Incident Management Policy

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1 INTRODUCTION

NHS Lothian is committed to the delivery of high quality, safe, effective, person centred care in a safe working environment. Prevention of injury and ill health arising from its undertakings is a key aim.

Appropriate management of incidents is a key component of the overall risk management process. Effective risk management is not about eradicating or avoiding risk altogether, but minimising the risk and its impact. A consistent approach is required across NHS Lothian, and is set out in this policy. This will ensure that when things do go wrong, learning is maximised and shared so that repetition can be avoided in the future. NHS Lothian recognises that incidents, including near misses, provide a rich source of key information on risk and recovery. It therefore strives to establish and maintain an environment, both physical and cultural, to promote safety and incident reporting.

The policy can be summarised as follows:

- It is the responsibility of all staff to report all incidents and near misses and be involved in review, investigation and learning from incidents as appropriate and relevant to their role;

- All incident reports require to be actively managed in a timely way, at different levels of the organisation. Reports are **routinely** offered to give assurance that lessons have been learned and that this learning has been routinely shared with all relevant groups. Feedback will be given to staff and inform decision making;

- Actions are reviewed by senior management in a manner that allows the NHS Lothian Healthcare Governance and Risk Management Committee and the NHS Lothian Health & Safety Committee to provide the Lothian NHS Board with an assurance statement;

This policy is in support of, and should be read in conjunction with, NHS Lothian Quality Improvement Strategy and NHS Lothian Health and Safety Policy. An operational procedure complements the policy and informs implementation by providing further detail of the standard methodology for incident management and specific processes for certain types of incident.

1.1 Definitions

The following terms are used to describe the types of incidents to be reported:

Incident
A broad term used to describe an unintended or unexpected event that led to, **or could have** led to, harm, including death, disability, injury, disease or suffering.

The incident can be described further depending on the consequence or potential consequence:

- **Significant Adverse Event**
  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, including suicides.

- **Adverse Event**
  An incident that led to actual harm for patients, public, staff or organisation, including: immediate or delayed emotional reactions, physical or psychological harm, financial loss (This includes all occurrences of theft, fraud, homophobic and sectarian verbal abuse incidents), contravention of Data Protection Act. This list is not exhaustive.

- **Near miss**
  An incident where a harmful outcome was avoided either by chance or by intervention.

A full glossary of terms used throughout this document is provided at Appendix 1.

1.2 National Context

Effective management of incidents, which includes promotion of a safety culture where individuals and teams are encouraged to report and can see the value of reporting through timely feedback, is a cornerstone to national policy in the NHS. A number of key publications support this policy, beginning with the Department of Health (2000) 'An Organisation with a Memory' and, most recently, NHS Quality Improvement Scotland (2006) 'Safe Today – Safer Tomorrow'. A list of references and useful resources is given in Appendix 2.

NHS Healthcare Improvement Scotland (HIS) has produced standards which came into effect in November 2005. These standards include key criteria relating to management of incidents as part of overall risk management. Every Health Board in NHS Scotland must work towards full compliance with the standards as part of the local delivery plan.

HIS also co-ordinates the Scottish Patient Safety Programme which builds on existing work carried out by the UK Safer Patients Initiative. The 2 key targets of the programme are:

- 15% reduction in mortality by December 2012
- 30% reduction in adverse events by December 2012

The law requires that certain types of incidents are reported to the Health and Safety Executive (HSE) under RIDDOR (Reporting of Injuries, Diseases and Dangerous Occurrences Regulations). Under the Corporate Manslaughter and Corporate Homicide Act (2007), organisations can be found guilty of corporate homicide as a result of serious management failures resulting in a gross breach of a duty of care. The accountable officer for controlled drugs needs to be informed of incidents relating to controlled drugs.

Consideration should be given to informing professional bodies e.g. the General Medical Council, Nursing and Midwifery Council and Health Professional Council.

Specific, and in some cases, statutory reporting requirements to external bodies, including the police, the Mental Welfare Commission, and Scottish Healthcare Supplies, also apply to a range of incidents. A list of the most relevant bodies is provided in Appendix 3.

1.3 Local policies and procedures

A number of NHS Lothian local joint policies and procedures will also have an impact on how an incident is handled. These include incidents involving Sudden Unexplained Death in Children, Child Protection, Adults at Risk and Drug-related Deaths.

Incidents involving drug-related deaths are covered by specific policies and local procedures which must be adhered to. The reporting and review of incidents concerning child protection and adults at risk are also included in this category. Arrangements for child protection incidents are detailed in the NHS Lothian Child Protection Procedures which recognises the particular nature, and importance, of a multi-agency approach to such occurrences. Arrangements for Adult Support and Protection can be found on the NHS Lothian Intranet.

2 STATEMENT OF INTENT

2.1 Aim

The aim of this policy is to ensure that all incidents are:

- Managed in partnership with patients, relatives, carers staff their staff side representatives and partnership representatives;
- Reported;
- Investigated;
- Learned from in such a way as will best support the control of risks to patients, staff, and others, and in accordance with national standards.

2.2 Objectives

A number of key objectives are identified as follows:

- To progress NHS Lothian's adverse events harm reduction target;
- To promote safety in an environment, both physical and cultural, which encourages reporting of incidents, including near misses, so that comprehensive information is available to facilitate learning and change;
- To be open and accountable to patients and the public;
- To facilitate local ownership of reporting systems by development and implementation of operational procedures and protocols;
- To ensure that clear procedures are in place to escalate information about relevant incidents without undue delay;
- To ensure active investigation and management in all services so that the greatest benefit is gained from incident reports;
- To assure every employee, their representative and members of the public , who reports an incident that it will be evaluated and reviewed within their service and that they will receive prompt feedback on any investigation;
- To provide support to staff who are involved in an incident;
- To monitor and review incident trends on a regular basis to maximise learning from low grade/high volume incidents;
- To establish clear systems and processes to promote the importance of learning and sharing the learning from incidents, including near misses;
- To provide intelligence on incidents and identify mechanisms for incident reduction through continuous quality improvement;
- To enable the organisation to comply with its legal duties in respect of incidents
- To promote effective communication with all patient groups in line with Patients Rights Legislation

2.3 Scope

This policy encompasses all incidents, including near misses and other occurrences, arising out of NHS Lothian business, whether on NHS Lothian premises or elsewhere. All permanent and temporary staff, including contractors, bank, NHS Lothian volunteers and agency staff, who work within or for NHS Lothian must comply with this policy.

3 RESPONSIBILITIES AND IMPLEMENTATION

3.1 Lead Director

The management of incidents and consequences needs to remain within the current line management structure to ensure the appropriate management and change. The Lead Director is defined as the Chief Operating Officer and CH(C)P General Managers in Primary Care and is responsible for Incident Management, including family liaison, and will be supported professionally by medical or nursing colleagues at local or board level as appropriate.

3.2 Individuals

- All staff should demonstrate an awareness of this policy and their responsibility to report incidents, including near misses;

- All staff have a duty of care to follow this policy and procedure to allow NHS Lothian to fulfil its legal obligations under the Health and Safety at Work etc. Act 1974 and the Reporting of Injuries, Diseases and Dangerous Occurrences Regulations (RIDDOR) 1995;

- NHS Lothian expects all staff to participate in incident investigations as required;

- All staff are required to undertake training as appropriate to their role on the content, implementation and management of this policy, procedures and local protocol. This will be covered at induction, through local orientation, and further training provided as appropriate with any amendments to policy or documentation;

3.3 Line Managers

All line managers are responsible for:

- Implementing the policy locally and ensuring that the correct procedure is followed. Where managers require further assistance, with these obligations, they should seek advice from the Health and Safety Department or Clinical Governance & Risk Management Team, or other appropriate person e.g. Facilities, Medical Physics etc. If the difficulties are of a managerial nature, the matter should be referred through normal line management channels;

- Identifying and investigating incidents reportable under RIDDOR which include dangerous occurrences and reporting these to the Health and Safety Executive;

- Ensuring that local procedures and protocols are in place to report all incidents and staff, (including locum agency and other supplementary staff groups) and contractors are aware of them;

- Ensuring appropriate level(s) of review and investigation are carried out and recorded and that partnership expertise is sought on the nature and extent of partnership involvement;

- Sharing lessons, providing feedback, considering recommendations for change and evaluating any changes;

- Evaluating risk identified through incident reporting and, if necessary, adding to risk assessments and the risk register;

- Demonstrating how learning from incidents and trends is being taken forward and implemented where appropriate.

The Quality Improvement Teams and local Health & Safety groups will support their management teams in these responsibilities.

3.4 Clinical Governance & Risk Management Team and Health & Safety Teams

The Clinical Governance & Risk Management Team is responsible for:

- Assisting managers in the investigation of incidents and provide expertise and support in reducing incidents and related harm;

- Facilitating the production of statistical information on incident trends and collating information relating to significant adverse events for deliberation and action planning by relevant groups and managers, including Healthcare Governance and Risk Management Committee/Groups, Health and Safety committees, Management and Quality Improvement Teams;

- Providing appropriate training for managers, staff and their representatives in relation to the requirements of this policy;

- Providing quality improvement advice and expertise to support the reduction in incidents, especially where a common trend has been identified in relation to multiple incidents.

Health & Safety are responsible for:

- Assisting managers in the investigation of incidents when requested by the relevant manager;

- Producing statistical information on staff and RIDDOR incident trends and collating information relating to significant adverse events for deliberation and action planning by relevant groups and managers, including Health & Safety Committees;

- Providing appropriate training for managers, staff and their representatives in relation to the requirements of this policy.

3.5 The Medical Director

The Medical Director is the executive with responsibility for the effectiveness of the incident management system. The Board of NHS Lothian will, through the Executive Management Team:

- Review incident statistics on a quarterly basis;

- Ensure follow up and investigation procedures are followed as appropriate and lessons that are learned are disseminated;

The Divisional Medical Director, University Hospital Division (UHD), in conjunction with the Divisional Nurse Director and the equivalent staff in the CHP/CH(C)Ps, will also carry out these roles at an operational level.

3.6 Caldicott Guardian and Information Governance

The Director for Public Health & Health Policy is the executive with responsibility for Information Governance and is the Board's Caldicott Guardian. The appointed Caldicott Guardian has responsibility for confidentiality guidelines with regard to patient identifiable information. Any incident that may involve issues surrounding confidentiality, information

security or access to further clinical information must be referred initially to the Guardian for advice. All employees of NHS Lothian are contractually responsible for confidentiality of information. Failure to comply with confidentiality guidelines may result in disciplinary action, which could include dismissal. All members of staff will be provided with the appropriate training and information on an ongoing basis.

3.7 Accountable Officer for Controlled Drugs (CDs)

All incidents involving CDs should be recorded and investigated. The Accountable Officer must be notified of the incident as soon as possible, without compromising the steps needed to ensure patient safety. The Accountable Officer must then be notified of the outcome of all incidents involving CDs, any learning points identified and the actions taken to prevent recurrence. Where there is suspicion of criminal activity, Lothian & Borders Police should be notified.

4 SUPPORT FOR STAFF

4.1 Support

It is recognised that the effect on staff resulting from an incident may have far-reaching consequences – partners, children and others may also be affected. Staff must therefore be treated as individuals so that support is provided in a meaningful way. 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) affected.

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

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

- Help with preparing statements; help with investigation, time out and ongoing day to day support;

- Collaborative debrief with in-house specialists, counselling, compassionate leave.

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

4.2 Open and Fair Culture

To promote an open and fair culture in NHS Lothian where staff feel able to report a patient safety incident without fear of reprimand, the investigation of an incident will focus on causes and system failures. Staff will not be reprimanded for such failures or their consequences. This, however, does not detract from individual accountability in accordance with professional codes that apply to both them and their professional practice.

All staff interviewed as part of an incident investigation must be made aware of these principles and of the fact that transcripts of any interviews and copies of any statements made by them as part of the investigation will be kept confidential. This may result in interviewees being interviewed/asked for statements more than once. Staff should be advised that the only exception is when it is required by the Police or under a court order.

Although the incident investigation is not in itself a disciplinary process, staff are entitled to request support from their trade union or professional organisation.

4.3 Training

All staff 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. Further training will be provided with any amendments to policy or documentation as necessary and at appropriate times.

The Clinical Governance & Risk Management Team provides training in Incident Investigation. This is available to all managers, partnership representatives and any member of staff who may be required to undertake investigations. It is recommended that all staff with management responsibility should attend as part of their training in health and safety and risk management.

An investigation team must have at least one member who has had training in Incident Investigation. This training must be commensurate with the level of investigation being undertaken (refer to section 6). For significant events the team leader should be experienced in incident investigation and a significant number of the team should have had incident training.

Health and Safety also provide training in incident investigation for managers, to meet both Health and Safety legislative and policy requirements.

5 INCIDENTS INVOLVING PATIENTS

5.1 Incidents involving Patients

Where an incident 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. Incidents must not be disclosed to the patient's next of kin, carer, GP, the media or other parties without the patient's consent. When consent is not possible (e.g. children, ventilated patients or vulnerable adults), discussion with a parent / carer or guardian may be appropriate. The manager or senior member of the clinical team should carry out this duty using advice from the Caldicott Guardian as appropriate

Information on any incident that may have a bearing on a patient's treatment should also be recorded in their health records. Individual rights must always be met regarding all aspects of communication

Senior Management, if appropriate, should inform the Complaints and Litigation teams about such incidents, in order for there to be joint working and support from an early stage.

Healthcare Associated Infection (HAI) Incidents

The HAI Incident Infection Tool (Watt Matrix) should be referred to along with the HAI reporting template, the Infection Control Policy and associated documentation in the Infection Control Manual as appropriate. All incidents should be reviewed against the appropriate tools and the report completed in accordance with the assessed outcome and timelines.

5.2 Being Open

When patients and relatives are affected by an incident, 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 guidance may be found in the publication: National Patient Safety Agency (2009) 'Being Open: Communicating Patient Safety Incidents with Patients and their Carers'.

When harm has occurred, the Clinical Director and/or the Chief Nurse of the relevant service should ensure that:

- The most appropriate staff to meet with the patient and/or relatives/carer are identified;
- A prior meeting between staff is held to establish facts and understand aims of meeting;
- A meeting with the patient and/or relatives/carer is held as soon after the incident as possible;
- The patient and/or relative is given information about how to make a complaint about the care or service they have received;
- Follow up in writing is made within 14 days and further opportunities to meet are offered. This may not be appropriate or required for minor harm**.**

6 SIGNIFICANT ADVERSE EVENTS

6.1 When a significant adverse event occurs, it must be managed appropriately. This includes:

- Appropriate immediate action to ensure the safety of people, equipment, premises and evidence where appropriate e.g. clinical records, equipment involved ensuring settings are not altered etc. Refer to Incident Management Operational Procedure for more detail;
- Considering need for an internal and/or external alert;
- Ensuring that details of the incident are communicated quickly and appropriately through line management (see algorithm - Appendix 4);
- Learning from significant adverse events so that generic learning outcomes can be shared;
- Ensuring appropriate support for staff (see section 4).

Examples of Significant Adverse Events are:

- Life threatening events
- Unexpected death (including suicide)
- Homicide on health service premises
- Unplanned ward/department/service closure
- Major outbreaks of infection
- Serious physical or verbal assault (including racial abuse)
- Serious injury or harm
- Near fatal acts of deliberate self-harm
- Events attracting undue/critical media attention
- Information Governance and related incidents
- Healthcare Associated Infection leading to major harm or death, and/or significant service disruption

Please note this list is not exhaustive.

Judgement is required in categorising an event as ‘significant’ and will be informed by use of the Grading matrix (see Appendix 5, Table 1).

6.2 Incident Investigation

All significant adverse events should have a comprehensive investigation (see Incident Management Procedure) carried out. However it is accepted that there could be exceptions to this and clinical judgement should be applied. These exceptions must be authorised by: (a) for UHD the Chief Operating Officer, the Divisional Medical Director or the Divisional Nurse Director, (b) in a CHP by the General Manager, Clinical Director or Chief Nurse. The lead director supported by senior nursing and medical colleagues may ask for an investigation to take place outside the service area. This includes the investigation of all suicides known to Mental Health Services within the last six months.

In certain circumstances the Medical Director or an Executive Director may also decide to commission an independent investigation. They will appoint the members of the investigation team and be responsible for ensuring the operational team are kept fully up to date with developments.

When a significant adverse event investigation is initiated within or outwith the service, a lead will be appointed and a review team convened. In agreeing membership of the team, consideration needs to be given to inclusion of members with appropriate objectivity to the event. A member of the team must be trained in incident investigation. A specialist pool of staff with advanced investigative skills will be available to advise investigation teams where this is required. Where appropriate, The Employee Director (or appointed deputy) will be contacted and the nature and extent of partnership/staff side involvement throughout the process will be agreed and actioned. This will be proportionate to the investigation.

6.3 Investigation Reports

All reports will use the standard NHS Lothian investigation templates, to ensure consistency in approach across NHS Lothian and be monitored to ensure completion of actions and effectiveness (see report templates and timescales set out in the Incident Management Procedure).

6.3.1 Approval of Investigation Reports

All investigation reports and improvement plans for significant adverse events must be formally signed off by the Lead Director, with final review by the Medical and Nursing Director. In addition to this, the report should also be submitted to the Clinical Governance and Risk Management Support Team, logged on Datix, as well as being shared locally as deemed appropriate. Datix is the NHS Lothian Incident Management online reporting process.

The Clinical Governance & Risk Management Team will quality-assure incident investigations by reviewing a random sample of reports and feed back findings and recommendations to appropriate areas/groups/committees.

The time spent on investigation should be commensurate and proportionate with the severity/potential severity of the event.

7 LEARNING FROM INCIDENTS

Many serious incidents have occurred because organisations have ignored the warning signs of previous incidents, or have failed to learn from the lessons of the past. Risk is inherent in health care delivery systems but resulting harm must be minimised. By learning from incidents the health service can reduce risk and minimise harm. Only a health service with an effective incident learning system can sustain a process of continuous improvement. Implementation of such a system will drive a cycle of continuous improvement which seeks to reduce incident severity to patients. The Institute of Health Improvement Model for Improvement should be used where appropriate to support this improvement plan.

This principle applies not only to information about incidents generated from incident management processes within Lothian, but also from external sources. In the same way as incidents are reported to external bodies as described in section 1.2 (also see Appendix 3),

information is shared both for action and learning in formats such as alerts, Safety Action Notices, National Patient Safety Agency (NPSA) alerts (via NHS HIS).

All staff must take responsibility for reporting incidents, assisting in identifying contributory factors and reviewing and acting upon relevant information from external sources, experience and lessons from incidents and near misses in order to drive change. The review of such information is a formal part of the process to be undertaken by every team and at all levels of management, working in partnership with staff and partnership representatives throughout the organisation. Operational managers are responsible, through management structures, for ensuring that the outcome of both internal and external incident reviews are shared widely and appropriately.

This will enhance opportunities:

- To provide information, including trends, to inform action planning;
- To identify the need for further attention by multi-disciplinary teams;
- For the formation of local learning groups, when appropriate;
- For sharing information which could be useful to others.

Unless it is essential, when reports are being produced for wide dissemination, every attempt must be made to remove any information which could lead to identification of either individual patients or staff.

8 MONITORING AND REVIEW

8.1 NHS Lothian Healthcare Governance and Risk Management Committee

The Healthcare Governance and Risk Management Committee will review all incident statistics 3-monthly, monitor trends and seek assurance that action has been taken. It will also ensure full liaison with staff side representation, professional groups and staff associations prior to and during the implementation of safety initiatives.

In addition the Clinical Governance & Risk Management Team, in conjunction with the Medical Director, will independently review a random sample of incident investigations, to ensure a consistent approach is being employed and good practice is being maintained. Where appropriate written feedback from the review will be given to local the teams involved in the investigations and to the HCGRM Committees. The data will also be used to measure our performance against the Incident Management Policy and Procedure and inform investigation training.

An annual report for the Healthcare Governance Risk Management Committee will be produced using the Key Performance Indicators (see Appendix 6), by the Clinical Governance & Risk Management Team in conjunction with the Medical Director and Nurse Director to deliver assurance of compliance with this policy and procedure. This report will also include compliance / performance data against hazard warning notices etc. issued over the financial year.

8.2 NHS Lothian Health & Safety Committee

The NHS Lothian Health & Safety Committee will take the lead in developing the general strategy for Health & Safety management, assisted by specialist advisors, reporting to Director of Occupational Health & Safety, and review reports and produce an annual report to Staff Governance. This committee will advise the Board about compliance with all statutory, local strategy/manual documentation.

8.3 UHD Clinical Management Teams/CHP Groups and Committees

Divisional/Primary & Community Services Healthcare Governance and Risk Management operational groups and Health and Safety Committees, will on a 3-monthly basis discuss the incident statistics and use these to inform organisational objective-setting and action plans. Healthcare Governance & Risk Management and Health & Safety Staff will support this work.

8.3.1 They will receive copies of all investigations for significant adverse events in their areas and monitor progress reports against investigation recommendations. Where appropriate they will also receive copies of other investigation reports which may be relevant to their area. They may elect to delegate this function to other specific groups who will report to them, such as Quality Improvement Teams. The Quality Improvement Teams will take forward improvement actions identified from incident investigations and share learning from these.

8.3.2 For non-clinical services, where alternative arrangements for Quality Improvement exist, this responsibility will be delivered through the appropriate existing management structures.

8.4 Internal audit

Managers are responsible for ensuring compliance with this policy. This will be supported by periodic independent audits by the internal auditors, as part of the NHS Lothian internal audit programme. They will also monitor compliance against recommendations in conjunction with the Clinical Governance & Risk Management Team and other local groups.

9 GOVERNANCE

NHS Lothian Healthcare Governance and Risk Management, Health and Safety and Staff Governance Committees have responsibility for providing assurance to the NHS Lothian Board that effective incident management is in place throughout the organisation, as part of the broader risk management processes.

CH(C)P/REAS/Divisional Management Teams (and Executive Directors in the case of single system services) are responsible, through their management structures, for assuring effectiveness of operational procedures within all relevant services, whether hosted or directly managed.

10 REVIEW OF POLICY

The policy will be updated by the Health & Safety and Risk Management Committees every 3 years. Changes may also be made by exception and through an annual review by any of the groups over oversight responsibility.

August 2011

GLOSSARY OF TERMS

Adverse event	An unintended or unexpected event that led to harm, including death, disability, injury, disease or suffering.
Consequence	Most predictable consequence to the individual or organisation if the circumstances in question were to occur.
CH(C)P	Community Health (and Care) Partnership
DATIX	An IT risk management information system. Comprises of a complex, modular, inter-relational database. Modules used in some parts of NHS Lothian are incident reporting, complaints, claims and risk register.
Escalation	The process of delegating upward, ultimately to the Board, responsibility for the management of a risk deemed to be impossible or impractical to manage locally.
Healthcare Governance	The system by which a healthcare organisation is directed and internally controlled to achieve objectives and meet the necessary standards of accountability, probity and openness in all three areas of clinical, corporate and staff governance.
Incident	An unintended or unexpected event that led to, or could have led to, harm including death, disability, injury, disease or suffering.
Likelihood	Probability of an event occurring, wherever possible based upon the frequency of previous occurrences.
Near Miss	An incident in which a harmful outcome was avoided, either by chance or by intervention.
Partnership	Staff side or other organisations
REAS	Royal Edinburgh Hospital and Associated Services
RIDDOR	Reporting of Injuries, Diseases and Dangerous Occurrences Regulations
Risk	The chance of something happening that will impact on the organisation's ability to achieve its objectives.
Risk Grade	The classification of risk expressed as a combination of its likelihood and severity of consequence.
Risk Management	Incorporates all the activities required to identify and control the exposure to risk which may have an impact on the achievement of an organisation's objectives.
Risk Register	A database of risks, always changing to reflect the dynamic nature of risks and their management. Its purpose is to help managers prioritise available resources to minimise risk to best effect and provide assurances that progress is being made.
Significant Adverse event	A significant adverse event 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.
System Failure	The most likely cause of an adverse event. Typically due to a flaw in the design or operation of a system of work rather than an individual's actions or inaction.

REFERENCES AND RESOURCES

Department of Health (2000), *An organisation with a memory: Report of an expert group on learning from adverse events in the NHS chaired by the Chief Medical Officer,* London, The Stationary Office

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NHS Quality Improvement Scotland (NHS QIS) Standards for Clinical Governance and Risk Management (November 2005)

A guide to the Reporting of Injuries, Diseases and Dangerous Occurrences Regulations (RIDDOR) 1995
http://intranet.lothian.scot.nhs.uk/NHSLothian/Corporate/A-Z/OccupationalHealthAndSafety/HealthAndSafety/health%20and%20safety/Documents/RIDDOR%20guide%20200908061416515836572 6.pdf

National Patient Safety Agency *Incident Decision Tree*
http://www.nrls.npsa.nhs.uk/resources/?EntryId45=59900

National Patient Safety Agency (2009) 'being open: communicating patient safety incidents with patients and their carers'
http://www.nrls.npsa.nhs.uk/resources/?entryid45=65077

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Dineen, M D, (2002), *Six steps to root cause analysis*, Oxford: Consequence

Mayatt, V L, (ed) (2002,) *Managing Risk in healthcare law and practic*e, Butterworths Tolley

NHS Lothian Complaints Policy 2010:
http://intranet.lothian.scot.nhs.uk/NHSLothian/Healthcare/ClinicalGuidance/General/Complaints%20Policy.pdf

NHS Lothian Safe Use of Medicines Policy & Procedures, December 2009
http://intranet.lothian.scot.nhs.uk/NHSLothian/Healthcare/ClinicalGuidance/General/Medicines%20Policy%20and%20procedures%20-%20December%202009.pdf

Hospital Infection Incident Assessment (HIAA) Tool, Health Protection Scotland:
http://www.documents.hps.scot.nhs.uk/hai/infection-control/toolkits/hiiat-2009-12.pdf

IHI Health Improvement Model:
http://www.institute.nhs.uk/

REPORTING BODIES

External bodies and organisations who may need to be informed of specific incidents

Health Protection Scotland e.g. Specific Communicable Disease Outbreak

National Services Scotland (NSS) includes Central Legal Office, Counter Fraud Services e.g. serious fraud and theft

Food Standards Agency e.g. Breaches of food law associated with an incident

Health and Safety Executive (HSE) – RIDDOR (Reporting of Injuries, Diseases and Dangerous Occurrences. Website: http://www.hse.gov.uk/riddor/

NHS Quality Improvement Scotland (who act on behalf of the Mental Welfare Commission) e.g. suicide

Police e.g. criminal law offences, theft/fraud

Procurator Fiscal e.g. sudden deaths, deaths relating to neglect or complaint, certain deaths associated with medical or dental care

Regulatory bodies (refer to NHS Lothian employment policies)

Scottish Healthcare Supplies (SHS) e.g. incidents involving medical device s or equipment

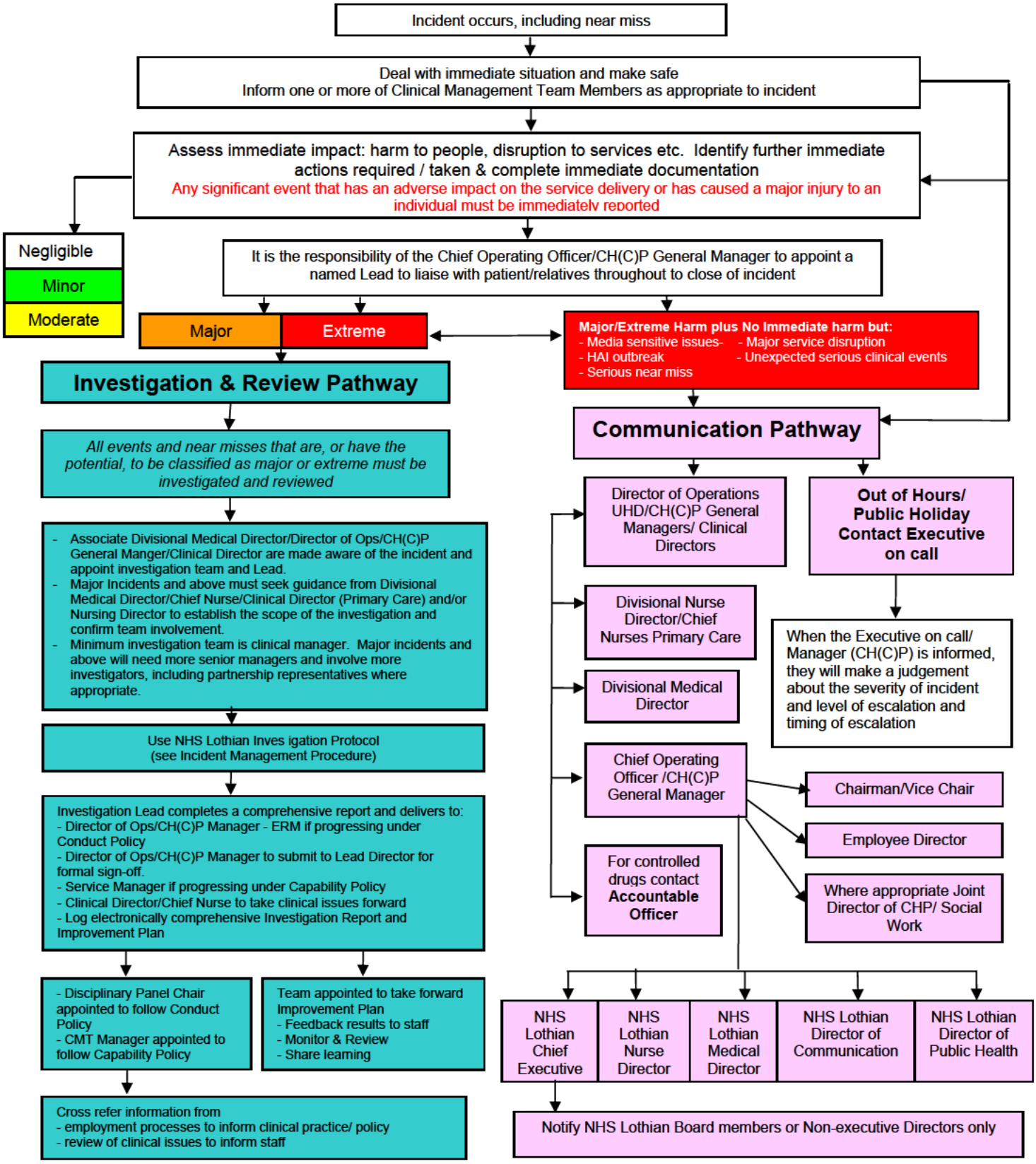
Serious Hazards of Transfusion (SHOT) e.g. adverse event such as wrong blood transfused, acute transfusion reaction

Scottish Environmental Protection Agency (SEPA) e.g. major spillages, leakages, exposures

This list is not exhaustive, but are those most commonly considered

Appendix 4

OPERATIONAL PROCEDURE FOR INVESTIGATION & COMMUNICATION OF ADVERSE EVENT OR INCIDENT



Director of Operations to consider informing / escalating to:

- University Deanery if involves Junior Doctor
- Central Legal Office
- Environmental Health
- Food Standards Agency
- Health & Safety Executive – Reporting of Injuries, Diseases and Dangerous Occurrences
- NHS Quality Improvement Scotland
- Police
- Procurator Fiscal
- Scottish Centre for Infection & Environmental Health (SCIEH)
- Scot ish Healthcare Supplies (SHS)
- Serious Hazards of Transfusion (SHOT)
- Scot ish Environmental Protection Agency (SEPA)

GRADING MATRIX

Table 1 – Impact/Consequence Definitions

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

Table 2 – Likelihood Definitions

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

Table 3 Risk Matrix

Likelihood	Consequences / Impact				
	Negligible	Minor	Moderate	Major	Extreme
Almost Certain	**Medium**	**High**	**High**	**V High**	**V High**
Likely	**Medium**	**Medium**	**High**	**High**	**V High**
Possible	**Low**	**Medium**	**Medium**	**High**	**High**
Unlikely	**Low**	**Medium**	**Medium**	**Medium**	**High**
Rare	**Low**	**Low**	**Low**	**Medium**	**Medium**

Grading Matrix - AS/NZS 4360:2005

Appendix 6

Table 1 – Incident Management Key Performance Indicators

KPI 1	The Risk Management Team submits incident reports to Healthcare Governance and Risk Management Committees/Groups 4 times per annum for review and action. Compliance Target 100%
KPI 2	Number of all incidents clinical/non-clinical with major harm or death/very high and/or graded as very high or high risk (red and orange), an investigation is **commenced** within 12 working days of being reported, expressed as a percentage of total incidents with major harm or death - Compliance target 100%
KPI 3	Number of all incidents clinical/non-clinical with major harm or death and/or graded as very high or high risk (red/ orange), have been fully closed within 60 working days of being reported and recorded on Datix - Compliance Target 100%
KPI 4	The number of incidents in which severity is moderate and/or graded as medium or low risk with a risk grading of moderate (yellow) a local investigation has been commenced within 12 working days of being reported, expressed as a percentage of total incidents with major harm or death – Compliance target 100%
KPI 5	The number of incidents in which severity is moderate and/or graded as medium or low risk with a risk grading of moderate (yellow) fully closed within 28 working days of being reported, expressed as a percentage of total of incidents reported as moderate - Compliance target 100%
KPI 6	Number of incidents graded as no harm or minor injury and/or is graded as low risk (green) approved within 10 working days of being reported, expressed as a percentage of total of incidents reported as low - Compliance 100%
KPI 7	The number of incidents graded as no harm or minor injury and/or is graded as low risk (green) fully closed within 20 days of being reported, expressed as a percentage of total of incidents reported as low - Compliance target 100%