Adverse Event Management Policy

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Executive Summary

NHS Lothian aims to support staff to provide high quality care that is safe, effective and person-centred for every person every time. However, provision of healthcare is complex, and adverse events can and do occur which do or could have a major effect on the people involved. It is important that as an organisation, we learn from these events, share that learning and make improvements to minimise the risk of recurrence and improve the safety and quality of our services.

The approach to learning from adverse events builds upon NHS Lothian values, which are reflected in the principles and requirements of this policy and associated procedure. These are:

- Care and Compassion
- Dignity and Respect
- Quality
- Teamwork
- Openness, Honesty and Responsibility

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

This policy is in support of and should be read in conjunction with the NHS Lothian Health and Safety Policy.

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1.0 Purpose

It is acknowledged that things can and do go wrong in the provision of healthcare. The purpose of this policy is to ensure that a consistent approach is taken by all services and in all settings to the management and review of these events when they do or could have occurred.

Adverse event management is one part of NHS Lothian's integrated approach to risk management and continuous improvement through learning and changing practice. Making improvements informed by learning from adverse events, complaints and claims, and robust implementation of processes to assess risk and put in place actions to mitigate that risk are the cornerstones of improving the safety and quality of healthcare. Governance and accountability for implementation of systems and processes for adverse event management are therefore aligned through operational management and governance arrangements.

2.0 Policy statement

NHS Lothian policy requires that adverse events and near-misses are reported and reviewed in a timely and effective way, in partnership with patients, carers, families and staff. Furthermore, that learning from review is identified, shared and used to inform improvements to services. The focus for adverse event review is on adopting a systems approach with a clear emphasis on learning and promoting best practice.

The Healthcare Governance Committee has delegated responsibility on behalf of the Board for governance oversight in relation to implementation of this policy.

3.0 Scope

The key focus of this policy is on adverse events which do affect, or could have affected people, and could have caused, or did result in harm. Events which did or could have led to harm to the organisation, such as damage to property, system failure, service disruption, financial loss or adverse publicity, are also included.

The policy covers all of NHS Lothian's services and activities including all staff and students.

The principles of this policy also apply to Primary Care independent contractors GP practices, dental practices, community pharmacies and optometrists. Work will be undertaken in partnership with national programmes led by Healthcare Improvement Scotland to explore how implementation can be supported in Primary care and also with our Health and Social Care Partnership colleagues in respect of health and social care integration.

4.0 Definitions

4.1 Adverse event

An adverse event is defined as "an event that could have caused, or did result in harm to people, including death, disability, injury, disease or suffering and/or immediate or delayed emotional reactions or psychological harm". Adverse events experienced as harassment on the grounds of age, disability, ethnicity or race, religion or belief, or sexuality are included. Harm is defined as "an outcome with a negative effect".

Harm to a person includes unexpected worsening of a medical condition and the inherent risk of an investigation or treatment. It is often not possible to determine whether or not the harm could have been avoided until a review is carried out.

Harm to parts, or all of, NHS Lothian as an organisation are also included, for example: system failure, service disruption, financial loss or adverse publicity.

A *near-miss* is an adverse event where a harmful outcome was avoided either by chance or by intervention.

4.2. Severity of harm

The actual level of harm (known as severity) is used in NHS Lothian to group adverse events. This will determine communication and escalation and guide the level of review required. High level definitions of severity are set out below and further detail provided in the adverse event grading table.

Death/ Major harm – unexpected death or major injury with either intervention required to sustain life or long-term incapacity or disability requiring medical treatment and/or counselling.

Moderate –significant injury (short-term effects), requiring medical treatment or counselling, agency reportable (e.g. police)

Minor – minor injury or illness, first aid treatment possibly required

No known adverse effect at this time – no harm resulting on this occasion, but had the potential to cause harm

Damage to or loss of property is similarly graded as major/moderate/minor/no known adverse effect at this time.

4.3 Significant Adverse Events (SAEs)

Adverse events resulting in major harm to people or death, or serious harm to the organisation, are known as Significant Adverse Events (SAEs) in NHS Lothian.

As noted in paragraph 3.1 above, harm to a person includes unexpected worsening of a medical condition and the inherent risk of an investigation or treatment **and** it is often not possible to determine whether or not the harm could have been avoided until a review is carried out.

5.0 Implementation roles and responsibilities

5.1. Implementation

An operational procedure complements the policy and informs implementation by providing further detail of the standard methodology for the management of adverse events and specific processes for certain types of adverse event which must be followed. (See associated materials section 6.0)

The key requirements for implementation can be summarised as follows:

- Adverse events and near-misses are reported and managed in a timely and effective manner in partnership with patients, carers, families and staff
- All people, including staff who are involved in an adverse event are offered support at a time and in a way which meets their needs
- Feedback is given to staff and will inform decision-making
- Learning from adverse events is identified and used to inform service improvements that enhance the safety and quality of healthcare provided
- Learning is shared both within and out with NHS Lothian to provide opportunities for improvement
- NHS Lothian complies with its legal duties in respect of adverse events, including compliance with the statutory organisational Duty of Candour requirements where applicable
- Actions are reviewed by senior management in a manner that allows the NHS Lothian Healthcare Governance Committee and the NHS Lothian Health & Safety Committee to provide the Lothian NHS Board with an assurance statement.

There are a number of key principles which underpin implementation, which reflect NHS Lothian values as described in section 1. These are set out below:

- An emphasis on learning and promoting best practice – the system is focused on learning at all levels - local team, service, Lothian and, where appropriate, nationally, and makes extensive use of improvement methodology to test and implement the necessary changes. Near-misses are reviewed regularly to promote learning and system improvements
- A systems approach – adverse events act as a ‘window’ on the healthcare system, allowing a systems analysis. This is important to allow a reflection on the weaknesses of the system, or in the case of near-misses, the strengths, and prevent future adverse events
- Openness about failures – adverse events are identified, reported and managed in a timely manner, and patients and their families are told what went wrong and why. Reviews of events happen quickly following their occurrence. Adverse event reporting is expected to increase as we move to a more open culture
- A just culture – individuals are treated fairly. Organisational culture is based upon the values of trust, openness, equality and diversity, which encourage and support staff to recognise, report and learn from adverse events

- A positive safety culture – avoidance, prevention and mitigation of risks is part of NHS Lothian's approach and attitude to all its activities, and 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
- 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 Whistle Blowing Policy. 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 providers is to patients, their families and carer
- Teamwork – everyone who works for NHS Lothian is an essential and equal member of the team and needs to be valued, treated well and empowered to work to the best of their ability. Teamwork is recognised as the best defence of system failures and is explicitly encouraged and fostered within a culture of trust, mutual respect and open communication.

It is recognised both throughout NHS Scotland and locally that there are challenges in reliable implementation of best practice, as described in this policy and associated procedure, in managing and learning from adverse events and applying that learning. NHS Lothian will therefore continue to work with staff to improve systems and processes and build capacity and capability through ongoing development.

5.2. Roles and Responsibilities

All staff have a responsibility for reporting adverse events and implementing this policy and associated procedure as appropriate to their role.

The Medical Director has lead executive responsibility for the management of adverse events. The Medical Director provides assurance to the Board through bi-annual reporting to the Healthcare Governance Committee on processes and outcomes for adverse event management and exception reporting on specific events or processes as required.

Managers, in line with operational management structures, have responsibility for the management and review of adverse events and consequences to ensure appropriate management and service improvement. Managers will be supported professionally by medical or nursing colleagues at local or board level as appropriate.

The Associate Director for Quality Improvement & Safety is responsible for development and maintenance of systems and processes to support the management of adverse events, including DATIX (the electronic integrated risk management system used to manage adverse events in NHS Lothian), provision of training, toolkits, guidance and expert support to the service and information for Board-level groups.

The Head of Health and Safety Services is responsible for providing expertise and support in relation to the review of occupational health and safety adverse events.

6.0 Associated Materials

An operational procedure complements the policy and informs implementation by providing further detail of the standard methodology for the management of adverse events and specific processes for certain types of adverse event which should be followed. The associated materials are documents below. The key processes included in the procedure must be followed including completion of standard documentation.

Reporting an Adverse Event

All events must be reported on Datix (NHS Lothian Risk management information system) link to reporting page

Document	Description	Approved By
paper record	Paper copy of adverse event reporting form (for use when Datix is unavailable)	Quality & safety assurance lead
Reporting Requirements Under RIDDOR	Details of the RIDDOR definitions and reporting requirements to Health & Safety Executive	Head of Health & Safety
Specific Types of Adverse Events (AEs)	A list of the most relevant external bodies that have additional actions and/or reporting requirements for specific types of adverse events	Quality & safety assurance lead
Responsibilities – Adverse Event Management.	Specific responsibilities for effective management of adverse events	Quality & safety assurance lead

Managing AEs with major harm or death

Document	Description	Approved By
Managing an Event with Major Harm or Death – Management Team Actions	Process map of the management teams responsibilities for managing events resulting in major harm or death	Medical Director
Level of Review for Major Harm and Death Events – decision making flowchart	Flowchart to guide decision making on the level of review	Medical Director
Communication & Escalation of Significant Adverse Events (SAEs)	Details the appropriate communication and escalation for Significant Adverse Events	Medical Director
Commissioning Checklist	Commissioning Checklist to assist in	Medical Director

for Level 1 SAE Reviews	Commissioning Level 1 SAE Reviews	
NHSL AE Review Template	Adverse Event Review template for recording Level 1 and Local Adverse Event reviews with major harm or death	Medical Director
Briefing Note Template	Briefing note for recording information to enable effective decision making on whether a Level 1 or Local AE review should be commissioned	Medical Director
Structured Mortality Review Tool (SMRT) Template	Structured Mortality Review Tool for reviewing deaths	Medical Director
Falls with Significant Harm / Grade 4 Pressure Ulcers	Process for reviewing and approving Patient Falls and Pressure Ulcers	Medical Director
Mental Health & Substance Misuse Protocol	Process for the review of unexpected deaths for Mental Health Services and Substance Use Services	Associate Medical Director for Mental Health
Maternity & Neonatal Services Protocol	Process for the review of Major Harm and Death events in Maternity and Neonatal Services	National guidance/AMD Women's services
Agreed Alternate Processes	Standard operational procedure for reviewing/approving major harm or death agreed alternative SAE processes. Including bespoke templates list.	Medical Director

Reviewing SAEs

Managing an Adverse Event with Major Harm or Death – Review Team Actions	Process map detailing the actions for the review team to follow when carrying out significant adverse event review	Medical Director
NHS Lothian Adverse Event Review Protocol	Sets out the standard process for reviewing adverse events in NHS Lothian	Medical Director

Communication and Support for People involved in Adverse Events

Document	Description	Approved By
Process & Checklist for Communicating with Patient & Families	Details the process for communicating with patient and families following a Significant Adverse Event Review and provides a checklist	Medical Director
Staff Support - Managers Action Flowchart	Details actions to be taken by managers to support staff following a significant adverse event	Quality & safety assurance lead
Information on Significant	Information leaflet for staff involved in	Quality & safety

Adverse Event Review Process for Staff	significant adverse events and the review process	assurance lead
Staff Support Checklist	Checklist of actions to be taken by managers in supporting staff following a significant adverse event	Quality & safety assurance lead
Staff Support following a Significant Adverse Event	Leaflet to provide information about support services available for staff who had been involved in a significant adverse event	Quality & safety assurance lead

7.0 Evidence base

This policy reflects the principles and requirements set out in Healthcare Improvement Scotland 'Learning from adverse events through reporting and review – a national framework for Scotland December 2019 (4th edition), which has been developed drawing on international evidence and best practice relating to the management of adverse events.

8.0 Stakeholder consultation

There has been wide consultation with service colleagues who are regularly involved in investigating and reviewing adverse events. Additional specialists such as Health and Safety colleagues were consulted on content, to ensure read across with other policy material. Policy displayed on the NHS Lothian Consultation Zone for 4-week period for all NHS Lothian staff to comment on.

9.0 Monitoring and review

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