse event trend information to identify themes to inform learning;
2. Implementing the learning to improve practice;
3. Sharing the learning locally and organisationally, and where agreed,
   i. share learning wider within NHS Scotland via Healthcare Improvement Scotland (HIS) Adverse Events Community of Practice website; and
4. Monitoring the implementation and effectiveness of changes

8.3 The aims of sharing any learning is to maximise opportunities to actively learn from each other and to put improvements into practice.

8.4 Whilst it is expected for operational directorates to have local processes in place within their areas of responsibility, there is a need to have a common approach to the wider sharing of learning as part of robust governance arrangements.

8.5 A more structured approach to organisational wide learning is in place in the form of Learning Summaries. The Learning Summary template can be found in Appendix 15 of the Adverse Event Policy Application Guidance. Further guidance can be sought from the Risk Management Team.

8.6 The purpose of this template is to ensure that there is a formalised, clearly understandable and transparent process for shared learning. This will support the organisation to deliver the requirements of the Quality Strategy, develop a quality improvement culture resulting in an organisation that continuously learns and improves.

8.7 As part of the Significant Adverse Event Analysis and Review process, a learning summary will be produced following the review to enhance organisational learning.

This will not be done where the investigation outcome code is 1 (Appropriate care/services: well planned and delivered/unavoidable outcome) and consideration given where the investigation outcome code is 2 (Issues identified but they did not contribute to the event). Where National learning is identified this will be published on the Community of Practice (NHS Education for Scotland) website.

8.8 The NHS Board is ultimately responsible for ensuring that the organisation effectively learns from adverse events and implements improvements in accordance with this Policy. The NHS Board through the Board's Governance Committees will receive assurance that learning and improvement has been implemented throughout NHSAA. Ultimately, all staff are responsible for working together to ensure learning from adverse events and their associated action plans are shared across the Organisation.

9.0 Governance Assurance

9.1 The Risk and Resilience Scrutiny and Assurance Group (RARSAG) will monitor compliance with adverse event reporting, review and final approval. Performance against the process will be presented to RARSAG on a quarterly basis with assurance being sought from the Directorates that any issues with compliance are being addressed. The terms of reference for RARSAG can be found in Appendix 12 of the Adverse Event Policy Application Guidance.

9.2 The Healthcare Governance Committee (HCG) will receive a status update report following presentation at RARSAG on a quarterly basis detailing progress of Significant Adverse Event Analysis and Reviews. This report is for final assurance and closure.

9.3 The Directorate AERGs will support the process to ensure that significant adverse events are escalated to the appropriate review level and monitor until completion of the process. In addition the AERG will review all adverse events which have been reported in the period between AERG meetings, identifying those where the group require further information to determine appropriateness of review level.

10.0 Access to Reports on Adverse Events

10.1 For patient/service user or staff requests for access to an Adverse Event Report or information relating to the adverse event, the requester can only request a copy of a report of an adverse event they have been involved in, under the General Data Protection Regulation (Regulation (EU) 2016/679). Requests should be made via 'Subject Access' to either of the Legal Desks at University Hospitals Ayr or Crosshouse in accordance with the Organisation's 'Access to personal information held about you' policy.

10.2 Where departments wish to analyse data for learning, individuals will have pre-authorised permissions to access reports for their service area. Individuals are reminded of their duties in relation to information sharing within the organisation.

10.3 Where a LMTR/SAER has been undertaken, a copy of the final report will be offered to those involved in reviewing the event, the staff involved in the event and also the patient/family involved. Each copy of the final report issued will be given a number and this will be recorded for audit purposes.

11.0 Information, Instruction and Training

11.1 Employees will be made aware of the importance of adverse event reporting and management, through both Corporate and Local induction, and ongoing formalised training. A competent advisory service is provided by the Risk Management Team. Risk Management Adverse Event training and frequency is detailed in Section 6 of the Adverse Event Policy Application Guidance.

12.0 Measuring Performance

12.1 This Policy will be reviewed on a two yearly basis (or sooner where necessary) by the Risk Management Team, ensuring that the process remains fit for purpose and complies with National Directives. The updated policy will be endorsed by Directorate Governance Groups and approved by the Risk and Resilience Scrutiny and Assurance Group.

13.0 Equality and Diversity Impact Assessment

13.1 This Policy has been impact assessed using the NHSAA Equality Impact Assessment Toolkit. No Equality & Diversity issues were identified.