### Author: Director of Quality

<table>
<thead>
<tr>
<th>Responsible Lead Executive Director:</th>
<th>Executive Medical Director</th>
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<tbody>
<tr>
<td>Endorsing Body:</td>
<td>Corporate Management Team</td>
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<td>Governance or Assurance Committee:</td>
<td>Healthcare Quality Assurance &amp; Improvement Committee</td>
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<td>Implementation Date:</td>
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<td>Responsible Person:</td>
<td>Director of Quality</td>
</tr>
</tbody>
</table>
## CONTENTS

i) Consultation and Distribution Record  
   Page 3

ii) Change Record  
   Page 3

### FOREWORD

Page 4

1. INTRODUCTION  
   Page 4

2. AIMS  
   Page 5

3. SCOPE  
   Page 6

4. DEFINITIONS  
   Page 7

5. ROLES AND RESPONSIBILITIES  
   Page 10

6. MANAGING AN ADVERSE EVENT  
   Page 12

7. ADVERSE EVENT ANALYSIS, ACTION PLANNING AND REVIEW  
   Page 13

8. SUPPORTING PEOPLE AFFECTED BY ADVERSE EVENTS  
   Page 14

9. TRAINING AND EDUCATION  
   Page 15

10. RESOURCE IMPLICATIONS  
    Page 16

11. COMMUNICATION PLAN  
    Page 16

12. QUALITY IMPROVEMENT – MONITORING AND REVIEW  
    Page 16

13. EQUALITY AND DIVERSITY IMPACT ASSESSMENT  
    Page 16

14. REFERENCES  
    Page 16

Appendices  
Pages 17-21

Version 3.2  
April 2019  
Page 2 of 21
# CONSULTATION AND DISTRIBUTION RECORD

<table>
<thead>
<tr>
<th>Contributing Author / Authors</th>
<th>Karon Cormack, Director of Quality</th>
</tr>
</thead>
<tbody>
<tr>
<td>Consultation Process Stakeholders:</td>
<td>Category 1 Review Group</td>
</tr>
<tr>
<td></td>
<td>Corporate Management Team</td>
</tr>
<tr>
<td>Distribution:</td>
<td>Corporate Management Team</td>
</tr>
<tr>
<td></td>
<td>Operational Units</td>
</tr>
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## CHANGE RECORD

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<td>May 2014</td>
<td>Carol McGhee</td>
<td>Previous Risk Management Guidance: Incident Management August 2013, superseded by this Policy aligned to the Healthcare Improvement Scotland (HIS) National Framework for Management of Adverse Events.</td>
<td>Version 1.1</td>
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<td>January 2015</td>
<td>Carol McGhee</td>
<td>Subsequent to the Vale of Leven Report and Recommendations (2014), specifically, recommendation 72, an addition has been made to Section 4.11.1.</td>
<td>Version 1.1</td>
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<td>Amendment: Removed any reference to working days, changed working days to days.</td>
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<td>Carol McGhee</td>
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<td>Carol McGhee</td>
<td>Separate Policy Statement from Procedures.</td>
<td>Version 3.1</td>
</tr>
<tr>
<td>Jan 2019</td>
<td>Karon Cormack</td>
<td>Reviewed and Updated</td>
<td>Version 3.2</td>
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FOREWORD

‘We know that the NHS in Lanarkshire already provides excellent care, but we also know that sometimes things go wrong. We understand the significant impact that adverse events can have on patients and/or their families/carers and staff.

This policy sets out how NHS Lanarkshire will identify and 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 commitment to supporting patients and/or their families/carers and staff when adverse events occur. NHS Lanarkshire is committed to promoting an open and honest culture, based on understanding why things go wrong, supporting those affected and working hard to minimise the impact and the recurrence of adverse events.

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 April 2015, Healthcare Improvement Scotland (HIS) issued the second editions of its framework “Learning from adverse events through reporting and review: A national framework for Scotland” following consultation and engagement with NHS Boards, clinicians, patients and a number of national groups and organisations. An interim revision of the framework was produced in July 2018 following the implementation of the statutory organisational Duty of Candour legislation on Scotland on 1 April 2018.

1.3 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.

1.4 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.

1.5 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.

1.6 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.

1.7 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.

1.8 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.

1.9 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 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;
- 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 Health and Safety Group;
- 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 supportive towards persons affected by the adverse events and apologises for any harm that occurred.

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.
ADVERSE EVENT MANAGEMENT POLICY

- 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.

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. DEFINITIONS¹

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

¹ As defined by Health Improvement Scotland, September 2013, revised April 2015 and July 2018
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 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.

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.

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<thead>
<tr>
<th>Category 1</th>
<th>Category 2</th>
<th>Category 3</th>
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<tr>
<td>Extreme</td>
<td>Major</td>
<td>Negligible</td>
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<tr>
<td>SIGNIFICANT HARM</td>
<td>SERIOUS HARM</td>
<td>MINIMAL OR NO HARM</td>
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**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, care delivery problems and contributory 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. 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 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 completed and documented using the defined Briefing Note template, which is then 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
- Any retained swab or surgical item
- Maternal death
- Any fetal loss meeting the MBBRACE criteria*
- Avoidable return to theatre
- Patient Suicide where there has been contact with MHS
- Wrong patient blood transfusion
- Re-use of a non-sterile 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.
- Child protection incident with potential learning for health

* Late fetal losses – the baby is delivered between 22+0 and 23+6 weeks 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.

As Duty of Candour events would be 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 completed 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 a patient safety incident that is wholly preventable where guidance or safety recommendations that provide strong systemic protective barriers are available at a national level and have been implemented by healthcare providers.

Never Events have the potential to cause significant or serious patient harm or death. However, significant or serious harm or death does not need to have happened as a result of a specific incident for that incident to be categorised as a Never Event.

For each Never Event type, there is evidence that the Never Event has occurred in the past and that the risk of recurrence remains.

NHS Improvement has set out a list of never events and this has been adopted by NHS Lanarkshire.

- Wrong Site Surgery
- Wrong implant / prosthesis
- Retained foreign object post procedure
- Mis-selection of a strong potassium containing solution
- Wrong route administration of medication
- Overdose of insulin due to abbreviations or incorrect device
- Mis-selection of high strength midazolam during conscious sedation
- Overdose of methotrexate for non-cancer treatment
- Failure to install functional collapsible shower or curtain rails
- Falls from poorly restricted windows
- Chest or neck entrapment in bedrails
- Transfusion or transportation of ABO-incompatible blood components or organs
- Misplaced naso- or oro-gastric tubes
- Scalding of patients
- Unintentional connection of a patient requiring oxygen to an air flow meter

All Never Events must be recorded on the Datix incident recording system. It is most likely that Never Events should have a SAER or a RIDDOR review so that the reason the failure of the system that occurred can be assessed, analysed and learning gained to reduce further events.

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 (or IR1 where there is no direct access) 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;
• Identify 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;
- Ensure systems are in place and/or implemented to provide feedback on local reviews of adverse events and near misses to the 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, 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 adverse events management 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
5.6 The Healthcare Quality Assurance and Improvement Committee, Staff Governance Committee and the Health and Safety Group, have a 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 near misses from the designated persons;
- Receive reports on specific significant adverse events;
- Monitor that appropriate action and learning has taken place following the identification and reporting of adverse events and near misses.

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

<table>
<thead>
<tr>
<th>Procedure 1</th>
<th>Initial Management of an Adverse Event</th>
</tr>
</thead>
<tbody>
<tr>
<td>Procedure 2</td>
<td>Reporting and Recording an Adverse Event</td>
</tr>
<tr>
<td>Procedure 3</td>
<td>The Types of Adverse Events to be Reported</td>
</tr>
<tr>
<td>Procedure 4</td>
<td>Adverse Event Grading</td>
</tr>
<tr>
<td>Procedure 5</td>
<td>Notification to the Chief Executive</td>
</tr>
<tr>
<td>Procedure 6</td>
<td>Consideration for the Level of Review and Timescales</td>
</tr>
<tr>
<td>Procedure 7</td>
<td>Commissioning a Significant Adverse Event Review (SAER)</td>
</tr>
<tr>
<td>Procedure 8</td>
<td>The Significant Adverse Event Review Process</td>
</tr>
<tr>
<td>Procedure 9</td>
<td>Involving Patients and/or their Families/Carers</td>
</tr>
<tr>
<td>Procedure 10</td>
<td>SAER Report Writing</td>
</tr>
<tr>
<td>Procedure 11</td>
<td>Joint Working and Multi-Agency Working</td>
</tr>
<tr>
<td>Procedure 12</td>
<td>Formal Sharing of Final SAER Reports</td>
</tr>
<tr>
<td>Procedure 13</td>
<td>Dealing with the Media</td>
</tr>
</tbody>
</table>

6.3 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.
ADVERSE EVENT MANAGEMENT POLICY

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.

7.5 This must be usual practice after the occurrence of serious adverse events and near misses with potentially serious consequences. Accredited staff side representatives should be involved in this process at the earliest opportunity when appropriate.

7.6 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 advise. Significant Adverse Event Reviews will not contain the names of patients or staff.

7.7 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 be completed accurately and factually.

7.8 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 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;
- Being invited to discuss whether and if so, how the patient and/or their families/carers will be involved such as if they have any 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;
- 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.

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 legislation will be complied with on all occasions. DoC guidance is available on FirstPort 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.

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 (July 2018, 3rd Edition).

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

NHS improvement Never Events list (January 2018).
## ADVERSE EVENT MANAGEMENT POLICY

### Appendix 1- NHSScotland risk assessment matrices

Table 1 - Impact/consequence definitions

<table>
<thead>
<tr>
<th>Descriptor</th>
<th>Negligible</th>
<th>Minor (including damage/loss/fraud)</th>
<th>Moderate</th>
<th>Major</th>
<th>Extreme</th>
</tr>
</thead>
<tbody>
<tr>
<td>Objectives/Project</td>
<td>Barely noticeable reduction in scope, quality or schedule.</td>
<td>Minor reduction in scope, quality or schedule.</td>
<td>Reduction in scope or quality of project; project objectives or schedule.</td>
<td>Significant project over-run.</td>
<td>Inability to meet project objectives; reputation of the organisation seriously damaged.</td>
</tr>
<tr>
<td>Injury</td>
<td>Adverse event leading to minor injury not requiring first aid.</td>
<td>Minor injury or illness, first aid treatment required.</td>
<td>Agency reportable, e.g. Police (violent and aggressive acts) Significant injury requiring medical treatment and/or counselling.</td>
<td>Major injuries/long term incapacity or disability (loss of limb) requiring medical treatment and/or counselling.</td>
<td>Incident leading to death or major permanent incapacity.</td>
</tr>
<tr>
<td>Staffing and Competence</td>
<td>Short term low staffing level temporarily reduces service quality (&lt; than 1 day).</td>
<td>Ongoing low staffing level reduces service quality. Minor error due to ineffective training/implementation of training.</td>
<td>Late delivery of key objective / service due to lack of staff. Moderate error due to ineffective training/implementation of training.</td>
<td>Uncertain delivery of key objective / service due to lack of staff. Major error due to ineffective training/implementation of training.</td>
<td>Non-delivery of key objective / service due to lack of staff. Loss of key staff. Critical error due to ineffective training/implementation of training.</td>
</tr>
<tr>
<td>Financial (including damage/loss/fraud)</td>
<td>Negligible organisational/personal financial loss (&lt; £1k). (NB. Please adjust for context)</td>
<td>Minor organisational/personal financial loss (£1-10k).</td>
<td>Significant organisational/personal financial loss (£10-100k).</td>
<td>Major organisational/personal financial loss (£100k - £1m).</td>
<td>Severe organisational/personal financial loss (&gt;£1m).</td>
</tr>
<tr>
<td>Inspection / Audit</td>
<td>Small number of recommendations which focus on minor quality improvement issues.</td>
<td>Recommendations made which can be addressed by low level of management action.</td>
<td>Challenging recommendations that can be addressed with appropriate action plan.</td>
<td>Enforcement action. Low rating. Critical report.</td>
<td>Prosecution. Zero rating. Severely critical report.</td>
</tr>
<tr>
<td>Adverse Publicity /Reputation</td>
<td>Rumours, no media coverage. Little effect on staff morale.</td>
<td>Local media coverage – short term. Some public embarrassment. Minor effect on staff morale / public perception of the organisation</td>
<td>Local media – long-term adverse publicity. Significant effect on staff morale and public perception of the organisation</td>
<td>National media / adverse publicity, less than 3 days. Public confidence in the organisation undermined Use of services affected</td>
<td>National / International media / adverse publicity, more than 3 days. MSP / MP concern (Questions in Parliament). Court Enforcement Public Enquiry/FAI</td>
</tr>
</tbody>
</table>

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### Table 2: Likelihood definitions

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

### Table 3 - Risk Matrix

<table>
<thead>
<tr>
<th>LIKELIHOOD</th>
<th>CONSEQUENCES / IMPACT</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Negligible</td>
</tr>
<tr>
<td>Almost Certain</td>
<td>MEDIUM</td>
</tr>
<tr>
<td>Likely</td>
<td>MEDIUM</td>
</tr>
<tr>
<td>Possible</td>
<td>LOW</td>
</tr>
<tr>
<td>Unlikely</td>
<td>LOW</td>
</tr>
<tr>
<td>Rare</td>
<td>LOW</td>
</tr>
</tbody>
</table>
Appendix 2 – National Coordinating Council for Medication Error Reporting and prevention – Index for Categorising Medication Errors

Definitions

Harm
Impairment of the physical, emotional, or psychological function or structure of the body and/or pain resulting therefrom.

Monitoring
To observe or record relevant physiological or psychological signs.

Intervention
May include change in therapy or active medical/surgical treatment.

Intervention Necessary to Sustain Life
Includes cardiovascular and respiratory support (e.g., CPR, intubation, etc.)

No Error
Error, No Harm
Error, Harm
Error, Death