University Hospitals Birmingham
NHS Foundation Trust

CONTROLLED DOCUMENT

Policy for the Reporting and Management of Incidents Including Serious Incidents

CATEGORY:	Policy
CLASSIFICATION:	Governance
PURPOSE	To set out the principles and framework for incident reporting and management (including investigation, Duty of Candour and learning).
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Will this Controlled Document impact upon any contracts held by the Trust?	☐ Yes[1] ☐ No
Approved By:	Board of Directors
On:	March 2020
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Distribution: • **Essential Reading for:** • **Information for:**	All Trust Staff in a permanent, temporary, voluntary or contractor role acting for or on behalf of the Trust.

[1] If this Controlled Document will have an impact on any contracts held by the Trust, once approved, this will need to be sent to the Procurement Team requesting that it be added to the Procurement Policy Portal

Contents

1. Policy Statement

1.1 University Hospitals Birmingham NHS Foundation Trust (the 'Trust') is committed to minimising risks to everyone who uses or works within its services.

1.2 The Trust must ensure robust systems are in place to recognise, report, investigate incidents and to improve the quality of care to patients and the safety of staff and members of the public, through the consistent monitoring and review of incidents.

1.3 The investigation of an incident forms part of a wider strategy for risk management, and advocates the use of Root Cause Analysis (RCA) as a systems-based investigation process that explores the problem (what?) the contributing factors to such problems (how?), and the root cause(s)/fundamental issues (why?). Understanding these factors allows lessons to be learnt and actions to be developed to minimise the risk of recurrence and improve safety.

1.4 Organisational learning and remedial action must be at the heart of any risk management approach and the reporting of all incidents is a key factor in enabling this.

1.5 Staff have a right, and a duty, to raise with their employer any matters of concern they may have about health service issues associated with the organisation and delivery of care. Therefore, the Trust requires all employees to comply with this policy and any associated procedures. See section 7 for a list of associated procedures.

2. Scope

2.1 This Policy applies to all individuals employed by the Trust, including contractors, volunteers, students, locum, bank and agency staff and staff employed on honorary contracts.

2.2 It applies to all incident types, including near misses, encompassing patient clinical, health and safety, facilities, security (including information security), Human Tissue Authority (HTA), Information and Communications Technology (ICT), information governance, radiation, and violence, including verbal abuse including sexist, racist and homophobic abuse and harassment.

2.3 For definitions of terms referred to in this policy, please see Appendix A.

2.4 If staff wish to raise concerns about the Trust in the public interest, they should refer to the Trust Policy and Procedure for Raising Concerns in the Public Interest (Whistle Blowing). These documents can be found on the Trust intranet site for guidance. For further advice in these

circumstances contact the Human Resources Department and/or the Freedom to Speak Up Guardian.

2.5 This policy excludes the management of “major incidents” which are subject to the Major Incident policy.

3. Framework

3.1 Policy framework

This policy describes the Trust’s approach to incident recognition, reporting and management (management includes immediate actions, external reporting, investigation, and learning) with the following elements:

3.1.1 It defines the types of incidents that may occur and clarifies the process of reporting and classification of incident type and severity (level of harm).

3.1.2 It defines the levels and process of investigation required for incidents according to their severity, complexity and potential for learning.

3.1.3 It outlines the follow up of projects and quality improvement activities arising from investigation of incidents.

3.1.4 This section describes the framework for the reporting and management of incidents including Serious Incidents (SI). Operational instructions are detailed in the Procedure for the Reporting Management of Incidents including Serious Incidents.

3.2 <u>Immediate Action Following an Incident</u>

3.2.1 When an incident occurs, the first actions should be to:

a) make the situation safe;

b) ensure that all practical and reasonable steps are taken to reduce risk and prevent re-occurrence;

c) preserve the scene together with equipment or other items that may be used as evidence in an investigation; and

d) ensure the appropriate senior clinicians/managers is informed, as soon as possible.

3.3 <u>Incident Reporting</u>

3.3.1 The Trust requires all clinical and non-clinical incidents, including near misses, to be formally reported. When an incident occurs, an incident report must be completed as soon as possible usually by the end of their shift in line with the Procedure for the Reporting and Management of Incidents Including Serious Incidents.

3.3.2 In addition, where an incident may have contributed to death or serious injury the staff member's manager/supervisor and the Clinical Governance and Patient Safety team must be notified at the earliest opportunity.

3.3.3 Safety concerns arising from complaints, mortality alerts and mortality and morbidity reviews (including by Medical Examiners) are to be reported as an incident and managed in line with this policy.

3.4 Initial incident Review

3.4.1 Within seven days of the incident being reported the person who has been identified as the 'Incident Handler' in Datix (see Appendix A - Definitions) will review the incident and document any immediate actions taken and provide initial feedback to the person who reported the incident.

3.4.2 The Clinical Governance and Patient Safety team will review all incidents reported the following working day to:

a) Categorise the incident according to the incident details; and
b) Review, according to the type and severity of the incident, the required level of investigation in accordance with section 3.5

3.5 Incident Investigation

3.5.1 Level of investigation

The nature, severity and complexity of incidents vary on a case-by-case basis and therefore the level of response should be dependent on and proportionate to the circumstances of each specific incident. The level of investigation may need to be reviewed and changed as new information or evidence emerges as part of the investigation process.

In accordance with the national SI Framework, there are three recognised levels of systems-based investigation. These are described in the table below.

Type of	Description

Investigation	
Local investigation	Suited to all investigations not requiring complex investigation (RCA) such as near miss, no harm, and low harm incidents.
Level 1 **Level 1 – Divisional & Executive RCA** **Concise SI Internal Investigation**	Suited to incidents which can be investigated by individuals within the Divisions. These will have Divisional (Divisional RCA) or Executive (Exec RCA) oversight. Suited to less complex incidents which can be managed by individuals or a small group at a local level. • Serious Incidents involving: o Grade 3 and 4 hospital acquired pressure ulcers, o Falls, o Hospital Acquired Thrombosis (HAT) and o Trust acquired infections.
Level 2 **Comprehensive Internal Investigation:** **Serious Incidents (SIs) and** **Internal Serious Incidents (ISIs)**	Suited to complex issues this includes: • Never events (in line with the Never Events National Framework); • Incidents resulting in severe or catastrophic harm as per NHS England's Serious Incident Framework (SIs); • All incidents which raise a serious concern but may not have resulted in severe harm and are not a systemic failing (ISIs). These are not reported to the CCG. 'Near Misses' may be investigated as an SI in accordance with the national Serious Incident Framework.
Level 3 **Independent External Investigation**	Required where the integrity of the investigation is likely to be challenged or where it will be difficult for an organisation to conduct an objective investigation. Independent investigations carried out by an individual external to the Trust and Commissioned by the Medical Director on a case-by-case basis. This category includes investigations conducted by the Healthcare Safety Investigation Branch (HSIB). The Trust can refer via the National Investigations Programme, and, all cases that meet the Each Baby Counts definition are referred to HSIB.

3.5.2 Timeframe for investigation

a) Local investigations - all incidents which do not require a Root Cause Analysis (as described in the above table) should be investigated within 28 calendar days.

b) Level 1 investigations should be completed within 40 working days (note 7 day Post Infection Review required for IPC incidents) and reported to the CCG within 60 working days.

c) Level 2 investigations should be completed and reported to the CCG within 60 working days. ISIs are to be completed within 60 days but are not reported to the CCG

d) There is no specified timeframe for Level 3 investigations and this should be agreed within the terms or reference of the investigation.

3.6 Being Open and Duty of Candour

3.6.1 Staff should adopt the principles of being open in an honest and timely fashion, with clear communication. Staff must adhere to the Duty of Candour Policy and Procedure and refer to the website for more information or speak to the Clinical Governance and Patient Safety Team.

3.6.2 Patients and relatives are to be asked if they have any questions they would like answered in the investigation as part of Duty of Candour

3.6.3 Certain investigations (eg Level 2 Serious Incidents) warrant an increased involvement of patients and families. In these cases they are to be offered the chance to play an active part in the investigation

3.7 Supporting Staff

3.7.1 The line manager is responsible for the assessing and provding the support required to ensure the safety and wellbeing of staff, including referring on to other processes.

3.7.2 This could be in the form of a 1:1 discussion, a debrief session or referral to Occupational Health.

3.7.3 Staff Support Services offer one-to-one counselling and long-term support. This service is independent of the management structure and is completely confidential.

3.8 Reporting to External Agencies

3.8.1 Where an incident is required to be reported to an external agency this will be done in accordance with Section 5 of the Procedure for reporting and Management of Incidents including SIs.

3.9 Incidents Involving other Organisations

3.9.1 Where an incident is linked to care or services where elements of that care or service are shared with other organisations, the Clinical Governance and Patient Safety team must contact the other organisation with details of the incident.

3.9.2 Conversely, if another organisation notifies any member of staff of an incident in their organisation involving elements of care or service at the Trust, the Clinical Governance and Patient Safety team must be notified and the incident reported and managed through Datix in accordance with this policy.

3.9.3 When the care provided is shared between organisations, it may be appropriate to arrange a joint investigation of the incident, particularly if there has been joint involvement in an SI and escalation to the commissioners. It can also be of benefit to jointly review other cases of shared care, for example those relating to patients with rare conditions, or cases that result in a serious outcome for the patient, but which do not fall into an SI category; to provide an opportunity for learning lessons and improving cross organisation pathways.

3.9.4 In such instances, an appropriate member of the Clinical Governance and Patient Safety Team, in discussion with the Medical Director (Level 2 SIs)/Chief Nurse (Level 1 SIs), will liaise with the relevant organisation to:

a) agree which organisation will lead the investigation/review;

b) ensure the appropriate stakeholders from each organisation are invited to contribute towards and attend the investigation/review meeting;

c) ensure each organisation has had input into the report and is involved in the sign off of the final report and associated action plan; and

d) monitor the implementation of action plan.

3.10 Learning from Incidents/Risk Reduction

3.10.1 It is important that there is learning from incidents and, where appropriate, that this learning is disseminated across the Trust.

3.10.2 Following the investigation of an incident, actions should be agreed by the Division to reduce the likelihood of recurrence of incidents.

3.10.3 Implementation of actions identified will be monitored by the responsible Division and Speciality with support from the Clinical Governance and Patient Safety team.

3.10.4 In line with the Duty of Candour Policy & Procedure, investigation findings and actions will be shared with patients and relatives and staff as appropriate.

3.10.5 Incidents will be analysed to identify quantitative and qualitative trends. The associated procedural documents provide further detail in relation to learning from incidents and aggregated reporting of complaints, incidents and claims.

3.10.6 Where a high risk theme or trend is identified that requires extensive support and/or a trust wide response, a quality improvement project may be initiated with a reporting line to the appropriate director.

3.10.7 Where relevant, risks highlighted via the Incident Reporting System (Datix) and from investigations will be added to the appropriate Risk Register in accordance with the Management of Risk Policy & Procedure.

3.11 External Reporting

3.11.1 Regular uploads to the National Reporting and Learning System (NRLS) are conducted regularly, at a minimum monthly. This enables NHSI and CQC visibility of incidents reported.

3.11.2 Serious Incidents are reported to CCGs and NHS England via STEIS in accordance with the National Serious Incident Framework.

3.12 Training

3.12.1 The Clinical Governance & Patient Safety Team will ensure provision of training as required by Directors, Managers, Supervisors, and any other staff groups to enable them to carry out their duties and responsibilities relating to incident report management and investigation. As a minimum this will include:

a) Incident reporting training;

b) Incident management and investigation training;

c) Search and data reporting tools;

d) One to one support and guidance as required for SI/RCA investigation processes.

4. Duties

4.1 Chief Executive

The Chief Executive is the accountable officer with overall responsibility for risk management. As such, the Chief Executive must receive assurance from the systems and processes for risk management and ensure these meet statutory requirements and the requirements of regulators.

4.2 Director of Corporate Affairs

The Director of Corporate Affairs is responsible for:

4.2.1 Overseeing compliance with this policy and providing assurance to the Board of Directors on compliance with this Policy; and

4.2.2 Approving all related procedures.

4.3 Executive Directors

The Executive Directors are responsible for:

4.3.1 Ensuring that all staff adhere to the Trust Incident reporting procedures; and

4.3.2 Ensuring that appropriate preventative action has been taken in all cases.

The Chief Nurse and Medical Director have specific responsibility for:

4.3.3 Approving the level of investigation required for an incident (via the Clinical and Professional Review of Incidents Group of which the Medical Director is Chair);

4.3.4 Approving the reporting of SIs to the relevant external agencies as appropriate; and

4.3.5 Approving the investigation reports (L1 SIs via NIQAM, L2 SIs and ISIs via CaPRI meeting)

4.3.6 providing a quality assurance of all externally reported investigation reports prior to Executive Director approval

4.4 Senior Information Risk Owner (SIRO)

The SIRO has a particular role to ensure that identified information security incidents are investigated and acted upon. The SIRO will be supported by the Information Governance Lead.

4.5 Director for Infection Prevention and Control

The Director for Infection Prevention and Control must ensure the Consultant in Communicable Disease Control (CCDC) and the Health Protection Agency (HPA) are informed of any reportable infection control incidents.

4.6 Chief Pharmacist

The Chief Pharmacist, supported by the Medication Safety Officer (MSO), is responsible for ensuring:

4.6.1 A review of all 'medication incidents' in Datix is undertaken on a monthly basis;

4.6.2 Relevant actions are put in place following the reporting of medication incidents; and

4.6.3 Appropriate incidents are reported to the Medicines and Healthcare Products Regulator Authority (MHRA).

4.7 Divisional Management Teams

The Divisional Management Teams are responsible for:

4.7.1 Ensuring that incidents which may require further investigation in line with the Procedure for the Reporting and Management of Incidents Including Serious Incidents are reported via a Trust incident report form, assisting in the identification of the staff involved in a Serious Incident;

4.7.2 Ensuring that the identified staff involved in an investigation participate with the investigation team and if requested, submit a statement and are available to attend any appropriate incident interview or roundtable;

4.7.3 Supporting the initial investigation case assessment/ to identify the level of investigation required;

4.7.4 Ensuring that the principles of 'Being Open' are adhered to and where required all aspects of the duty of candour requirements are adhered to (this may include attending meetings with the

patient and or relatives to feedback the outcome of an investigation);

4.7.5 Attending IQAM and NIQAM to review the draft investigation report with the group members and Investigation Officer and to agree the action plan in response to any recommendations; and

4.7.6 Ensuring that the agreed action plan is implemented and provide the Clinical Governance and Patient Safety team with assurance of the implementation of actions.

4.8 **Clinical Service Leads, Matrons, Operations Managers**

These staff must ensure:

4.8.1 Ensure arrangements are in place at a ward or departmental level to enable appropriate and timely incident identification, reporting, management and investigation for all areas within their responsibility;

4.8.2 Ensure that a Datix incident report is completed;

4.8.3 Undertake an investigation into incidents utilising RCA and obtain witness statements in line with this procedure;

4.8.4 Produce a quality improvement plan outlining the required actions to be implemented to ensure lessons are learned;

4.8.5 Ensure investigation documents and quality improvement plan and any correspondence with the patient/family is recorded on Datix;

4.8.6 Feedback the outcome of investigations to directorate staff as appropriate;

4.8.7 Ensure that staff receive appropriate support;

4.8.8 Ensure that the patients, relatives or carers are informed about the incident in a timely manner in accordance with the Trust's Duty of Candour Policy and document this discussion on Datix; and

4.8.9 Monitor progress against action plans produced as a result of incident investigations.

4.9 **Ward/Department Manager**

The Ward/Department Manager must ensure that:

4.9.1 Review of all online incident report forms within the timescales specified in the policy for the reporting and management of incidents including serious incidents and take appropriate remedial action, where possible, to prevent a future occurrence;

4.9.2 Oversee the management of incidents reported within the ward /department, liaising with other disciplines / departments as required to ensure full, appropriate and timely response to all incidents;

4.9.3 Immediately inform a member of the speciality or divisional management team and staff from other departments who need to be aware of any incident believed to be serious;

4.9.4 Ensure compliance with the Trust's Duty of Candour policy;

4.9.5 Document remedial action on the incident report to complete the approval process and provide feedback where appropriate to the incident reporter;

4.9.6 Reviewing and acting upon incident analysis themes and key learning points;

4.9.7 Ensure appropriate feedback is given regarding the investigation outcome/preventive actions to staff; and

4.9.8 Ensure that staff are provided with appropriate support.

4.10 Information Governance Lead

The Information Governance Lead must ensure that:

4.10.1 Relevant actions are taken following the reporting of information governance incidents; and

4.10.2 Information governance/data protection incidents are investigated and reported in line with the guidance issued by the Health and Social Care Information Centre (HSCIC) for dealing with information incidents.

4.11 Clinical Governance and Patient Safety team

Members of the Clinical Governance and Patient Safety Team must:

4.11.1 Undertake quality checks on all reported incidents through the Datix system;

4.11.2 Identify incidents which may require further investigation in line with the Procedure for the Reporting and Management of Incidents Including Serious Incidents;

4.11.3 Analyse incidents and associated investigations to identify trends and report these to the appropriate Group within the Trust.

4.11.4 Manage the investigation process by:

a) Reporting to the CCG and ensuring other external agencies are notified as required;

b) Informing patients, families and carers that a level 2 investigation has been commissioned and involve the patient/family as appropriate;

c) Ensuring the Divisional Management Teams develop action plans following a SI and ISI investigation and monitor completion of the actions through the action plan module in Datix;

d) Overseeing and facilitating compliance with the Duty of Candour Policy and Procedure; and

e) Monitoring compliance with the Policy.

4.12 **Health and Safety Team**

Members of the Health and Safety Team must:

4.12.1 Monitor health and safety incidents including support for handlers and the recording of recommendations using the Trust incident reporting database (Datix);

4.12.2 Analyse Trust incident data to identify Trust trends;

4.12.3 Provide quarterly incident reports to the Trust Health, Safety and Environment Committee and its sub committees;

4.12.4 Identify health and safety incidents which require further investigation;

4.12.5 Provide expert support and assistance to the investigation of health and safety incidents;

4.12.6 Provide expert advice to management on appropriate action following an incident;

4.12.7 Analyse incidents, associated investigations and appropriate follow ups within individual departments as part of the health and safety audit programme; and

4.12.8 Having received approval from the Director of Corporate Affairs, complete external reports as appropriate e.g. to the Health and Safety Executive (HSE), insurers and lawyers. This includes incidents that are reportable under the **'Reporting of Injuries, Diseases and Dangerous Occurrences Regulations 1995'** (RIDDOR).

4.13 Radiation Protection Advisor

The Radiation Protection Advisor must:

4.13.1 Advise on the radiological impact of incidents with respect to dose and risk; and

4.13.2 Advise the departmental/service manager whether the incident needs to be reported to an external organisation. (The Manager will then ensure that the Group Manager, Divisional Director of Operations, and Chief Operating Officer are aware of any notification about to take place).

4.13.3 Escalate incidents requiring further investigation in line with this policy to the Head of Clinical Governance and Patient Safety and report to IRMER/CQC.

4.14 Medical Devices Manager

The Medical Devices Manager must:

4.14.1 Report to the Medicines and Healthcare Products Regulator Authority (MHRA) any incidents related to a medical device or piece of equipment, including disposables, which fails and which compromises patient care;

4.14.2 Ensure that failed Medical Devices are examined and impounded if necessary; and

4.14.3 Ensure any follow up actions from reported medical device incidents are documented on the incident reporting database.

4.15 Local Security Management Specialists

The Local Security Management Specialist must ensure:

4.15.1 Relevant actions are taken following the reporting of security incidents; and

4.15.2 Violence/aggression and security incidents are reported to external agencies as required.

4.16 **Designated Individual for the Post-Mortem Licence Issued by the Human Tissue Authority**

The Designated Individual for the Post-Mortem Licence issued by the Human Tissue Authority must:

4.16.1 Ensure all incidents related to storage and release of bodies, and organs and tissue removed from body post-mortem are reported and investigated;

4.16.2 Ensure SI incidents are reported to the Human Tissue Authority; and

4.16.3 Ensure relevant actions are put in place following the investigation of incidents related to storage and release of bodies, and organs and tissue removed from body post-mortem.

4.17 **Designated Individual (DI) and Persons Designated (PDs) for the Human Application Licence issued by the Human Tissue Authority**

4.17.1 These personnel that are named on the licence are responsible for reporting all suspected incidents to the Human Tissue Authority within 24 hours of discovery.

4.17.2 QEHB is a licensed tissue establishment and has an obligation in law to report all incidents which are linked to the procurement, testing, storage and distribution of tissues and cells that occur within the licensed establishment, associated end user establishments and third parties

4.18 **Hospital Transfusion Team/Transfusion Practitioners**

The Hospital Transfusion Team are responsible for:

4.18.1 Reviewing incidents relating to blood transfusion, including reactions and adverse events

4.18.2 Reporting to Serious Hazards of Transfusion (SHOT) or Serious Adverse Blood Reactions or Events (SABRE) as required

4.19 **Head of Midwifery**

The Head of Midwifery is responsible for reporting Maternity related incidents to Healthcare Safety Investigation Branch (HSIB) and Each Baby Counts as per their reporting criteria.

4.20 **Incident Handlers**

Incident Handlers are responsible for:

4.20.1 Reviewing all incidents reported for their area and completing the handler section (including feedback to staff) of the incident report form within 7 days of the incident being reported;

4.20.2 Providing feedback to the individual who reported the incident on any relevant action taken;

4.20.3 If appropriate, informing the relevant Departmental Manager, Matron or Divisional Management Team;

4.20.4 Adhering to the Duty of Candour Policy and Procedure;

4.20.5 Taking action to prevent recurrence where required and documenting this on the incident report form;

4.20.6

4.20.7 Documenting the investigation and action outcome and close the incident within the timeframes outlined in section 3.5.2

4.20.8 Ensure appropriate feedback is given regarding the investigation outcome/preventive actions to staff; and

4.20.9 Supporting staff in accordance with Section 3.7.

4.21 **Consultant Medical Staff**

4.21.1 Consultant medical staff are responsible for ensuring incidents are reported, including providing support for trainee and locum doctors to report incidents

4.21.2 Consultants are expected to perform the handler role (as per 4.20) and take a lead in their team for the reporting and investigation of incidents, and participate actively in any investigation as required

4.22 **All Staff**

All staff must:

4.22.1 Comply with the Policy and all related procedures;

4.22.2 Take all practical and reasonable steps to prevent re-occurrence of the incident and ensure the area is safe;

4.22.3 Report incidents in accordance with the Procedure for the Reporting and Management of Incidents Including Serious Incidents;

4.22.4 Where applicable, cooperate with any incident investigation and provide any information requested in a timely manner; and

4.22.5 Attend any risk training deemed necessary for their role.

5. Implementation and Monitoring

5.1 The Policy and the associated procedural documents will be available on the Trust intranet.

5.2 Education will be made available as outlined within the associated procedural documents.

5.3 Appendix C provides full details on how the policy will be monitored by the Trust.

5.4 The associated procedural documents provide further details of implementation and monitoring.

6. References

National SI Framework 2015

Never Event Framework 2018

Duty of candour - Health and Social Care Act 2008 (Regulated Activities) Regulations 2014: Regulation 20.

Organisation with a memory, Department of Health (2000)

National Framework for Reporting and Learning from Serious Incidents Requiring Investigation NPSA (2010)

Steps to Patient Safety, NPSA (2004)

Human Application Standards, Human Tissue (Quality and Safety for Human Application) Regulations 2007 (as amended)

The Healthcare Safety Investigation Branch (HSIB) Trust Introduction Pack (2019)

7. Associated Policy and Procedural Documentation

Duty of Candour (Being Open) Policy & Procedure

Claims Handling Policy & Procedure

Patient Relations Policy & Procedure

Reviewing Inpatient Death Policy & Procedure

Inoculation Injury Management Including Sharps and Splashes with Body Fluids Procedure

Information Security and Access Policy

Manual Handling Procedure

Medical Devices Policy and Procedure

Procedure for the Prevention, Reduction and Management of Slips, Trips and Falls Including Work at Height

Policy and Procedure for Raising Concerns in the Public Interest (Whistle blowing)

Procedure for the Reporting and Management of Incidents including Serious Incidents

Radiation Safety Policy

Security Policy and Procedures

Appendix A: Definitions

Incident	An unplanned or unexpected event that may or may not lead to injury, damage or loss to an individual or the Trust.
Near Miss	An unplanned or unexpected event that had the potential to lead to injury, damage or loss to an individual or the Trust, but was prevented.
Assault	The intentional application of force against the person of another without lawful justification, resulting in physical injury or personal discomfort
Verbal aggression	The use of inappropriate words or behaviour causing distress and/or constituting harassment
Hazard	Any thing or process that could cause injury, harm or loss to patients, staff, visitors, or the structure/financial integrity of the organisation.
Patient Safety Incident	Any unintended or unexpected incident(s) that could have or did lead to harm for one or more persons receiving NHS-funded healthcare.
Harm	Harm is defined using the NRLS definitions as per Appendix B
Serious Incident	In broad terms, serious incidents are events in health care where the potential for learning is so great, or the consequences to patients, families and carers, staff or organisations are so significant, that they warrant using additional resources to mount a comprehensive response. There is no definitive list of events/incidents that constitute a serious incident. See the SI Framework for more information and definitions.
Incident Handler	The individual who is responsible for ensuring the appropriate management and investigation of an incident in line with this policy.

Appendix B – NRLS definition of level of harm

- **Low**

Any unexpected or unintended incident that required extra observation or minor treatment and caused minimal harm to one or more persons.

Examples

Perforation of the bowel during surgery,that was repaired at the time and the area was appropriately washed out. Only antibiotic treatment is required.

A patient is given someone else's medication. The medication is the same as they normally take, but at a slightly higher dose, and they need to go to bed earlier due to drowsiness.

Continuing treatment with warfarin without monitoring clotting levels, which results in prolonged clotting times, and in turn causes bruising.

An ambulance crew are called to a patient at home with chest pain. On arrival they decide to administer oxygen, and are then told the patient has had a laryngectomy. There are no laryngectomy masks on the vehicle so the crew have to attempt to oxygenate the patient using a face mask over the stoma. On arrival in A&E the patient's oxygen saturation levels have dropped from 92% to 85%.

Blood is given to the wrong patient and causes a minor rash and temporary rise in temperature.

- **Moderate**

Any unexpected or unintended incident that resulted in further treatment, possible surgical intervention, cancelling of treatment, or transfer to another area, and which caused short-term harm to one or more persons.

Examples

Perforation of the bowel during surgery was not picked up at the time. It results in septicaemia and a return to theatre for repair.

A patient is given someone else's medication. The medication is stronger than their own and they suffer prolonged drowsiness for a week. The patient needs frequent observation of their respiratory rate.

Continuing treatment with warfarin without monitoring clotting levels, which results in an overdose and bleeding problems.

An ambulance crew are conveying a patient from the ambulance to A&E on a trolley bed. The patient is left unattended for a short period and the trolley bed tips over. The patient suffers short-term loss of consciousness and needs to be admitted to hospital for observation. There is no longer-term head injury.

Wrong blood is given to a patient, resulting in temporary renal failure.

- **Severe**

Any unexpected or unintended incident that caused permanent or long-term harm to one or more persons.

Examples

Perforation of the bowel during surgery, requiring a temporary colostomy and subsequent major operations.

A patient is given someone else's medication. They have an allergic reaction to it, have a cardiac arrest and suffer brain damage as a result of receiving the medication.

Continuing treatment with warfarin without monitoring clotting levels, which results in a brain haemorrhage and brain damage.

An ambulance is called to a patient who has fallen from scaffolding. On arrival the patient is conscious but lying awkwardly, with a leg that is clearly fractured and twisted. Before carrying out a full assessment or immobilising the cervical spine, the crew reposition the patient to straighten the leg. After repositioning, the patient is unable to move any of their limbs, and later investigations identify that they have a cervical fracture and spinal cord damage. The spinal cord was, however, immobilised immediately after repositioning. The patient is left with long-term paralysis from the neck down.

Wrong blood is given to a young woman, who then develops anti-D antibodies that will affect any future pregnancy.

- **Death**

Any unexpected or unintended event that caused the death of one or more persons.

Examples

Death as a direct consequence of perforation of the bowel during surgery.

A patient is given someone else's medication. They have an allergic reaction to it, have a cardiac arrest and die as a result of receiving the medication.

Continuing treatment with warfarin without monitoring clotting levels, which results in a brain haemorrhage and death.

An ambulance responding to an emergency call on blue lights goes through red traffic lights at an intersection. A car approaching the intersection has a green light, does not see the ambulance and attempts to cross. The ambulance is unable to stop and hits the car on the driver's side. The driver of the car suffers multiple injuries and later dies in hospital.

Wrong blood is given to a patient resulting in multi-organ failure and death.

Appendix C **Monitoring Matrix**

Monitoring of Compliance	Monitoring Lead	Reported To Person/ Group	Monitoring Process	Monitoring Frequency
When an incident occurs, an incident report must be completed as soon as possible and by the end of their shift,	Datix Manager/ Clinical Risk Lead	- Clinical Quality Monitoring Group (CQMG) - Divisional management teams - Specialty management teams	- Divisional Quality Report - Clinical Risk Report to CQMG- Volume of incidents reported across sites and operational divisions Review of benchmarking Organisation data reported on NRLS	CQMG & Divisions Monthly Speciality Management Teams Quarterly

Monitoring of Compliance	Monitoring Lead	Reported To Person/ Group	Monitoring Process	Monitoring Frequency
Within seven days of the incident being reported the person who has been identified as the 'Incident Handler' in Datix will review the incident and advise on what actions have been taken and feed this back to the person who reported the incident **All incidents which do not require a Root Cause Analysis (as described in the above table) should be managed within 28 days.**	Datix Manager/ Clinical Risk Lead	- CQMG - Divisional management teams	- Weekly Divisional performance report - Report of overdue incidents to CQMG	Divisions Weekly CQMG & Divisions Monthly

Monitoring of Compliance	Monitoring Lead	Reported To Person/ Group	Monitoring Process	Monitoring Frequency
Serious Incidents are reported to Commissioners and NHS England via STEIS in accordance with the National Serious Incident Framework. **Level 1 & 2 (SI) investigations should be completed within 60 working days**	Clinical Governance & Patient Safety team	- CaPRI - CQMG - Divisional management teams	- SI Monitoring report - CaPRI case assessments and tracker - Report of ongoing investigations – Clinical Risk report and Governance report	Monthly Quarterly
Regular uploads to the National Reporting and Learning System (NRLS) are conducted regularly, at a minimum monthly.	Clinical Governance & Patient Safety team	- - CG&PST Managers Meeting	KPI report	Monthly

Monitoring of Compliance	Monitoring Lead	Reported To Person/ Group	Monitoring Process	Monitoring Frequency
Implementation of actions identified will be monitored by the responsible Division and Speciality with support from the Governance Facilitation teams.	Clinical Governance & Patient Safety team	- CQMG - Divisional management teams	- Report on the implementation status of actions identified following a SI or ISI investigation.	Monthly
Reporting – Incidents will be analysed to identify quantitative and qualitative trends. Aggregated report of incidents, complaints, claims and PALS	Clinical Governance & Patient Safety team	Board of Directors CCG	- Aggregated Report	Quarterly