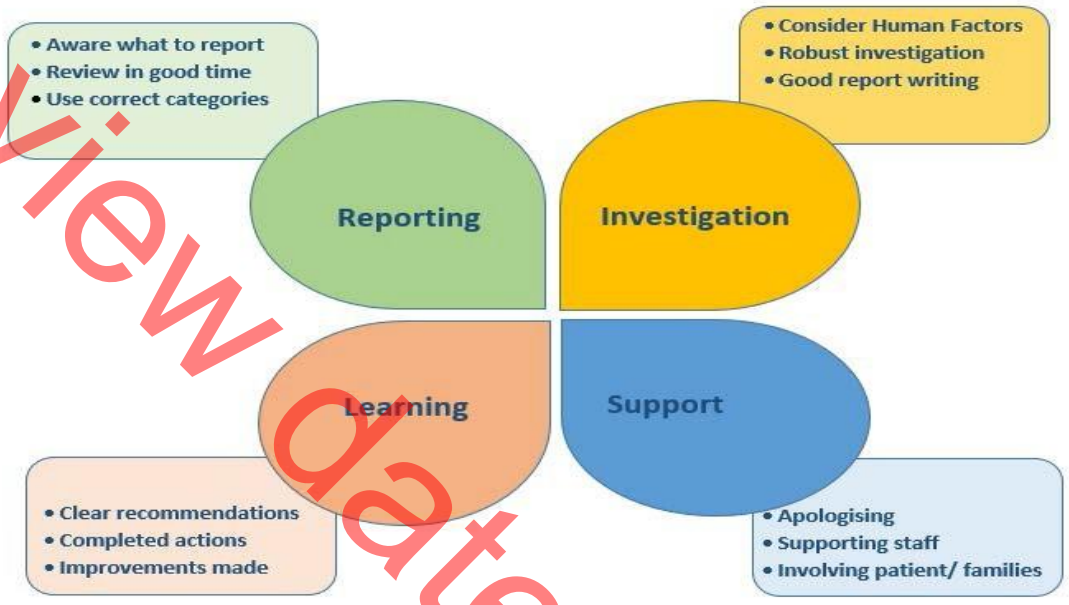
ADVERSE EVENTS MANAGEMENT POLICY



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CONSULTATION AND DISTRIBUTION RECORD	
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CHANGE RECORD			
Date	**Author**	**Change**	**Version No.**
May 2014	C. McGhee	Previous Risk Management Guidance: Incident Management August 2013, superseded by this Policy aligned to the Healthcare Improvement Scotland (HIS) National Framework for Management of Adverse Events.	Version 1.1
January 2015	C. McGhee	Subsequent to the Vale of Leven Report and Recommendations (2014), specifically, recommendation 72, an addition has been made to Section 4.11.1.	Version 1.1
May 2015	C. McGhee	Amendment: Removed any reference to working days, changed working days to days.	Version 1.1
November 2015	C. McGhee	Section 4.7 – Notification to Chief Executive – updated and endorsed through CMT.	Version 1.1
January 2016	C. McGhee	Full Review of Policy through SLWG from December 2015 to March 2016.	Version 2
May 2016	C. McGhee	Separate Policy Statement from Procedures.	Version 3.1
July 2018	L.A. Smith	Separate Policy Statement from Procedures and review content in line with HIS National Framework for Management of Adverse Events (July 2018).	Version 3.2
January 2019	K. Cormack	Reviewed and Updated	Version 3.2
February 2022	K. Cormack	Reviewed and Updated	Version 3.3

FOREWORD

Healthcare is a complex, high-risk environment where despite everyone trying to provide excellent care and treatment, we recognise that sometimes things go wrong. Maintaining staff and patient safety is a Board responsibility that is taken seriously.

Adverse events can have a significant impact on patients and/or their families/carers so we want to ensure we are open, honest and offer support to help understanding of what happened and why it happened.

Staff also need support as they may be harmed due to an event or involved in a patient adverse event. They need support to recover from what happened and to implement learning.

This policy provides guidance to enable the staff of NHS Lanarkshire to identify and effectively manage adverse events, with a clear emphasis on transparency, prompt remedial action, and learning for quality improvement so that recurrence of adverse events is minimised. The policy also emphasises our obligation to support patients and/or their families/carers and staff when adverse events occur. NHS Lanarkshire is committed to learning from adverse events, minimising the chance of recurrence and improving our services.

1. INTRODUCTION

1.1 NHS Scotland aims to provide high quality care that is safe, effective and person- centred. However, it is recognised that the NHS is a complex system and adverse events can and do occur with the potential to have a significant effect on the people involved. Whilst recognising this, it is also an opportunity to learn and to improve in order to increase the safety of our healthcare systems for everyone.

1.2 In September 2013, Healthcare Improvement Scotland (HIS) issued the first version of its framework “Learning from adverse events through reporting and review: A national framework for Scotland” following an extensive consultation and engagement across Scotland. It aimed to support NHS boards to standardise processes for managing and learning from adverse events; whilst acknowledging that the framework did not have all the answers, they committed to review and update the framework as the programme developed.

1.3 A revised second edition was published in April 2015 following the development of a number of tools to support implementation of the framework.

1.4 The third edition of the framework was produced following the implementation of the statutory organisational duty of candour legislation in Scotland on 1 April 2018. The requirements of this legislation were incorporated into the revised third edition of the framework.

1.5 To reflect the direction provided by the Cabinet Secretary for Health and Sport on 10 September 2019, a fourth edition was published.

1.6 In developing this policy and associated procedures, NHS Lanarkshire has taken cognisance of literature on best practice on the management adverse events and the HIS national framework. The policy will be reviewed against any future editions of the framework and amended accordingly.

1.7 NHS Lanarkshire is committed to continually and systematically reviewing and improving its healthcare processes and working practices to prevent or reduce the risk of harm. It is also committed to complying with its statutory responsibilities. This ensures, as far as is reasonably practicable, the health, safety and welfare of all its employees and other persons on its premises or using the service.

1.8 Adverse event reporting is one of the key methods for alerting an organisation to issues that, if left unattended, may pose a serious risk to either the patients in its care, the staff it employs or to others for which it has a responsibility e.g., visitors, contractors, volunteers etc. Without an effective system, the organisation may be blind to some of this risk exposure and cannot make the necessary improvements to support safety.

1.9 Due to the complex nature of healthcare, the causes of adverse events or near misses go far beyond the actions of individuals immediately involved. There are a number of systems and contributory factors which influence the likelihood of adverse events occurring. It is with this in mind that NHS Lanarkshire is committed to advocating an 'Open and Fair' culture. A culture where errors or service failures can be reported and discussed, lessons learned, and necessary changes put in place is essential.

1.10 There will be rare instances where individuals must be held accountable for their actions, for example if there is evidence of gross negligence, recklessness or criminal behaviour. This will be managed through the Board's agreed Human Resources (HR) policies and procedures.

1.11 The reporting and management of adverse events and near misses is an essential part of the systems and processes that support clinical governance and risk management, health and safety management and staff governance within NHS Lanarkshire.

1.12 NHS Lanarkshire has in place an adverse event reporting and recording system that will support good practice and compliance with legal duties from a range of bodies including Healthcare Improvement Scotland (HIS), and the Health & Safety Executive (HSE). NHS Lanarkshire uses the **R L Datix** electronic incident reporting system for recording and grading clinical and non-clinical incidents.

2. AIMS

2.1 This policy aims to ensure that all adverse events are reported, acted upon and analysed as appropriate and that the knowledge thus gained is regularly disseminated to improve quality, patient safety, staff safety and performance of the organisation. This will encourage and strengthen a learning culture in which the quality of care for patients and working lives for staff will continuously be improved.

- All individuals are aware of what constitutes an adverse event or 'near miss';
- There is a clear and reliable system for the management, recording and reporting of all adverse events and near misses and staff know how to use it;
- All reported adverse events are graded according to the actual impact;
- Adverse events are subject to analysis including causal analysis according to the significance of the event, and where appropriate, improvement plans are developed and monitored;
- Reports of adverse events are prepared and disseminated and analysed across the organisation and discussed at ward/department level; at operational, site or unit quality/governance/patient safety group; and on an NHS Lanarkshire level at the Healthcare Quality Assurance & Improvement Committee (HQAIC) and the Occupational Health and Safety Performance Group (OHSPG);
- Lessons are learned from individual adverse events, from reviews, thematic analysis and from wider experiences, including feedback from agencies/bodies and through benchmarking. Improvement plans aimed at reducing risk to future patients, directly employed staff and others including visitors, contractors and volunteers are implemented and monitored by NHS Lanarkshire;
- Employees are motivated to report adverse events by ensuring that they are aware that their concerns are being acted upon and are provided with timely feedback on changes that have taken place as a result of their reporting;
- NHS Lanarkshire recognises that whilst it is important to promote a culture of learning and 'closing the loop' with regards to adverse event management, the effect on staff directly involved in an adverse event or review should not be underestimated. Arrangements are in place to support staff involved in adverse events.

2.2 When patient care does not go to plan it is important to be open and honest with patients and their relatives about what has happened and what action will result from this. This is a general principle as with any aspect of patient care.

However, a legislative or organisational Duty of Candour procedure requires to be followed for adverse events that have resulted in death or serious harm that are the responsibility of the organisation (i.e., should have been avoided). Compliance with the regulations will ensure that NHS Lanarkshire is open, honest and apologises for any harm that occurred and supportive towards persons affected by the adverse events.

2.3 NHS Lanarkshire has a statutory duty, under the Health & Safety at Work Act, 1974, to protect employees and non-employees (e.g., patients, service users, contractors, visitors etc.) from risks to their health and / or safety that arise out of, or in connection with the activities of our work.

2.4 We also have a duty to report certain outcomes that are caused by adverse events such as deaths, any over 7-day staff absences, specific injuries, dangerous occurrences and occupational diseases under the Reporting of Injuries, Diseases and Dangerous Occurrences Regulations (RIDDOR) 2013, to the Health and Safety Executive (HSE), if they happen 'out of, or in connection with work'. The fact that there is an accident within the work premise does not in itself mean that the accident is 'work-related' – the work activity itself must contribute to the accident.

An accident is 'work-related' if any of the following played a significant role:

- The way the work was carried out;
- Any machinery, plant, substance or equipment used for work; or
- The condition of the site or premises where the accident happened.

The Health and Safety team will be involved in the investigation of these type of events and should be contacted at the earliest opportunity.

2.5 There is also a requirement to report specific events to external organisations. This includes:

- 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.**

- Sudden 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,**

- Serious crimes (homicides, serious assault, and serious sexual assault) by an individual who is receiving care from mental health or learning disability services to the **Mental Welfare Commission for Scotland.**

- Maternal deaths, late fetal losses, stillbirths and neonatal deaths are reported to **Mothers and Babies: Reducing Risk through Audit and Confidential Enquiries across the UK (MBRRACE UK).**

2.6 This Adverse Event Management Policy is supported by Adverse Events Management Procedures which will provide description of the processes to be followed.

3. SCOPE

3.1 This policy applies to all staff employed by NHS Lanarkshire.

3.2 The policy encompasses any adverse event affecting patients, clients, staff, students, volunteers, contractors or visitors (including carers, relatives and advocates).

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.

4. DEFINITIONS[1]

4.1 Adverse Event

4.1.1 An **adverse event** is defined as any unintended or unexpected event that could have**,** or did result in, harm to people or groups of people. Serious Incidents are also likely to produce significant legal, media or other interest which, in addition to harm, loss or damage, may result in loss of the Board's reputation or assets.

4.1.2 **Harm** is defined as injury (physical or psychological), disease, suffering, disability, ill health or death to a person. Harm to a person or groups of people may result from worsening of a medical condition, the inherent risk of an investigation of treatment, violence and aggression, system failure, provider performance issues, service disruption, financial loss or adverse publicity.

4.1.3 All harm is not avoidable, for example the worsening of a medical condition or the inherent risk of treatment. This policy applies to harm directly caused by an adverse event however, it may be the case that a review is required to identify if the harm could have been avoided.

4.1.4 **People** are defined as:

- Service users
- Patients
- Members of staff
- Carers
- Family members
- Visitors, and
- Contractors
- Students

4.1.5 **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.

4.1.6 The term **near-miss** can cover two different scenarios. One is where an error or omission occurred which could have caused harm to a patient, member of staff or others, but fortunately on this occasion there was no adverse outcome. For example: - the wrong medication was given but it did not harm the patient.
The other description when near-miss applies is where the error was about to take place and a *'last minute'* intervention either by chance or design, prevented the incident from occurring. For example: - there was a medication prescription error, but it was identified before administration.
Reports of near- miss events are helpful as they identify the same weaknesses in the system that would cause an adverse outcome, without harm being caused; therefore, are as rich a source of learning as adverse events resulting in harm.

[1] *As defined by Health Improvement Scotland, September 2013, revised April 2015, July 2018 and December 2019*

4.2 Adverse Event Categorisation

4.2.1 Grading of the adverse event is mandatory in NHS Lanarkshire. The grading outcome will be based on the severity of the impact and will be expressed as either: Category 1, Category 2 or Category 3 adverse event.

Category 1		Category 2		Category 3
Extreme	Major	Moderate	Minor	Low

SIGNIFICANT HARM	SERIOUS HARM	MINIMAL OR NO HARM

Category 1 – Events that may have contributed to or resulted in death, permanent harm or intervention required to sustain life, severe financial loss (£>1m), ongoing national adverse publicity (likely to have been graded as major or extreme impact on NHS Scotland risk assessment matrix (Appendix 1), or Category G, H or I on National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP) index (Appendix 2)).

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 (likely to have been graded as minor or moderate impact on NHS Scotland risk assessment matrix, or Category E or F on National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP) index).

Category 3 – Events that had the potential to cause harm but i) an error did not result, ii) an error did not reach the person iii) an error reached the person but did not result in harm (likely to have been graded as negligible impact on NHS Scotland risk assessment matrix, or Category A, B, C or D on National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP) index).

4.2.2 All adverse events that are reported require to be reviewed. For some events this will be straightforward requiring little intervention and can be managed locally by the ward or department. However, there will be other events that require a more formal, extensive review due to the complexity or the potential for learning. These reviews are called Significant Adverse Event Reviews (SAER) and require investigation and system analysis techniques to comprehensively examine the chronology, system and care delivery problems and contributory human factors.

Significant Adverse Events are those events that have or, could have significant or catastrophic impact on the patient and may adversely affect the organisation and its staff and have potential for wider learning (i.e., learning that can be gained for future care delivery).

The category of patient outcome can help decide the level of review required and all category 1 events should be considered for SAER review and require a briefing note to senior management. However, it must be stressed that a severe or tragic patient outcome is not the only indicator of a SAER. Near miss events with no or transient adverse outcome and complex lower severity incidents can also warrant investigation within this process due to the potential for learning that has been exposed.

Considering the potential for learning from the event aims to ensure that responses are not overly focused on the impact or outcome. This aims to gain an insight on underlying weaknesses of the system or areas where the system could be improved. It can also be the case that although a severe harm has been reported it is recognised as a known complication that was unable to be avoided.

The following decision-making prompts may help to determine the potential for learning:

- Is the outcome a known complication of the disease, treatment or process?
- Has there been any known breach or deviation in policy or procedure?
- Are there unknowns surrounding the event?
- Does the event activate duty of candour procedures?
- Is there learning to be gained/would you do anything differently next time?
- Is the patient, service user, family or management concerned about the event?
- Is there interest from the fiscal?
- Has there been a serious equipment, system or process failure?

All reviews of events being considered as an SAER must be documented by completing the defined Briefing Note for Potential SAER template. This is reviewed by a senior manager to decide if further review is required. Following the decision, the Briefing Note is attached to the reported incident in Datix as a record of the decision making.

The following are adverse events that should be **considered** as a SAER.

This is not an exhaustive list but merely a guide as to the type of events that should be screened.

- Death /serious injury (head injury, major fracture) from an avoidable fall
- Any deaths associated with severe Clostridium Difficile Infection (CDI)
- Any deaths associated with Staph. Aureus Bacteraemias (SAB)
- Avoidable Grade 3 and 4 Pressure Ulcers developed under NHS Care
- Avoidable return to theatre
- Patient Suicide where there has been contact with MHS
- Re-use of a non-sterile device/instrument

- Homicide (where perpetrator is a patient)
- Medication incident with a serious or potentially serious patient outcome
- Delay in treatment or diagnosis that has significantly influenced health or life expectancy
- Maternal death
- Any fetal loss meeting the MBBRACE criteria
    - Late fetal losses – the baby is delivered between 22+0 and 23+6weeks of pregnancy showing no signs of life, irrespective of when the death occurred
    - Terminations of pregnancy - resulting in a pregnancy outcome from 22+0 weeks gestation onwards
    - Stillbirths – the baby is delivered from 24+0 weeks gestation showing no signs of life
    - Early neonatal deaths – death of a live born baby (born at 20 weeks gestation of pregnancy or later or 400g where an accurate estimate of gestation is not available) occurring before 7 completed days after birth
    - Late neonatal deaths – death of a live born baby (born at 20 weeks gestation of pregnancy or later or 400g where an accurate estimate of gestation is not available) occurring between 7 and 28 completed days after birth
- Adult / Child protection incident with potential learning for health
- Never events *(for more information see Never Events section further in the policy)*

As Duty of Candour events would be a n outcome grading of category 1 and upper category 2 (moderate) that have been caused / not prevented by the organisation, they should have a Significant Adverse Event Review and by following the process for this type of review, the requirements for the Duty of Candour legislation will be met.

All significant adverse events must be recorded on the Datix incident recording system and the extra fields Risk Facilitators section completed to record vital information and to demonstrate the process has been followed correctly.
(See section 7 and Adverse Event Management Procedure 4).

If the adverse event involves more than one service, Directorate or Board a joint review is required involving both parties with one party taking the lead to avoid two separate reviews for the same event.

4.2.3 A **Never–Event** is an incident that should be avoidable if available preventative measures have been implemented and when occur are associated with tragic consequences. Investigation and closer scrutiny of never events seeks to assure the safety and reliability of the existing systems and processes in place. This does not mean NHS Lanarkshire tolerates the occurrence of other types of harm. It is imperative all adverse incidents are thoroughly investigated.

However, the occurrence of an entirely avoidable harm may be an indicator of failings or weaknesses in the organisation's core safety processes. As such, this list of harms warrants particular scrutiny in terms of the potential for organisational learning.

Adverse events are a key source of intelligence to alert organisations to safety issues within their healthcare settings. Reporting of such events is widely recognised as an essential component of a just and safe learning culture.

Defining Never Events

Never Events may highlight potential weaknesses in how an organisation manages fundamental safety processes and so defining them within an Adverse Event Policy and framework provide an essential lever for improving patient safety.

The following statement apply to never events:

- patient safety incidents that are wholly preventable
- guidance or safety recommendations that provide strong systemic protective barriers* are available at a national level
- guidance or safety recommendations are expected to have been implemented
- each event has the potential to cause serious patient harm or death (however, if by chance the outcome is not so serious, the event is still a never event)
- there is evidence at a national level that the never event has occurred in the past
- the risk of recurrence for these events remains

** Strong systemic protective barriers are defined as barriers that must be successful, reliable and comprehensive safeguards or remedies – for example, a uniquely designed connector that stops a medicine being given by the wrong route.*

Each Never Event type must be able to be clearly defined and its occurrence easily recognised – this requirement helps minimise disputes around classification and ensures focus on learning and improving patient safety.

NHS LANARKSHIRE NEVER EVENTS LIST

1. Administration of medication by the wrong route
2. Chest or neck entrapment in bed rails
3. Failure to install functional collapsible shower or curtain rails
4. Falls from poorly restricted windows
5. Misplaced naso- or oro-gastric tubes
6. Mis-selection of high strength midazolam during conscious sedation
7. Mis-selection of a strong potassium solution
8. Overdose of insulin due to abbreviations or incorrect device

9. Overdose of methotrexate for non-cancer treatment
10. Retained foreign object post procedure
11. Scalding of patients
12. Transfusion or transplantation of abo-incompatible blood components or organs
13. Unintentional connection of a patient requiring oxygen to an air flowmeter
14. Wrong implant/prosthesis
15. Wrong site surgery

Reporting and recording Never Events

When a Never Event occurs, regardless of the outcome, it must be reported on the Datix system, and a briefing note completed. Supporting staff to recognise Never Events is essential so that the opportunity to investigate, learn and improve can be identified in a timely way before vital information is lost.

In some circumstances it may not be apparent that an incident is a Never Event until there has been some degree of investigation. In these circumstances, the possibility that a Never Event has occurred should be reported as soon as it is identified.

Failure to report a Never Event requires management review to establish the reason why this occurred.

Reviewing Never Events

Central to the concept of never events being wholly avoidable is the existence of strong systemic measures which, when fully implemented, should render the occurrence of the event impossible. Therefore, when the event occurs there is guidance and suggestions to examine of what should have been in place to prevent the occurrence.
It is important that the problems in care are identified and analysed through full investigation using a systems-based investigation method therefore all Never Events require a Significant Adverse Event Review to ensure that all possible learning is gained. This should include the context of the circumstances that led to the event and the failure of any safety systems that should have prevented the event. This will mean effective and targeted action can be taken to prevent recurrence.

Learning from Never Events

Monitoring of Never Events is important to provide organisational assurance that the safety systems in place are working effectively.
This would include:

- data on the type and number of Never Events, including historical context

- the learning stemming from the incidents, with a particular focus on the system changes made to reduce the probability of recurrence

- how learning has been shared at all levels in the organisation and if appropriate externally

5. ROLES AND RESPONSIBILITIES

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

Specifically, staff have a responsibility to:

- Take care of their own safety and that of others including patients, clients, colleagues, volunteers, contractors or visitors;
- Eliminate unlawful discrimination and unlawful harassment, promote equality of opportunity and promote good relations between different population groups;
- Report any adverse event or near miss to their manager or other responsible person;
- Record through the Datix system and submit this to the appropriate manager as soon as is practical to do so after the adverse event has been dealt with, and ideally within 24 hours after the adverse event has occurred;
- Participate and contribute to investigations / reviews as appropriate;
- Take remedial action where appropriate.

5.2 All managers within NHS Lanarkshire have the responsibility for the management of adverse events and the consequences to ensure appropriate management and service improvement. Managers will be supported professionally by medical and nursing colleagues at local and board level as appropriate and administratively by designated Risk Facilitators. Specifically, managers have a responsibility to:

- Ensure that, as a first priority, any person affected by an adverse event receives appropriate first aid or medical treatment; ensure that action is taken to prevent further danger to others. Equipment involved in the adverse event must be made safe, removed from use and retained for inspection. In exceptional circumstances, the surrounding area of the event should be isolated, pending any necessary analysis;

- Ensure that reporting procedures are complied with if any adverse event affects any patients, clients, members of staff, students, volunteers, contractors, visitors or premises for which they are responsible, including the completion of an initial action/improvement plan; including ensuring staff report the adverse event;

- Arrange a debrief for staff involved in the adverse event where appropriate;
- Ensure that staff involved in an adverse event are given appropriate support and an opportunity to access the occupational health service or other relevant services if required;
- Identify and escalate RIDDOR reportable adverse events to the Health and Safety Team as soon as possible after the adverse event to ensure timely reporting to the HSE; undertake reviews of adverse events and near misses, in liaison with other managers where necessary; grading and reporting details of investigation regarding the adverse event within the electronic Datix record;
- Ensure any significant adverse events are reported to the relevant Director and/or their Clinical Director;
- Consider if Duty of Candour applies and ensure open communication with the patient or their relative;
- Provide the opportunity for staff to discuss, de-brief and feedback on specific adverse events and near misses;
- Involve and consult accredited Health & Safety staff side representatives, making information and knowledge of adverse events available;
- Monitor trends within their area of responsibility; use pre-set reports to monitor trends in own area and share this information with staff;
- Contribute to dissemination of lessons learned and implement any actions identified as their responsibility, or the responsibility of their team.

5.3 Operational Unit (Acute Services, North and South Health & Social Care Partnerships (HSCPs) Medical and Nurse Directors, Clinical Directors/Lead Nurses/Professional Leads have a responsibility to undertake the following through the Operational Unit/Site/Locality Support, Care and Clinical Governance/Quality & Safety Groups:

- Ensure systems are in place and/or implemented to review all reported adverse events and near misses within areas on a regular basis and agree any necessary actions or improvements required;
- Monitor that appropriate action and learning has taken place following the identification and reporting of adverse events and near misses;
- Ensure systems are in place and/or implemented to provide feedback on local reviews of adverse events and near misses to the appropriate Quality and Patient Safety Groups / Support, Care and Clinical Governance Committee as necessary;

- Initiate a review of significant adverse events or near misses in liaison with specialist advisors and staff side Health & Safety representatives where necessary;

- Ensure systems are in place and/or implemented to robustly assess all near misses and adverse events for potential learning, and where appropriate implement action/improvement plans that includes dissemination of the learning;

- Where relevant, ensure that adverse events are finally approved within the Datix system and that all investigations where actions are outstanding are followed up within the agreed timescales;

- Ensure consideration is given to findings and recommendations from significant adverse events occurring elsewhere in NHS Lanarkshire which have wider relevance.

5.4 Specialist Advisors/Managers (e.g., Health and Safety Advisors, Moving and Handling Advisors, Management of Violence and Aggression Advisors, Infection Control and Prevention Managers, Tissue Viability Managers, Resuscitation Officers, Fire Officers, etc.) have a responsibility to:

- Provide expert advice to review teams if any adverse event arose out of, or in connections with work activities and/or is RIDDOR reportable to the HSE. This may include clinically orientated tasks and function e.g., bed rail management, choking patients, wandering patients;

- Provide advice, guidance and support to managers and other employees when requested;

- Assist in adverse event analysis as required and to provide expert advice as necessary to ensure incident reports are prepared within the agreed timescale;

- Make recommendations to reduce residual risk based on adverse event analysis;

- Ensure systems are in place to review findings and recommendations from significant adverse events occurring elsewhere in NHS Lanarkshire which have wider relevance

5.5 The Adverse Event Team within the Quality Directorate are responsible for the development and maintenance of systems and processes to support the management of adverse events, including DATIX. The team also:

- Provide training, guidance and expert support to the service on using Datix, adverse events management, SAER investigation and Duty of Candour

- Provide reports for services and information for Board-level groups
- Provide a monitoring function to ensure timescales are met for review to ensure quality of process
- Provide thematic analysis reviews
- Produce a Learning Bulletin to share lessons learned and adverse events related updates across the organisation.

5.6 The Healthcare Quality Assurance and Improvement Committee have responsibility to:

- Ensure that the organisation develops a fair, open and risk aware culture;
- Ensure that the organisation develops a culture of reporting and learning from adverse events and near misses;
- Receive regular reports on trends and outcomes of adverse events and assurance regarding Duty of Candour procedures;

6. MANAGING AN ADVERSE EVENT

6.1 It is recognised that adverse event management is one part of effective risk management. There are six stages of adverse event management, and it is important that these are implemented consistently to ensure a robust response:

1. Risk assessment and prevention
2. Identification and immediate actions following an adverse event, including consideration of duty of candour
3. Initial reporting and notification
4. Assessment and categorisation
5. Review and analysis
6. Improvement planning and monitoring

6.2 When considering what type of review should be commissioned, whether it should be a Significant Adverse Event Review (SAER) or as a Briefing Note Review (BNR), it's helpful to remember that the main reason for a briefing note is to escalate something serious that has happened *(which can often have a serious outcome for the patient)* and support the decision to be made if a SAER is required.

In order to write a briefing note, an initial review must have been undertaken to provide the commissioner with enough information to decide if a SAER is required or not. This is why if a SAER is not commissioned, it is not that no review has been undertaken as a BNR has been done. This provides organisational assurance that someone senior has looked at all the significant adverse events and decided if further investigation is required or not.

A SAER would be required if:

- The event is or could be duty of candour i.e., serious harm and likely to be the organisation's responsibility.
- The event met the criteria for a Never Event.
- There are multiple unanswered questions relating to what occurred and why it happened.
- There is complexity to the case that will require time to sort through the information to establish the facts.
- Staff will require to be interviewed to establish required information.
- The patient or their family are expecting an investigation report regarding the event.
- A significant clinical adverse event is converted from a complaint.
- A review group was required.
- The causation is likely to be 3 or 4 with serious harm indicated.
- The procurator fiscal is interested in the case.

A BNR is acceptable if:

- No further information is required to make an assessment that a SAER is not required.
- Minimum extra information is required to make an assessment that a SAER is not required.
- Although there may be harm, the information on the briefing note provides assurance that the event was not preventable / avoidable.
- Information on the briefing note indicates another type of review is taking place such as a Child Protection review.
- Information provided on the briefing note indicates no benefit by commissioning a SAER as the majority of the information has been gathered and either there is very low harm or there is a low causation code (1 or 2) with minimal recommendations.

6.3 To support the management of adverse events, detailed procedures have been developed which cover:

Procedure 1	Initial Management of an Adverse Event
Procedure 2	Reporting and Recording and Adverse Event
Procedure 3	The Types of Adverse Events to be Reported
Procedure 4	Adverse Event Grading and Severity
Procedure 5	Notification to the Chief Executive
Procedure 6	Consideration for the Level of Review and Timescales
Procedure 7	Commissioning a Significant Adverse Event Review (SAER)

Procedure 8	Significant Adverse Event Review (SAER) / Briefing Note Review (BNR)
Procedure 9	Never Events
Procedure 10	The Significant Adverse Event Review Process
Procedure 11	Involving Patients and/or their Families/Carers
Procedure 12	SAER Report Writing
Procedure 13	Joint Working and Multi-Agency Working
Procedure 14	Formal Sharing of Final SAER Reports
Procedure 15	Sharing Learning
Procedure 16	Dealing with the Media

6.4 A number of NHS Lanarkshire local joint policies and procedures will also have an impact on how an adverse event is handled, including Sudden Unexplained Death in Children. There are also arrangements in place for Adult Support and Protection and NHS Lanarkshire Child Protection Procedures, which recognise the particular nature and importance of a multi-agency approach to such occurrences.

6.5 When dealing with a child protection incident the learning review for this should be multi-agency, to bring practitioners together with the review team in a structured process in order to reflect, increase understanding and identify key learning. Further information and guidance is available on the following link – https://www.gov.scot/publications/national-guidance-child-protection-committees-undertaking-learning-reviews/documents/

6.6 For an adult support and protection incident that results in a review being carried out, this should be seen in the context of a culture of continuous improvement and will focus on learning and reflection around day to day practices and the systems within which practice operates; with consideration always being given to the involvement of staff in reviews and subsequent feedback to them at the conclusion of the review. Further information and guidance is available on the following link - https://www.gov.scot/publications/interim-national-framework-adult-protection-committees-conducting-significant-case-review/documents/

7. ADVERSE EVENT ANALYSIS, ACTION PLANNING AND REVIEW

7.1 All adverse events and near misses require to be reviewed and assessed in relation to the harm caused to the individual affected by the event. This is described as a range from category 1 to category 3 with further information in Adverse Event Management Procedure 4.

7.2 Where it is appropriate, analysis of contributory (human) factors should be undertaken in order to understand what influenced the adverse event to occur and what systems may need to be changed to assess if the adverse event could have been prevented. Any underlying problems with NHS Lanarkshire's systems and processes that are identified must be resolved and learning shared across the organisation.

7.3 Any recommendations formed from an adverse event review must form an

action plan which must detail a timetable for actions, responsible individual and/or teams and a schedule for review.

7.4 Debriefing and encouraging informal and formal discussion about the adverse event will assist individuals, services and the organisation to learn from adverse events. This must be usual practice after the occurrence of serious adverse events and near misses with potentially serious consequences.

7.5 **Confidentiality**

Whilst any member of staff can record an adverse event on Datix, only authorised staff members can access the details of the Datix record to maintain confidentiality.

In line with Information Governance policy, information contained within adverse event forms will only be disclosed when necessary to aid review of the adverse event. When reporting to groups or committees all personal information will be anonymised. The Information Governance manager can provide further guidance if required. Significant Adverse Event Reviews will not contain the names of staff or patients (unless requested by patient family to use deceased patient name).

7.6 **Legal Consideration**

Recording of an adverse event does not constitute any admission of liability on any person. Adverse event records may require to be made available in the event of legal proceedings and will require to be completed ***accurately*** and ***factually***.

7.7 For further guidance please refer to the Adverse Event Resource Pack, available from the Adverse Event Team and on FirstPort **Adverse Events**

8. SUPPORTING PEOPLE AFFECTED BY ADVERSE EVENTS

8.1 Patients/Families

8.1.1 Effective communication with patients and/or their families/carers is a vital part of the process of dealing with errors or problems in their care and treatment. In doing so NHS Lanarkshire aims to reduce the trauma suffered by patients and their families.

8.1.2 NHS Lanarkshire expects that patients should be provided with the following information about adverse events which affect them:

- Acknowledgement that the event has happened and of the distress that the adverse event has caused;
- A sincere and compassionate statement of regret for the distress that they are experiencing;
- A factual explanation of what happened (as much as is known at the time);
- A clear statement of what is going to happen from then onwards;
- A plan about what can be done medically to repair or redress the harm.

8.1.3 If a Significant Adverse Event Review (SAER) is to be carried out, then patients and/or their families/carers should be involved as follows:

- Being informed that a detailed review is taking place and the expected timescale;
- Being invited to discuss if and how the patient and/or their families/carers would want to be involved and if they have any information or questions they wish to be addressed as part of the review;
- Given a name and contact details concerning the review
- Being made aware of the process and the purpose and logic which underpins it, including provision of the information leaflet;
- Being kept up to date with the progress of the review;
- Being informed of the outcome and the actions which NHSL will take following the outcome in a written format such as the SAER report or a letter;
- Being offered the opportunity of a meeting to discuss the investigation results.

8.1.4 Duty of Candour adverse events should be investigated as SAER or RIDDOR events. If the procedure above in 8.1.2 & 8.1.3 is followed, then the Duty of Candour (DoC) legislation will be complied with on all occasions. DoC guidance is available on First Port **Duty of Candour** and **LearnPro.**

8.2 Counselling and Support for Staff

8.2.1 Managers are responsible for ensuring that staff are given the opportunity to be de- briefed following an adverse event with serious or potentially serious consequences.

8.2.2 Managers will ensure that staff are informed of how to access Occupational Health Services, Chaplaincy Service and Psychology Services if appropriate and other counselling / therapy services.

8.2.3 Managers should ensure that staff are encouraged to seek support from accredited staff side representatives where appropriate.

8.2.4 The Significant Adverse Event Information Leaflet for Staff is available and includes information on support services available from the Staff Care & Wellbeing Team, this is in addition to support being available from relevant professional bodies and partnership representation. Link to access the **SAER Leaflet for Staff**

8.2.5 The Staff Care & Wellbeing Team also have a published leaflet with more detailed information on various support services which staff can access via First Port link **Staff Care Leaflet**

9. TRAINING AND EDUCATION

9.1 All staff are required to undertake training on the content, implementation and management of this policy, procedures and local protocols. This will be covered at induction and through local orientation. LearnPro modules are also available for Datix Incident Forms 1 (DIF1) and 2 (DIF2) and Duty of Candour. Further training will be provided with any amendments to policy or documentation as necessary and at appropriate times.

9.2 The Adverse Event Team, in collaboration with the Risk Facilitators, provide support and coordinate training in all aspects of adverse event management and review.

9.3 For significant adverse events, the review team must include at least one person who has appropriate skills and experience in adverse event review.

9.4 Health and Safety staff also provide support for adverse event reviews to meet both Health and Safety legislative and policy requirements as and when required.

10. RESOURCE IMPLICATIONS

10.1 It will be necessary for the Operational Units to have designated risk management and administrative support quantified and resourced within their existing budgets to undertake the range of procedures necessary to effectively manage adverse events.

10.2 Training requirements need to be identified to the Quality Directorate to enable NHS Lanarkshire to have a cohort of skilled adverse event reviewers to undertake, and lead on adverse event analysis and review.

11. COMMUNICATION PLAN

The Policy will be posted on the NHS Lanarkshire's website and on its intranet for access by all staff. The full cascade with be through the Divisional Management Teams and staff briefings. Communication will be supported through the Staff Briefings.

12. QUALITY IMPROVEMENT – MONITORING AND REVIEW

Implementation of the policy will be monitored through its application in response to adverse event management, specifically, the Key Performance Indicators for closure of adverse events and the SAER process and documentation management.

13. EQUALITY AND DIVERSITY IMPACT ASSESSMENT

This policy meets NHS Lanarkshire's EDIA (tick box) ✓

14. REFERENCES

Healthcare Improvement Scotland Learning from adverse events through reporting and review: A national framework for Scotland (December 2019, 4th Edition).

Adverse Event Management: NHS boards self-evaluation report (September 2019)

National Patient Safety Practice (NPSA) Safer Practice Notice 10: Being Open When Patients Are Harmed (2005).

NHS Improvement Never Events policy and framework (Revised January 2018)

Appendix 1- NHSScotland risk assessment matrices[2]

Table 1 - Impact/consequence definitions

Descriptor	Negligible	Minor	Moderate	Major	Extreme
Patient Experience	Reduced quality of patient experience / clinical outcome not directly related to delivery of clinical care.	Unsatisfactory patient experience / clinical outcome directly related to care provision – readily resolvable.	Unsatisfactory patient experience / clinical outcome, short term effects – expect recovery <1wk.	Unsatisfactory patient experience / clinical outcome: long term effects – expect recovery - >1wk.	Unsatisfactory patient experience / clinical outcome: continued ongoing long-term effects.
Objectives/ Project	Barely noticeable reduction in scope, quality or schedule.	Minor reduction in scope, quality or schedule.	Reduction in scope or quality of project; project objectives or schedule.	Significant project over-run.	Inability to meet project objectives; reputation of the organisation seriously damaged.
Injury (Physical and psychological) to patient / visitor / staff.	Adverse event leading to minor injury not requiring first aid.	Minor injury or illness, first aid treatment required.	Agency reportable, e.g., Police (violent and aggressive acts) Significant injury requiring medical treatment and/or counselling.	Major injuries/long term incapacity or disability (loss of limb) requiring medical treatment and/or counselling.	Incident leading to death or major permanent incapacity.
Complaints/ Claims	Locally resolved verbal complaint.	Justified written complaint peripheral to clinical care.	Below excess claim. Justified complaint involving lack of appropriate care.	Claim above excess level. Multiple justified complaints.	Multiple claims or single major claims. Complex justified complaint.
Staffing and Competence	Short term low staffing level temporarily reduces service quality (< than 1 day). Short term low staffing level (> 1 day), where there is no disruption to patient care.	Ongoing low staffing level reduces service quality. **Minor error** due to ineffective training/implementation of training.	Late delivery of key objective / service due to lack of staff. **Moderate error** due to ineffective training/implementation of training. Ongoing problems with staffing levels.	Uncertain delivery of key objective / service due to lack of staff. **Major error** due to ineffective training/implementation of training.	Non-delivery of key objective / service due to lack of staff. Loss of key staff. **Critical error** due to ineffective training/implementation of training.
Financial (including damage/ loss/ fraud)	Negligible organisational/personal financial loss (< £1k). (**NB**. Please adjust for context)	Minor organisational/personal financial loss (£1-10k).	Significant organisational/personal financial loss (£10-100k).	Major organisational/personal financial loss (£100k - £1m).	Severe organisational/personal financial loss (>£1m).
Inspection / Audit	Small number of recommendations which focus on minor quality improvement issues.	Recommendations made which can be addressed by low level of management action.	Challenging recommendations that can be addressed with appropriate action plan.	Enforcement action. Low rating. Critical report.	Prosecution. Zero rating. Severely critical report.
Adverse Publicity / Reputation	Rumours, no media coverage Little effect on staff morale	Local media coverage – short term. Some public embarrassment. Minor effect on staff morale / public attitudes.	Local media – long-term adverse publicity. Significant effect on staff morale and public perception of the organisation	National media / adverse publicity, less than 3 days. Public confidence in the organisation undermined Use of services affected	National / International media / adverse publicity, more than 3 days. MSP / MP concern (Questions in Parliament). Court Enforcement Public Enquiry/FAI

[2] NHS Quality Improvement Scotland (February 2008) sourced AS/NZS 4360:2004 'Making it Work' (2004)

Table 2: Likelihood definitions

Descriptor	Rare	Unlikely	Possible	Likely	Almost Certain
Probability	Can't believe this event would happen again – will only happen in exceptional circumstances	Not expected to happen again, but definite potential exists	Has happened before on occasions – reasonable chance of re-occurring	Strong possibility that this could happen again	This is expected to frequently happen again – more likely to re-occur than not

Table 3 - Risk Matrix

LIKELIHOOD	CONSEQUENCES / IMPACT				
	Negligible	Minor	Moderate	Major	Extreme
Almost Certain	MEDIUM	HIGH	HIGH	VERY HIGH	VERY HIGH
Likely	MEDIUM	MEDIUM	HIGH	HIGH	VERY HIGH
Possible	LOW	MEDIUM	MEDIUM	HIGH	HIGH
Unlikely	LOW	MEDIUM	MEDIUM	MEDIUM	HIGH
Rare	LOW	LOW	LOW	MEDIUM	MEDIUM

Appendix 2 – National Coordinating Council for Medication Error Reporting and prevention – Index for Categorising Medication Errors