

This policy is applicable to services provided by Heartlands, Good Hope and Solihull Hospitals Divisions.

Incident Reporting and Management Policy and Procedure vs.1

Policy Statement:

This Policy describes the Trust's approach to incident recognition, investigation, response (including fulfilment of duty of candour) and learning from. It encompasses all types and levels of incidents and subsequent investigation.

Key Points

- What incidents should you report and why
- Guidance for staff and managers on incident management
- · Reporting requirements and processes
- Duty of candour requirements
- Responding to and learning from incidents
- Process for follow up of quality improvement plans
- Contractual timescales for incident reporting and investigation

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Revision History

Version	Status	Date	Consulted	Comments	Action from Comment
1.1	Review	July 2008		Review to ensure compliance with practice and healthcare standards	Policy reviewed and updated
2.0	Review	Oct 2008		•	Policy reviewed and updated
3.0		Nov 2009		i -	Policy reviewed and updated
4.0		Jan 2010	Information Governance	· ·	Policy reviewed and updated

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		2010	Governance	practice and NHSLA requirements	and updated
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	changes	2011	Governance	changes in incident reporting module	and updated
				and process	
8.0	Major	Feb	Wide	Amalgamation of SUI Policy v3.0 and	Policy reviewed
	change	2015	consultation	Incident Reporting Policy v7.0.	and updated
			Includes new contractual & national guidance on timescales & duty of candour. Includes comments from QA lead on screening incidents.		
8.1	Minor	Aug	Quality	Alignment with NHS England:	Policy reviewed
	Changes	2015	Committee	Serious Incident framework (2015)	and updated

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1. Circulation

This Policy applies to all staff in a permanent, temporary, voluntary or contractor role acting for or on behalf of The Heart of England NHS Foundation Trust (HEFT). It also applies to any subcontracted services (ie. 'Recovery at Home' or commissioned private acute services). The Policy should be read in conjunction with the associated procedural document entitled Attachment 1 - Incident Reporting and Management Procedure and Attachment 2 - Incident Management Flowchart.

2. Scope

Includes

- This Policy describes the Trust's approach to incident recognition, reporting and management (management includes investigation, Duty of Candour and learning).
- 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)
- It defines the levels and process of investigation required for incidents according to their severity, complexity and potential for learning.
- It outlines the follow up of quality improvement plans arising from investigation and themes of incidents.

Excludes

- This Policy excludes the management of "major" incidents which are subject to Major Incident policy.
- Other methods to raise concerns are included in "Raising Concerns Policy" (including whistle blowing)
- Investigations into gross misconduct or other issues that fall under HR policies are also excluded from this policy.

3. Reason for development

The Trust is responsible for the safety of everyone who uses or works within its services and must ensure robust systems are in place to recognise, report, investigate and respond to incidents and to improving the quality of care to patients and the safety of staff and members of the public, through the consistent monitoring and review of incidents which result, or had the potential to result in injury, damage or other loss.

Serious Incidents in healthcare are rare, but it is acknowledged that systems and processes have weaknesses and that errors will happen. A good organisation will recognise harm and the potential for harm and will seek to undertake swift, thoughtful and practical action in response, without inappropriately blaming individuals.

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 minimize the risk of the recurrence.

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.

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.

4. Definitions

Incident - An Incident is defined as an event or circumstance occurring during NHS funded care which causes or has the potential to cause any of the following:

- Harm to an individual
- Financial loss to an individual or the Trust
- Damage to the property of an individual or the Trust
- Disruption to services provided by the Trust
- Damage to the reputation of the Trust
- Non-compliance with regulation or Trust Policy

Incident severity - This is the actual outcome of an incident (not what could have happened) according to the level of harm caused and is categorised as one of the following:

- No Harm
- Low Harm
- Moderate Harm
- Severe Harm
- Catastrophic/Death

Serious Harm - Any incident which appears to have resulted in severe harm or catastrophic harm, Chronic pain¹ or psychological harm, impairment to sensory, motor or intellectual function or impairment to normal working or personal life which is not likely to be temporary²

Serious Incident (SI) - Serious incidents in health care are adverse events, including "near miss" incidents where the consequences to patients, families, and carers, staff or organisations are so significant or the potential for learning is so great that a heightened level of response is justified. Serious Incidents can be isolated, single events or multiple linked or unlinked events signalling systematic failures within a commissioning or health system.

There is no national or local definitive list of events / incident that constitutes an SI as this can lead to inconsistency or inappropriate management of incidents. All incidents must be considered on a case by case basis using the guidance from the National Framework (Attachment 1)

Never Event - Is defined by the Department of Health as a "serious, largely preventable patient safety incident that should not occur if the available preventable measures have been implemented by healthcare providers". The management of Never Events is undertaken in line with the Never Events Policy Framework and the Never Events List³.

Level of Investigation - The level of incident investigation required depends on the nature of the incident, the level of harm or the potential for learning. The level of investigation should be proportionate to the individual incident. Broadly speaking this can be summarised as follows:

 Local learning and optional RCA: No, low or moderate harm incidents which are not never events and do not fall within the definition of an

SI⁴

Concise Investigation
 Suited to less complex SI's and Never Events.
 Mandatory RCA managed by individuals or a small

group at local level.

¹ Continuous, long term pain of more than 12 weeks or after the time that healing would have been thought to have occurred in pain after trauma or surgery

² Has lasted, or is likely to last for a continuous period of at least 28 days

³ The Never Events List 2013/14, NHS England, December 2013.

⁴ Except where the incident is considered under the NHS England Serious Incident Framework 2013

•	Comprehensive Investigation:	Suitable for more complex SI's and Never Events. Mandatory RCA which should be managed by a multidisciplinary team including experts or specialist investigations.
•	Independent investigation:	Suitable for incidents where the integrity of an internal investigation is likely to be challenged or where the size of the organisation, capacity / capability of the available investigators would make it difficult to conduct an objective internal investigation.

Details of the investigation requirements for each level of incident can be found at Attachment 2.

RCA - Root Cause Analysis: - A structured investigation that aims to identify the true cause of a problem, and the actions necessary to eliminate it (Anderson B, Fagerhaug T (2000)

A systematic investigation technique that looks beyond the individuals concerned and seeks to understand the underlying causes and environmental context in which the incident happened (RCA toolkit NPSA).

Multi incident investigation root cause analysis⁵ moves the focus from repeated investigation to learning and improvement and can be used for the thorough investigation of reoccurring problems of a similar nature, setting or group of patients in order to identify the common problems, contributing factors, root causes and enables one action plan to be developed and monitored.

Duty of Candour - The statutory duty requires providers to notify anyone who has been subject (or someone lawfully acting on their behalf, such as families and carers) to an incident involving, moderate, severe or catastrophic harm or death. This notification must include an appropriate apology and information relating to the incident.

Incidents related to NHS Screening Programmes will be managed in line with Managing Safety Incidents in NHS Screening Programmes (2015) summarised at **Attachment 5.** Where relevant this will involve Specialised Commissioning and appropriate commissioner groups.

5. Aims and Objectives

The aims and objectives of this policy are to:

- Promote an open, honest and fair approach to the identification, management and learning from errors and accident
- Provide staff with an agreed method of reporting, investigation and management of incidents and development of quality improvement plans, where appropriate
- Enable collection and use of robust data to inform and promote organisational learning and improvement, providing appropriate assurance to internal and external stakeholders as required.
- Use incident investigation and RCA to identify any deficiencies in care or service, learning from these findings through the development of safer practices and environments for the benefit of patients, staff and visitors
- Establish an incident reporting and management framework which is proportionate to the incident being reported and fulfils statutory and contractual requirements in line with national best practice.
- Support openness and transparency and assure patients / their representatives that appropriate review, investigation and learning from incidents are embedded within the organisation.

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⁵ http://www.nrls.npsa.uk/resources/?entryid45=75355

6. Standards

When an incident occurs the first action should be to make the situation safe, preserving the scene together with equipment or other items that may be used as evidence in an investigation ((Attachment 3) provides guidance on how this should be done). The standards that must be followed relate to the reporting, management and learning from incidents as follows:

• Reporting: All staff have access to and know how to report an incident.

Management: All potential SI's are reported promptly and reviewed with 48 hours.
Management: Within a week of reporting all incidents are reviewed by an appropriate

department lead.

Management: Within a month of reporting all non-SI incidents are closed by an

appropriate department lead.

Management: Duty of Candour⁶ is complied with.

• Management: Incident reports are promptly reviewed and graded.

Management: Investigation of incidents is undertaken according to this policy.

Management: Incidents are reported to external bodies as appropriate.
 Management: Staff are supported according to the Supporting Staff Policy.

Learning: Actions are agreed that reduce the likelihood of recurrence and these.

actions are shared with patients and relatives and staff as appropriate.

Learning: Actions are followed up and reviewed to ensure appropriate

implementation.

Learning: Incidents are analysed to identify quantitative and qualitative trends and

this is shared within the Trust.

7. Roles and Responsibilities

7.1 Individual Responsibilities

All Staff

All staff are required to report and manage incidents in line with this policy. Where an incident occurs staff must take appropriate immediate remedial action at the time of an incident to prevent further harm to patients; staff; general public and Trust assets.

Chief Executive

The Chief Executive is responsible for ensuring the infrastructure is in place to identify, report, manage, investigate and analyse incidents in order to learn lessons. The Chief Executive delegates responsibility to the Chief Nurse.

Chief Nurse

The Chief Nurse is responsible to the Trust Board and Chief Executive in relation to incident management and will provide regular reports to the Trust Board in this regard. He/she also has particular duties regarding management of serious incident investigations these are:

- In conjunction with the Executive Medical Director, Deputy Director of Governance and Head
 of Investigations and Legal, commission serious incident investigations as required following
 scoping.
- In collaboration with the Executive Medical Director, Deputy Director of Governance and Head of Investigations and Legal, appoint appropriate investigation lead for patient/clinical incidents or senior manager for corporate incidents
- Ensure suitable processes are in place to quality assure and sign off SI investigation reports.

⁶ In line with national best practice, CQC regulation 20 and statutory requirements.

- As executive lead for patient experience, PALS and complaints functions, ensure appropriate arrangements are in place to escalate incidents highlighted through these processes, to enable appropriate consideration of serious incident investigations.
- Ensure effective incident reporting arrangements are in place with commissioners in line with contractual and best practice requirements.
- Ensure an appropriate training needs analysis has been undertaken and that training and resources are in place to support all staff involved in the incident reporting management and learning process

All Executive Directors

All Executive Directors have a role to encourage incident reporting, support incident investigations and share lessons and themes from incidents across their areas of responsibility

Executive Medical Director

- As executive lead for Communications, ensure development and coordination of appropriate media / stakeholder communication strategies for individual or groups of incidents, where appropriate, in liaison with the Chief Nurse, Deputy Director of Governance and Head of Investigations and Legal or on call Executive Lead
- In conjunction with the Chief Nurse, Deputy Director of Governance and Head of Investigations and Legal, commission serious incident investigations as required following scoping.
- In collaboration with the Chief Nurse, Deputy Director of Governance and Head of Investigations and Legal, appoint appropriate investigation lead for patient/clinical incidents or senior manager for corporate incidents

Company Secretary

 As executive lead for information governance function, ensure an appropriate infrastructure is in place for the management of Information Governance related incidents in line with national requirement.

Senior Information Risk Owner (SIRO)

• The SIRO has a particular role to ensure that identified information security incidents and risks are investigated and acted upon.

7.2 Board and Committee Responsibilities

Board of Directors

The Board of Directors is responsible for ensuring that appropriate systems are in place to enable the organisation deliver its objectives in relation to this framework. It delegates this responsibility to the Quality Committee

Quality Committee

The Quality Committee is responsible for assuring the Board of Directors that:

- The Trust has a strong incident reporting culture in which incidents are promptly identified and reported.
- SI investigations are being appropriately identified, managed and investigated using RCA and any resulting risks are being addressed.
- Trends in incidents are being reviewed and managed on a Trust wide basis.
- Learning from incidents is being identified and improvements implemented

In collaboration with the Divisional Quality and Safety Committees, the Quality Committee will also ensure that directorates and divisions are:

Reporting, managing and investigating incidents in line with this policy.

• Ensuring implementation of recommendations and quality improvement plans from serious incident investigations

They also have a role in the analysis of incident data, triangulating this information with other sources to identify trends and request assurance and improvement where required

Serious Incidents and Risks Under Scrutiny (SIRIUS) Panel

The SIRIUS Panel will examine evidence of progress with, and effectiveness of, quality improvement plans resulting from all Serious Incidents which are subject to a Comprehensive (Trust level) investigation (in line with this policy)

- The panel will receive and review regular update on ongoing quality improvements plans
- Review and challenge evidence to ensure sufficient assurance of completion and effectiveness of actions that have been delivered.
- Request further evidence of progress or commission further scrutiny as required
- Escalate issues or barriers to progress with the Delivery Unit Meeting or other Trust operational committees.

Division Q&S committees

Divisional Quality and Safety Committees have delegated responsibility for the quality and safety of the clinical services that are within their remit.

These committees are responsible for:

- Ensuring appropriate and timely incident identification, reporting, management and investigation arrangements are in place for all areas within their responsibility.
- Monitoring the implementation of recommendations from serious incident investigations and quality improvement plans relevant to their division
- Ensuring appropriate prioritisation and allocation of resources to most effectively implement these plans
- Reviewing and acting upon incident analysis themes and key learning points and triangulating with other risk information to inform improvement priorities
- Escalating assurance/exceptions to appropriate Trust level Committees / individuals

7.3 Directorate Responsibilities

Safety & Governance Directorate

Under the leadership of the Chief Nurse and the Deputy Director of Governance specific teams have roles and responsibilities to support this Policy which are outlined below:

Datix Support Team

- To maintain the Trust's incident reporting database (Datix), acting as administrators for the complete database.
- To provide training in reporting incidents to Trust staff as appropriate.
- Review coding and grading of all incident reports, escalating as required, and finally approve incidents before disclosure to appropriate third parties (ie. NRLS, RIDDOR) in collaboration with other directorate teams.
- To provide incident analysis and trend reports for Trust committees and to fulfil commissioning contract requirements.
- Liaise with incident handlers and specialty leads (for falls, TV, HCAI) to promote timely review of incidents and prompt investigation.
- Supply data to support implementation and compliance with this policy for both internal and external use.

Investigations Team

The investigation team will play a lead role in the implementation, monitoring and reporting of "Duty of Candour" requirements, as well as the analysis of trends and learning from serious incidents and investigations. They also have specific roles in relation to the investigation process:

- Ensure all incidents reported with an outcome of "severe harm" are reported externally via STEIS.
- To initiate scoping, in collaboration with local team, for serious incidents likely to require investigation (including Never Events), ensuring completion within 72 hours (excluding weekends and bank holidays).
- To support the Chief Nurse or Executive Medical Director in holding a teleconference with the appropriate Clinical Commissioning Group lead within 72 hours⁷ of the confirmation of any potentially high profile serious incident (excluding incidents relating to TV, Falls, HCAI, Pharmacy, safeguarding).
- Report all serious incident investigations onto STEIS in collaboration with specialty leads (for TV, Falls, HCAI, Pharmacy, safeguarding and maternity) to ensure all required incidents are reported onto within contractual requirements and timeframes.
- Support serious incident investigations, working alongside clinical investigations lead, facilitating initial and final roundtable meetings and providing progress reports to internal and external stakeholders.
- To ensure all witnesses are aware of the other potential uses of their statements (ie. HMC, legal process, HR processes, police investigation, regulatory and professional body investigations).
- To ensure a member of the relevant CCG is invited to attend the 2nd round table meeting.
- To provide staff with support and advice in line with Supporting Staff Policy.
- To communicate with patients/representatives where possible, advising them of investigation and progress in line with duty of candour and provide them with a specific point of contact.
- To promote timely completion of serious incident investigations and within required timescales, identifying and escalating barriers to progress as required and facilitating executive sign off.
- Along with the lead investigator, meet with the patient/representative following completion of investigation to share the report and investigation findings.
- To work with investigation lead to ensure that all staff involved in the investigation are debriefed and the findings of the investigation shared with them.
- To complete summary reports for serious incidents within one month of the investigation being signed off to enable sharing of key information across the Trust and support organizational learning.
- Working with the Directorates and Clinical Governance team, facilitate implementation of quality improvement plans from serious incident investigations escalating barriers to progress and monitoring through to completion.
- To notify post graduate tutors of the names of any junior or specialist trainees involved in any incident causing severe or catastrophic harm and their role in the incident.
- To provide post graduate tutors with a copy of the final report/RCA for incidents as appropriate.

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⁷ excluding weekends and bank holidays

Clinical Governance and Audit & Effectiveness team

- To facilitate and support the Divisional Quality and Safety frameworks to enable effective discussion, follow up and learning from incidents.
- Working with the Directorates and Investigations team, facilitate implementation of quality improvement plans from serious incident investigations escalating barriers to progress and monitoring through to completion.
- To maintain SitRep reporting process to enable awareness and monitoring of serious incident investigations and enable widespread sharing of incident analysis and learning information.
- To integrate quality improvement plans into audit and Quality Improvement processes as appropriate to support sustained improvement.

Health and Safety Team

- To review incidents that are reported under the health and safety and security categories on the incident reporting system. The review will incorporate - correct use of category, subcategory and grading.
- To provide advice and guidance to managers in relation to the investigation and management of incidents under these categories.
- To collate information reported to identify trends. Report trends to the trust Safety Committee and Security Committee.
- Following notification from managers that incidents that meet the criteria for reporting to the Health and Safety Executive (HSE) under the Reporting of Injuries, Diseases and Dangerous Occurrences Regulations, (RIDDOR) are reported in a timely manner.
- Maintain a register of RIDDOR Reportable incidents (Attachment 4).
- Provide information to external bodies such as the HSE, NHS Protect and the Police as required.

Post Graduate Tutors

• To ensure appropriate debrief/support and learning is put in place for junior or specialist trainees, liaising with and escalating to the Deanery and Head of School as required.

Directorate Management Team (Clinical Director, Matron and Operational Manager)

- Ensuring 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.
- To inform the investigations team immediately by telephone of any serious incidents following initial assessment and ensure that a Datix incident report is completed.
- To undertake an investigation into incidents utilising RCA and obtain witness statements in line with this policy.
- To produce a quality improvement plan outlining the required actions to be implemented to ensure lessons are learned.
- To provide the Investigations Team with the investigation paperwork, this should include the RCA, quality improvement plan, statements and any correspondence with the patient / family.
- To feedback the outcome of investigations to directorate staff as appropriate.
- Ensure that staff receive appropriate support in line with the Supporting Staff policy.
- Ensure that the patients, relatives or carers are informed about the incident in a timely manner in accordance with the Trust's Being Open Policy and document this discussion on Datix and in the medical record.

- To support and formally monitor, at Directorate meetings, progress against quality improvement plans produced as a result of incident investigations.
- To ensure that any improvements, highlighted as a result of an incident investigation and which cannot be completed, are placed on the Directorate Risk Register.

Ward/Department Manager

- To review all online incident report forms within the timescales specified in this policy and take appropriate remedial action, where possible, to prevent a future occurrence.
- 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.
- Immediately inform a member of the directorate management team and staff from other departments who need to be aware of any incident believed to be serious.
- Ensure that the patient's relatives or carers are informed about the incident, where appropriate, in a timely manner in accordance with the Trust's Being Open policy.
- Ensure local arrangements and support is in place to ensure statutory Duty of Candour requirements are fulfilled.
- Document remedial action on the incident report to complete the approval process and provide feedback where appropriate to the incident reporter.
- Reviewing and acting upon incident analysis themes and key learning points and triangulating with other risk information to inform improvement priorities.
- Provide appropriate feedback regarding the investigation outcome/preventive actions to staff.
- Ensure that staff are provided with appropriate support, in line with the Trust's Supporting Staff policy.
- To inform the Health & Safety Manager within 24 hours of the incident occurring to enable the prompt reporting to the Health and Safety Executive if an incident is RIDDOR reportable.

Details relating to RIDDOR reportable incidents are included in Attachment 4.

8. Training

The Safety and Governance Directorate will ensure provision of training as required to 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:

- Incident reporting training (Datix)
- Incident management training (Datix)
- Search and data reporting tools (Datix)
- Managing investigations
- RCA training, resources and links
- Duty of Candour training and resources
- One to one support and guidance as required for SI investigation processes

9. Learning

The Trust is committed to ensuring local and organisational learning from incidents. Quality Improvement Plans will be developed that mitigate the risk of incidents reoccurring based on the outcome of incident investigations and RCA. These improvements will be shared with patients, relatives and staff as appropriate.

The Quality Improvement Plans will be agreed and owned by relevant directorates with the directorate triumvirate responsible for the effective and sustained implementation of the Quality Improvement Plans.

To ensure improvements are completed, Divisional Quality and Safety Committees are responsible for reviewing progress of Quality Improvement Plans with Directorate management teams.

The SIRIUS Panel will also support local and Trust wide learning and improvement from SI's.

Aggregated data (quantitative and qualitative) and safety lessons will be reported via the SITREP. The Trust's Quality Committee will review actions arising from the SITREP and monitor progress against identified improvements to ensure the implementation of risk reduction measures.

The SITREP report will also be shared across the local health economy through reporting arrangements with the Clinical Commissioning Group.

10. Monitoring and Compliance

The Safety & Governance Directorate is responsible for producing the safety situation report (SITREP). This will be used by the Trust for the monitoring serious incident investigations and overview of incident trends and learning. This policy will be monitored through:

Minimum Criteria	Monitoring Method	Frequency	Monitoring Committee / individual
All staff have access to report incidents	Incident audit	Annual	Quality Committee
Incidents promptly reviewed and graded	Incident performance metrics	Monthly	Site and Nursing performance
Investigations are undertaken according to this policy	Incident checklist	Annual	To be confirmed
Incidents are reported to external bodies as appropriate	Incident checklist	Annual	To be confirmed
Duty of candour fulfilled	CCG dashboard	Monthly	To be confirmed
Information shared via STEIS	CCG dashboard	Monthly	CQCRM
Supporting staff and debrief	Incident checklist	Annual	Deputy Director of Governance
Incidents are analysed and key learning shared	SitRep	Monthly	Quality Committee
Follow up of improvement plans	Annual Review of SIRIUS Panel	Annual	SIRIUS

11. Attachments

Attachment 1 Incident Reporting and Management Procedure

Attachment 2 Incident management Flowchart

Attachment 3 Definition of a Serious Incident (SI): Extract from National SI framework

Attachment 4 Guidance on the management of an incident scene

Attachment 5 Details of RIDDOR reportable incidents

Attachment 6 Managing Safety Incidents in NHS Screening Programmes

Attachment 7 Reporting to External Agencies

Attachment 8 RCA Tool

Attachment 9 Guidance for staff in preparing statements

Attachment 10 Procedure for the reporting and investigation of inappropriate access to electronic patient records

Attachment 11 Equality and Diversity Checklist

Attachment 1: Incident Reporting, Management and Learning Procedure

There are certain requirements that must be fulfilled when an incident occurs as follows:

• Take Immediate Action:

 When an incident occurs the first action should be to make the situation safe, preserving the scene and equipment or other items that may be used as evidence in an investigation.

• Report the incident:

- Staff will have appropriate access to report the incident by completing an online incident report on Datix which should record the facts of the incident and immediate actions that have been taken.
- Duty of candour will be fulfilled for all incidents graded moderate harm and above and this should also be reported on Datix.

• (i) Management of the Incident - Escalation

- Incidents will be escalated to senior management according to type, complexity and severity of the incident and in line with Attachment 2.
- Severe Harm, Catastrophic incidents or Never Events should be notified to your line manager/senior person on shift and, for the most serious or urgent incidents, to the on call management team.
- Incidents will be reported/escalated to external agencies in line with statutory requirements and as outlined in **Attachment 6**.

3. (ii) Management of the Incident - Initial management of incident report

- All incidents will be reviewed by the incident handler:
 - o within 48 hours (for potential SI's).
 - o within a calendar week (for all other incidents).
- All incidents will be closed within a calendar month if appropriate (excluding SI's).
- Incidents related to the National NHS Screening Programmes will be managed in line with Attachment 5.

3. (iii) Management of the incident - Scoping

- Incidents that may be Never Events or Serious Incidents will be scoped within 72 hours of being reported to confirm the grading.
- Incidents will be scoped by clinical teams to determine the initial facts, level of harm, immediate action taken, and will be used to determine required level of investigation in collaboration with investigations team.

3. (iv) Management of the incident - Investigation

- Investigations will be carried out in line with Attachment 2 using RCA as a tool to understand the sequence of events and identify the root causes and contributory factors to the incident. Templates to support RCA investigation are at Attachment 7.
- Where statements are required from staff the guidance and proforma at **Attachment 8** should be used.

3. (v) Management of the incident - Supporting Staff

- Supporting staff involved in incidents should be undertaken in line with the Trust's Supporting Staff Involved in Traumatic Events Policy V3.0, signposting access to support resources as needed.
- Management of staff involved in incidents will be informed by application of the NPSA Incident Decision Tree.
- Staff involved in the incident and investigation will be offered a debrief and opportunity to share the findings from the investigation.

3. (vi) Management of the incident - Quality Assuring the investigation report

- Investigation reports will be quality assured at a directorate and divisional level.
- SI's will be subject to Executive level sign off.

4. (i) Learning from the incident - Sharing findings

 Patients / their representatives (where appropriate and in line with Duty of Candour) will be invited to meet with investigation leads to share the outcome of serious incident investigations and Quality Improvement Plans which have been developed in response to these investigations.

4. (ii) Learning from the incident - Follow up of Quality Improvements

- Quality improvements from Comprehensive (Trust led) investigations will be monitored by the SIRIUS group.
- Quality improvements from Concise (local) investigations will be monitored through local divisional and directorates governance processes.

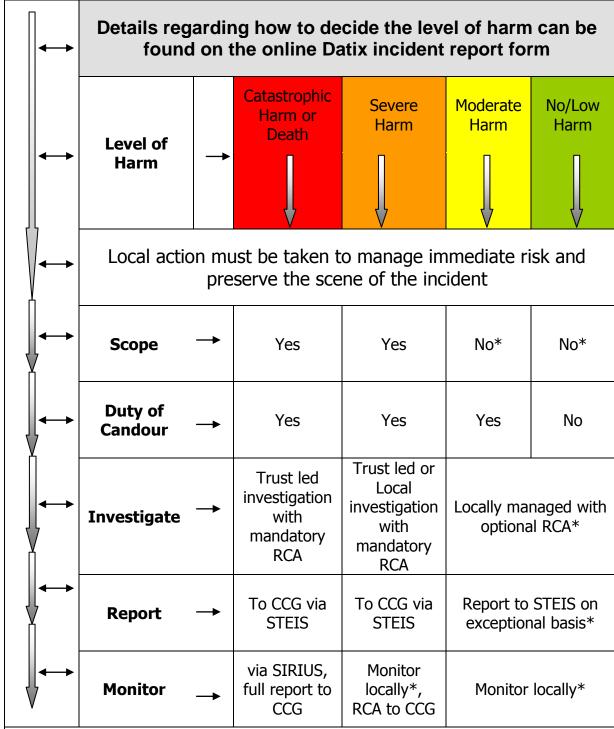
4. (iii) Learning from the incident - Trends and Sharing Learning

- All incidents will be subject to quarterly high level analysis to identify trends/themes.
- In addition to this, trends and themes from serious incident investigations will be subject to bi-annual further analysis and sharing through Safety SitRep.
- Both incident analysis reports will be provided to Quality Committee and Divisional Quality and Safety Committees for appropriate action / sharing.

5. Documentation

- Datix will act as document repository for completed RCA's.
- Supplementary documents may be stored and managed by directorates at a local level and kept in line with the Corporate Records Policy.
- Additional records will be kept by the Safety and Governance Directorate for serious incident investigations.

Attachment 2: Incident Management Flowchart



^{*}Exclusions are

- 1. Never events will be managed in line with the Never Events National Framework and subject to either Comprehensive (Trust led) or Concise (local) RCA, dependent upon the nature and complexity of the incident.
- 2. Incidents that fall to be considered under the National Serious Incident Framework 2015 will be subject to either Comprehensive (Trust led) or Concise (local) RCA, dependent upon the nature and complexity of the incident.
- 3. Tissue Viability, Falls and HCAI incidents have specific requirements for grading, reporting and investigation processes which should be followed.
- 4. Incident related to National Screening Programs should be managed according to the relevant national guidance.

Attachment 3: Definition of a Serious Incident (SI): Extract from National SI framework

What is a 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. Serious incidents can extend beyond incidents which affect patients directly and include incidents which may indirectly impact patient safety or an organisation's ability to deliver ongoing healthcare.

The occurrence of a serious incident demonstrates weaknesses in a system or process that need to be addressed to prevent future incidents leading to avoidable death or serious harm⁸ to patients or staff, future incidents of abuse to patients or staff, or future significant reputational damage to the organisations involved. Serious incidents therefore require investigation in order to identify the factors that contributed towards the incident occurring and the fundamental issues (or root causes) that underpinned these. Serious incidents can be isolated, single events or multiple linked or unlinked events signalling systemic failures within a commissioning or health system.

There is no definitive list of events/incidents that constitute a serious incident and lists should not be created locally as this can lead to inconsistent or inappropriate management of incidents. Where lists are created there is a tendency to not appropriately investigate things that are not on the list even when they should be investigated, and equally a tendency to undertake full investigations of incidents where that may not be warranted simply because they seem to fit a description of an incident on a list.

The definition below sets out circumstances in which a serious incident must be declared. Every incident must be considered on a case-by-case basis using the description below. Inevitably, there will be borderline cases that rely on the judgement of the people involved.

Serious Incidents in the NHS include:

- 1. Acts and/or omissions occurring as part of NHS-funded healthcare (including in the community) that result in:
 - Unexpected or avoidable death⁹ of one or more people. This includes
 - suicide/self-inflicted death; and
 - homicide by a person in receipt of mental health care within the recent past¹⁰
 - Unexpected or avoidable injury to one or more people that has resulted in serious harm
 - Unexpected or avoidable injury to one or more people that requires further treatment by a healthcare professional in order to prevent:
 - the death of the service user; or
 - serious harm;

⁸ Serious harm:

- Severe harm (patient safety incident that appears to have resulted in permanent harm to one or more persons receiving NHS-funded care);

- Chronic pain (continuous, long-term pain of more than 12 weeks or after the time that healing would have been thought to have occurred in pain after trauma or surgery); or

- Psychological harm, impairment to sensory, motor or intellectual function or impairment to normal working or personal life which is not likely to be temporary (i.e. has lasted, or is likely to last for a continuous period of at least 28 days).

⁹ Caused or contributed to by weaknesses in care/service delivery (including lapses/acts and/or omission) as opposed to a death which occurs as a direct result of the natural course of the patient's illness or underlying condition where this was managed in accordance with best practice.

¹⁰ This includes those in receipt of care within the last 6 months but this is a guide and each case should be considered individually - it may be appropriate to declare a serious incident for a homicide by a person discharged from mental health care more than 6 months previously

- Actual or alleged abuse; sexual abuse, physical or psychological ill-treatment, or acts of omission which constitute neglect, exploitation, financial or material abuse, discriminative and organisational abuse, self-neglect, domestic abuse, human trafficking and modern day slavery where:
 - healthcare did not take appropriate action/intervention to safeguard against such abuse occurring¹¹; or
 - Where abuse occurred during the provision of NHS-funded care.

This includes abuse that resulted in (or was identified through) a Serious Case Review (SCR), Safeguarding Adult Review (SAR), Safeguarding Adult Enquiry or other externally-led investigation, where delivery of NHS funded care caused/contributed towards the incident

- 2. A Never Event: All Never Events are defined as serious incidents although not all Never Events necessarily result in serious harm or death. See Never Events Policy and Framework for the national definition and further information 12;
- 3. An incident (or series of incidents) that prevents, or threatens to prevent, an organisation's ability to continue to deliver an acceptable quality of healthcare services, including (but not limited to) the following:
 - Failures in the security, integrity, accuracy or availability of information often described as data loss and/or information governance related issues
 - Property damage;
 - Security breach/concern^{13;}
 - Incidents in population-wide healthcare activities like screening¹⁴ and immunisation programmes where the potential for harm may extend to a large population;
 - Inappropriate enforcement/care under the Mental Health Act (1983) and the Mental Capacity Act (2005) including Mental Capacity Act, Deprivation of Liberty Safeguards (MCA DOLS);
 - Systematic failure to provide an acceptable standard of safe care (this may include incidents, or series of incidents, which necessitate ward/ unit closure or suspension of services¹⁵⁾; or
 - Activation of Major Incident Plan (by provider, commissioner or relevant agency)¹⁶
- 4. Major loss of confidence in the service, including prolonged adverse media coverage or public concern about the quality of healthcare or an organisation.¹⁷

¹¹ This may include failure to take a complete history, gather information from which to base care plan/treatment, assess mental capacity and/or seek consent to treatment, or fail to share information when to do so would be in the best interest of the client in an effort to prevent further abuse by a third party and/or to follow policy on safer recruitment.

Never Events arise from failure of strong systemic protective barriers which can be defined as successful, reliable and comprehensive safeguards or remedies e.g. a uniquely designed connector to prevent administration of a medicine via the incorrect route - for which the importance, rationale and good practice use should be known to, fully understood by, and robustly sustained throughout the system from suppliers, procurers, requisitioners, training units, and front line staff alike. See the Never Events Policy and Framework available online at: http://www.england.nhs.uk/ourwork/patientsafety/never-events/

¹³ This will include absence without authorised leave for patients who present a significant risk to themselves or the public.

¹⁴ Updated guidance will be issued in 2015. Until that point the Interim Guidance for Managing Screening Incidents (2013) should be followed.

¹⁵ It is recognised that in some cases ward closure may be the safest/ most responsible action to take but in order to identify problems in service/care delivery , contributing factors and fundamental issues which need to be resolved an investigation must be undertaken

For further information relating to emergency preparedness, resilience and response, visit: http://www.england.nhs.uk/ourwork/eprr/

Assessing whether an incident is a serious incident

In many cases it will be immediately clear that a serious incident has occurred and further investigation will be required to discover what exactly went wrong, how it went wrong (from a human factors and systems-based approach) and what may be done to address the weakness to prevent the incident from happening again.

Whilst a serious outcome (such as the death of a patient who was not expected to die or where someone requires on going/long term treatment due to unforeseen and unexpected consequences of health intervention) can provide a trigger for identifying serious incidents, outcome alone is not always enough to delineate what counts as a serious incident. The NHS strives to achieve the very best outcomes but this may not always be achievable. Upsetting outcomes are not always the result of error/ acts and/ or omissions in care. Equally some incidents, such as those which require activation of a major incident plan for example, may not reveal omissions in care or service delivery and may not have been preventable in the given circumstances. However, this should be established through thorough investigation and action to mitigate future risks should be determined.

Where it is not clear whether or not an incident fulfils the definition of a serious incident, providers and commissioners must engage in open and honest discussions to agree the appropriate and proportionate response. It may be unclear initially whether any weaknesses in a system or process (including acts or omissions in care) caused or contributed towards a serious outcome, but the simplest and most defensible position is to discuss openly, to investigate proportionately and to let the investigation decide. If a serious incident is declared but further investigation reveals that the definition of a serious incident is not fulfilled- for example there were no acts or omissions in care which caused or contributed towards the outcome- the incident can be downgraded. This can be agreed at any stage of the investigation and the purpose of any downgrading is to ensure efforts are focused on the incidents where problems are identified and learning and action are required.

Can a 'near miss' be a serious incident?

It may be appropriate for a 'near miss' to be a classed as a serious incident because the outcome of an incident does not always reflect the potential severity of harm that could be caused should the incident (or a similar incident) occur again. Deciding whether or not a 'near miss' should be classified as a serious incident should therefore be based on an assessment of risk that considers:

- The likelihood of the incident occurring again if current systems/process remain unchanged; and
- The potential for harm to staff, patients, and the organisation should the incident occur again.

This does not mean that every 'near miss' should be reported as a serious incident but, where there is a significant existing risk of system failure and serious harm, the serious incident process should be used to understand and mitigate that risk.

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¹⁷ As an outcome loss in confidence/ prolonged media coverage is hard to predict. Often serious incidents of this nature will be identified and reported retrospectively and this does not automatically signify a failure to report.

Attachment 4: Guidance on the management of an incident scene

i) Introduction

This guidance should be considered in conjunction with the Incident Reporting and Management Policy and Procedure. It aims to provide anyone that either discovers an incident scene, or is involved with the initial management of the incident with guidance on how to preserve and manage the scene.

When an un-witnessed or suspicious incident has occurred that has resulted in serious harm it is imperative that the incident scene, the victims property and any associated equipment is protected to enable an investigation. Such incidents may include:-

- 1. A person found in a public area with serious injuries either within a hospital building, or in the grounds of the hospital.
- 2. An incident involving equipment (either a medical device or general work equipment).
- 3. An incident involving a weapon.

Employers or owners of the buildings also have an obligation to ensure that appropriate enforcing bodies are informed in the event of certain incidents examples of these are detailed below:-

Police - the police should be informed as soon as is reasonably practicable following a suspicious incident, particularly if the victim has been found in a public area of the hospital, or if a weapon is likely to be a contributing factor to the incident.

Health and Safety Executive - the Reporting of Diseases and Dangerous Occurrences Regulations detail specific incidents that must be reported. The health and safety team will usually report the incident to them on your behalf, however if the incident has resulted in a fatality they should be notified as soon as is reasonably practicable following the incident.

Department of Health and Commissioners - should be informed of incidents that are declared as a serious untoward incident or that is included in the list of never events. The Safety and Governance Directorate will be responsible for reporting these.

Please note that the Executive Director overseeing the incident at the time will take responsibility for authorising notification to the appropriate external body.

ii) Action to take to preserve an incident scene

- Restrict access to the scene to essential personnel only. (This will usually be the team providing medical care, or personnel required to make the environment safe).
- Report the incident in line with the incident reporting policy and initiate treatment for the injured person.
- The Manager on duty will assume the incident manager role, until next manager in the escalation plan is available.

Establish a cordon around the scene, taking care not to disrupt access required to provide immediate medical care (the cordon may be a physical barrier or manned by personnel, the type of cordon will be dependent on the area that the incident occurred).

Preserve the scene/evidence:-

- If it is possible photograph the scene and surrounding area, without disturbing any evidence (this will aid the investigation process especially if it is not possible to keep the area closed for a prolonged period of time).
- Ensure that any equipment associated with the incident is not tampered with and remains at the scene, until authorisation from the incident manager has been sought.
 When authorised, the equipment should then be removed and taken to a secure quarantine area. Ensure the completion of the evidence log.*
- Ensure that all clothing removed from the person/persons involved in the incident remains at the scene, until authorised to be removed. Ensure the completion of the evidence log.

Via the executive director and incident manager ensure that relevant external agencies have been informed of the incident:-

- **Police** should be notified for unwitnessed or suspicious incidents that occur either within hospital buildings or the grounds.
- The Health and Safety Executive should be notified for incidents that are reportable under RIDDOR (the health and safety team will usually do this for you).
- Commissioners should be notified if the incident is declared as a serious untoward incident, or a never event (the Safety and Governance Directorate will take responsibility for this).

When authorised to do so by the incident manager stand down the cordon and prepare the area for normal working activity.

INCIDENT EVIDENCE LOG

DA/PC/Scene preservation guidance/2012

Evidence loggist name	Date
	Time
Site	Exact Location

Name of person entering the scene	Time of entry to the scene	Reason for entering the scene and activity undertaken	Time leaving scene

Attachment 5: Details of RIDDOR Reportable Incidents

The following guidance has been taken from the guidance developed by the Health and Safety Executive (Health Services Sheet No. 1)

The Reporting of Injuries Diseases and Dangerous Occurrences Regulations 1995 (RIDDOR) require employers and others to report accidents and some diseases that arise out of or in connection with work. These reports enable the enforcing authorities to identify where and how risks arise and to investigate serious accidents.

What needs to be reported?

The following are examples of accidents that should be reported if they arise out of or in connection with our work

- Accidents which result in an employee or self-employed person dying, suffering a major injury, or being absent from work or unable to do their normal duties for more than three days.
- Accidents which result in a person not at work suffering an injury and being taken to a hospital, or if the accident happens at a hospital, suffering a major injury.
- An employee or self-employed person suffering one of the specified work related diseases.
- One of the specified 'dangerous occurrences' these do not necessarily result in injury but have the potential to do significant harm.

Accidents

- Accidents include acts of physical violence to people at work, but not violence to other people, such as patients or visitors.
- You do not need to report accidents arising directly from the conduct of an operation, examination or other medical treatment, carried out or supervised by a doctor or dentist.
- For an accident to be reportable it must arise out of or in connection with work, accidents
 which arise solely from the condition of the injured person are not reportable neither are
 suicides.

Examples of situations involving patients:-Reportable

- A Confused patient falls from a window on an upper floor and is injured.
- A hospital patient is scalded by hot bath water and has to receive treatment for burns.

Not reportable

- A frail elderly patient falls and breaks their leg, there are no obstructions or defects in the premises or equipment that contribute to the fall.
- · A patient commits suicide.

Note: Incidents that are not reportable to RIDDOR are still reportable to the Trust in line with this policy.

Death or major injuries

You need to report the following incidents connected with work:-

- An employee (wherever they are working), or a self-employed person working on our premises that is killed or suffers a major incidents (including as a result of physical violence).
- Someone not at work is injured in an accident at the hospital and suffers a major injury.

Examples of reportable major injuries include:-

- Fractures, except to fingers, thumbs or toes.
- Amputation.
- Dislocation of the shoulder, hip, knee or spine.
- Loss of sight (temporary or permanent).
- Chemical or hot metal burn to the eye, or any penetrating injury to the eye.
- Injury resulting from an electric shock or electrical burn, leading to unconsciousness or requiring resuscitation or admittance to hospital for more than 24 hours.

- Acute illness requiring medical treatment, or loss of consciousness resulting from the absorption of any substance by inhalation, ingestion or through the skin or exposure to a biological agent.
- Any other injury which leads to hypothermia, heat-induced illness or unconsciousness.
- Requires resuscitation or admittance to hospital for more than 24 hours, or if the injured person is already in hospital, then the injury would have resulted in admission for more than 24 hours.

Over 7 day injuries

You must report accidents connected with work (including acts of physical violence) which result in an employee, or self-employed person working on your premises being away from work or unable to do their normal duties for more than three days (including non-working days).

Examples of over 7 day injuries include:-

- A member of staff suffers a back injury when lifting a heavy load and is unable to work for four days.
- A member of staff is punched by an angry patient and suffers severe bruising and is off work for a week as a result of the incident.

Dangerous Occurrences

Dangerous occurrences are specified events which may not result in a reportable injury, but have the potential to do significant harm.

Reportable dangerous occurrences include:-

- The collapse, overturning or failure of load bearing parts of lifts and lifting equipment.
- The accidental release of a biological agent likely to cause severe human illness (hazard group 3 or 4 pathogen).
- · A patient hoist falls due to overload.
- Asbestos is released from ducting during maintenance work.

Not reportable

- A member of staff suffers a needle stick injury the source of the sharp is unknown.
- A urine specimen container is broken and the contents are spilled.
- A member of staff is injured by a sharp containing a patient's blood and the patient is not known to have any infection.

HOW TO REPORT

Major incident or dangerous occurrences must be reported to the Health and Safety team as soon as is reasonably possible to ensure that we inform the Health and Safety Executive at the earliest opportunity.

Please ensure that:-

- The scene is preserved. The Health and Safety Executive may come onto site to initiate an investigation.
- The escalation process in the Incident Reporting Policy is started.
- · Telephone the Health and Safety Team.

Over 7 day injuries

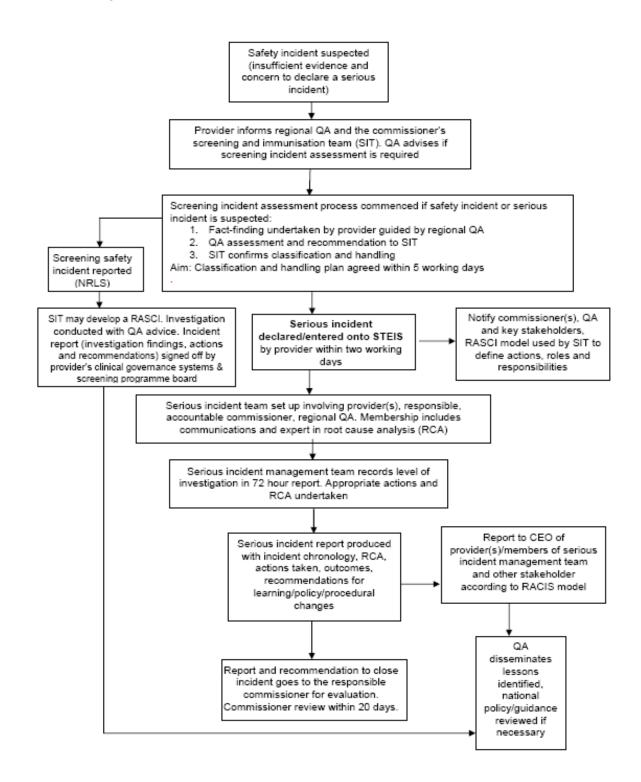
Please ensure that if you are aware that a member of staff has reported in sick as a result of an accident at work you clearly indicate that on the IR1 report. If possible telephone the Health and Safety team to inform them.

Health and Safety Team - telephone numbers

Health and Safety Office numbers - 41481, 41600 or 42040 Health and Safety Manager - 42639

Attachment 6: Managing Safety Incidents in NHS Screening Programmes

The process for managing a safety incident that occurs in the National NHS Screening Programmes is outlined in the flow diagram below. Full guidance, is available at www.screening.nhs.uk/incidents.



Source: Managing Safety Incidents in National NHS Screening Programmes (March 2015).

Attachment 7: Reporting to External Agencies

The Trust has a statutory duty to report certain kinds of accidents, violent incidents, dangerous occurrences and occupational ill health under the Health and Safety at Work Act 1974 and in accordance with the Reporting of Injuries, Diseases and Dangerous Occurrences Regulations (RIDDOR) 1995.

It is also a requirement to report certain incidents to other national organisations, as outlined below:

Organisation	Responsible	Frequency
HSE	Health and Safety Manager	As appropriate, but within 10 days of the incident being reported to them
ICO	Head of Information Governance	As appropriate
NRLS	Governance Information Manager	Weekly
MRHA	Medical Devices Manager	As appropriate
NHS Protect	Local Security Management Specialist	As appropriate
National Screening Programs	Trust Quality Lead for Bowel, AAA, Breast, Cervical, Antenatal and Newborn and Diabetic Eye Screening Programs	As Appropriate

The following process is to be followed:

- Incident is reported via Trust incident reporting system.
- Relevant manager (as per table above) is notified of the incident via a Datix message.
- Relevant manager (as outlined in table above) is responsible for informing the relevant agency as per external agencies own arrangements.

Attachment 8: Root Cause Analysis Tool

Root Cause Analysis is an investigative tool used to understand why an incident has occurred. RCA emphasises the critical exploration of underlying and contributory factors. The Trust has adopted the Root Cause Analysis tool for the investigation of claims, complaints and incidents in line with NPSA guidelines.

Purpose

The Trust has a statutory duty to report certain kinds of accidents, violent incidents, dangerous occurrences and occupational ill health under the Health and Safety at Work Act 1974 and more specifically in accord with the Reporting of Injuries, Diseases and Dangerous Occurrences Regulations (RIDDOR) 1995.

All Severe and Catastrophic harm incidents need to be reported to the Clinical Commissioning Group (CCG) and it is also a requirement to report certain incidents to a national body (ie. Medicines and Healthcare Regulatory Agency, National Screening Programmes) within a specific timeframe. Currently the timeframe for serious untoward incidents is 45 days.

How to Complete This Document

- This document is designed to be completed electronically.
- Complete the right hand column for all sections relevant to the investigation.
- Review the explanatory guidance text in the right hand column to understand the type of issues to consider and positively enter information. For example, in section 4, even if policies were followed and were in-date, state this otherwise there is no evidence that you have considered the possibility.
- The examples given in the right hand column are not exhaustive but are provided as examples. Consider whether anything similar might be relevant to your particular incident investigation.
- If you are unsure about any section, please contact the Investigations team on ext. 42639 or 40285 for guidance.
- Once you have entered your text into each section of the right hand column, delete the explanatory guidance.
- Following completion of the RCA review any areas in which you have ticked "yes". For each section with a "yes" you should consider an action to prevent or minimise the problem from recurring.
- In developing your actions consider the problem by way of the following hierarchy of controls, in order:
 - **Eliminate**-can you eliminate the problem, for example stopping a high risk procedure altogether or not using a hazardous piece of equipment?
 - **Substitute-**can you substitute the problem with something less harmful?. An example is the use of latex free gloves for staff allergic to latex.
 - Isolate/distance-can you isolate or distance the problem from people?
 - Safe Systems Of Work-can you create, or improve upon, safe operating procedures to minimise or eliminate the problem?
 - Training/knowledge/information/Supervision-can you provide additional training or supervision to staff to minimise or eliminate the problem?
 - **Personal Protective equipment-**can you provide protective equipment to staff or patients to minimise harm to them. Examples include hip protectors for patients at risk of falls, eye protectors to prevent splash injuries, sharps boxes to prevent sharps injuries, etc.
- For any quality improvement identified, which cannot be managed locally, please document that these issues have been included in the Directorate Risk Register.

	Questions		Findings	
1	Give a background history and description of the event.	The reaRelevant	onsider in this section include: son for the patient's admission (where the incident involves a patient). It patient medical history including level of confusion, mobility, etc. (where the incident involves a patient). The incident involves a patient fall, the number of previous falls and details of falls risk assessments.	
2	Confirm day, date, time of incident.			
3	Where did the incident occur?			
4	Did deviation from current systems or processes contribute to the event?	Yes No (Delete as applicable)	 Issues to consider in this section include: Whether any policies, procedures or protocols (or the lack of them) affected the incident. Were policies, procedures or protocols followed, out of date, ambiguous or unavailable? 	
5	Did staff actions contribute to the event?	Yes No (Delete as applicable)	 Issues to consider in this section include: Staff motivation - ie. boredom, low job satisfaction. Personality issues - ie. low self-confidence or overconfidence. Domestic or lifestyle issues. Physical ability, fatigue, stress, mental impairment due to illness, drugs, alcohol, etc. 	
6	Did inadequate staff training/skill contribute to the incident?	Yes No (Delete as applicable)	 Issues to consider in this section include: The quality of any relevant training staff had undergone including local induction. The level of experience of the staff. Whether staff had adequate supervision and/or mentoring. Had staff had refresher training to update themselves? Were the staff subject to regular appraisal? 	
7	Did inadequate staffing resources contribute directly to the incident?	Yes No (Delete as applicable)	Issues to consider in this section include: Skill mix. Staff to patient ratio. Use of agency/bank staff.	

8	Did poor communication or	Yes	Issues to consider in this section include:
	information contribute to the		Conflicting information, either verbally or within medical records, etc.
	incident?	No	Inaccurate information.
		(Delete as applicable)	 Poor communication due to language barriers, inappropriate medium (ie. email, fax, etc).
		аррисавісу	Relevant persons not included in communication.
			Poor/absent documentation within medical records.
9		Yes	Issues to consider in this section include:
	equipment appear to contribute to		Whether the equipment was subject to an up to date maintenance programme.
	the adverse event?		 Whether the equipment was familiar to those using it and if they were competent to use it.
		(Delete as applicable)	Whether a safety mechanism failed.
10	Did controllable environment factors	Yes	Examples might include water on the floor, a door that was locked preventing entry/exit, poor flooring,
	directly affect the outcome?		inadequate lighting and poor ventilation.
		No	
		(Delete as applicable)	Has the area been subject to a risk assessment? If answering yes, provide a copy. If answering no, state why.
11	Are there any uncontrollable external	Yes	Examples might include an ambulance strike, a failure of BT systems rendering pagers inoperative, etc.
	factors truly beyond the	NIa	
		No	
	why.	(Delete as applicable)	
12	Are there any other factors that have	Yes	Please detail.
	directly influenced this outcome?	No	
		(Delete as	
		applicable)	

Lead Investigator Name:	Signature

Date:

Designation



Significant action delays, will not meet timescale.

Delayed action still within target date.

Action Complete

QUALITY IMPROVEMENT PLAN

STEIS No.	:		
		RAG Rating :	

Date :

Recommendation	Action	Lead	Assurance Evidence	Timescale	RAG Rating

Version 1: October 2015

Attachment 9: Guidance for Staff in Preparing Statements

You have been asked to write a statement following an incident that was reported to Safety and Governance. You may have been asked for a statement because you either:

- witnessed the incident or
- were involved in the patient's care or the incident

or you have relevant knowledge and/or experience to help the Investigator determine how the incident occurred.

The incident is being investigated to ascertain how it occurred, so that lessons can be learned and improvements made. The purpose is not to apportion blame on any staff members. Please do not include opinions in your statement unless you have been explicitly asked for an opinion.

Your statement is intended to be your accurate and factual account. It should be confined to facts you recall about the patient and your treatment, or facts which you are able to recall after refreshing your memory from entries made by you (or other staff) in the patient's medical notes.

Please note, in some circumstances, your statement may be disclosed to the Coroner, and/or used to respond to a formal complaint and claim.

Start your statement with personal information such as: full name, job title, work address, etc.

Set out your professional qualifications, which should include the year they were obtained and an explanation of abbreviations, ie. RN - Registered Nurse. You should set out your current position and number of years in post and your position at the time of the incident.

- 1. Include the source of the information you are providing, for example, is the information taken from your memory, or the medical records? Did you witness the incident? Do you have a good recollection of events?
- 2. Now you should set out a detailed, chronological narrative (including dates and timings where possible) of your involvement in the incident, which should be set out in paragraphs. Where applicable, describe the patient's condition and relevant details such as:
- The patient's history and presenting complaints.
- The investigations carried out and subsequent results.
- The diagnosis made and treatment provided.
- What was communicated to the patient and their family.

You should set out as much detail as possible for each attendance as even the most routine action can be critical or relevant.

This request has been made in line with the Incident Reporting Policy and Procedure, which is stored on the policy Sharepoint site on the intranet. If you have any questions or queries please contact the Lead Investigator a member of the Investigations Team.

Statement Pro-forma

Name of Patient	
Patient's Date of Birth	
PID No	
Date of Incident	
Incident reference number	
Full Name of Person	
Providing Statement	
Department	
Hospital And Address	
Professional Qualifications	
(including Year(s) obtained	
and an explanation of any	
abbreviations	
Include Relevant Training /	
Experience	
Current Position and number	
of years in post	
Your position at time of the	
incident	

Chronological narrative of your involvement in the incident (as set out in item 4 of guidance)
Statement of Truth:
I believe that the facts stated in this statement are true
Sign:
Date :

Attachment 10:Information Governance Serious Incidents Requiring Investigation (SIRI) Procedure

Information Governance incidents should be reported according to the Trust's Incident Reporting Policy using the online reporting form (IR1). The category of the incident should be 'Records and Documentation', the sub category should be 'Data Protection/Confidentiality'. Reporting the incident is the trigger for the investigation process to begin and anyone receiving verbal notification of potential incident should ensure that an incident report is completed.

SIRI Reporting

The Health and Social Care Information Centre (HSCIC) have introduced a reporting tool to be used to report Serious Incidents Requiring Investigation (SIRIs).

All NHS Trusts are required to use this reporting tool. There is no simple definition of a serious incident. What may at first appear to be of minor importance may, on further investigation, be found to be serious and vice versa.

As a guide:-

- Any incident which involves actual or potential failure to meet the requirements of the Data Protection Act 19981 and/or the Common Law of Confidentiality.
- This includes unlawful disclosure or misuse of confidential data, recording or sharing of inaccurate data, information security breaches and inappropriate invasion of people's privacy.
- Such personal data breaches which could lead to identity fraud or have other significant impact on individuals.
- Applies irrespective of the media involved and includes both electronic media and paper records.

Grading Incidents

The Information Governance team receive automatic alerts for all incidents reported on Datix which are categorised as *Confidentiality/Data Protection*. Where reports are received in other ways, ie. via HR or through a phone call, an incident form *must* be completed.

The incidents are scored on a spreadsheet using the SIRI tool, as follows:

- 0 Information about less than 10 individuals
- 1 Information about 11-100 individuals
- 2 Information about 101-1,000 individuals
- 3 Information about 1,001 + individuals

This baseline score is then adjusted using the following:

Low: For each of the following factors reduce the baseline score by 1					
-1 for each	No sensitive personal data (as defined by the Data Protection Act 1998) at risk nor data to which a duty of confidence is owed				
	Information readily accessible or already in the public domain or would be made available under access to information legislation - ie. Freedom of Information Act 2000				
	Information unlikely to identify individuals				

High: For each of the following factors increase the baseline score by 1					
	Detailed information at risk - ie. clinical/care case notes, social care notes				
	High risk confidential information				
	One or more previous incidents of a similar type in past 12 months				
	Failure to implement, enforce or follow appropriate organisational or technical				
	safeguards to protect information				
+1 for each	Likely to attract media interest and/or a complaint has been made to the ICO by a				
	member of the public, another organisation or an individual				
	Individuals affected are likely to suffer substantial damage or distress, including				
	significant embarrassment or detriment				
	Individuals affected are likely to have been placed at risk of or incurred physical				
	harm or a clinical untoward incident				

Incidents involving HR

Where HR is involved in an incident the incident will be managed by either HR or the IG team as appropriate. The main type of incident which will have HR involvement is likely to be unauthorised access to records.

If unauthorised access to records is suspected an incident form must be completed. Once this has been completed the Information Governance team can carry out an initial audit on the records and report the findings back to HR. This will include confirmation as to:

- what records were accessed.
- who accessed the records.
- · when the records were accessed, and
- any amendments made to the record.

The HR Consultant and the IG team will work together to

- conduct further investigation to determine the root cause of the incident.
- provide details of the incident to the ICO as required.

If it is a level 2 incident the member of staff will be informed by the IG team of this.

The HR Department will carry out appropriate action based on the individual circumstances of each incident. This may include arranging training sessions or undertaking disciplinary proceedings; report to the professional bodies of the staff member involved. Both the NMC and GMC have confirmed that they undertake fitness to practice hearings based on this subject and would also expect to be notified where the Trust confirm that a potential breach of the Data Protection Act 1998 has taken place. The HR department will liaise with the IG team as appropriate.

Reporting Externally

Following the initial scoring, the score is finalised with the Information Governance Manager, and noted on Datix.

If an incident is a level two incident then senior managers will be notified. The Trust is required to report all level 2 incidents on the Information Governance Toolkit Incident Reporting Tool; this automatically informs the Department of Health and ICO of the incident. The incident will also be reported via STEIS. Level 2 incidents are reported quarterly to Monitor.

Incidents classified at severity level 1 will be managed locally. An Information Governance Investigation document will be completed by the Information Governance team for all level 1 incidents; this may include a recommendation that relevant training is undertaken. Level 1 incidents will be reported quarterly to the Information Governance Committee and will be reported as statistics in the annual report.

Examples of Unauthorised Access

All of the following scenarios have been encountered in investigating inappropriate access to healthcare records. In these simple terms each would be deemed to be in breach of Trust Policy and may constitute an offence under the Data Protection Act 1998.

- 1. A work colleague is off sick and you decide to check their records to see if it is something serious so that you can send them a get well card.
 - No. Access to healthcare records should be for healthcare purposes only.
- 2. You have attended the Trust as a patient and decide to check your records to see what has been recorded.
 - No. If you want to access information held about you then this should be done as a Subject Access Request under the Data Protection Act 1998. There are situations where you may not be entitled to access the complete record.
- 3. The Trust's Communications Bulletin announces that a former member of staff has died; you access their record to see what they were suffering from.
 - No. Healthcare records remain confidential even after death. If access does not form a part of your job then do not do it.
- 4. A colleague left the Trust a short time ago and you would like to invite them to a reunion so you check their records to find their telephone number.
 - No. Access to healthcare records should be for healthcare purposes only.
- 5. A relative is due to attend the Trust; you check their record to make sure their details are correct and confirm their attendance.
 - No. If access does not form a part of your job then do not do it.
- 6. A member of staff tells you that they are absent from work to attend a hospital appointment, you check their healthcare record to confirm this.
 - No. Access to healthcare records should be for healthcare purposes only.
- 7. You know it is your colleague's birthday and would like to send a surprise gift to them at their home address so you check their records to find their address.
 - No. Access to healthcare records should be for healthcare purposes only.
- 8. Your child has been treated by the Trust and you check their records to have a look at the treatment they have received.
 - No. Access to healthcare records should be for healthcare purposes only. If you want to view any records then you must make an application to view records in line with the Trust's Access to Healthcare Records Policy.
- 9. You think a colleague has looked at your records so you have a look at theirs in return.
 - No. If you think unauthorised access to any records has taken place then you should report it as an incident. The category of the incident should be "Governance", the sub category should be "Data Protection/Confidentiality".

Attachment 11: Equality and Diversity - Policy Screening Checklist

Policy/Service Title: Incident Reporting Policy	Directorate: Corporate Nursing Directorate					
Name of person/s auditing/developing/authoring a policy/service: Safety & Governance Department						
Aims/Objectives of policy/service:						

Policy Content:

For each of the following check the policy/service is sensitive to people of different age, ethnicity, gender, disability, religion or belief, and sexual orientation? The checklists below will help you to see any strengths and/or highlight improvements required to ensure that the policy/service is compliant with equality legislation.

1. Check for DIRECT discrimination against any group of SERVICE USERS:								
	estion: Does your policy/service contain any ements/functions which may exclude people from	Response		Action required		Resource implication		
using the services who otherwise meet the criteria under the grounds of:		Yes	No	Yes	No	Yes	No	
1.1	Age?		X					
1.2	Gender (Male, Female and Transsexual)?		X					
1.3	Disability?		X					
1.4	Race or Ethnicity?		X					
1.5	Religious, Spiritual belief (including other belief)?		X					
1.6	Sexual Orientation?		X					
1.7	Human Rights: Freedom of Information/Data Protection		X					
If yes is answered to any of the above items the policy/service may be considered discriminatory and requires review and further work to ensure compliance with legislation.								
2. Check for INDIRECT discrimination against any group of SERVICE USERS:								
				A - 4	:	Dage		

2. Check for INDIRECT discrimination against any group of SERVICE USERS:							
Question: Does your policy/service contain any statements/functions which may exclude employees		Response				Resource implication	
fron	n operating the under the grounds of:	Yes	No	Yes	No	Yes	No
2.1	Age?		X				
2.2	Gender (Male, Female and Transsexual)?		X				
2.3	Disability?		X				
2.4	Race or Ethnicity?		X				
2.5	Religious, Spiritual belief (including other belief)?		X				
2.6	Sexual Orientation?		X				
2.7	Human Rights: Freedom of Information/Data Protection		х				

If yes is answered to any of the above items the policy/service may be considered discriminatory and requires review and further work to ensure compliance with legislation.

TOTAL NUMBER OF ITEMS ANSWERED 'YES' INDICATING DIRECT DISCRIMINATION =

3. Check for DIRECT discrimination against any group relating to EMPLOYEES:							
Question: Does your policy/service contain any conditions or requirements which are applied equally to everyone, but disadvantage particular persons' because they cannot comply due to:		Response		Action required			
		Yes	No	Yes	No	Yes	No
3.1	Age?		Х				
3.2	Gender (Male, Female and Transsexual)?		Х				
3.3	Disability?		Х				
3.4	Race or Ethnicity?		Х				
3.5	Religious, Spiritual belief (including other belief)?		Х				
3.6	Sexual Orientation?		Х				
3.7	Human Rights: Freedom of Information/Data Protection		X				
If y	es is answered to any of the above items the policy/ and requires review and further work to ensu		•				,
4. C	heck for INDIRECT discrimination against any g	roup i	relatir	ng to l	EMP	LOYE	ES:
Question: Does your policy/service contain any statements which may exclude employees from		Response		Action required		Resc impli	ource cation
ope	rating the under the grounds of:	Yes	No	Yes	No	Yes	No
4.1	Age?		Х				
4.2	Gender (Male, Female and Transsexual)?		Х				
4.3	Disability?		Х				
4.4	Race or Ethnicity?		Х				
4.5	Religious, Spiritual belief (including other belief)?		Х				
4.6	Sexual Orientation?		Х				
4.7	Human Rights: Freedom of Information/Data Protection		X				
If yes is answered to any of the above items, the policy/service may be considered discriminatory and requires review and further work to ensure compliance with legislation.							
TOT	AL NUMBER OF ITEMS ANSWERED 'YES' INDICATII	NG IND	IREC	T DISC	RIMI	NATIO	N =
Sig	Signatures of authors / auditors :						

Date of signing :

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