Adverse Event Policy

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Contents

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 should be read in conjunction with NHSAA's Risk Management Strategy.

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 national approach to learning from adverse events (through reporting and review) developed by Healthcare Improvement Scotland (HIS) (CEL 20 (2013) 4th Ed (HIS December 2019))[4]. CEL 20 sets out the expectation that NHS Boards 'adopt this framework to improve their local approaches to handling adverse events'.

1.4 The Maternity and neonatal (perinatal) adverse event review process for Scotland guidance was launched on 15th September 2021 and has been produced in consultation with HIS and acts as an addendum to the HIS 'Learning from adverse events through reporting and review'- A National Framework for Scotland. Stages 1 to 3 are consistent with the Framework and the operational guidance document provides additional information that apply to Stages 4 to 6 of the process.

1.5 The Policy reflects the 'Being Open in Scotland – Guidance on implementing the Being Open Principles' January 2015, and the terminology, definitions, overarching principles and methodology outlined in this Policy document reflect the national frameworks from both documents.

1.6 This Policy sets out the actions required to effectively identify, report, review and learn from adverse events across NHSAA Board. Staff should also be aware of the NHS Board's Code of Corporate Governance and Risk Management Strategy. The Policy should also be read in conjunction with the Risk Assessment Procedure and the Risk Register Guidance and the ***Adverse Event Policy Application Guidance***.

[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
[4] Learning from adverse events through reporting and review: A national framework for NHS Scotland 2nd4th Ed (HIS December 2019) (CEL 20 (2013) www.sehd.scot.nhs.uk/mels/CEL2013_20.pdf)

1.7 Disclosure of adverse events, both clinical and non-clinical (including near misses) is a legal, contractual and professional requirement of all NHSAA employees. Within the Organisation reporting and review is facilitated by using the electronic Adverse Event Reporting Form within the electronic Risk Management System (Datix). For the purpose of this Policy, the reporting form/system will be referred to as the **'Adverse Event Reporting System'**.

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.

2.2 The primary focus is the provision of a safe environment combined with working practices and policies that take into account risk. NHSAA recognise the importance of learning lessons from adverse events and through the introduction of standardised reporting and management arrangements, the NHS Board aims to ensure that the lessons learned are shared across all healthcare areas and with other key partner agencies.

2.3 The review of an adverse event forms part of a wider strategy for risk management, which advocates the use of root cause analysis and human factors methodology/principles to understand why an adverse event has occurred. The emphasis is upon critical exploration of the underlying and contributory factors, which if allowed to persist, could create the potential for the same adverse event to be repeated again. Learning, improvement and change are the primary purpose of adverse event review. In accordance with the HIS national approach, the stages of adverse event review are described in the Adverse Event Policy Application Guidance.

2.4 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;
- Ensuring that where staff do not have access to the Adverse Event Reporting System (Datix), 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;

- 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.

2.5 In addition, NHSAA will:

- Take care of, make safe and/or support those involved at the time of the adverse event;
- Maximise safety to patient/service users, family, carers, staff, and members of the public;
- Foster a "Just Culture" where individuals are accountable and treated fairly. NHSAA's culture is based on caring, safe and respectful behaviours which encourages and supports staff to recognise, report and learn from adverse events;
- Regularly review the systems, procedures and guidance to support efficient reporting and management of adverse events; and

2.6 In relation to learning from Adverse Events, NHSAA will:

- Ensure an effective and robust review, which identifies the contributory factors and/or root causes of adverse events, taking cognisance of findings from previous adverse events to identify gaps and weaknesses in the agreed actions;
- Share the learning and outcomes of adverse events by providing effective feedback to patient/service users, families and staff involved across NHSAA (including partnerships), event themes and trends to inform improvement priorities and learning; and
- Provide assurance to Board Governance Committees that improvement is implemented and learning shared.

2.7. Being Open and Fair

2.7.1. 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.

2.7.2. NHSAA is committed to delivering high quality healthcare for the people of Scotland. The national approach to learning from adverse events aims to support NHS Scotland to effectively manage adverse events, to learn from them, and allow best practice to be actively promoted across Scotland so that we can continually improve the safety of our healthcare system for everyone.

2.7.3. 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 when things go wrong is key to the partnership between patients and those who care for them. We have a professional duty to acknowledge when something has gone wrong and provide an honest explanation. Openness about what happened and discussing adverse events promptly, fully and compassionately can help people cope better with the after-effects of adverse events.

2.7.4. 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.

2.7.5. We are committed to an open and honest approach and fully endorse the principles outlined in the Being Open Framework

- Acknowledgement
- Truthfulness, timeliness and clarity of communication
- Apology
- Recognising expectations
- Culture and professional support
- Risk management and systems improvement
- Multidisciplinary responsibility
- Clinical governance
- Confidentiality
- Continuity of care

2.7.6. The purpose of a review is to identify underlying causes which led to the adverse event occurring. Being open when things go wrong is pivotal to the partnership between patients and those who care for them. When adverse events are openly and fully discussed compassionately, this enables individuals to cope better with any after effects they may have after an adverse event. Being Open (2009) provides a suite of tools to support communication with those who have suffered harm from an adverse event.

2.7.7. NHSAA is committed to a "Just Culture" in creating "an environment where learning and accountability are fairly and constructively balanced" (Dekker, 2012)[5]. 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 ensure the highest standard of safety, therefore staff must be encouraged and feel supported, safe and confident to report adverse events.

2.7.8. The spirit of the review will be characterised by an open and fair culture. In this content, 'open and fair culture' means that the purpose of the review is to identify causes and/or weaknesses in systems, actions and inactions. Registered professional staff have additional responsibilities under their professional codes of practice.

2.7.9. Adverse event review does not preclude use of the Management of Employee Conduct process where there has been an alleged act of misconduct or serious breach of professional practice.

2.7.10. Although the review is not in itself a disciplinary process, staff are entitled to request support from their trade union or professional regulating body.

2.7.11. In the unlikely event that the review uncovers any criminal or potentially criminal act, then the review must stop and the appropriate enforcement agencies will be informed.

2.7.12. If the review uncovers misconduct, including malicious or reckless behaviour may be construed as gross misconduct or a serious breach of the individual's professional code of conduct, then the Management of Employee Conduct process will be invoked. The two processes may proceed in parallel, provided the rights of the individual are not compromised.

2.7.13. An adverse event may also be under review as a complaint and will be reviewed in accordance with NHS Scotland Complaints procedure. Where a complaint arises regarding an adverse event, the complaints process will cease and the adverse event review will take precedent. Concerns identified within a complaint that do not pertain to the adverse event will be handled via the recognised complaints process.

A link to NHSAA's Feedback and Complaints team site on Athena, can be found here:

http://athena/patcommrels/complaints/Pages/default.aspx

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

2.8 Duty of Candour

2.8.1 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).

2.8.2 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. 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 3)
- the flowchart for Maternal Death and Stillbirths (Adverse Event Policy Application Guidance Appendix 4), and;
- the specialist knowledge of the advisors of the group.

2.8.3 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.

2.8.4 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.

2.8.5 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.

2.8.6 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.

2.8.7 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.

2.8.8 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.

2.8.9 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.

2.9 Commitments to those involved in an adverse event

2.9.1 NHSAA has agreed what those involved can expect to happen when an adverse event has or could impact on their wellbeing or experience of the service.

2.9.2 NHSAA is committed to ensuring that when an adverse event occurs the immediate situation will be managed effectively to ensure:

- The patient/service user and their family are safe and supported;
- Staff members are safe and supported; and
- The organisation learns from the event and ensures any required improvements are made.

2.9.3 NHSAA is committed to developing and shaping organisational culture with values, beliefs and behaviours that recognise the impact that an adverse event can have on those involved. The organisational response to such an event will be:

- Compassionate;
- Treated with dignity and respect;
- Transparent;
- Show openness, honesty and responsibility;
- Timely; and
- Consistent

2.9.4 **NHS Ayrshire & Arran will:**

- Acknowledge when the service has been perceived not to have reached the expected standard; and
- Provide a sincere and honest apology where failings have been identified[6].

2.9.5 **NHS Ayrshire & Arran commits to**:

- Recognising the importance of its' staff in delivering quality services;
- Supporting its Managers and Leaders to value staff, their health, safety and wellbeing; and
- Fostering an honest, fair and just culture underpinned by respect and dignity.

2.9.6 In order for NHSAA to ensure the Organisational culture and values are embedded within the process for the review of adverse events, staff must understand their roles, responsibilities and maintain professional conduct. Additionally, staff will be encouraged to have multi-disciplinary involvement within reviews which is critical to the 'being open' process.

2.9.7 Staff should feel supported through the adverse event review process as they too, may be traumatised by their involvement in the event. Staff care is available from the Occupational Health Service, Staff Care Service and Staff Side representatives.

[6] Apologies (Scotland) Act 2016 which came into force 19th December 2016.

2.9.8 Staff Governance Standards are recognised as a feature of high performance which enables staff to have a positive employment experience in which they are fully engaged with their job, their team, and their organisation. These Standards ensure staff are managed fairly, which has a positive impact on organisational performance (and therefore on the quality of the services provided), it is also an important component in providing all employees with dignity at work.

2.9.9 The learning outcomes from adverse event reviews will be promoted and disseminated to healthcare professionals promptly utilising the organisations learning summary process where appropriate for sharing learning.

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[7] 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 **an event that did result in, harm**, loss or damage to a patient/service user, member of staff, visitor, contractor or to NHS Ayrshire & Arran 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 Department of Health (DoH) list can be found in 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.

[7] Public Bodies (Joint Working) (Scotland) Act 2014

	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.
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 6 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 • 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 NHS Ayrshire & Arran to deliver healthcare such as Local Authority, Care/Residential homes, Scottish Ambulance Service and Higher Education Institutions.
Consequence Grading	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**.
Significant Adverse Event Analysis and Review (SAER)	a review of Consequence level 4/5 (HIS Category I). The Leadership Oversight Group will determine the appropriate chair for such reviews i.e. independent/external to the service or service led.
Local Management Team Review	a review of Consequence level 4 (HIS Category I) 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 monitored via the Occupational Health & Safety Adverse Event Review Group.
Ward/Departmental Review by Line Manager	a review of consequence levels 1-3 (HIS Category II or III) which is led by the service where the adverse event has occurred.
Adverse Event Review Group (AERG)	a governance group that provides a co-ordinated and integrated approach to managing all significant adverse events and complaints linked to an adverse event occurring within the respective service. The Directorate Governance Groups are responsible for scrutinising evidence and providing assurance to their relevant AERG, Risk and Resilience Scrutiny and Assurance Group and Healthcare Governance Committee that adverse events are being addressed, improvements implemented and learning shared. An example 'Terms of Reference' can be found at Appendix 2 of the Adverse Event Application Policy Guidance.
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 system (Datix) access permissions.
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 (Datix) access permissions.
Root cause analysis (RCA)	is a method of problem solving aimed at identifying the root causes of adverse events. A suite of RCA tools are available within the SAE toolkit on the Risk Management AthenA site
Executive Sponsor	the **Executive Sponsor** for commissioning and approving/closing a significant adverse event review is the Medical Director and/or the Nurse Director. Further information can be found in Section 6.

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 In conjunction with the other **Directors**, the **HR Director** will ensure that there are processes in place for suitable and sufficient training in relation to adverse event reporting and review.

5.2.5 The **Assistant Director for Occupational Health, Safety and Risk Management** support the adverse event review level decision process (Appendices 7 and 8 of the Adverse Event Application Policy Guidance) by providing specialist clinical and health and safety advice.

5.3. **Directors, Assistant and Associate Directors (including Associate Medical and Nurse Directors (AMD/AND)) which includes Health and Social Care Partnerships (H&SCP)**

5.3.1 Directors, Assistant and Associate Directors (including AMDs/ANDs) are responsible for:

- 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' (Datix 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;
- 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;
- Ensuring staff support training;
- To ensure the legal requirements of Duty of Candour are met within; and
- Ensure actions are implemented and improvements are made.

5.4. **Clinical Directors, Clinical Nurse Managers, General/Service Managers, Heads of Service (HoS)**

5.4.1 Clinical Directors, Clinical Nurse Managers, General/Service Managers and HoS are responsible for the overall implementation, management and compliance of the Adverse Event Policy and procedures within their areas of responsibility. They will ensure that:

- They demonstrate leadership behaviours and actions that support a positive safety culture and commitment to being open;
- They have attended training to enable robust review and final approval of adverse events;
- Their Managers have attended training to enable robust review and final approval of adverse events;
- They support their Managers to release staff for training on identification, reporting and review of adverse events;
- They lead and/or participate in Significant Adverse Event Analysis and Reviews; and/or LMTRs as appropriate;
- They support staff;
- They perform the role of 'Final Approver' (Datix System), confirming that a robust and proportionate review has been undertaken following the adverse event, escalating where necessary and ensure closure of the report on the system;
- They have identified a named Deputy for periods of absence;
- The development, delivery and completion of action plans, identify and share learning outcomes locally, and across the wider organisation if applicable;
- They contribute to organisational learning by adopting lessons learned;
- They regularly analyse data to identify trends requiring further review;
- They provide assurance to their Governance committee of adverse event performance; and
- To ensure the legal requirements of Duty of Candour are met within their area of responsibility.

5.5 **Senior Charge Nurses, Specialty Consultants and Department Managers /Supervisors/Line Managers (including named Deputy)**

5.5.1 Senior Charge Nurses, Specialty Consultants and Department Managers / Supervisors / Line Managers (including named Deputy) are responsible for the local implementation, management and compliance of the Adverse Event Policy and procedures within their areas of responsibility. They will ensure that they:

- 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 in accordance with Figure 1 of the Adverse Event Application Policy Guidance;
- 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.

5.6 **All Employees**

5.6.1 To facilitate NHSAA s commitment as an exemplary employer, all employees are expected to adhere to the Staff Governance Standards.

5.6.2 All NHS Staff, including bank staff, agency staff, trainees (including students and work experience), volunteers and those staff undertaking NHS healthcare activity have a 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. They have a duty to follow the processes within this Policy to allow NHSAA to comply with its statutory obligations. They must co-operate with any review/investigation being conducted and are required to adhere to any instruction, information or training session on content, implementation and management of this policy document including duty of candour processes.

5.6.3 Demonstrate leadership behaviours and actions that support a positive safety culture and commitment to being open.

5.6.4 All staff must adhere to NHSAA's Social Media Policy in relation to the appropriate use of social media and data protection. NHSAA has a reputation to uphold and the public must be able to trust staff's integrity, confidentiality and values.

5.6.5 Those involved directly/indirectly in an adverse event may be requested to provide a Recollection of Events using the organisational template and 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.

5.6.6 All agency staff, trainees (including students and work experience), volunteers, and contractors should report adverse events to their supervisor, who is responsible for ensuring the adverse event is reported. The relevant third party provider should be notified e.g. secondary school or university. The Department Manager in which the adverse event occurred is responsible for notifying either the third party provider directly or the key contact to the provider.

5.6.7 Staff are equally responsible for seeking feedback of the review of an adverse event that they have been involved in when feedback has not been provided in a timeous manner by the reviewer.

5.7. **Contractors**

5.7.1 **Building and Service Contractors** have a duty of care to report adverse events arising out of, or in connection with work. They have a duty to follow the processes within this Policy to allow NHSAA to comply with its statutory obligations. They must co-operate with any review/investigation being conducted and are required to adhere to any instruction, information or training session on content, implementation and management of this policy document.

5.7.2 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.

5.7.3 **All Independent Contractor Groups**

Independent Contractor reviews fall out with the scope of NHSAA's Adverse Event Policy. In the event that an adverse event is raised in the Secondary Care sector with respect to the actions of an Independent Contractor in any of the contractor groups, this will be managed in accordance with their legal and professional duties and associated governance structures.

6.0 Managing an Adverse Event

6.1 All NHS Staff, including bank staff, agency staff, trainees (including students and work experience), volunteers and those staff undertaking NHS healthcare activity have a 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.

6.2 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.

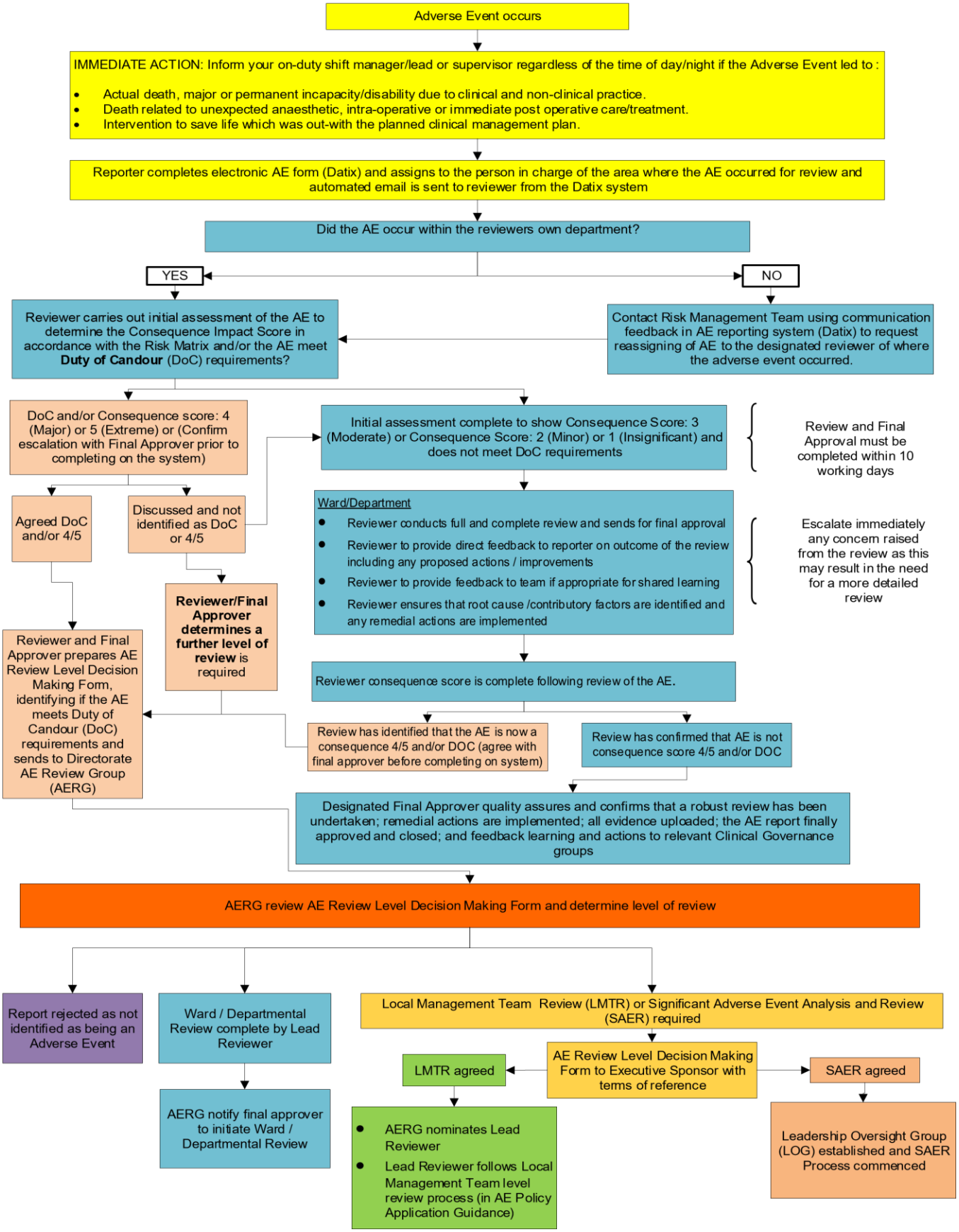
6.3 Therefore, the response to each adverse event should be proportionate to its scale, scope, complexity and opportunity for learning. There are six stages to adverse event management:

1. Risk Assessment and prevention
2. Identification and immediate actions following an adverse event
3. Initial reporting and notification
4. Assessment and categorisation
5. Review and analysis
6. Improvement planning and monitoring

6.4 Further information and detail on each stage of management can be found within the Adverse Event Policy Application Guidance.

6.5 In order for us to meet the requirements of robust review and learning, the following flowchart demonstrates the process to follow to determine the review level for adverse events.

Adverse Event Process



6.6 Once the required level of review has been determined, the pathway for each review level as detailed in Table 1 below must be applied. 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)'.

- Ward/Departmental Review by Line Manager;
- Local Management Team Review; and
- Significant Adverse Event Analysis and Review

Table 1: Adverse Event Review Pathway

Level of Review	Significant Adverse Event Analysis & Review	Local Management Team Review	Ward/Department Review by Line Manager
Type of Review	The review team should be sufficiently removed from the event and have no conflict of interest to be able to provide an objective view. SAER Group uses Root Cause Analysis (RCA) methodology.	Service/General/Clinical Manager with Multi-disciplinary Team input. Group uses Root Cause Analysis (RCA) methodology.	Ward/Department Reviewer or Deputy undertakes review of adverse event using appropriate tools and Root Cause Analysis (RCA) methodology. Directorate Review Groups may carry out multidisciplinary reviews and carry out trend analysis of all adverse events.
Level of authority *(Decision making)*	**Adverse Event Review Group (AERG)** will: • Review AE SBAR; • Propose review level as SAER; • Send decision to Executive Sponsor for approval • The Leadership Oversight Group (LOG) sets the Terms of Reference. The Director for the area the Adverse Event took place appoints the Lead Reviewer and the Medical Director sends the commissioning email informing the Lead Reviewer.	**Adverse Event Review Group (AERG)** will: • Review AE SBAR; • Authorise the Local review; • The General Manager for the area the Event took place appoints the Lead Reviewer with RCA skill; and • Set the Terms of Reference.	Final Approver quality assures the review, confirming that a robust review has been undertaken and finally approves and closes the record.
Review Team	The review team will consist of: • A Lead Reviewer with RCA skill; • Representative from Service; • Subject Matter Experts; • Patients/ Service User or family contact; and • Staff contact N.B. Some members may act in a dual capacity e.g. the Service Representative can be the staff contact.	Lead Reviewer appoints the team, consisting of: • Subject Matter Experts; • Patients/Service User or family contact; • Staff contact; and • Others if deemed necessary N.B. Some members may act in a dual capacity e.g. the Lead Reviewer can be the patient/service user or family contact.	A Team is not necessary however; the review should not be undertaken in isolation where other services are involved. Specialist advice should be sought where appropriate.

Key principles that must be followed	All reviews must have a: • LOG; • Terms of reference; • Tabular timeline of events; • Review Report on the Organisations' agreed format; • Action Plan if required; and • Organisational Learning Summary • Completion of Duty of Candour procedure (if triggered)	All reviews must have a: • Terms of reference; • Tabular timeline of events; • Review Report on the Organisations' agreed format; and • Completion of Duty of Candour procedure (if triggered)	The review must document • What led to the event happening? • When did the event happen? • How did the event happen? • Why did the event happen? • Impact of the event and learning.
Governance/ Performance	Report and recommendations to be approved by the relevant AERG. Action Plan with evidence then submitted to the respective service Clinical Governance Group for scrutiny and approval. Completed action plan is presented to the AERG for approval and then to the Risk and Resilience Scrutiny and Assurance Group and then Healthcare Governance Committee.	Report and recommendations to be approved by the relevant AERG. Action Plan with evidence then submitted to the respective service Clinical Governance Group for scrutiny and approval. Completed action plan is presented to the AERG for assurance.	Local monitoring by Ward/Department/Service Managers.
Time-scale	Review must be commissioned within 10 working days of the Adverse Event being reported on electronic Adverse Event Reporting System (Datix). Commence and close review (report submitted for approval to LOG within 90 working days of the commissioning date). Action plan to be developed within 10 working days from report being approved.	Commence and close review (report submitted for approval through AERG) within 30 working days of the Adverse Event being reported on the electronic Adverse Event Reporting System (Datix). 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.	Adverse Event finally approved within 10 working days.

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 within the Adverse Event Policy Application Guidance.

A list of events that would require reporting to external agencies includes:

- deaths and injuries due to a work related accident to the **Health and Safety Executive** as set out in the Reporting of Injuries, Diseases and Dangerous Occurrences Regulations 2013 (RIDDOR)
- events involving health, social care, estates and facilities equipment to the **Incident Reporting and Investigation Centre (IRIC)** within Health Facilities Scotland as set out in CEL 43 (2009)
- events relating to blood to the **Medicines and Healthcare Products Regulatory Agency (MHRA)** as required by the UK Blood Safety and Quality Regulations 2005 and the EU Blood Safety Directive
- adverse drug reactions, defective medicines and counterfeit medicines via the Yellow Card Scheme to the **MHRA**
- suicides of individuals in contact with mental health services to **Healthcare Improvement Scotland**
- all Category I adverse events reported monthly to **Healthcare Improvement Scotland**
- deaths associated with medical or dental care to the **Procurator Fiscal**
- relevant information to UK-wide national audits and enquiries managed by the **Healthcare Quality Improvement Partnership (HQIP)**
- information governance events to the eHealth Division within **Scottish Government** and the **Information Commissioners Office**
- Ionising Radiation adverse events to the **Warranted Inspector for IR(ME)R**16**,** and
- serious crimes (homicides, serious assault, serious sexual assault) by an individual who is receiving care from mental health or learning disability services to the **Mental Welfare Commission for Scotland**

Key Note: Staff using these additional reporting systems/processes must ensure that these adverse events are also recorded on the adverse event reporting system (Datix). Specific arrangements for laboratory reporting are detailed within the Adverse Event Policy Application Guidance.

8.0 Learning from Adverse Events

8.1 As part of our purpose to work together to achieve the healthiest life possible for everyone in Ayrshire & Arran, the organisation is committed to supporting its workforce to create an open, fair, just and learning culture.

8.2 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.

8.3 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 (http://athena/execmed/riskmgt/Pages/Learningsummary.aspx). The Learning Summary templates can be found in Appendices 16 and 17 of the Adverse Event Policy Application Guidance. Further guidance can be sought from the Risk Management Team.

8.6 The purpose of these templates 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. Copies of these summaries will be published on NHS Ayrshire & Arran public website and if National learning is identified this will be published on the Community of Practice (NHS Education for Scotland) website (http://www.knowledge.scot.nhs.uk/adverse-events.aspx).

8.8 As part of the LMTR process, a learning summary will be produced if learning has been identified.

8.9 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.

8.10 There are 4 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.

9.0 Governance Assurance

9.1 The Risk and Resilience Scrutiny and Assurance Group will monitor compliance with adverse event reporting, review and final approval. Performance against the process will be presented to the Risk and Resilience Scrutiny and Assurance Group – Governance meeting bi monthly.

9.2 The AERG will review all adverse events which have been reported over the preceding seven days to allow the group to review all adverse events ensuring that appropriate grading using the Risk Matrix has been applied; identifying those where the group require further information to determine appropriateness of review level.

9.3 The Risk Management Team will provide fortnightly reports to each Adverse Event Review Group detailing all Consequence 4/5 (HIS Category I) adverse events which will be returned to the team for assurance that these adverse events have been reviewed in line with the Adverse Event Policy and that review level decision making is recorded.

9.4 An SAER status update report will be provided to the Risk and Resilience Scrutiny and Assurance Group on a six weekly basis detailing progress of Significant Adverse Event Analysis and Reviews, prior to the report being tabled at Healthcare Governance Committee for final assurance and closure.

9.5 Directorates will provide assurance that outcomes and learning arising from adverse events are tabled through their own governance structures, the relevant AERG then to RARSAG and finally to the Healthcare Governance Committee using the template provided in Appendix 18 of the Adverse Event Policy Application Guidance, and to the H&SCP Clinical and Care Governance Committee where appropriate. Directorates must evidence that adverse event management is a standing agenda item at directorate clinical governance group meetings.

9.6 On completion of a Significant Adverse Event Analysis and Review, the SAER Coordinator will issue all those involved with an evaluation form to assess the effectiveness of the process. Evaluation forms can be found in Appendix 19 of the Adverse Event Policy Application Guidance.

10.0 Access to Reports on Adverse Events

10.1 NHSAA is committed to an open and sharing culture that encourages positive learning from adverse events. The process of access to reports on adverse events recognises this approach and the need to preserve patient, and staff confidentiality.

10.2 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.

10.3 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.

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 8 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 ratified 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.