Adverse Event Management Procedure

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Adverse Event Management Procedure			
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Adverse Event Management Procedure

Contents

1.0 Purpose

This document is complementary to, and should be read in conjunction with, the NHS Lothian Adverse Events Management Policy**.** This procedure is designed to ensure consistency of approach in the management of, and learning from adverse events. This will provide the data required to identify weaknesses in systems so that they can be addressed.

2.0 Scope

The key focus of this procedure is on adverse events which do affect, or could have affected people, and could have caused, or did result in harm. Events which did or could have led to harm to the organisation, such as damage to property, system failure, service disruption, financial loss or adverse publicity, are also included. The procedure applies to all of NHS Lothian's services and activities, and all staff. Further details of responsibilities are referenced in section 6.5.2.

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

3.0 Definitions

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

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

A Significant Adverse Event (SAE) is defined as "an extraordinary event that could have, or did, have serious consequences, including immediate or delayed emotional reactions, physical or psychological harm for patients, public, staff or organisation". The severity of the actual outcome of such adverse events in terms of harm will either be 'Death' or 'Major'.

Occasionally a Significant Adverse Event will have no actual harm, but is deemed significant because there is either a potential for serious harm or it is a media-sensitive issue.

Examples of Significant Adverse Events include:

- Death or major injury connected with employment, care, treatment, or related to participation in research activity
- Death or injury of patient, member of staff/visitor/ other where foul play is suspected

- Death of a patient where suicide may have been the cause
- Patient/staff member/other person's death resulting from violent, suspicious or unexplained cause
- Any adverse event which may be experienced as harassment on the grounds of age, disability, ethnicity or race, gender, religion or belief, or sexuality
- 'Near miss' events such as a patient absconding, an accident, violent, suspicious or unexplained adverse events which may not result in injury or disability but which could be an indicator of potential suicide or danger to others
- Major outbreaks of infection
- Serious medication errors
- Major clinical errors
- Systematic screening / diagnostic errors
- Failure in infrastructure putting people at risk e.g. electricity, medical gases
- Fire involving injury and or financial loss
- Unauthorised interference with or malfunctioning of medical equipment or supplies
- Loss of patient confidential data
- Suspected theft
- All fractures with the exception of fingers and toes.

The circumstances surrounding each adverse event will vary in terms of:

- severity of harm
- numbers of people involved
- risk exposure
- financial loss
- media interest, and
- the need to involve other stakeholders.

Therefore, the response to each adverse event should be proportionate to its scale, scope and complexity. The severity of harm set out in table 1 (section 6.3) will largely determine the escalation and communication pathway and level of review required.

Adverse Event Grading Table
Communication & Escalation of Significant Adverse Events (SAEs)

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

4.0 Managing Adverse Events

4.1 Overview

It is recognised that adverse event management is one part of effective risk management. Avoidance, prevention and reduction of risks should be the primary defence to prevent adverse events occurring. It is therefore important that risk assessment and prevention is seen as the first step in effective adverse event management. However, when adverse events do occur, it is important that the process set out below is implemented consistently to ensure a robust response.

The key elements of the process are that:

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

4.2 Supporting people affected by Adverse Events

4.2.1 Patients and families

The first consideration following an adverse event is that the patient must be cared for, their, and other patients', health and welfare secured and further risk mitigated. The patient's family or carers must be similarly cared for and involved where a patient has died or suffered serious harm.

Where an adverse event has a direct impact on a patient, it should be discussed with them by the most appropriate member of the clinical team as soon as is practical. Information and support to the patient, relatives and carers involved should be provided, including information on support systems available. Compassion and understanding should be demonstrated at all times, and arrangements for ongoing contact should be agreed with the patient/family/carer to keep them informed of the progress of reviews and/or improvement plan implementation.

When patients, families and carers are affected by an adverse event, NHS Lothian will demonstrate transparency and openness and give an apology. Saying sorry is not an admission of liability, but an understanding of the distress or worry experienced. Further information has been published for Scotland that builds on the principles within the National Patient Safety Agency's (NPSA) *Being Open Framework* (2009): Being Open in

NHSScotland: Guidance on Implementing the Being Open Principles (2015). Further information can be found on 'Communicating with Patients and Families' intranet page.

The Institute for Healthcare Improvement (IHI) within their publication the *Respectful Management of Serious Clinical Adverse Events (Second Edition)*[1]suggests that an adverse event does not necessarily break down the trust between patient and staff; however, the way in which the organisation responds after such events often does. The document provides a number of ways in which organisations should never lose sight of the patient and family when responding to an event.

NHS Lothian is committed to promoting a culture of 'Being open' with patients and families when an 'adverse event' occurs. Furthermore, that communicating openly about an adverse event is accepted as a continuation of good, clinical communication and not something separate which is instigated when an adverse event occurs. 'Being Open' is a process of actions and behaviours that are determined by the Ten Principles of Being Open (ref. NPSA) and requires a culture which visibly encourages key behaviours, including:

- Honesty
- Openness
- Appropriate sharing of information
- A willingness to learn from experience and to change how the organisation functions

As noted in section 3, it is recognised that it is often not possible to determine whether or not the harm could have been avoided until a review is carried out. For the purpose of 'Being open' with patients and families, it is helpful to think of an adverse event as something unexpected and unwelcome occurring. It is NHS Lothian's ambition to ensure that the principles and process of 'Being Open' is followed whenever something unexpected and unwelcome happens.

Further guidance is set out in 'Communicating with Patients and Families' intranet page.

Process & Checklist for Communicating with Patient & Families

4.2.2 Duty of Candour

All health professionals already have a professional 'Duty of Candour', which means that patients should be well informed about all elements of their care and treatment and have a responsibility to be open and honest.

As from 1 April 2018, NHS Lothian has an organisational, statutory Duty of Candour which applies to a subset of adverse events and defined levels of harm. An event which activates the duty is defined as an individual who has received a health, social care or social work service has been the subject of an unintended or unexpected 'incident', and in the reasonable opinion of a registered healthcare professional has resulted in or could result in:

[1] Respectful Management of Serious Clinical Adverse Events *(Second Edition).* Conway J, Federico F, Stewart K, Campbell MJ. IHI Innovation Series white paper. Cambridge, Massachusetts: Institute for Healthcare Improvement; 2011

- death of the person
- a permanent lessening of bodily, sensory, motor, physiologic or intellectual functions
- an increase in the person's treatment
- changes to the structure of the person's body
- the shortening of the life expectancy of the person
- an impairment of the sensory, motor or intellectual functions of the person which has lasted, or is likely to last, for a continuous period of at least 28 days
- the person experiencing pain or psychological harm which has been, or is likely to be, experienced by the person for a continuous period of at least 28 days
- the person requiring treatment by a registered health professional in order to prevent:
    - the death of the person, or
    - any injury to the person which, if left untreated, would lead to one or more of the outcomes mentioned above.

Duty of Candour requires us to:

- Notify the person affected of the event (and/or family/relative if appropriate)
- Provide an apology
- Offer and arrange a meeting with the person (and/or family/relative if appropriate)
- Provide the person affected with an account of the event
- Provide information about further steps taken
- Make available, or provide information about, support for persons affected by the event
- Carry out a review into the circumstances leading to the event
- Offer to share outcome of review and/or copy of final report with patient/family
- Prepare and publish an annual report on the Duty of Candour

The Duty of Candour procedure and associated toolkit is available on the Communicating with Patient and Families Intranet pages

4.2.3 Staff

Working in the NHS can involve staff facing a range of challenges and unpredictable situations. Such events can be difficult for the individuals directly involved, their colleagues and managers, and may have far-reaching consequences for partners, children and others. The organisation must demonstrate, through the actions of staff and managers, that it cares about the harm that may have been caused, and about the well-being of the individual(s) involved.

Staff who are involved in an adverse event in any way may be psychologically and/or emotionally affected, as well as possibly physically injured. This may arise from witnessing an event or being responsible for its cause through accident, error or negligence. It is

important that all staff who have had ANY involvement in or exposure to an adverse event have the opportunity to be supported.

Individual reactions to such event can vary enormously, as will individual support networks and attitudes towards asking for help. Therefore, it is a manager's responsibility to check with all concerned as to how they are coping and to identify appropriate support for both individuals and teams.

Research informs us that the acknowledgement of a traumatic event by managers, and early informal support, has a major impact on long-term recovery.

Support for staff therefore needs to be pro-active, and may include a combination of practical and emotional support, for example:

- Help with preparing information; help with review, time out and ongoing day-to-day support
- Collaborative debrief with in-house specialists, counselling, compassionate leave.

Managers must ensure such needs are considered and met where necessary. Staff and Partnership representatives are able to assist in supporting staff with such issues.

Detailed guidance is available on Adverse Event Management Intranet page Support for staff

5.0 Support and Training

DATIX is the electronic risk management information system used by NHS Lothian to record information relating to adverse events, complaints, claims and risk registers. DATIX should be used throughout all stages of the management of adverse events to record all information, communications, outcomes and associated actions, so that an audit trail is evident.

NHS Lothian must ensure that managerial staff are provided with appropriate education/training in the conduct of adverse event reviews.

All staff - including staff with managerial responsibility - are required to undertake training sessions on the content, implementation and management of this policy, procedures and local protocol. This will be covered at induction and through local orientation and relevant on-the-job training.

Guidance is available on a range of topics on the Adverse Event Management intranet pages.

Two e-learning modules are available within in LearnPro for NHS Lothian:

- Adverse Event Reporting – found within section 4 of the NHS Lothian Health & Safety course
- Datix – Guide to Adverse Event Management' – found within the CPD Section

Datix Support
Datix E-Learning Modules

The Health and Safety Service provide education/training to managers on request with modular sessions on RIDDOR reporting and on the principles of Adverse Event Investigation. Further information can be accessed on the link below.

Health & Safety Intranet Page

The Quality Department staff are responsible for development and maintenance of systems and processes to support the management of adverse events, including DATIX (the electronic integrated risk management system used to manage adverse events in NHS Lothian). The team also provide tailored, team based training, toolkits, guidance and expert support to the service and information for Board-level groups.

- Health and Safety Advisers will assist managers or lead in review of adverse events to provide expertise and support in relation to the review of occupational health and safety adverse events including RIDDOR
- Health and Safety Advisers also provide input and support to management teams on the effectiveness of management systems when investigating adverse events involving vulnerable patients and their safety
- Health and Safety Advisers also provide advice, support, and facilitation to managers during Health and Safety Executive (HSE) investigations on the effectiveness of management systems for some clinical related adverse events
- The Health and Safety Advisers do not provide advice on matters of professional clinical practice during any adverse event review but will assist in when requested in the review process to determine the effectiveness of management controls, communication processes, competence (e.g. training) and cooperation mechanisms.
- The Health and Safety Advisers provide advice and support to Health and Safety Committees/Groups as required.

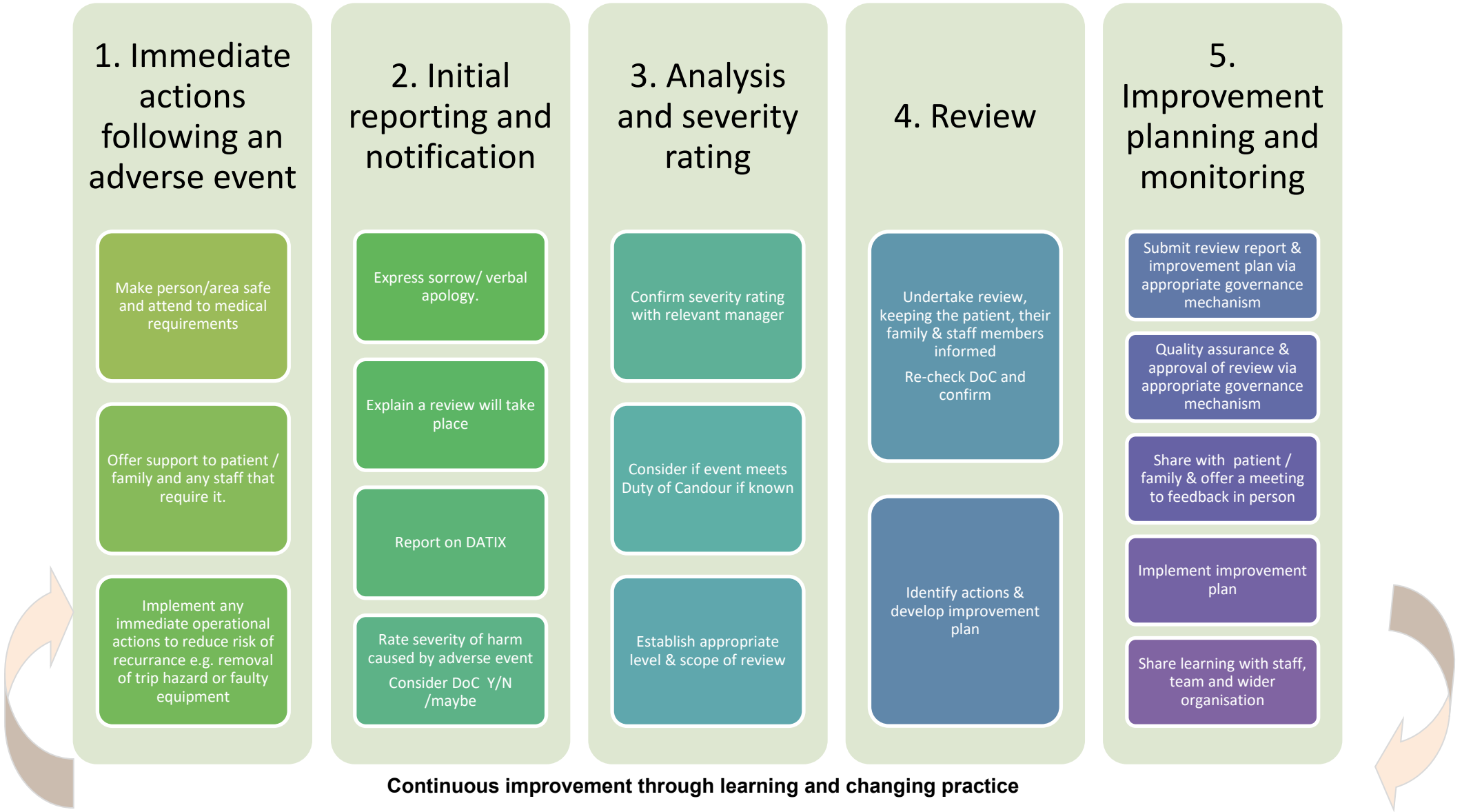
6.0 The Process

Managers have responsibility for the appropriate management of adverse events and consequences to ensure service improvement. Overall operational management responsibility, including patient/family liaison, therefore rests with the Nurse/Medical Directors for Acute services and HSCP Joint Directors.

The five stages involved in managing adverse events are summarised in the following sections and illustrated in the Flowchart of actions to be taken to effectively manage adverse events below (Figure 1).

There are also a number of additional actions and/or reporting requirements for specific types of adverse events. In some cases, these are statutory reporting requirements to external bodies, including the Health and Safety Executive (HSE), Police, the Mental Welfare Commission, and Scottish Healthcare Supplies. A list of the most relevant bodies and their roles is provided in Specific Types of Adverse Events (AEs). Advice on reporting requirements can be sought from the Quality Directorate Staff and the Health and Safety Advisers.

Figure 1: Flowchart of actions to be taken to effectively manage adverse events



6.1 Stage 1 – Immediate actions following and Adverse Event

The first priority following any adverse event is to ensure that the needs of individuals affected are attended to. When an individual member of staff becomes aware of an adverse event, they must act immediately to ensure that:

- they do not put themselves in situations of danger
- any urgent clinical care that may reduce the harmful impact of the event is given immediately
- If there are steps that can be taken immediately to reduce the risk of recurrence, then these should be implemented
- a safe environment is re-established as soon as possible
- the appropriate line manager/supervisor/person in charge is contacted (for guidance in relation to Management, Communication and Escalation of Significant Adverse Events as defined in 3 please see:

Operational procedure for Communication & Escalation of Significant Adverse Events (SAE)
Management and Event with Major Harm or Death – Management Team Actions

- the patient, relatives and carers, where appropriate, are informed by the responsible person, their needs met, and support provided.
- colleagues are informed and support secured from other professionals
- any faulty medicine or equipment is removed, retrieved, isolated and labelled so as to prevent future use
- a timely and objective entry is made in the patient's clinical records.

Once aware of the event, the relevant manager is responsible for ensuring that all appropriate actions outlined above have been taken and to ensure that patients, families and staff/volunteers are supported. The nature and timing of communication will depend on the severity of the harm of the SAE.

Support for staff following a Significant adverse event (SAE)
Communicating with patients and their families about adverse events

6.2 Stage 2 – Initial Reporting and notification

6.2.1 How to report

When an adverse event (including a near-miss) occurs, this must be recorded on DATIX using the adverse event reporting form. This should happen as soon as possible after the event, preferably within one working day, unless there are exceptional reasons for delay (if for example the event was identified retrospectively following a complaint or claim). Training in adverse event reporting is provided to all staff as part of induction, and should be re-emphasised as part of local orientation. Further guidance is available on the Adverse Event Management Intranet pages.

DATIX can be accessed from the home page of the intranet by selecting from the applications menu.

If the electronic Adverse Event Reporting Form is unavailable DUE TO SYSTEMS FAILURE, a paper record of the adverse event should be made and submitted to the Line Manager, who is responsible for it being submitted electronically as soon as possible.

If it is not possible for the person(s) involved to complete a form, it should be completed by the Line Manager with assistance from witnesses where required. If the member of staff has been injured, the supervisor/line manager should complete the Adverse Event Reporting Form.

The adverse event should normally be reported to the Team of Department responsible for providing the care, service, equipment or facility that potentially contributed to the adverse event. This is the team that will manage and coordinate the adverse event review. They will be the team best placed to identify and understand the potential safety issues and to implement any learning to prevent similar adverse events from happening again.

(If a member of staff has been involved – the line manager must ALWAYS be informed, likewise for patients involved in an adverse event – the lead service for their care must always be informed. The Adverse event manager should add the line manager, or patients lead clinician, as a reviewer if appropriate.)

Staff working in the community should report an adverse event as soon as possible after returning to their base. Staff working in areas provided by other agencies should report the adverse event to the relevant external facilities manager as well as their line manager.

DATIX is set up to notify relevant managers automatically via email that an adverse event has been reported. However, this does not replace personal and timely communication. Escalation procedures should be followed appropriate to the severity of the adverse event as set out in the Communication and escalation pathway.

Additional email notifications may be sent depending on the type of adverse event and the severity of harm caused. For example, all major harm and death is reported to the Senior Management Team responsible for that service, and adverse events involving controlled drugs to the responsible officer for controlled drugs.

As previously noted in section 6.0 there are specific, and in some cases statutory, reporting requirements to external bodies, including the Police, the Health and Safety Executive (HSE), the Mental Welfare Commission, and Health Facilities Scotland – Incident Reporting and Investigation Centre (IRIC) also apply to a range of adverse events. Specific arrangements are detailed in: Specific Types of Adverse Events (AEs)

The line manager must ensure that they identify adverse events reported under the Reporting of Injuries, Diseases and Dangerous Occurrences Regulations 2013 (RIDDOR), which must be reported by managers to the Health and Safety Executive (HSE) (for information on specific time scales see link below). Managers should contact Health & Safety Advisor for advice prior to reporting to HSE.

Reporting Requirements Under RIDDOR

6.2.2 What to report

Any adverse event/near miss, event or circumstance arising during NHS service provision that could have or did lead to unexpected harm, loss or damage should be reported. Harm may be physical, emotional or psychological (so includes verbal and emotional abuse).

If an adverse event is not immediately apparent it should be reported retrospectively (e.g. back pain a few days after a manual-handling manoeuvre, an event identified following a complaint). Types of adverse events will be broad and varied therefore it would be inappropriate to attempt to provide a comprehensive list however, some examples are listed below:

- Personal accidents to patients or staff e.g. slips or falls, needle stick injury
- Clinical adverse events/near misses regarding patient care or treatment e.g. medication error, misdiagnosis, infection, x-ray performed on wrong patient
- Security adverse event e.g. missing patient, intrusion, theft and fraud
- Information governance e.g. data loss
- Violence, abuse, harassment including any adverse event which may be experienced as harassment on the grounds of age, disability, ethnicity or race, gender, religion or belief or sexuality2
- Building/ facilities e.g. inappropriate waste disposal, fire.

6.2.3 Good practice principles

- Complete all relevant information on a Datix form to avoid delays in making improvements
- When reporting an adverse event – staff should pick the best fit from the available list

[2] It is important to consider at the time of any adverse event whether it could have been motivated by racism, sexism etc and this should be included in the report and reviewed appropriately.

- Record only facts, avoid speculation and subjective statements – reports can become publicly available documents
- Do not use other people's names in the report. These should be recorded in the 'people involved' section
- Avoid the use of abbreviations and/or jargon
- Submit any supplementary information to the Line Manager as required.

6.3 Stage 3 – Analysis and rating the severity of harm

Following initial reporting of an adverse event or near-miss, the relevant manager will assess the DATIX report form to confirm that the appropriate severity has been selected and to consider the level of review required. For adverse events which are recorded as 'near misses', the potential severity of harm should be recorded to ensure that consideration is given to the appropriate level of review and escalation. The Adverse event Grading Table – Identification and decision to review sets out how severity of harm should be rated.

No Adverse Effect	**Minor**
No harm apparent at the time of reporting, and/or near miss	Minor injury or illness, first aid treatment possibly required. Minor harm to organisation example: Local or short term adverse publicity, minor financial loss (<£10K), short term disruption to service
Moderate	**Death or Major Harm**
Significant injury requiring medical treatment and/or counselling, short-term effects. Agency reportable e.g. police (violent & aggressive acts), HSE (RIDDOR – work related injuries resulting in over 7 day absence) Moderate harm to organisation / temporary loss of service, significant financial loss, adverse publicity.	Intervention required to sustain life Long term incapacity or disability requiring medical treatment and/or counselling All fractures with exception of fingers and toes, including work related (RIDDOR) All Dangerous Occurrences (RIDDOR) – e.g. needle stick injury (known high risk patient), a patient hoist collapses or overturns All Reportable Occupational Diseases (RIDDOR) – e.g. Carpal Tunnel Syndrome, Occupational Dermatitis Serious harm to organisation e.g. severe financial loss (>£1 million), ongoing adverse publicity

Please note that individual services may have developed definitions or local examples of specific types of adverse events.

At this point a check should be made of the decisions to escalate (or pass information to others) and/or review. Note the actual effect on a person.

All RIDDOR events should be graded moderate or above and investigated/reviewed in line with the requirements of the Policy and Procedure.

6.4 Stage 4 – Adverse Event Review

6.4.1 Purpose of an Adverse Event Review

The purpose of the review is to determine what happened, how it happened, why it happened, and whether there are learning points for the service or wider organisation. It should follow the principles of a just culture[3] and take a systems-approach, meaning that it should not focus on individuals. If the review team considers that there are any issues about the performance of an individual member of staff, this should be referred to the appropriate line manager and should not be part of the review.

In summary, the review seeks to learn from adverse events and so make improvement by:

- establishing the facts of the adverse event
- identifying contributory factors rather than causes, especially weaknesses in systems and processes
- establishing changes/improvements which may be needed
- enabling support to be provided for the patients, families and staff involved.

6.4.2 Level of review

This will depend primarily on the severity rating of actual harm or potential harm, as defined in section 6.3.

The severity rating of actual harm or potential harm, however, should not be the only factor considered. For example, a 'near miss' event where there is no adverse outcome, or where the harm could have been more serious may require a higher level of review if there is potential for learning in identifying weaknesses in systems and opportunities for systems improvement.

6.4.3 Unexpected major harm or death events

A flowchart has been developed to guide decision- making on the type of review for adverse events where the outcome for the person is **major harm or death**. The decision-making process and rationale for deciding on the level of review must be clearly recorded in DATIX.

The types of review are summarised below, and detailed requirements for each level of review are set out in the Adverse Event Grading Table.

[3] Just Culture Guide – NHS England and NHS Improvement

- Level 1:SAE review and analysis,
- Structured Mortality Review
- Briefing Note Review
- Local AE Review
- Specific process – falls, PUs, Local Case Reviews (Mental Health) etc

The first consideration will always be whether the event meets the Healthcare Improvement Scotland's (HIS) definition of a category 1 event (events that may have contributed to or resulted in permanent harm, for example unexpected death, intervention required to sustain life, severe financial loss (£>1m), ongoing national adverse publicity) and therefore requires the highest level of review (level 1: SAE review and analysis).

In certain circumstances, the Medical Director or an Executive Director may decide to commission an independent review. This may utilise a review team from out with the service or external to NHS Lothian. The Director will appoint the members of the review team and be responsible for ensuring the operational team are kept fully up-to-date.

Some judgement is required by relevant line management in deciding the level of review for some 'near misses'. For example, there will be occasions where a near miss with no harm has been reported as having potential to cause major harm or death and may therefore require the same level of review as a Significant Adverse Event (SAE).

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 involvement of the Procurator Fiscal?

A number of services also have local protocols or agreed processes approved by the NHS Lothian Healthcare Governance Committee to aid decision-making, which have been agreed through the uniqueness of their client group and service provision. These protocols should be used where they exist.

Falls with Significant Harm / Grade 4 Pressure Ulcers
Agreed Alternate Processes
Mental Health & Substance Misuse Protocol
Maternity & Neonatal Services Protocol

If following an alternate process a Level 1 SAE review is indicated then the process for Level 1 SAE review should be followed and the decision recorded in Datix. The event will then be notified to HIS.

Information relating to the adverse event, communications, outcomes and associated actions and/or improvement plans should be recorded and stored in DATIX so that an audit trail is evident.

Level of Review for Major Harm and Death Events – decision making flowchart
Managing an adverse event with Major Harm or Death – Management Actions
Adverse event Grading Table – Identification and decision to review
Commissioning Checklist for Level 1 SAE Reviews
AE Review Template
Structured Mortality Review Tool (SMRT) Template
Briefing Note Template

6.4.4 Review Protocol

The principles of adverse event review are essentially the same, whether an individual reviewing a minor adverse event or a large team reviewing a significant adverse event. The standard process is set out in the NHS Lothian Adverse Event Review Protocol (based on the London Protocol)[4] and summarised in the Adverse Event Review and Analysis Process Flowchart below.

The protocol outlines a process of adverse event review and has been developed in the light of experience and research (Reason JT1993)[5] into adverse event review both within and outside healthcare. The protocol focuses on harm to people but is suitable for all reviews where there is harm or potential harm to people or the organisation.

NHS Lothian Adverse Event Review Protocol
Managing an Adverse Event with Major Harm or Death – Review Team Actions

The purpose of the protocol is to ensure a consistent, systematic and thoughtful approach to the review of adverse events to promote a greater climate of openness and opportunities to identify system failures and to make service improvements.

[4] Systems analysis of clinical Incidents - London Protocol (2nd edition) toolkit
[5] Reason, J.T. The human factor in medical accidents. In Vincent C.A. editor. Medical Accidents. Oxford: Oxford Medical Publications; 1993.

Adverse Event Review and Analysis Process Flowchart

Use of the protocol should be separate from any disciplinary or other procedures used for dealing with persistent poor performance by individuals.

6.4.4.1 Level 1: SAE Review and Analysis

All SAE reviews must:

- use defined methodologies to ensure a structured and consistent approach to identifying the care/service delivery problems and their contributory factors, details of the care provided and if any lessons about that care could inform service improvement or reduce recurrence;
- have a comprehensive, accessible file of review documentation. Please note staff statements / notes of interviews with staff should not be attached in the Datix system. This should be retained by the review team and once review has been completed sent to the Quality Department for secure storage (link to SOP)

The review team must:

- be multidisciplinary and include a professional with experience relevant to the event being reviewed.
- be sufficiently removed from the event, have no conflict of interest (real or perceived) to be able to provide an objective view
- include someone with experience in conducting reviews and trained in review methodologies and their application
- include a pharmacist if the adverse event involves a medication error

- have access to a subject matter expert if applicable or required.

The focus of any review will always be on systems and processes; therefore, the reviewer's expertise is in review methodology rather than the service or the specialism involved in the event. It is recognised however, that it may not be appropriate for example, for a psychiatrist to review a theatres event, as there will be a need for some level of understanding of systems and processes in similar settings. A colleague reviewing an event who may cover on call and annual leave would not be appropriate.

In addition, reviewers should not be those responsible for governance of the service e.g. the CD/AMD/CNM/CSM for that service.

The report of the review must:

- present the findings, conclusions and recommendations of the review, using the standardised template
- be anonymised so that no staff members or patients can be identified
- be agreed by the review team, and all staff involved in the adverse event should receive feedback on the outcomes of the review
- be approved by the Medical and Nurse Directors through the governance approval process.

Governance Approval Process

The patient, family and carer must be offered the opportunity to receive feedback and discuss the outcome of the review.

6.4.4.2 Review Templates and Tools

There are a number of tools available to support the implementation of the protocol and recording of review findings.

Templates and process documents:

Managing Adverse Events with Major Harm and Death – Review Team Actions
Adverse Event Review Template
Briefing Note Template
Structured Mortality Review Tool (SMRT) Template
Falls Review Template
Pressure Ulcer Review Template
Invitation Letter to attend Interview
Summary of Interview process
Role of Lead Reviewer

Guide to Human Factors
Significant Adverse Events: How to write a good review
Anonymisation Guidelines

There are various analysis tools available to comprehensively examine the chronology, CDPs and contributory factors.

Guidance for completing timelines with template
Fishbone Template Model
Contributory Factors Mapping Document
The 5 Whys
Reactive Barrier Analysis
Change Analysis Template

The relevant senior management team is responsible for ensuring that the review process is followed and that relevant timescales are met.

6.4.5 Fair treatment of staff

It is important that all staff who have had any involvement in, or exposure to, an adverse event are supported. It is a Manager's responsibility to check that all staff involved are coping and to identify appropriate support for both individuals and teams.

The spirit of the review will be characterised by an open and fair culture using human factors approach. In this context, 'open and fair culture' means that the purpose of the review is to identify causes and/or weaknesses in systems. Staff will not be reprimanded for such failures or their consequences; however, individuals retain responsibility for their own actions or inactions. Registered professional staff have additional responsibilities under their professional codes of practice.

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

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

Staff Support following a Significant Adverse Event
Staff Support - Managers Action Flowchart
Staff Support Checklist
Information on Significant Adverse Event Review Process for Staff

In the unlikely event that the review uncovers any criminal or potentially criminal act, then the review must stop and the appropriate criminal review process should be used.

If the review uncovers misconduct, including malicious or reckless behaviour which may be construed as gross misconduct or a serious breach of the individual's professional code of conduct, then the disciplinary process will be invoked. The two processes may proceed in parallel, provided the rights of the individual are not compromised. The Just Culture Guide is a useful tool to aid decision-making in this regard.

Just Culture Guide

6.4.6 Confidentiality

Confidentiality in the context of the review means:

- Notes taken during staff interviews will remain confidential to the review team and stored securely once review has been completed. Direct quotes or specific information which is attributable will be shared with the interviewee prior to being included in the report. All names within the report will be anonymised.
- The findings of the Review Team will at all times be dealt with in a manner that respects the confidentiality of individual patients, families and staff.
- Notes of interviews and statements may be made available to the Police if required or when requested under a court order. This will normally be done with the individual's knowledge and consent although a lack of consent cannot override due legal process.
- The review team's report and recommendations will be provided to any disciplinary review but individual interview notes and statements recorded by the review team will only be released with the permission of the individual. This may result in individuals being interviewed/asked for statements more than once.

6.4.7 Submission and approval of adverse events reports

All completed reports must be approved by the appropriate manager. All Level 1 SAE Review and Local AE Review reports should be approved as follows in accordance with the SAE Governance and Approval Process.

- **Signed off** by HSCP Joint Director or nominated member of SMT or REAS Service Director or Acute Services Site or Service Director or nominated member of CMT
- **Approved** by HSCP Clinical Director/Chief Nurse or REAS Associate Medical Director/Chief Nurse or Acute Services Medical and Nurse Directors
- **Final approval** by NHS Lothian Medical and Nurse directors
- **Closed on DATIX** by Quality Improvement Support Team

Major Harm and Death events which are not Level 1 SAE Reviews or Local AE Reviews have an agreed approval process which is as follows:

- **Final Approval** by SMT/CMT
- **Closed on DATIX** by Quality Improvement Support Team

Adverse events with Major Harm and Death can only be closed by the Quality Improvement Department at the end of the agreed governance approval process.

6.4.8 Feedback of findings and learning

Managers at the relevant level must ensure that feedback is given to patients and families where appropriate, and staff, including NHS Lothian volunteers, either individually or collectively in line with local processes.

The refreshed framework: Learning from adverse events through reporting and review: A national framework for Scotland (December 2019) highlighted the aim to have a learning summary for every significant adverse event.

The aim of learning summaries is to ensure:

- A consistent approach for sharing any learning points to improve services, and
- We are open and transparent with findings form significant adverse event reviews with staff, patients, families and carers.

Learning Summary Template

6.5 Stage 5 – Improvement planning and monitoring

Managers at the relevant level must ensure that improvements identified as part of the review are completed. This includes escalating outstanding issues to an appropriate channel for further action which may not be in the gift of the service. The Actions module within DATIX should be used to record and monitor actions.

Senior Management Teams (SMTs) are responsible for having procedures in place to monitor Improvement plans in their area to ensure they are carried through to completion.

- The improvement plan should set out how each recommendation from the Adverse Event Review will be actioned, monitored, implemented, measured and resultant learning shared. The plan should include owners, timescales for delivery and review dates.
- The outcome from the review and improvement plan should be shared with those who reported and were involved in the adverse event.
- All adverse event reviews should be monitored and reviewed and assurances should be sought about learning and the embedding of improvement plans through regular thematic reviews.
- Learning, improvements and best practice should be actively promoted and implemented locally and nationally.
- Evaluation should take place to evidence that changes made have led to sustainable improvements in care.

6.5.1 The use of Quantitative and Qualitative Information

The use of quantitative and qualitative information on adverse events as well as effective communication of trends and outcomes of adverse events, including near misses, is crucial in order to drive the improvement of current processes, practices and systems, including identification of contributory factors.

The review of adverse events is a formal part of the review process to be undertaken by every team and levels of management throughout the organisation. When reports are being produced for wide dissemination, staff should make every attempt to remove patient and staff identification. For example, this would include names, sex, and references to the patient's profession.

The outcomes of adverse event reviews:

- provide information, trends etc to inform action planning
- identify actions requiring further attention by multi-disciplinary teams
- inform the development of local learning groups
- inform the information to be shared with others

6.5.2 Responsibilities

Responsibility for the effective management of adverse events and providing assurance to the NHS Lothian Board that learning is translated into service improvement rests with operational management at all levels and with the Healthcare Governance and Health and Safety Committees. Specific responsibilities are detailed in Responsibilities – Adverse Event Management.

7.0 Media Enquiries

In all instances, external enquiries regarding any adverse event **must** be referred to the Director of Communications who, along with the appropriate Executive Director, will agree a response. Communications with the media **will only be** via the Nurse/Medical Director/HSCP Joint Director, Director of Communications or another designated senior manager.

Managers should expect and prepare for media interest in any serious adverse event within NHS Lothian. Such interest is most likely where a child or a vulnerable adult is involved, wrong treatment is given, or where groups of people are put at risk as a result of service failures, e.g. in a diagnostic reporting process or where there has been an outbreak of food poisoning. Therefore, inform Communications Team when escalation of an adverse event takes place so they are prepared. Link: lothian.communications@nhslothian.scot.nhs.uk

Media contact can be achieved through a variety of means, including a press conference, the releasing of a press statement or being available for ad hoc press enquiries.

8.0 Key Performance Indicators

Managers are responsible for ensuring compliance with the procedures and achievement of the following Key Performance Indicators, that are identified in the Adverse Event Grading Table – Identification (section 6.3). Reports are submitted to the Healthcare Governance Committee every six months.

9.0 Monitoring and review

Implementation of the procedure will be monitored through routine operational management processes as referenced in 6.5.1. The NHS Lothian Healthcare Governance Committee maintains oversight and receives regular reports.

The procedure itself will be continuously reviewed by the Quality Improvement Support Team and Health and Safety Department. Changes may also be made by exception and through formal review every three years by any of the groups with oversight responsibility.