Incident Management Policy
(Including Serious Incidents)

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Executive summary

The vision of Leeds GP Confederation (The Confederation) is to:

- Help practices remain sustainable by building on the attributes of primary care
- Enable practices to play a full and active role in quality improvement, service integration and pathway development, aligned with the local care partnership vision
- Create a governance system that enables practices be active in contributing to both local and citywide strategy.
- Create an organisational structure which is able to hold contracts and deliver services across general practice in Leeds and in partnership with other providers in the city. Listen & Act

The delivery of high quality care is identified as one of the ways of achieving this vision. Key to the provision of high quality care is ensuring that when things go wrong, events are reported and investigated, actions are implemented to reduce future likelihood of recurrence and learning takes place.

This policy sets out to outline the processes for all incident management including serious incidents (SI's) so that all staff are aware of their responsibilities and understand their contribution to patient safety.

Implementation of this policy supports and contributes to the Confederation Risk Management Policy and Procedure and the governance framework within which risk is managed.

The policy also contributes to the compliance with the following:

Care Quality Commission (CQC) Statutory Notification Requirements:

- Notification of death of a person who uses services
- Notification of death or unauthorised absence of a person who is detained or liable to be detained under the Mental Health Act 1983.
- Notification of other incidents

Health and Social Care Act 2008 (Regulated Activities) Regulation 2014 (Part 3)

Regulation

- Safe care and treatment (12)
- Good Governance (17)
- Duty of Candour (20)

Changes made to this version:

Section	Detail of each change made

Contents

1 Introduction

The Leeds GP Confederation is committed to the delivery of a safety culture which is open and transparent and in which all Confederation employees proactively identify, assess, report and manage risk. The Confederation acknowledges that incident reporting is a vital part of minimising risk to patients, staff, visitors, contractors and the organisation. Any incident, whether resulting in an unintended or unexpected event that could have led to or did lead to harm or damage, must be reported. This enables the organisation to learn from near misses, incidents and serious incidents (SI), to manage risks and improve safety.

The Confederation has a systematic approach to incident reporting, which enables the organisation to investigate incidents effectively; to review practice; and to identify trends and patterns in order to ensure every incident results in learning and improvement . It enables the quick detection and resolution of any problems resulting from inadequate procedures, lack of training, or pressure of work.

This policy sets out the process for the identification and reporting of incidents and then details how the incident should be managed. This includes escalation of incidents as SI's (Serious Incidents) and the external reporting requirements.

This policy should be read in conjunction with other relevant Policies and Strategies, in particular the Confederation Risk Management Policy, Being Open and Duty of Candour Policy and Procedure, Health & Safety Policy and freedom to Speak Up Policy, alongside the NHS England Serious Incident Framework March 2015.

In order to improve safety and minimise risk the organisation is committed to being open and learning from mistakes.

1.1 Scope

This Policy applies to all staff employed by the Leeds GP Confederation and encompasses any incidents involving patients, clients, staff (including trainees and locum), volunteers, contractors or visitors (including carers, relatives and advocates).

This policy covers all incidents and near misses both clinical and non-clinical. Staff can report incidents without fear of prejudice for doing so as long as the information provided is done so in good faith. Incident reports must be focused on the facts of the event and the consequences of the incident.

Concerns about service provision or performance of individual members of staff should be raised by an alternative route. Where incident investigations give rise to concerns regarding staff performance, Human Resources (HR) advice must be sought to ensure that appropriate policies are followed. Alternatives are detailed in the Trust's Freedom to Speak Up Policy.

2 Aims and objectives

The aim of this policy is to support a safety culture in which all Confederation employees proactively identify, report and manage incidents through the implementation of this Policy.

The objectives are to ensure that:

- staff know how to report an incident;
- staff are aware of their responsibilities in incident and SI management;
- incidents are thoroughly investigated;
- incidents are assessed in terms of risk to patients and staff;
- staff receive appropriate support and advice;
- managers feedback findings of investigations
- actions are taken to reduce risk of reoccurrence;
- learning is shared across the organisation;
- learning is shared externally where appropriate;
- the Trust complies with regulatory, legislative and statutory requirements

3 Definitions

3.1 Incident

An unintended or unexpected occurrence or event that could have led to, or did lead to, harm or damage. It includes events which:

- May have caused harm to patients, staff and visitors:
- May have caused harm to property or equipment
- May have caused harm to reputation
- May have caused financial harm
- May have had the potential to cause harm but this has been averted;
- May indicate that change is needed to maintain quality of patient care.

This definition covers all areas including patient, client or visitor injury, together with adverse patient or client incidents; fire, theft, fraud incidents of violence and aggression including verbal, physical, significant loss or damage; assault and employee accidents.

3.2 Serious Incident (SI)

The revised **NHS England Serious Incident Framework** 2015 identifies a serious incident as 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.

There is no definitive national list of specific events/ incidents that constitute a Serious Incident and local lists should not be created as this can lead to inappropriate management of an incident.

However, there are some circumstances in which a Serious Incident MUST be declared. Serious Incidents in the NHS include:

A. Acts and/or omissions occurring as part of NHS-funded healthcare (including in the community) that result in:

- Unexpected or avoidable death [1] of one or more people, including:
  - suicide/self-inflicted death; and

  - homicide by a person in receipt of mental health care within the recent past[2];

- 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;

- 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 occurring[3], 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.

[1] 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.

[2] 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.

[3] 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.

B. A Never Event (NE):

The Department of Health (DoH) identifies what incidents are 'Never Events'. All these are defined as serious incidents although not all Never Events necessarily result in serious harm or death. See the DoH NE policy and framework for the national definition and further information. There is a published list of Never Events available as well as a frequently asked questions document to assist with understanding Never Events.

C. 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;

- Incidents in population-wide healthcare activities like screening 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 services); or
- Activation of Major Incident Plan (by provider, commissioner or relevant agency)

D. Major loss of confidence in the service, including prolonged adverse media coverage or public concern about the quality of healthcare or an organisation.

E. A 'Near Miss' may also constitute an SI 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.

3.3 Investigation

A formal process of analysing an event and recording the outcomes

3.4 Likelihood

The chance of a given event occurring (or recurring).

3.5 Risk

The possibility of suffering harm, loss or damage. Risk is the combination of likelihood and consequence of a risk/harm materialising.

3.6 Grade

A measurement of the risk useful for assessing the priority for control measures for the treatment of different risks.

3.7 Risk Reduction

The strategies and process by which the Trust can seek to reduce risks through the introduction of control measures.

3.8 Root Cause Analysis

A structured approach to the analysis and investigation of an incident and the identification of the underlying cause(s) of an incident and the actions necessary to eliminate or reduce its reoccurrence.

3.9 Contributing factors

Contributory factors are those which may have had an effect on the delivery of safe and effective care to patients, or had an impact on the circumstances of the incident. They may have an influence on the occurrence or outcome of the incident. Generally speaking the removal of a contributory factor may not always prevent incident recurrence but will generally improve safety.

3.10 Root Cause

The prime reason(s) why an incident occurred. A root cause is a fundamental contributory factor. Removal of these will either prevent, or reduce the chances of a similar type of incident from happening in similar circumstances in the future.

4 Responsibilities

All staff employed by The Leeds GP Confederation must work in concordance with the Leeds Safeguarding Multi-agency Policies and Procedures and local guidelines in relation to any safeguarding concerns they have for service users and the public with whom they are in contact.

4.1 Confederation Executive

The Executive has overall responsibility for the quality, health, safety and welfare of patients, staff and members of the public, and to ensure that the Confederation complies with its statutory obligations in this regard.

The Executive must be assured by the Audit Committee and Internal and External Auditors that there are systems and processes in place to manage Incidents and Serious Incidents. The Medical Director has delegated responsibility for ensuring these processes are implemented effectively.

The Board will receive a confidential report of all Serious Incidents, any resulting inquests and mitigating action to reduce risks at the private section of every Board meeting.

4.2 Chief Executive (CE) or Designated Deputy

The Chief Executive has ultimate responsibility for all aspects of incident management including the implementation and monitoring of this policy.

The CE as the accountable officer will, via the governance structures ensure:

- Remedial action is taken to manage SI’s and reduce risk to others
- External organisations are notified as necessary
- Communications and media statements are prepared
- Action plans from investigations are implemented and monitored

4.3 Medical Director

The Medical Director has delegated authority from the Chief Executive to ensure there is a suitable process for the management of all incidents and it is functioning in accordance with this Policy.

4.4 Executive Directors or second on call

- Inform the Chief Executive and the Chair at the earliest opportunity of any SI
- Retain overall responsibility and accountability for the investigation and assign a Lead Investigator to conduct the investigation. (The Clinical Governance Team will complete this in hours)
- Inform a member of the Communications Team if necessary – see section 4.9 (The Clinical Governance Team will complete this in hours)
- Ensure that appropriate remedial action is taken and management of action plans are monitored through the committee structure and reported to the Trust Board
- Attend Executive Director review panel meeting prior to submission of the final investigation report

See the Timeline for responsibilities for managing an SI (Appendix 9)

In addition, Out of hours:
Contact the Chief Executive and Chair immediately if the SI is of an exceptional nature e.g. likely to result in catastrophic impact on the reputation of the organisation or attract significant media attention.

4.5 General Manager / Clinical Lead / First on Call

- Implement the Risk Management Policy and this Policy
- Ensure incident reporting procedures are in place
- Ensure persons throughout the incident reporting process understand their roles and responsibilities and have the capabilities to contribute effectively to the incident reporting process
- Appropriately delegate the responsibility for the investigation process, providing support where required. This may involve taking on the role of lead investigator depending on the severity of the incident
- Ensure investigations are undertaken in a fair and equitable manner
- Consider relevant Confederation HR Policies if appropriate
- Monitor the quality and effectiveness of the investigation process
- Ensure all actions identified following investigation are implemented and arrangements agreed for inclusion of risks on the appropriate risk registers if required
- Ensure relevant timescales, both internal and external, are adhered to
- Enable learning is shared across the organisation
- Where there is media interest (actual or potential) the affected patients and staff are informed, when appropriate, before the media.

In addition out of hours:

- Prompt staff to complete an Incident Report Form via Datix® before their shift is over
- In the event of a suspected SI, the second on call must be contacted and follow the timeline for responsibilities for managing an SI (Appendix 9)

- The incident is handed over to the respective service manager in hours so that they can continue to manage the incident.

4.6 Line Manager / Handler

- The line manager / incident handler is responsible for managing the incident as it unfolds and ensuring the patient continues to receive treatment where appropriate
- Will ensure that the duty of candour requirements are fulfilled through an initial Being Open discussion with the patient/patient representative
- Will perform a risk assessment to identify immediate measures to prevent recurrence
- Act as first point of contact and support for staff who have witnessed or been involved in an incident
- Review all incident reports via Datix® submitted by their staff within two working days
- Ensure the completion of the investigation of all incidents within the appropriate timeframe
- Ensure any actions recommended to the investigator by the specialist reviewer are completed in the requested timescale and recorded via Datix®
- Follow up and escalate where necessary if actions not complete
- Provide final approval via Datix®
- Develop and implement actions plans, monitor progress and record outcomes where this is necessary to reduce overall risk
- Run reports to identify and analyse themes and trends
- Establish if any complaints are linked to the incident
- Take on the role of lead investigator or delegate the role to a member of the team
- Assess the situation to determine that the appropriate actions have been taken to ensure ongoing safety for staff and patients.
- Keep relevant patients, carers, staff and others informed of the progress and outcomes of any investigations
- Reinforce the value of, and need for, incident reporting and provide feedback to staff on the outcomes of the reports they have made
- Ensure all staff involved with traumatic/stressful incidents are offered support following the incident
- Attend relevant training identified in the training needs analysis
- Share learning from incidents within team and with the wider organisation as required

In the event of a suspected SI, the Line Manager must contact their General Manager or Clinical Lead/First On call immediately and follow the timeline for responsibilities for managing an SI (Appendix 9).

4.7 All Employees

All Confederation employees must:

- Be aware that incident reporting is a part of their own responsibility for governance
- Be engaged with the principles of being open and duty of candour, offering apology when care / outcomes are not as expected
- Report any incidents to the Manager/Supervisor responsible for the area in which the incident occurred.

- Report incidents by the end of their shift via Datix® incident management system in accordance with this policy
- Report any Serious Incidents immediately to the appropriate manager to minimise harm and ensure ongoing safety for staff and patients
- Document a record of all incidents affecting patient safety in the patient's record.
- Be familiar with the Trust's Incident Management Policy and comply with this in conjunction with the Risk Management Policy, Being Open and Duty of Candour Policy and Procedure, Departmental Clinical policies and Health and Safety Procedures

All employees have a duty to their patients, employer and fellow colleagues to co-operate fully with an investigation. This is to ensure that an incident is thoroughly investigated, with appropriate outcomes.

The employer responsible for the employment of a contractor must complete an incident report on Datix® Web for incidents involving a contractor.

4.8 Head of Governance

The Head of Governance has overall responsibility for ensuring the Confederation has effective systems and processes in place to effectively and appropriately manage SI's. It is the responsibility of the Head of Governance to ensure that:

- The organisation has robust systems and processes in place to effectively manage incident and serious incidents and the Datix® system is maintained
- Compliance with the policy is monitored and developed as necessary
- Access to incident reporting via Datix® is enabled
- Information from all reported incidents is received and collated
- Incident data quality is monitored to ensure that correct coding and grading has been applied as per the Trust Risk Matrix
- Ensure timely reporting to NHS England through the National Learning and Reporting System (NRLS) and to disseminate NRLS incident reports.
- Advice on external reporting is provided
- All incidents relating to the building structure owned by other NHS Trusts where Confederation staff are working will be forwarded to the appropriate risk team
- Assistance is provided for the reporting and investigation of incidents, including the role as critical friend following an SI.
- Liaison with the relevant managers to ensure that sufficient investigation has been undertaken and action plans completed
- Incident themes and trends are aggregated and reported to the relevant Directorate, Patient Safety and Experience Governance Group, Quality Committee and Trust Board via required reporting mechanisms
- Wider learning is disseminated to appropriate services and committees
- Serious incidents are escalated to an Executive Director
- Standard Operating Procedures are followed to ensure the SI process is adhered to, within dedicated timeframe
- Appropriate incidents are reported to the Health & Safety Executive (HSE) under the Reporting of Injuries, Diseases & Dangerous Occurrences Regulations (RIDDOR) 2013

- Appropriate incidents are reported to the Medicines and Healthcare Products Regulatory Agency (MHRA)
- Triage and dissemination of relevant Central Alerts (CAS), including National Patient Safety Agency, Pharmacy, and equipment alerts
- Identifying need for changes in practice as a result of an incident investigation and implementation of National Safety alerts
- Requesting relevant clinical audit where appropriate.

In the event of an SI the Head of Governance will work with the Medical Director to ensure that:

- The management of Serious Incidents is co-coordinated including the external reporting
- Inform the Commissioners Team of the occurrence of an SI and keep them informed of scheduled significant events.
- The appropriate SI procedures are followed in the given timeframes
- Managers undertaking incident investigations are supported and advised as appropriate
- Advice on root cause analysis (RCA) processes is given
- Communication between the Trust and legal parties takes place as required
- Coordinate and attend the Executive Director review panel meeting prior to submission of the final investigation report
- Action plans are monitored and signed off plans are forwarded to external agencies as appropriate
- Lessons learnt are both disseminated throughout the organisation and uploaded to external databases where required.

4.9 The Communication Team

Communications are a vital element of supporting and delivering effective management of serious incidents. All bodies with a remit under the requirements of this policy framework are responsible for ensuring that robust communications and media management arrangements are in place for both internal and external communication.

In many cases serious incidents can lead to a high level of media attention and not only in the immediate aftermath. The management, investigation and learning from incidents can be triggers for media coverage for an extended period after the incident itself. In forensic/criminal cases, the police lead all communications with the media.
The Communication Team will:

- Develop a media handling strategy in relation to the incident in conjunction with the Executive Director or CE. This may include the preparation of a press statement depending on the issue.
- Liaise with the Commissioner Communications team immediately if there is the possibility of adverse media coverage, so that a media handling strategy can be agreed together.
- Liaise with other organisations regarding a communications strategy as appropriate
- Ensure all future press releases are completed in consultation with the Chief Executive, taking account of the relevant circumstances.
- Manage the flow of information to the Trust staff as a whole
- Document the flow of information to all parties.

Out of hours:
Clinical Commissioning Group (CCG) On-Call will provide out of hours communication support as part of their regional role. Confederation On-Call managers should advise the CCG On-Call communications team regarding any media contact.

4.10 Information Governance

Information relating to serious incidents including information held on national systems such as STEIS/UNIFY, local databases and internal reports, including investigation reports and root cause analysis and other documents, could be subject to a request for disclosure under the Freedom of Information Act 2000. Any request for information regarding a serious incident/s should follow Freedom of Information Act policies of the organisation that has received the request and should be referred to the Information Governance Department immediately.

4.11 Specialist Reviewers

To ensure an appropriate response to particular incidents a number of specialist reviewers have been identified who will receive notification of all incidents within their sphere of expertise. For example all medication incidents are reviewed by a member of the medicines management team.

Specialist reviewers are required to:

- review all incidents forwarded to them
- advise on appropriate action where it is necessary
- provide quarterly incident action logs pertinent to their specialist field
- use the action log to analyse incident data, trends and actions required to mitigate risk
- Feed reports via the relevant Governance structure into appropriate groups for review and acceptance and share with Clinical Leads where appropriate

A list of specialist reviewers and the incident types they are required to review is available from the Clinical Governance Team

4.12 Critical Friend

The Critical Friend will normally be a non-executive director. The Critical Friend will:

- support the Lead Investigator with the process of their investigation
- assist with production of the serious incident investigation report
- advise investigator on relevant policies (i.e. Duty of Candour)
- provides challenge to ensure a robust investigation
- provide quality assurance of the investigation information
- support the investigator when attending SI review panel

5 Incident Management

5.1 Principles

The Confederation is committed to reducing avoidable harm for users and patients and indeed to staff and visitors. However, it is well recognised and documented that in a busy healthcare environment there are complex and fallible human factors that contribute to the systems in place and errors and incidents will always occur. When this happens the Trust's priority is to ensure efficient and effective management and to prevent recurrence.

It is the policy within the Confederation that all incidents are reported promptly, investigated fully and, where appropriate, change in practice identified, approved, put in place and monitored. This will ensure that the Trust is not only a learning organisation but one with an informed safety culture.

It is the Confederation policy to be open and honest with patients / carers and all service users when things go wrong. The Confederation endorses the CQC regulations relating to Duty of Candour and strives to provide patients and/or carers with an apology and explanation as soon as possible after a patient safety incident has occurred. Staff are encouraged to apologise on the spot as this is the right thing to do and is not an admission of liability.
Patients have a right to expect openness in their healthcare under the principles of duty of candour and all explanations of the facts as they are known at the time should be offered as part of a 'being open' discussion at the time of the incident. Further information is given in section 2.5.1 and the Being Open and Duty of Candour Policy and Procedure.

Individual investigations of incidents may overlap with those of complaints, disciplinary procedures, managing performance, litigation, coroner's investigations, professional registration, child protection, safeguarding, domestic homicide, Health and Safety Executive (HSE) or police enquiries. It is vital that links are made between ongoing investigations and information shared as directed. Staff need to be aware of the correct sequence and take advice if uncertain.

The Confederation recognises that incident management can have a significant effect on staff directly involved in an incident or investigation and this should not be underestimated and all incident investigations should consider the support required to staff as highlighted in section 2.5.

5.2 Incident Reporting Process

Identification, recording and analysing information on incidents are essential steps in reducing risk, creating a safer environment for both patients and staff, and ensuring that lessons learnt are acted on and fed back into practice. Collation of all information and facts is of paramount importance. It may also prove invaluable in the event of a subsequent complaint or claim or external investigation.

The Confederation is committed to an incident investigation process that is:

- Fair and equitable
- Focused on identifying root causes
- Focused on embedding learning, change and improvement

All staff must take responsibility for completing an incident report form (via Datix® web electronic reporting system) when they experience or witness any incident or near miss. Staff should report all incidents and near misses, irrespective of severity, and should be aware that several similar reports may indicate a growing trend or allow a possible serious incident to be foreseen and averted. Advice is available from the Clinical Governance Team where needed.

For all incidents the member of staff, where possible, should discuss with a manager whether any immediate action / notification to other team members is required.

5.2.1 Reporting an incident

All incidents must be reported via Datix® by the end of the working day by the individual witnessing, experiencing or being alerted to the incident. This person is the reporter and must complete all mandatory fields and indicate the actual impact i.e. severity (what has actually been the seriousness of the outcome of this incident). See appendix 3 for definitions of harm.

Datix® will generate an automatic email notification to the chosen Handler (selected by the Reporter – in the majority of cases this will be the reporter's Line Manager) and other designated managers based on the subject nature and severity.

The reporter / handler need to ensure all categories chosen are correct and appropriate (see appendix 4 for further information on categories of incidents).

Wherever the incident is of a serious nature (see Section 1.4.2), a phone call to the relevant Service Manager, Clinical Lead and Medical Director must be complete prior to completing an incident report. The incident may require escalation as a serious incident (SI).

Where there is any doubt or uncertainty a phone call to the Clinical Governance Team to seek clarity must be made. The Datix® web record should be the main form of all correspondence between the handler, investigator and Clinical Governance Team using the communication and feedback function where possible.

5.2.2 Delegation

If the Handler or investigator receiving the incident for investigation and action feels it more appropriate that it should be dealt with by another member of the team, such as another discipline, or another business unit they must pass on the incident to them without delay. They must gain agreement as to who will become the incident handler and then assign them in the Datix® record (see appendix 5 for details).

5.2.3 Incidents on Non-Confederation property

In the event an incident occurs in a building owned by a third party e.g. Leeds Teaching Hospital Trust or other Provider Trust, a Prison site or a LIFT building, this must also be reported as per local process for that area unless this building is being occupied by the Confederation for the purpose of delivering a service it is contracted to provide.

5.2.4 Grading of incidents and SIs

The reporter and incident handler have first line responsibility for ensuring that incidents are graded accurately. This is quality assured within the Clinical Governance Team in accordance with the NHS England National Reporting Learning System (NRLS) coding system. All incident data (incidents that relate to patient safety) will be validated before adding to the NRLS database.

Incidents are graded based on a 5 level system (1-5) with three overall colours (green, amber and red).

Green incidents have generally caused insignificant/low or no harm to individuals.
Amber incidents are those where moderate harm has been identified. These incidents may trigger the duty of candour process and some will fulfil the criteria for SI reporting although not all will necessarily be considered Serious Incidents.
Red incidents are where major / severe harm / death has occurred and the SI criteria is reached. These incidents are all considered SI's and must be reported immediately to the Clinical Lead / Manager on call and Clinical Governance Team via Datix® reporting. Red incidents are categorised as either major or catastrophic level.

	Grade	Type	Example	Level of investigation	Internal Reporting	External Reporting
Minor	**1 Green**	**Insignificant / No Harm**	Minor non compliance with standards / targets. No harm to individuals. Local media < 1 day coverage	**Line manager Service Lead**	Service Teams QPF Committee	None
Low	**2 Green**	**Minor**	Single failure to meet internal standards / targets. Minimal impact – low harm to individuals. No risk of litigation. < 3 days extended hospital stay or < 3 days staff absence. Local media < 7 day coverage.	**Line manager Service Lead**	Service Teams QPF Committee	None
Moderate	**3 Amber**	**Moderate** (may be SI)	Several failures to meet internal targets / standards. Risk of litigation. Moderate increase in treatment / significant harm to individual. 3 days extended hospital stay or > 3 days staff absence & reportable to HSE. National media < 3 day coverage.	**Investigation led by Executive Director** Level 1 SI Investigation (if applicable)	Clinical Forums QPF Committee Exec (if SI)	NRLS (PSI's) CCG (if SI)

Major	**4 Red**	**Major (SI)**	Serious adverse incidents, significant issues of standards, quality of care, safeguarding, that may cause lasting problems, multiple injuries, serious long term harm to individuals or death. Local/regional media >7 days coverage	**Investigation Led by Medical Director** Level 2 SI Investigation	Clinical Forums QPF Committee Exec	NRLS (PSI's) CCG Coroner & PPO (DiC)
Catastrophic	**5 Red**	**Catastrophic (SI Requiring Independent Enquiry)**	Multiple fatalities, gross failure to meet professional standards/targets causing long-term damage or death. Criminal offence, gross substandard care or gross professional misconduct. Full public enquiry. Gross data loss (level 3-5) National / international media > 3 day coverage.	**Investigation (RCA) Outwith Trust** Level 3 SI Investigation	Clinical Forums QPF Committee Exec	NRLS (PSI's) CCG Coroner & PPO (DiC) CQC / Monitor

5.2.5 External Reporting

The Confederation has legal and statutory obligations to record and report certain defined incidents externally as identified in 2.2.4. This is determined by either the grade or the type of incident.

The following table describes the incident types and the receiving agency:

Incident Type	Reportable to	Responsibility
Information Governance	Information Commissioners Office	Head of Information Governance or Clinical Governance Team in their absence
Medical Device Incidents	Medicines and Healthcare Products Regulatory Agency (MHRA) http://www.mhra.gov.uk/index.htm	Investigating Manager (link available via Datix®) - A copy of the externally filed report should be uploaded to the Datix® incident
Medication – suspected adverse drug reactions (yellow card scheme)	Medicines and Healthcare Products Regulatory Agency (MHRA) http://www.mhra.gov.uk/index.htm	Investigating Manager A copy of the externally filed report should be uploaded to the Datix® incident
Patient Safety Incidents	National Reporting & Learning System (NRLS)	The Clinical Governance Team reports all patient safety incidents to the NRLS via a dedicated web link
Physical Assault on Staff	NHS Security Management Service (automatically sent to LSMS if correct category chosen)	Local Security Management Specialist (LSMS)
RIDDOR (see section 2.3.4) NB: Some patient safety incidents which result in hospital treatment are also reportable. Contact the Clinical	Health & Safety Executive To report use the link via the HSE website http://www.hse.gov.uk/riddor/	Investigating Manager (link available via Datix®) - A copy of the externally filed report should be uploaded to the Datix® incident NB: if the HSE make contact with the Service to visit, ensure Line Manager and the Clinical Governance Team are informed immediately to provide support

Governance Team for guidance		
Section 17 returning after 12MN	Care Quality Commission	Investigating manager in discussion with Director of Nursing and Clinical Governance Team
Serious Adverse Blood Reactions & Events (SABRE)	Medicines and Healthcare Products Regulatory Agency (MHRA) http://www.mhra.gov.uk/index.htm	Investigating Manager A copy of the externally filed report should be linked to the Datix®incident
Serious Incidents	Clinical Commissioning Group (CCG) / NHS England / other Commissioners	Clinical Governance Team via STEIS

5.3 Management of Incidents

All incidents require some level of investigation in order to identify the underlying causes of how and why the incident has occurred. The level of the investigation will depend upon the degree of harm to the patient/carer/relative or staff member and the risk of future harm. For this reason, all incidents require a likelihood / consequence grading by the team / service manager when completing the incident form.
All incident investigations must commence immediately if safe and legal to do so, and comply with the timescales outlined in section 2.3.1 and appendix 6 – 10.

At the start of the process of investigation, issues that require an immediate specific risk assessment may be highlighted to identify the current risk and actions required to minimise the immediate risk. This may need escalating to senior managers to consider logging onto their local risk register via the appropriate risk owner.

5.3.1 Level of Investigation

Green incidents will be investigated locally by the service within which they occurred by the handler for the incident as recorded on Datix®, or by another investigator and reviewed by the handler. Outcomes of the investigation and actions taken must be documented on the Datix® incident report. The handler will sign-off the actions as complete and update Datix®. The incident can then be closed in Datix® but will, of course, contribute to trend reports. The timescale for green incidents will be 15 working days from reporting to closure. The handler is responsible for ensuring that the timescale is met.
These incidents should be discussed locally at team meetings and any learning shared within the Business Unit or escalated to the Quality, Performance and Finance Committee for further discussion.

Amber incidents are investigated within the business unit within which they occurred. If they are Patient Safety Incidents within Confederation care they require a robust investigation and the RCA approach should be utilised. Outcomes of the investigation and actions taken must be documented on the Datix® incident report and an RCA report will be completed and attached by the incident handler. Learning from these incidents will be discussed at Quality, Performance and Finance Committee and within local teams and clinical forums. The timescale for amber incidents is 30 working days from reporting to closure, unless the amber incident fulfulls the SI criteria. In this case the RCA will be submitted as per the SI process.

Red incidents will be investigated outwith the Service involved as an SI and will be reviewed at Quality, Performance and Finance Committee. A catastrophic incident requires an independent enquiry therefore the investigation is outwith the Confederation. Red incidents will require external reporting and/or SI reporting. The timescale for SI's is determined by the CCG under the NHS England Serious Incident Framework and will be 60 working days from reporting to submission of final report.

In addition, all incidents where the outcome has been death will be discussed at the mortality surveillance meetings.

The Business Unit will ensure that appropriate handlers and investigators are assigned to each incident. The Clinical Governance Team will follow up on all incidents to ensure closure within the timescales and highlight overdue incidents.

Additional staff for example Specialist Reviewers, Quality and Professional Development, Health and Safety Adviser, clinical, HR, managerial or technical staff may need to be identified to provide expert advice as part of the investigation team.

Where the investigation is complex and involves other organisations, these will be agreed by the Executive Director leading the investigation and they will be approached for their involvement. There may be instances where the Confederation is the Lead Provider, but they are not the main provider.

In very serious cases, particularly where there is likely to be significant public interest and external parties involved, it may be necessary to commission an external review or include an external representative on the panel conducting the internal inquiry. An Executive Director will advise on where this is appropriate.

5.3.2 Equipment

In certain circumstances the scene of the incident may need to be preserved or equipment retained for inspection. Any equipment involved suspected to have precipitated or caused harm must be quarantined and reported to the Medicines and Healthcare Products Regulation Authority (MHRA). The equipment must not be used until it has been checked and certified safe for use by the MHRA or the Equipment contractor.

5.3.3 Medication and Controlled Drugs

All incidents involving medication will be reviewed by the Specialist Reviewer for medication from the Trust's Medicines Management Team who will advise on the incident investigation to be implemented. All incidents involving a controlled drug (as defined by Schedules 1-4 of the Misuse of Drugs Regulations 2001) will be reported to the Executive Medical Director as LCH Accountable Officer by the Medicines Management Team.

Reporting of Injuries, Diseases and Dangerous Occurrences Regulations (2013) RIDDOR

Certain incidents need to be reported to the Health and Safety Executive (HSE) under RIDDOR regulations. If it proves impractical to complete this form within 48 hrs and the circumstances require reporting through RIDDOR, it will be necessary for the senior manager to fax/phone basic details about injured staff members to the Occupational Health Service. The investigating manager must complete the RIDDOR report via the link available in Datix® and upload a copy of the externally filed report to the Datix® incident. If the HSE make contact with the Service to visit, Line Manager and the Clinical Governance

Team must be informed immediately to provide support. See also the Confederation Health and Safety Policy.

5.3.4 Internal investigations and other inquiries

Internal inquiries must not interfere with other investigations e.g. police, Health & Safety Executive. Reference must be made to the Memorandum of Understanding between the Department of Health, Health and Safety Executive (HSE) and Association of Chief Police Officers (February 2006).

This indicates that careful consideration needs to be given to the conduct of any NHS investigation once a matter has been referred to the police, HSE or other statutory bodies.

In such cases immediate patient and staff safety must be assured with further investigation taking place only after discussion with an Executive Officer who may establish an Incident Coordination Group. The primary concern of all agencies is that of public safety. While there is nothing in law that states the police's duty to investigate ranks higher than the NHS' duty to ensure patient safety, interference with a police investigation could undermine potential legal proceedings. Any request by the police for the NHS organisation involved not to discuss the incident with others can never override the NHS organisation's obligations to do this.

5.3.5 Professional Issues and Criminal Acts

If, during an investigation, matters relating to professional standards, conduct and performance are identified, the investigating team or individual must refer these matters to the investigating General Manager / Clinical Lead and a decision made about whether to pursue the issues through alternative Confederation policies, for example Managing Concerns about Performance or Disciplinary Policy. Professional Leads should be notified where there is a regulatory requirement to report i.e.to professional bodies such as the HCPC, NMC or GMC? Consideration must be given in respect of whether members of staff can continue their duties and if suspension with or without prejudice is necessary. Such decisions can only be made by the Executive Director.

Where there are serious concerns about the actions of an individual health professional and they are considered likely to be seeking work with other employers who would be unaware of the concerns, the Confederation will liaise with commissioners, other providers and regulatory bodies.

If there are concerns that a criminal act has taken place then the lead investigator must ensure the scene of the incident is secured and preserved. All investigations must cease and the police notified immediately.

5.3.6 Postgraduate Trainees

When an incident is reported as an SI the Local Education and Training Board (Health Education Yorkshire and Humber) requires notifying of all postgraduate trainees involved in the incident. The lead investigator will forward the names of all postgraduate trainees involved in the SI for the attention of the Medical Director and the Trust Portfolio Lead for Postgraduate & Undergraduate Education; who will be responsible for informing HEYH / the deanery.

5.4 Serious Incident (SI) Process

All incidents that are graded as “red” on the incident grading matrix should be escalated to the Clinical Governance Team and the relevant clinical lead as a potential SI as set out in section 1.4.2.

The potential SI is discussed with the Clinical Governance Team and the incident handler / clinical lead to ascertain if the SI criteria is met. Further discussion may be required with an Executive Director, Chief Executive, Clinical Commissioning Group Lead or NHS England Governance Manager for SI’s if further clarification is required.

When the SI is declared a grade of investigation must be agreed in accordance with the NHS England Serious Incident Framework grading guide, a summary of which is presented below.

Information in this table provides an outline of the levels of systems-based investigations recognised in the NHS (currently referred to as RCA investigation). Within the NHS, most serious incidents are investigated internally using a comprehensive investigation approach. Resources to support systems-based investigation in the NHS are available online from: http://www.england.nhs.uk/ourwork/patientsafety/root-cause/				
Level	**Application**	**Product/ outcome**	**Owner**	**Timescale for completion**
Level 1 **Concise internal investigation**	Suited to less complex incidents which can be managed by individuals or a small group at a local level	Concise/ compact investigation report which includes the essentials of a	Provider organisation (Chief Executive / relevant deputy) in which the incident occurred, providing principles for	Internal investigations, whether concise or comprehensive must be

		credible investigation	objectivity are upheld	completed within 60 working days of the incident being reported to the relevant commissioner All internal investigation should be supported by a clear investigation management plan
Level 2 **Comprehensive internal investigation** (this includes those with an independent element or full independent investigations commissioned by the provider)	Suited to complex issues which should be managed by a multidisciplinary team involving experts and/or specialist investigators where applicable	Comprehensive investigation report including all elements of a credible investigation	Provider organisation (Chief Executive/relevant deputy) in which the incident occurred, providing principles for objectivity are upheld. Providers may wish to commission an independent investigation or involve independent members as part of the investigation team to add a level of external scrutiny/objectivity	
Level 3 **Independent 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 internally due to the size of organisation or the capacity/ capability of the available individuals and/or number of organisations involved	Comprehensive investigation report including all elements of a credible investigation	The investigator and **all** members of the investigation team must be independent of the provider. To fulfil independency the investigation must be commissioned and undertaken entirely independently of the organisation whose actions and processes are being investigated.	6 months from the date the investigation is commissioned
National reporting templates should be used unless agreed that adaptions are required. National templates will be reviewed on a continuous basis. Recommendations to inform changes should be sent to england.RCAinvestigation@nhs.net				

Level 1- Concise internal investigation
These will usually be amber incidents or red on occasions and will fulfil the level 1 criteria and require a concise Root Cause Analysis (RCA) investigation. This will be completed using the specific templates for falls or pressure ulcers and will usually be completed within the relevant Business Unit, and scrutinised at a validation panel.

Level 2 – Comprehensive internal investigation
All red (major) incidents will fulfil the level 2 criteria and require a comprehensive Root Cause Analysis (RCA) investigation. This will be completed using the Trust agreed comprehensive SI template and should be led by an investigator from another Business Unit where possible.

Level 3 – Independent investigation
All red (catastrophic) incidents will fulfil the level 3 criteria and require an independent investigation. This will be completed by agreement with the Trust Directors and Commissioning Body.

5.5 Communication

The Confederation endorses the principles of being open and honest when safety incidents occur and encourages effective communication channels and support for both patients and staff. The Duty of Candour regulations have been embedded into the incident investigation process and all incidents that meet the trigger criteria will have DoC applied and documented.

5.5.1 Being Open

Where a patient is harmed as a result of a mistake, error in their care, or patient safety incident, The Confederation must ensure that the individual, their family or those who care for them; receive an apology, are kept fully informed as to what has happened, have their questions answered and know what is being done in response.

The Confederation Being Open and Duty of Candour Policy and Procedure endorses our commitment to:

- Communicate openly and transparently with patients and their representatives regarding their care and treatment

- Be honest about unintended outcomes in care delivery
- Be honest when things have gone wrong
- Apologise for any harm caused irrespective of any proven/unproven mistake/error
- Explain, openly and honestly, what has happened
- Describe what will be done in response to the event to ensure the risk of recurrence is minimised
- Offer support and counselling services if appropriate
- Identify a contact person for continued discussion / queries / updates
- Provide updates on the results of any investigation

These principles should be standard and applied to every patient safety incident as best practice.

5.5.2 Duty of Candour

The Health and Social Care Act 2008 (Regulated Activities) Regulations 2014: Regulation 20 is intended to ensure that providers are open and transparent with people who use services in general in relation to care and treatment. It also sets out some specific requirements that providers must follow when things go wrong with care and treatment, that build on the general principles of being open outlined in 2.5.1.

Duty of Candour is triggered when a notifiable safety incident causes moderate or severe harm or death directly as a result of the incident.

In practice the main elements of implementing Duty of Candour are:

- Employ the principles of being open an transparent
- Acknowledge to the patient / representative that there has been a notifiable safety incident as soon as possible following identification of the incident
- Offer a sincere apology for the incident
- Ensure an explanation is given of the facts as known at the time
- Discuss what support, if any, is required to assist the patient with the consequences of the incident and arrange if appropriate
- Explain that an incident investigation will be undertaken and what process this will follow
- Offer the opportunity for any specific questions or concerns of the patient to be included in the investigation terms of reference
- Offer to share the investigations findings and discuss the wishes of the patient regarding how this will be done

A Duty of Candour acknowledgement letter must then be completed which summarises the discussion held and the wishes of the patient. This must be attached to the incident report and shared with the lead investigator (if different to the person holding the being open conversation).

On completion of the investigation, the findings must be shared according to the documented wishes of the patient.

This must be done in a timely manner and allow the patient / representative the opportunity for discussion, questions and explanation.

A final Duty of Candour letter should then be sent to summarise what has been found and how this has been shared. Further full details relating to the Duty of Candour regulation can be found in the Being Open and Duty of Candour Policy and Procedure.

5.5.3 Support for staff

Line Managers must ensure all staff involved with traumatic/stressful incidents are offered support following the incident. In the first instance a debrief session must be held as soon after the event as possible to allow staff an opportunity to reflect on the situation and explore their feelings and concerns with regards to the incident, the manager will usually lead with this. The exact nature of the support mechanisms used will be partly dependent on the type and severity of the incident and the needs of the individuals involved and will always follow the principles of 'being open' as detailed in the Being Open Policy and Procedure.

The manager may consider actions to protect the individual's well-being at this time. As appropriate, staff will be offered access to:

- Immediate medical treatment if required
- Advice from Human Resources
- Occupational Health Services
- Independent and confidential counselling
- Legal advice (at the discretion of LCH)
- Time away from work if appropriate (nature of leave to be agreed on a case by case basis)
- Time to consult with their Staff Side representative and/or professional body

Subsequently managers must ensure that staff have access to ongoing peer support and Clinical Supervision within and/or external to the team. Further debrief sessions may be required for particular incidents/staff. Any discussions that take place must be documented and retained with the personal staff records.

In the event of staff being called as a witness by the police or coroner in relation to an incident, the line manager must ensure that the staff member has access to appropriate advice and support. The Clinical Governance Team can be contacted and legal advice or representation considered for the member of staff. This will be funded by the service and the Clinical Governance Team can provide relevant resource documents to support this process.

It is important that all staff involved in investigation of an incident are aware that there may be a range of reactions from staff involved and the impact on individuals must be considered. The investigator must ensure that the above support is offered as appropriate and that communication is clear and concise about what the investigation will entail and the process to be followed. If issues of clinical competence are identified this needs to be investigated separately through the appropriate clinical or HR route.

5.5.6 Record Keeping

Details of incidents will be entered on LCH Datix® system, which is a secure database. All records are kept in line with the Confederation Records Management Policy. All correspondence should use the Feedback and Communication function in Datix®.

5.6 Timeframes in management of Incidents

The management of safety following any incident must be immediate and consider the condition of patients / staff members / public involved and the immediate risk to others.

An immediate risk assessment must be undertaken in the department of origin of the incident to identify if any immediate actions are necessary to prevent deterioration or recurrence of the incident.

All incidents where there is uncertainty over the severity, or if the incident fulfils Si criteria must be discussed with the relevant line manager / Clinical Governance Team within 1 working day of incident.

The timeframes for investigation are outlined in section 2.3.1 and further details can be found in appendix 6 - 10.

5.7 Serious Incidents involving more than one organisation

5.7.1 Other NHS organisations:

Where a Serious Incident involves another NHS organisation (eg a patient affected by system failures both in the Community and an acute hospital or other provider organisation);

- The organisation which identified the incident should make the initial notification having first made contact, wherever possible, with the organisation where it originated.
- A decision should be made jointly by the Organisations concerned about where the frequency/severity of the problem(s) appears to have been greatest, if necessary referring to the CCG responsible for SI management for advice.
- A lead organisation must be identified and their clear responsibilities including appropriate information sharing at all stages agreed.
- The named lead / point of contact should be clearly identified to the CCG and the lead organisation will report the SI and take responsibility for the investigation, involving the other NHS organisation(s) concerned. In practice, separate meetings in different organisations may take place, but the CCG would expect to see a single investigation report and action plan submitted by the reporting organisation, that has been agreed by all organisations involved in the SI.

5.7.2 Other Non-NHS organisations

Where a Serious Incident involves another organisation outside the NHS (eg a patient affected by system failures both in the Community and another care provider such as private care home / Leeds City Council);

- The incident must be recorded as per the local process for that organisation
- The Confederation must inform the organisation where the incident originated if identified by Confederation staff
- A decision should be made jointly by the Organisations concerned about where the frequency/severity of the problem(s) appears to have been greatest, if necessary referring to the CCG responsible for SI management for advice
- The Confederation must establish communication with the other organisation and identify clear responsibilities including appropriate information sharing at all stages agreed

- The named lead / point of contact should be clearly identified to the CCG with details of what conversations had been held and arrangement agreed
- This must also be clear in the Datix® record as to what information and been shared with whom

5.8 Principles of Investigation

Identifying the root cause of a problem rather than the 'underlying cause' is an essential part of the process of investigating serious incidents. It provides an opportunity for the Trust to identify actions required to eliminate the risk of the incident occurring again, and thus make a positive impact on on-going quality and safety of care. Corporate departments and Business Units are responsible for ensuring a Root Cause Analysis is performed for amber incidents causing moderate harm, amber and red incidents that have been declared SI's and developing an action plan to reduce recurrence.

- Each lead investigator will have support from a critical friend
- Lead investigators may be shadowed and assisted by others so that junior colleagues gain experience of serious incident management.
- The Lead Investigator must meet initially with the critical friend to review the terms of reference, scope the investigation and determine an investigation plan.
- The Lead Investigator must also meet or discuss with relevant others, where appropriate, to identify any specific questions to include in the terms of reference and ensure arrangements for contact are made.
- Clinical Leads / Quality Leads will provide support for the investigator throughout the SI process
- The Clinical Governance Team are available to offer support and advice on the investigation process and Duty of Candour
- Contact with the patient / carers needs to be agreed from the start and a framework for communication and investigation progress updates
- The Lead investigator will take responsibility for the incident investigation, gathering evidence, identifying witnesses and assessing the scope of the incident.
- A time log and lists will be kept by the lead investigator of all incidents, decisions, dates, times, evidential items, names, addresses, telephone calls and persons involved.
- A full RCA investigation report in accordance with the terms of reference will be produced using the Confederation RCA or SI templates
- An action plan will be developed and submitted with the investigation report
- The identified Action Plan lead will ensure actions are completed
- Monitoring of the action plans will be completed by the Quality Leads for each Business Unit
- Updates from this monitoring will be provided for assurance to the Clinical Governance Team

5.9 Learning from Incidents

Learning and sharing lessons learnt from incidents is critical to the delivery of safe and effective services by The Confederation. The analysis of findings from incident investigations must be used to identify areas for change, recommendations and sustainable solutions to help minimise reoccurrence in the future. The relevant persons/team/department where the incident occurred or related to, or the investigating manager for the incident (if different) should take responsibility to disseminate any lessons learnt from the investigation.

To provide assurance that real improvements and lessons have been learnt from investigations, periodic clinical audit should be performed. This should form part of the initial action plan and the results of the clinical audit should be shared with the relevant team/service or individuals affected by the incident.

Where audits indicate that improvements have not occurred, the full clinical audit or improvement cycle should be commenced and the clinical audit policy should be followed. Where appropriate, risks to quality should also be assessed and cited on the appropriate risk register as per the Trust risk management strategy.

The following methods are utilised to support learning lessons from incidents:

- **Email correspondence**
  Alerts from the NRLS and the Central Alerting System (CAS) will be distributed to all relevant managers for appropriate action and dissemination, with a full audit trail maintained

  Where either organisational, or discipline specific learning is identified through incident investigation, and this learning needs to be shared immediately to prevent further harm, a Learning for Patient Safety memo will be issued and distributed

- **Intranet site information**
  All Learning for Patient Safety Memos are available via the intranet

- **Training events**
  Learning with regard to practice and changes in practice is shared with managers, professional leads and clinicians identified in SI action plans

  If appropriate specific training/ awareness sessions will be organised
  Specific incidents may be used as examples in relevant training

- **Briefings**
  Individual Serious Incident Reports will be made available to Executive Directors and General Managers / Clinical Leads so that learning can be disseminated.

  Learning from Patient Safety (LPS) memos circulated when learning is identified from a specific incident, or group of incidents, by any specialist review group.

- **Meetings**
  Management Teams will ensure that learning is discussed appropriately at team meetings and professional / clinical forums. Sharing of incidents, action plans resulting from investigation and learning must be a standing item on management team meeting agendas.

  The Quality, Performance and Finance Committee will receive details of incident investigations, identify learning for the organisation and formulate methods for dissemination of learning.

- **Documentation and practice development**
  If appropriate, guidelines and policies will be developed or updated

  Action Plans will reflect any learning identified as part of an investigation and Management Teams will ensure that action plans are fully implemented

  Learning from incidents should be incorporated into audit plans as appropriate to ensure lessons learnt are embedded into practice

- **Sharing with external organisations**
  If appropriate, lessons learnt from investigations should be shared with any external organisation involved in the incident by prior agreement.

6 Governance Reporting

The incident reporting process is governed through the Confederation's formal committee structure, see below:

6.1 Quality Performance and Finance Committee

The Executive has delegated authority to the QPF Committee to assure the Executive of the Quality and Safety of services. The Committee reports bi-monthly to the Executive through the Chair'

6.2 Other Committees and Groups

Other relevant Committees and Groups will review incidents pertinent to their terms of reference. It is their responsibility to facilitate or directly respond to trends or patterns of those incidents and take the necessary action including incorporating them on the relevant risk registers. Competent and appropriate persons should undertake a full risk assessment and action plan and submit this to the appropriate committee / group for approval and monitoring.

7 Risk Assessments

Reference is made to risk assessment throughout the document. Escalation of high risk or high frequency incidents will be discussed with the appropriate Senior Managers and entered onto the risk register.

Incident action logs are used to identify themes and action required to reduce risk.

8 Mental Capacity Act (MCA 2005 Code of Practice)

This Act applies to all persons over the age of 16 who are assessed to lack capacity to consent or withhold consent to treatment or care. Under the MCA there are occasions when anyone lacking capacity should, or may require an Independent Mental Capacity Advocate, where treatment or residence decisions have a significant impact on an individual's life and rights.

The Trust must ensure that the MCA is considered in relation to all individuals affected by any incident and that the management reflects the individual needs under these safeguards.

9 Deprivation of Liberty (DoL)

In March 2014 it was ruled that a person without capacity is deprived of their liberty if they are both subject to continuous supervision and control and unable to leave.

Any deprivation of liberty of a person who lacks capacity has to be carried out in accordance with law. If a Confederation staff member is aware of anyone they believe is or is likely to be deprived of their liberty, they must act in accordance with the MCA policy and DoL's guidance or they must discuss their concerns with a member of the Adult Safeguarding Team.

10 Safeguarding

10.1 General principles

This policy describes the roles and responsibilities for the Trust in relation to the safeguarding of children and young people. All provider organisations commissioned by NHS Leeds Clinical Commissioning Group (CCG) have a responsibility to ensure they meet the agreed standards for Section 11 of the Children Act 2004, and statutory guidance outlined in Working Together to Safeguard Children 2013.

They are expected to follow the multi-agency procedures, comply with this policy and assist in taking the necessary action to safeguard children experiencing or at risk of abuse. The CCG's have a duty to take reasonable care to ensure the quality of the services commissioned. It is an expectation that all provider organisations, including Leeds GP Confederation, demonstrate robust safeguarding systems and safe practice within agreed local multi-agency procedures.

The Children Acts of 1989 and 2004 and the statutory guidance Working Together to Safeguard Children (2013) set out the safeguarding principles for and promoting the welfare of children and young people.

Working Together to Safeguard Children (2013, page 7) defines safeguarding children and young people as:

- Protecting from maltreatment
- Preventing impairment of health and development
- Ensuring that children and young people are growing up in circumstances consistent with the provision of safe and effective care; and
- Taking action to enable all children to have the best outcomes

The Children Act 2004 emphasises that we all share a responsibility to safeguard children and young people.

10.2 Safeguarding Incidents

If at any time during the investigation Safeguarding Vulnerable Adults or Children concerns arise, it is the responsibility of the lead investigator to refer to, and follow, the appropriate Confederation policies.

Serious Case Reviews and Safeguarding Adult Reviews:

The Local Authority via the Local Safeguarding Children Board or Local Safeguarding Adult Board (LSCB, LSAB as applicable), has a statutory duty to investigate certain types of safeguarding incidents/ concerns. In circumstances set out in Working Together to Safeguard Children24 (2015) the LSCB will commission Serious Case Reviews and in circumstances set out in guidance for adult safeguarding concerns the LSAB will commission Safeguarding Adult Reviews. The Local Authority will also initiate

Safeguarding Adult Enquiries, or ask others to do so, if they suspect an adult is at risk of abuse or neglect.

Healthcare providers must contribute towards safeguarding reviews (and enquiries) as required to do so by the Local Safeguarding Board. Where it is indicated that a serious incident within healthcare has occurred, the necessary declaration must be made. Whilst the Local Authority will lead SCRs, SARs and initiate Safeguarding Enquiries, healthcare must be able to gain assurance that, if a problem is identified, appropriate measures will be undertaken to protect individuals that remain at risk and ultimately to identify the contributory factors and the fundamental issues (in a timely and proportionate way) to minimise the risk of further harm and/or recurrence. The interface between the serious incident process and local safeguarding procedures must therefore be articulated in the local multi-agency safeguarding policies and protocols. Providers and commissioners must liaise regularly with the local authority safeguarding lead to ensure that there is a coherent multi-agency approach to investigating and responding to safeguarding concerns, which is agreed by relevant partners. Partner organisations must follow the West Yorkshire Consortium policy and procedures for Children and Adult safeguarding concerns.

Named safeguarding professionals must link with the Clinical Governance Team and Head of Service for Safeguarding who is responsible for reporting the following:

(a) Any case where there is prima facie evidence (i.e. initial concerns) that a child or adult has sustained a potentially life-threatening injury which may be through abuse, neglect, serious sexual abuse, or sustained serious permanent impairment of health or development through abuse or neglect.

(b) A prima facie case where a child dies (including death by suicide) and abuse or neglect is known or suspected to be a factor in the child's death and there will be a Serious Case Review (SCR). ('Working Together', 2015). See appendix 5 for the Time Line and Responsibilities for Managing SUDIC

These cases must be reported to the Commissioners and Executive Safeguarding Lead for the Confederation by the Head of Service for Safeguarding as soon as practically possible and as a maximum the working day after the incident.

It is recognised that the timing of the SCR is not within the control of NHS organisations. However, the NHS does have a duty of care to future patients and should therefore not unduly delay any necessary action pending the outcome of the SCR. The Head of Service for Safeguarding is the lead investigating officer and should update the Commissioner at least every eight weeks and in between if necessary on developments pertaining to health services or health care that may occur during the course of the review. If the action plan/details of action already taken are satisfactory, the SI will be closed.

11 Training Needs

Staff are directed to the Confederation Statutory and Mandatory Training Policy (including Training Needs Analysis). In addition, Datix® training sessions are available via the Clinical Governance Team for new users of Datix® which provide support for staff in the correct use of the system for incident reporting and incident investigation.

12 Monitoring Compliance and Effectiveness

Monthly reports relating to Incidents, Compliments, Comments, Concerns and Complaints and Patient Experience are triangulated for the performance reporting to the Quality Performance and Finance Committee and are reviewed bi-monthly. These are reported to the Executive through the Chair's Assurance Report.

Aggregated qualitative and quantitative data is analysed, with a view to identifying trends over identified time periods, locations and services. Other aggregated data relating to incidents, complaints and claims to be reviewed will be:

- Overall degree of harm
- Most common categories/sub-categories
- Most common themes
- Actions required for areas not addressed through formally recognised improvement activity. This will include risk assessing themes and citing them on the risk register via the appropriate risk guardian – in particular when no improvement activity has been identified or can be initiated.

Any emerging trends, improvement activities or learning will be communicated to relevant staff groups through management cascade and Learning for Patient Safety memos.

Minimum requirement to be monitored / audited	Process for monitoring / audit	Lead for the monitoring/audit process	Frequency of monitoring / auditing	Lead for reviewing results	Lead for developing / reviewing action plan	Lead for monitoring action plan
Reporting all incidents/near misses involving staff, patients and others	Reporting to the Quality Performance and Finance Committee: *Degree of harm, Top categories/ themes, SI's, Reporting rates, Benchmarking, DoC compliance*	Director of Delivery Business and Operations Manager	Bi-Monthly report	Quality Performance and Committee		
Reporting of Serious Incident	SI report to include: *SI themes* *Reporting compliance* *Submission to deadline* *Closure and Action Plan progress*					
Implementation of incident management policy	Sample Audit to assess: *Correct Grading* *Completion of all required aspects of incident management* *DoC* *Appropriate action plans*	Head of Governance	Annual	Audit Committee		
Staff training, as identified in the training needs analysis	Refer to the Statutory and Mandatory Policy (including Training Needs Analysis) for the monitoring of training and the non attendance of staff training					

Approval and Ratification process
The policy has been approved by the Quality Performance and Finance Committee and ratified by the Executive.

Dissemination and Implementation
Dissemination of this policy will be via the Confederation Website and Intranet.

Implementation will require:
- Operational Directors / Heads of Service / General Managers / Clinical Leads to ensure staff are informed of, and have access to this policy and understand their responsibilities for incident management
- The Executive to provide appropriate support and advice to staff on the implementation of this policy

Review arrangements
This policy will be reviewed in three years following ratification by the Executive or sooner if there is a local or national requirement.

Associated documents
- Disciplinary Policy
- Freedom to Speak Up Policy
- Managing Concerns with Performance Policy
- Acceptable Standards of Behaviour Policy and Procedure
- Statutory & Mandatory Training Policy
- Patient Experience Policy
- Being Open Policy
- Records Management Policy
- Adults at Risk Policy
- Safeguarding Children Policy
- Infection Prevention and Control Policy
- Counter fraud and anti-bribery Policy and Procedure
- Risk Management Policy and Procedure

Related documents - External
- NHS England - Serious Incident Framework - Supporting learning to prevent recurrence 2015

References

- National Patient Safety Agency. (2004) Seven steps to patient safety. The full reference guide.
- National Patient Safety Agency. (2004) National Framework for Reporting and Learning from Serious Incidents requiring investigations.
- NHS England Serious Incident Framework March 2015
- Department of Health. (2008) High Quality Care for All – NHS Next Stage Review final report.
- Care Quality Commission. (2009) A quality service, a quality experience.
- Care Quality Commission – Guidance for providers on meeting the regulations 2015 http://www.cqc.org.uk/
- Costa, A. and Kallick, B.(1993) "Through the Lens of a Critical Friend" Educational Leadership 51(2) 49-51
- Department of Health the “never events” list 2015/16Policy framework for use in the NHS
- Department of Health, Association of Chief Police Officers and Health &Safety Executive, Memorandum of Understanding - February 2006
- Equality Act 2010 http://www.legislation.gov.uk/ukpga/2010/15/pdfs/ukpga_20100015_en.pdf
- Health & Safety Executive, Reporting of Injuries, Diseases and Dangerous Occurrences Regulations (RIDDOR) 2013 http://www.hse.gov.uk/riddor/
- HM Government ‘Working Together Working Together to Safeguard Children
- A guide to inter-agency working to safeguard and promote the welfare of children’ 2010
- LCH Risk Management Strategy 2014
- Medicines and Healthcare products Regulatory Agency website (MHRA)
- http://www.mhra.gov.uk/
- The Misuse of Drugs Regulations 2001 http://www.legislation.gov.uk/uksi/2001/3998/contents/made
- NHS England - Serious Incident Framework - Supporting learning to prevent recurrence 2015

Appendices

Appendix 1: Definitions of Harm

Minimum (low) Harm:
Any unexpected or unintended incident that required extra observation or minor treatment and caused minimal harm to one or more persons.

Moderate Harm:
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.

Major (severe) Harm:
Any unexpected or unintended incident that caused permanent or long-term harm to one or more persons.

Death / Catastrophic Harm:
Any unexpected or unintended incident that caused the death of a service user or permanent significant harm to one or multiple persons.

The CQC definitions in relation to the Statutory Duty of Candour trigger are:

'Moderate harm' means harm that requires a moderate increase in treatment, and significant, but not permanent, harm,

'Prolonged pain' means pain which a service user has experienced, or is likely to experience, for a continuous period of at least 28 days;

'Prolonged psychological harm' means psychological harm which a service user has experienced, or is likely to experience, for a continuous period of at least 28 days.

Appendix 2: Categories of Incidents

When selecting "incidents affecting the patient" you need to consider is the incident attributable to the Confederation or another provider.

- **Patient Incident - Occurred whilst receiving Care from Confederation Services. This is for patients who are receiving care from a Confederation service whether that is the, reporter of the incidents service, or another Confederation service.**
- **Patient Incident - Occurred whilst receiving Care from other Providers (eg Hospitals, GP) this is for patients where the incident is attributable to another provider even though they are receiving care from a Confederation service.**
- **Patient Incident - Not known to Confederation Services i.e they are not receiving care from a Confederation service".**

Below are a number of common examples for each of the categories. You will then be required to choose the relevant Sub category and detail relevant to your incident.

Category	Eg. Of Incident being reported.
Abusive, violent, disruptive or self-harming behaviour	• Any form of verbal or physical abuse by a patient, carer or staff. This would include abuse of staff by patients or their carers and vice versa. *(This would not be used for abuse of staff by staff. HR process should be followed in this instance)* • Self-Harm, Attempted suicide
Access, Appointment, Admission, Transfer, Discharge	• Secondary referrals not being made in a timely manner, leading to delay in treatment. • Patient sent appointment letter with incorrect date, location, time
Accident that may result in personal injury	• Any incident that caused or could lead to injury. (Not Self Harm) • Slips, trips, falls. • Sharps injury or sharps found. • Exposure to environmental hazards eg body fluid splashes, electrical, smoke. • Road Traffic Accident, • Strain injury caused whilst providing care to a patient. • Work related upper limb disorder • Manual handling.
Clinical assessment (investigations, images and lab tests)	• Failure to undertake full assessment or failed to request appropriate advice. • Unable to access test results as not sent or unable to open. • Incorrect test results given • Failure to act on test results
Consent, Confidentiality or Communication	• Confidential information sent to incorrect recipient. • Lost patient information / records • Failure in communications between staff and staff groups • Inadequate consent obtained
Diagnosis, failed or delayed	• Failure to diagnose • Commence on inappropriate care plan. • Failure to act on adverse symptoms
Financial loss	• Errors in the monitoring of the Cold Chain for the storage of medication leading to disposal. • Unaccounted for stock items
Implementation of care or ongoing monitoring/review	• Failure to act promptly to test results. • Failure to request appropriate tests.

	• Care plans not being followed • Pressure ulcers. • Inadequate pain management
Infrastructure or resources (staffing, facilities, environment)	• Issues relating to staffing levels leading to the appointment not taking place or being delayed: • Lack of interpretation service, lack of escorts to bring patients to appointments, concerns over unsafe staffing levels. • Issues relating to the work environment affecting patient care. • Lack or unavailability of equipment to provide care • Information Technology issues such as: Lack of mobile phone coverage. Lack of access to IT system, • Unauthorised access to IT system, • Miss use of IT.
Medical device/equipment	• Failure of a medical device / equipment whilst providing care. • Damage to equipment. • Injury caused by Medical device. • Medical device not available to provide care. • Use of out of date medical device. • Incorrect medical equipment used.
Medication.	• Prescription, dispensing, preparation administration and monitoring of medication errors eg wrong drug, wrong dose, and wrong patient wrong time and wrong route. • Missed patient contraindications, • Unaccounted for medication. • Adverse reaction to medication, • Incorrect record keeping of medicines, • Incorrect storage, disposal, • No valid authorisation to administer or supply.
Patient Information (records, documents, test results, scans)	• Where there are issues identified relating to patients records they would be recorded under this category. • Missing entries or missing patient records. • Information entered on to wrong patient record. • Missing / lost test results • Missing referral letters.
Security	• Theft or damage to property. Eg car being broken into. • Missing equipment. • Clinical locations and secure cupboards left unlocked. Missing keys. • Not adhering to lone worker policy. • Lost ID/smart card or mobile working equipment. • Unauthorised access to secure locations. • Patients referred to service with known behavioural issues not passed to service.
Treatment, procedure	• Wrong site of treatment. • Incorrect treatment given • Inappropriate referral for treatment. • Medical emergency requested eg Dr to attend or Ambulance • Infection control failures in systems

- Issues relating to being unable to give correct medication at correct time / wrong medication administered

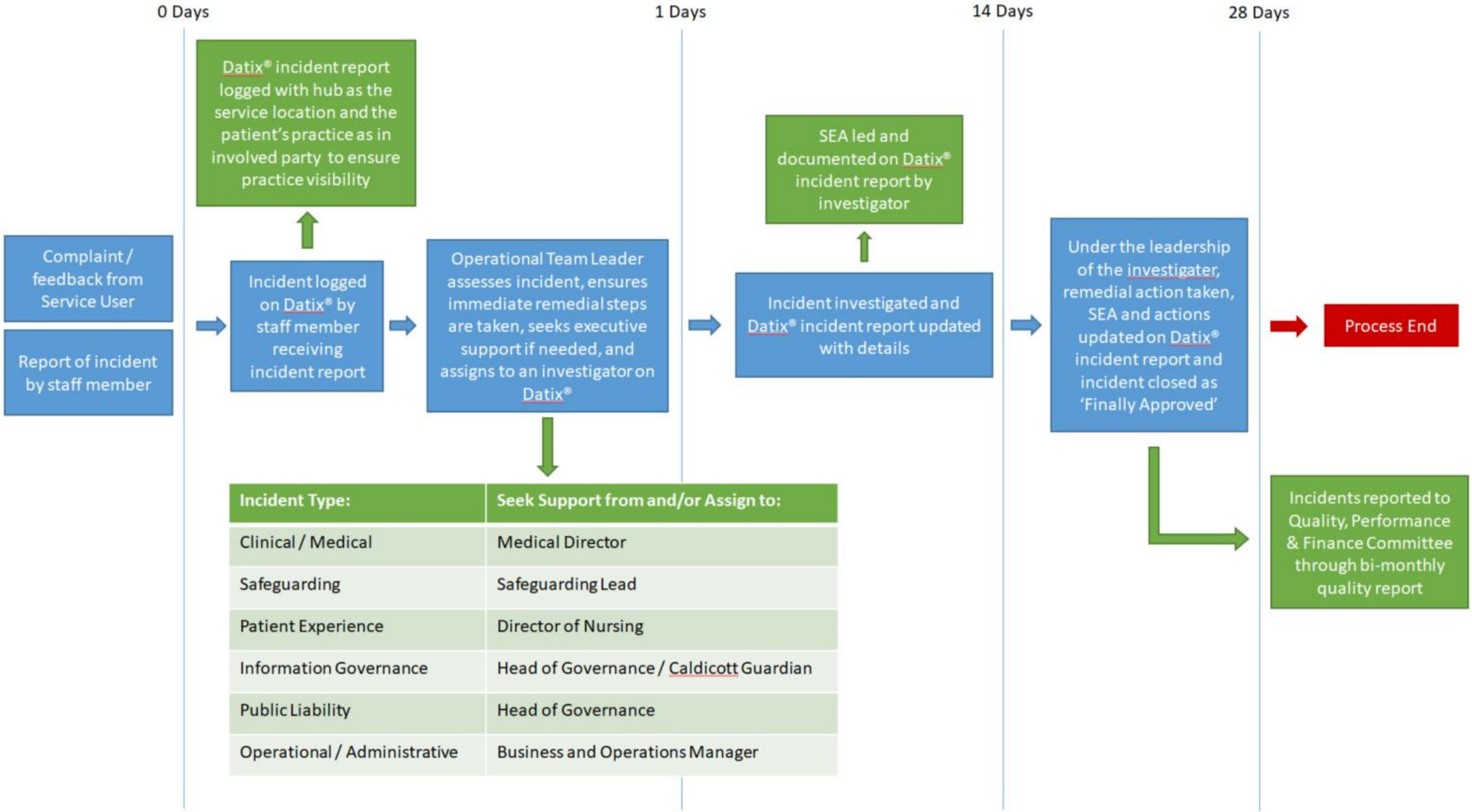
Staff Safety Incidents

When selecting "incidents affecting staff" as the incident type an additional box will appear asking:

1. **Is this a RIDDOR reportable incident? An incident is reportable to RIDDOR if the member of staff has suffered a major injury (e.g. a broken leg) or the accident has resulted in the member of staff requiring 7 or more days off work.**

Incident being reported	Category	Sub category	Detail
Staff fall	Accident that may result in a personal injury	Slips, Trips, Falls and Collisions	Select as appropriate
Strain injury caused whilst providing care to a patient	Accident that may result in a personal injury	Lifting Accidents	Lifting or moving a patient or other person
Needle stick Injury	Accident that may result in a personal injury	Needle stick injury or other incident connected with sharps	Select as appropriate
Used needles found within a healthcare setting	Accident that may result in a personal injury	Needle stick injury or other incident connected with sharps	Sharps or needles found
Road Traffic Collision	Accident that may result in a personal injury	Accident cause by some other means	Road Traffic Accident in the course of employment or care
Lost ID card	Security	Security incident related to premises, land or real estate	Other incident related to security
Malicious damage to or theft of a car whilst used in the course of business	Security	Security Incident related to a vehicle	Select as appropriate
Lost/missing keys	Security	Security incident related to premises, land or real estate	Other incident related to security
Not adhering to Lone Working Policy	Security	Security – other	Other incident related to security
Verbal abuse by a patient	Abuse, Violent, Disruptive or Self-Harming Behaviour	Abuse etc., of staff by patients	Verbal abuse or disruptive behaviour
Lack of mobile phone coverage	Infrastructure or resources	Information technology	Failure or overload of IT or telecommunications system
False fire alarm – this type of incident would actually be classed as an "incident affecting the Trust"	Security	Fire, Fire alarms and fire risks	False fire or intruder alarm

Appendix 3. Incident Management Process



Incident Type:	Seek Support from and/or Assign to:
Clinical / Medical	Medical Director
Safeguarding	Safeguarding Lead
Patient Experience	Director of Nursing
Information Governance	Head of Governance / Caldicott Guardian
Public Liability	Head of Governance
Operational / Administrative	Business and Operations Manager

Appendix 9: Policy Consultation Process

Title of Document	Incident Management Policy (Including Serious Incidents)
Author (s)	Rachel Howitt, Incident and Assurance Manager (LCH) Simon Boycott, Head of Development and Governance
New / Revised Document	New
Lists of persons involved in developing the policy	
List of persons involved in the consultation process	