Adverse Event Management Policy

DOCUMENT CONTROL SHEET

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V2.5	25-02-21	Revision following consultation with Clinical Directorate	SM/CT	No
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L MacLennan	Head of Equality and Engagement, SPST	06-10-20	V 2.3
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1. INTRODUCTION

NHS National Services Scotland (NSS) is a national NHS Board operating across NHSScotland. Our aim is to support the delivery of safe, effective and efficient health and social care throughout Scotland. NSS's role can be complex and carry risk. Due to the complexity of NSS services and relationships, it is inevitable that sometimes things will go wrong. In order to evolve and grow, we must identify the learning potential from these events, share that learning and make improvements to minimise the risk of recurrence by improving the quality of our systems and processes.

This policy is closely aligned to the national approach to learning from adverse events developed by Healthcare Improvement Scotland.[1] In addition, this policy incorporates the requirements of the statutory organisational duty of candour legislation, which came into force on 1 April 2018.[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 that has resulted in death or harm that is not related to the course of the condition for which the person is receiving care. Systems for managing adverse events and the NHS Model Complaints handling procedure should be aligned so that learning and improvement activity are integrated and co-ordinated.

Should members of staff have questions about any aspect of this policy or its application, they should discuss this with their Line Manager and if necessary seek further advice from a Strategic or Support Business Unit (SBU) adverse event lead or organisational information governance lead or clinical lead specific to the relevant clinical area.

2. AIMS AND PURPOSE

This policy aims to set out a consistent and co-ordinated approach to the identification, reporting and management of adverse events and allows good practice to be actively promoted, creating an environment where adverse events are seen as opportunities to learn. This includes:

- raising staff awareness of adverse event reporting i.e. what and how to report
- an electronic adverse event management system to facilitate reporting and review of events
- ensuring that all NSS staff have access to report adverse events including those who cannot access the electronic system
- supporting all NSS staff to manage adverse events in a timely and effective manner
- all individuals, including staff, who are involved in an adverse event are offered support at a time and in a way which meets their needs
- providing the opportunity for learning for all NSS staff by ensuring that feedback is shared across services and the organisation and nationally, as appropriate, to support wider learning and improvement
- ensuring the highest possible standard for all adverse event reviews regardless of the agreed level of review
- regular review of systems, procedures and guidance to support efficient reporting and management of adverse events
- providing assurance to the Board Governance Committees that improvement is implemented and learning shared
- ensuring that any legal and statutory requirements, for example to regulatory authorities, the Scottish Government and individuals affected by adverse events, are met
- ensuring robust governance arrangements are in place to support implementation and monitoring of this policy

The NSS Adverse Event Management Policy is supported by an operational adverse event procedure, which provides further detail of the standard methodology for the management of adverse events and specific processes for certain types of adverse event.

3. SCOPE

The NSS Adverse Event Management Policy covers all adverse events and near misses. In NSS, these are categorised as information governance[3] and/or clinical[4] adverse events.

The policy applies to all services provided, supported and commissioned by NSS.

The policy applies to all permanent, honorary or temporary staff who work for or are under contract to NSS, including contractors, students, agency, bank staff and volunteers, and non-executive board members (hereafter referred to as staff).

All staff must meet the standards of practice outlined in this document as well as those included within their terms of employment. Those who are registered healthcare professionals must also abide by their own regulatory organisation's standards of conduct and practice.

This policy recognises that the generic use of the term 'adverse event' does not equate to the legal definitions by which some NSS activities are regulated by the Medicines and Healthcare Products Regulatory Agency (MHRA). NSS will report Serious Adverse Events[5] and Serious Adverse Reactions[6] to MHRA in adherence with legal requirements. Clinical adverse events are identified using agreed processes which are mapped to the national category definitions to ensure effective reporting and assurance to the relevant NSS Board sub-committees.

4. OVERARCHING PRINCIPLES

4.1 NSS Values

The approach to learning from adverse events builds upon NSS values, which are reflected in the principles and requirements of this policy and associated procedure. These are: committed to each other, customer focus, integrity, openness, respect and care, and excel and improve.

4.2 Principles

There are a number of principles which support the aims and purpose of this policy and which reflect NSS values. NSS will uphold these principles.

- **Emphasis on learning and promoting best practice** - the system is focussed on learning at all levels from local teams, across services within NSS and nationally, where appropriate. Quality Improvement methodology should be considered where deficiencies in process or actions lead to adverse events. Near misses will be reviewed to promote learning and service improvements. The NSS Clinical Governance and Quality Improvement Framework reinforces this principle.

- **Systems approach** - adverse events act as a 'window' into NSS. This is important to allow reflection on the weaknesses of our systems, or in some cases, the strengths, and prevent future adverse events.

- **Openness about failures** – adverse events are identified, reported and managed in a timely manner. Where NSS is directly responsible, those affected are told what went wrong and why, and receive an apology for any harm that has occurred. Reviews of events happen frequently and quickly following their occurrence. Adverse event reporting is expected to increase as we move to a more open organisational culture.

- **Just culture** – individuals are treated fairly. Organisational culture is based upon the values of trust, openness, equality and diversity which encourages and supports staff to recognise, report and learn from adverse events.

  A just culture seeks to identify lessons from organisational processes and system errors, which contribute to most adverse events, improving them after review and action. However, it is imperative that staff understand their individual responsibility and accountability and do not abdicate responsibility for their actions. A just culture is not a 'no blame' culture; reckless or malicious behaviour will be challenged and managed through the application of

appropriate organisational policies. In the unlikely event that a review uncovers evidence of a criminal act, the appropriate enforcement agencies will be informed. Where there is evidence of misconduct, including malicious or reckless behaviour, Human Resources processes will be invoked where appropriate. This is not part of the adverse event review although both processes can run in parallel provided the rights of the individual are not compromised.

- **Positive safety culture** – avoidance, prevention and mitigation of risks is part of the NSS approach to all its activities and this is recognised at all levels of the organisation. Decisions relating to the management of adverse events are risk-based, informed and transparent to allow an appropriate level of scrutiny. This is supported by the NSS Integrated Risk Management Approach.

- **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, in line with the Scottish Government Whistleblowing policy.[7], [8] Roles and responsibilities will be explicit and clearly accepted with individuals understanding when they may be held accountable for their actions. The principal accountability of all NHS care and service providers is to patients, donors, screening participants, their families and carers.

- **Teamwork** – everyone who works for NSS 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 NSS will explicitly encourage and foster teamwork within a culture of trust, mutual respect and open communication.

Supporting cultural change is fundamental to implementing this policy and supporting procedure. NSS strives to achieve a positive safety culture that is open, just and informed, in which reporting and learning from error is seen as good practice. Achieving cultural change is challenging and will not happen overnight, but the

approach outlined as part of this policy, procedure and other supporting documentation should support positive change in how we manage adverse events in NSS. It is the duty of all NSS staff to report adverse events in line with this policy.

5. DEFINITIONS

5.1 Adverse Event

An **adverse event** is defined as **an event that could have caused (a near miss), or did result in, harm to people or groups of people or the organisation**. **Harm** is defined as **an outcome with a negative effect**. Harm to a person or groups of people may result from unexpected worsening of a medical condition, escalation of treatment, the mishandling of person identifiable information, system failure, service performance issues, service disruption, financial loss or adverse publicity. These are examples and not an exhaustive list.

Not all harm is avoidable, for example the worsening of a medical condition as a natural progression of disease or the inherent risk of treatment. It is not always possible to determine whether harm was avoidable until a review is carried out. Areas for improvement and learning should always be identified if possible.

People are defined as:

- service users
- patients
- donors
- members of staff
- carers
- family members
- visitors

Groups of people include any functional grouping of individuals such as an organisation. This means that adverse events that result in, for example, reputational harm or financial harm are included within the scope of this policy. Also included are populations of users of a particular service, for example screening service users.

5.2 Near Miss

A near miss is defined as when an error or omission has occurred which could have caused harm but there was no adverse outcome or where the error was about to take place but was prevented from happening, either by chance or intervention.

5.3 NSS and External Adverse Events

As a national board supporting and commissioning services across NHSScotland the reporting, reviewing and managing of adverse events and near misses is complex. It is vital that we keep a comprehensive record of events where NSS has had direct responsibility, or where NSS services are partially responsible for the management of an event that has occurred in another NHS health board or other third party. For example, national IT contracts or national screening programmes.

5.3.1 NSS adverse events

These are:

- an event occurred within NSS and for which NSS has direct responsibility
- an event occurred within systems or processes where NSS has joint responsibility and for which NSS has accepted full or partial responsibility

5.3.2 External adverse events

An adverse event can occur within another organisation and staff must still report these external events to NSS and take action to 1. make the originating organisation or individual aware of the error and 2. minimise the impact of the error. External adverse event can occur:

- in a localised or board environment external to NSS, however, whilst these events have taken place externally to NSS, they may be considered programmatic adverse events within a service for which NSS has overall responsibility or oversight
- externally where NSS does not deliver the service, for example business confidential, person identifiable or clinical information sent in error by another health board, external organisation or member of the public

- externally within systems or processes, for which NSS has joint responsibility in delivering the service. For example, a third party service contractor experiences a malware breach which affects their service to NSS or missed/lost samples within a health board such as in the newborn screening programme

Where more than one SBU is involved in the response to an adverse event, whether internal or external, senior managers must identify the lead SBU and jointly agree a co-ordinated response.

It is worth noting that there may be an occasion whereby NSS, through its third party involvement, becomes the agent of discovery for a possible adverse event. NSS would be expected to inform the relevant NHS Board or practitioner that in its view an adverse event should be raised and/or that the duty of candour procedure should be activated. For example:

- where NSS does not directly deliver a service but does have a duty of governance, for example in dental governance oversight through the National Dental Governance Committee
- where NSS administer for, or on behalf of another agency, for example, in dental tribunals on behalf of territorial boards in conjunction with the Scottish Government and the General Dental Council which are hosted by NSS which then holds information related to the tribunal or investigation

5.4 Adverse Event Categories

Grading of the adverse event is mandatory in NSS. The following categories are used to group adverse events in line with the national framework. This will help determine the level of review and if other escalation is required. High level definitions are set out below.

- **Category 1 – 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, breach of highly sensitive personal information relating to several health boards.

- **Category 2 – 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, loss of medical records during transit.
- **Category 3 – Events that had the potential to cause harm but no harm occurred,** for example near miss events (by either chance or intervention) or low impact events where an error occurred, but no harm resulted.

5.5 Duty of Candour

There is a legal duty on all organisations 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. An event which has triggered the organisational duty of candour must be reported as an adverse event and the process documented within the event record.

5.6 Legal and Statutory Requirements

Specific events must be reported to external regulators/competent authorities at a national or UK level. This includes:

- all significant adverse event reviews commissioned for a national category 1 adverse event reported to Healthcare Improvement Scotland
- personal data breaches likely to result in a risk to individuals' rights and freedoms to the Information Commissioners Office (ICO) and to the Scottish Government for information only
- events where there is an impact on the provision of an essential service reported to the competent authority, i.e. Scottish Government, in line with the Network and Information Systems (NIS) Regulations 2018
- events relating to blood services and blood products in SNBTS to the 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

- events involving the loss of NSS devices, such as laptops and mobile phones, to Police Scotland
- events involving health, social care, estates and facilities equipment to the Incident Reporting and Investigation Centre (IRIC) as set out in CEL 43 (2009)
- Ionising Radiation adverse events to Healthcare Improvement Scotland

5.7 Significant Adverse Event

A significant adverse event is an event that caused death or major harm to people, or serious harm to the organisation, such as a penalty or fine (£>1,000k), or severe impact on reputation and stakeholder relations. These are national category 1 adverse events in NSS. The adverse event national category can help decide the level of review required and all national category 1 adverse events must be considered for a Level 1 significant adverse event review.

6. ROLES AND RESPONSIBILITIES

The **Chief Executive** has overall responsibility and is accountable to the NSS Board for ensuring that policies and procedures for adverse event management, systems for reporting and learning and delegation of roles and responsibilities to the Executive Management Team members are in place.

The **NSS Medical Director** and **Interim Director of Digital and Security** are jointly named Executive leads for this policy. Corporate responsibility sits with the **Associate Director for Nursing, Clinical Governance and Quality Improvement** and **Deputy SIRO**.

All staff (as defined in section 3) have a responsibility to follow this policy and associated procedures as appropriate to their role. All staff should maintain a safe environment, safe systems of work and take proactive measures to reduce the risk of an event occurring. They must report adverse events using the electronic reporting form, participate in reviews, and support implementation of recommended actions and learning. Any adverse events training, including duty of candour, appropriate to their area of work should be completed.

The **Associate Director for Nursing, Clinical Governance and Quality Improvement** has corporate responsibility for providing assurance through reporting within and from SBUs to the NSS Clinical Governance and Quality Improvement Committee through the Clinical Directorate. They are responsible for driving a culture where organisational learning and improvement is at the core of all adverse event reviews and outcomes. They are supported by the **Information and Clinical Governance Manager** who is responsible for development and maintenance of the electronic system used to manage adverse events systems including user training.

The **Executive Management Team** provides staff support and training and ensures actions are implemented. Where indicated, members of the Executive Management Team are responsible for ensuring engagement with donors and patients and their families.

Information Asset Owners are responsible for the information assets assigned to them on behalf of the NSS Board and thereafter the public. They are responsible for reporting any data breach / loss when they occur and ensuring that the adverse event is managed appropriately. They must ensure that the **NSS SIRO** and/or **NSS Data Protection Officer** are informed immediately of a serious data breach.

Line Managers, or any staff member who carries management responsibility, have a responsibility to ensure compliance with this policy and associated procedures, ensure their staff have access to available adverse event awareness, training and support, and for implementation of learning to support service improvements.

The **Medical Director** acting as **Caldicott Guardian** and **Duty of Candour Lead** provides advice to the SIRO about the ethical and appropriate use of a patient's personal information following an adverse event. In each SBU, there are nominated Caldicott Guardians and deputies who assist the Medical Director and provide local support and advice to staff. They are responsible for ensuring that the legislative requirements of the organisational duty of candour are adhered to.

SBU Adverse Event Leads are responsible for supporting and ensuring staff awareness and compliance with adverse event policies and procedures, staff support and advice, system training, supporting review of adverse events and monitoring implementation of learning to support service improvements within their SBU.

SBU Directors/Associate Directors/Senior Managers are responsible for ensuring staff awareness and compliance with adverse event management policies and procedures, reviewing and managing significant adverse events, progression of action plans and follow-up, dissemination of learning and staff support within their SBU. Roles and responsibilities of Senior Managers involved in a Level 1 Review are detailed in the adverse event management procedure.

The **SIRO** provides overall accountability and decision-making for reporting information governance and security events to the NSS Audit and Risk Committee and other external authorities such as the Information Commissioner's Office, Scottish Government. They will take ownership of all information governance policies including adverse events, leading a culture that values, protects and uses information in a way that reduces the possibility of events, and staff support and advice. The **Deputy SIRO** and **NSS Data Protection Officer** support them.

Subject Matter Experts (such as the NSS Data Protection Officer, NSS Information Security Officer, Clinical Lead or Advisor) and for duty of candour the Registered Health Professional provide specialist advice, guidance and support to staff managing adverse events, advising on legal, statutory or regulatory reporting requirements and supporting completion as required, and assisting in adverse events risk assessment and reviews.

7. GOVERNANCE

NSS is responsible for ensuring governance systems are in place with clear lines of accountability and clearly defined roles and responsibilities to support the effective management of adverse events.

SBU Clinical and Information Governance Groups and Senior Management Teams ensure compliance with adverse event management policies and procedures, reviewing and overseeing management of adverse events, including monitoring progression of improvement plans and follow-up, dissemination of learning and staff support. Where indicated, Senior Management Teams are also responsible for ensuring engagement with donors, patients, carers and families.

The **NSS Clinical Governance and Quality Improvement Committee** reviews and scrutinises reports on clinical adverse events, duty of candour events, clinical risks and complaints (related to safety of services or clinical staff fitness to practice), including their identification, causes, management, lessons learnt and service improvement implemented.

The **NSS Audit and Risk Committee** must be satisfied that each NSS SBU has processes in place to monitor and report on information governance adverse events, risks and complaints.

The **NSS Board** seeks assurance from the NSS Clinical Governance and Quality Improvement Committee and NSS Audit and Risk Committee that there are effective local systems and procedures in place around adverse event management.

8. EQUALITY IMPACT ASSESSMENT

This policy has been impact assessed using the NHS NSS Equality Impact Assessment.

9. POLICY REVIEW

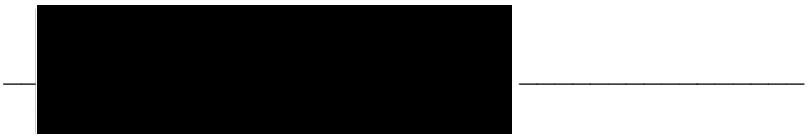
This policy is reviewed every two years from its effective date to ensure that arrangements put in place are appropriate to the operating requirements of NHS National Services Scotland. The policy will be reviewed sooner in response to any future editions of the Healthcare Improvement Scotland national framework for adverse events and amended accordingly.

Date policy is effective: 1 February 2022

Reviewed by: Partnership Forum, Clinical Governance and Quality Improvement Committee

Agreed by: **Date: February 2022**

On behalf of Chair, Staff Governance Committee:



10. REFERENCES

[1] Healthcare Improvement Scotland, Learning from adverse events through reporting and review: A national framework for Scotland, (HIS) (CEL 20 (2013) 4th Edition, December 2019 www.healthcareimprovementscotland.org/our_work/governance_and_assurance/learning_from_adverse_events/national_framework.aspx (accessed 13/05/2021)

[2] Duty of Candour (Scotland) Regulations 2018 www.legislation.gov.uk/ssi/2018/57 (accessed 13/05/2021)

[3] **Information governance** is "a framework for handling information in a confidential and secure manner to appropriate ethical, legal and quality standards."

[4] **Clinical governance** is "a system through which NHS organisations are accountable for continuously improving the quality of their services and safeguarding high standards of care by creating an environment in which excellence in clinical care will flourish." (Scally and Donaldson, 1998, p.61)

[5] A serious adverse event is "any untoward occurrence associated with the collection, testing, processing, storage and distribution, of blood or blood components that might lead to death or life-threatening, disabling or incapacitating conditions for patients or which results in, or prolongs, hospitalisation or morbidity." (Blood Safety and Quality Regulations 2005) www.legislation.gov.uk/uksi/2005/50 (accessed 13/05/2021)

[6] A serious adverse reaction is "an unintended response in a donor or in a patient that is associated with the collection or transfusion of blood or blood components that is **fatal, life-threatening, disabling or incapacitating**, or which results in or prolongs hospitalisation or morbidity." (Blood Safety and Quality Regulations 2005) www.legislation.gov.uk/uksi/2005/50 (accessed 13/05/2021)

[7] NHSScotland Workforce Policy for Whistleblowing, April 2021 https://workforce.nhs.scot/policies/whistleblowing-policy/ (accessed 13/05/2021)

[8] Raising Whistleblowing Concerns – A Guide for NSS www.nhsnational-hr.scot.nhs.uk/2.NATIONAL%20BOARDS/NSS/POLICY%20PROCESS%20AND%20Ts%20AND%20Cs/People%20Advice%20and%20Support/Whistleblowing/Whistleblowing%20Process%20NSS.docx (accessed 13/05/2021)